

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

2:23 CV 3349

UNITED STATES EX REL,
RHETT HOLLAND

c/o Mowery Youell & Galeano, Ltd.
485 Metro Place South, Suite 220
Dublin, Ohio 43017

Service to:
Kenneth L. Parker
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and

Service to:
Merrick Garland
Attorney General for The United States
950 Pennsylvania Avenue NW
Washington, DC 20530-0001

Plaintiff-Relator,

vs.

ADENA HEALTH SYSTEM

c/o Craig Babbitt, Statutory Agent
272 Hospital Road
Chillicothe, Ohio 45601

and

ADENA MEDICAL GROUP, LLC

c/o Craig Babbitt, Statutory Agent
272 Hospital Road
Chillicothe, Ohio 45601

and

: CIVIL ACTION NO:

: Judge:

JUDGE SARGUS

MAGISTRATE JUDGE DEEVERS

: [FILED IN CAMERA AND
: UNDER SEAL PURSUANT TO
: 31 U.S.C. 3720(b)(2) AND SOUTHERN
: DISTRICT OF OHIO CIVIL
: RULE 3.2]

: COMPLAINT WITH JURY DEMAND

FILED
2023 OCT 10 PM 3:54
U.S. DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
COLUMBUS, OHIO

ADENA HEALTHCARE
COLLABORATIVE, LLC
c/o Craig Babbitt, Statutory Agent
272 Hospital Road
Chillicothe, Ohio 45601

Defendants.

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I. INTRODUCTION

1. This is a *qui tam* action brought by Relator Rhett Holland (“Relator”), for himself and on behalf of the United States, to recover damages and civil penalties arising from Defendant Adena Health System (“AHS”), an Ohio corporation, Adena Medical Group, LLC, (“AMG”), an Ohio limited liability company, and Adena Healthcare Collaborative, LLC, (“AHC”), an Ohio limited liability company, for their unlawful acts which resulted in multiple violations of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (“FCA”) and O.R.C. §4113.52.

2. From January 2022 through the present, AHS, AMG and AHC, individually and jointly, have knowingly submitted false claims for payment to the United States relating to medical procedures performed by their agents and identified as Transcatheter Aortic Valve Replacements (“TAVRs”) which procedures were not reasonable and necessary pursuant to 42 U.S.C. § 1395y(a)(1)(A).

3. Relator investigated and reported Defendants unlawful acts and, in response AHS unlawfully retaliated and terminated Relator’s employment in violation of 31 U.S.C. §3730(h) and O.R.C. §4113.52.

4. In accordance with the FCA, the Relator, on behalf of the United States, seeks recovery of damages and civil penalties for AHS, AMG and AHC’s presentment of false and fraudulent claims for payment to Medicare, Medicaid and TRICARE/Champus government medical benefit programs.

5. This Complaint is being filed under seal and must remain under seal while the United States investigates the allegations and determines whether it will intervene in the action.

6. Pursuant to 31 U.S.C. § 3730, this Complaint is being filed in camera. Unless the Relator concurs in a request to extend the timeframe for intervention, the Complaint shall remain under seal for a period of at least 60 days after the United States has received the Complaint, material and information required under the statute. None of the allegations in the Complaint or Disclosure Statement are based upon any public disclosure as defined under the FCA.

II. JURISDICTION AND VENUE

7. This action arises under the FCA.

8. Jurisdiction is proper in accordance with 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331.

9. This Court has supplemental jurisdiction over Relator's state law claims pursuant to 31 U.S.C. § 1367(a) as Relator's Ohio law claim is so related to the claims asserted in this action that it forms part of the same case or controversy.

10. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1391(b)(1), and 28 U.S.C. § 1391(b)(2). Venue is proper because AHS, AMG and AHC each has its principal place of business within this District, each Defendant transacts business inside this District, a substantial part of the events and/or omissions giving rise to the claims herein occurred in this District, including but not limited to, the presentment of false claims for payment to the United States, and in connection with those claims, each Defendant has received monies in payment to which they are not entitled.

11. On or about October 4, 2023, and pursuant to 31 U.S.C. § 3730(e)(4)(B), Relator, as an "original source," voluntarily disclosed by email the information and facts alleged herein to

the United States Attorney for the Southern District of Ohio. Relator brings this case pursuant to 31 U.S.C. § 3730(b).

12. Relator's FCA claims herein are timely pursuant to 31 U.S.C. § 3731(b) and have been brought within 3 years of the date the material facts to the FCA claims were known. Relator's claim pursuant to O.R.C. § 4113.52 is timely brought within 180 days from his last adverse employment action.

III. THE PARTIES

13. The main party in interest for the claims in this action is the United States of America.

14. Relator is a resident of the State of Ohio. Relator was the Vice President of Quality and Safety for AHS prior to, during, and after Defendants began performing TAVR procedures at AHS. Relator, as part of his job duties and responsibilities at AHS, investigated the requirements for and Defendants implementation of TAVR procedures for compliance and patient safety purposes. Therefore, he has personal, direct and independent knowledge of all facts herein.

15. AHS is a corporation organized under the laws of the State of Ohio with its principal place of business in Chillicothe, Ross County, Ohio. AHS is a health system that provides medical services for patients in Southern Ohio.

16. AMG is an Ohio limited liability company with its principal place of business in Chillicothe, Ross County, Ohio. AMG employs the physicians on staff at AHS.

17. AHC is an Ohio limited liability company with its principal place of business in Chillicothe, Ross County, Ohio. AHC is an accountable care organization that provides inpatient care to Medicaid patients through Accountable Care Offerings and the Medicare Shared Savings Program.

IV. THE LAW

A. The False Claims Act (31 U.S.C. §§ 3729-33)

18. The FCA provides for an award of treble damages and civil penalties against any person for, inter alia, knowingly causing the submission of false or fraudulent claims for payment to the United States Government or making or using false statements which are material to false or fraudulent claims paid by the United States.

19. Under the FCA, 31 U.S.C. § 3729, a person is liable to the United States for:

- (A) knowingly presenting, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
- (G) knowingly makes, uses, or causes, 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 knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

20. The standard of proof under the FCA is preponderance of the evidence. 31 U.S.C. § 3731(c).

B. Federal Health Care Programs

21. In 1965 Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain health care services. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A.

22. Part A of the Medicare Program authorizes payment for institutional care, including for care provided at hospitals, skilled facilities, and home health care. *See* 42 U.S.C. §§ 1395c-1395i-4.

23. Part B of the Medicare Program authorizes payment for outpatient health care expenses and physician fees. These fees are administered through Medicare carriers, and payments are made through a trust fund (“the Medicare Trust Fund”). *See* 42 U.S.C. §§ 1395j-1395w-4.

24. AHS, AMG, and AHC derived and continue to derive substantial revenue from the Medicare Program.

25. The Department of Health and Human Services (“HHS”) has overall responsibility for the administration and supervision of the Medicare Program. The Center for Medicare and Medicaid Services (“CMS”) is an agency of HHS, and it is directly responsible for the administration of the Medicare Program. The responsibility for processing claims and making distributions from the Medicare Trust Fund on behalf of the United States is delegated by CMS to certain contracted agents.

26. Payment of Part A claims made to hospitals under the Medicare Program are administered by fiscal intermediaries. In Ohio, the fiscal intermediary is National Government Services.

27. Outpatient hospital and physician claims made under the Medicare Program are paid separate and apart from hospital Part A claims, pursuant to a Medicare reimbursement schedule.

C. Other Federally Funded Health Insurance Programs

28. Federal health care programs also include any plan or program that provide health benefits directly or indirectly through insurance or that are otherwise funded directly, in whole or in part, by the United States Government. 42 U.S.C. § 1320a-7b(f)(1). These include military benefits through the TRICARE/Champus program, the Federal Employees Health Benefit Program, and other federally funded insurance (excluding federal workers compensation claims).

29. State Medical Assistance (or “Medicaid”) programs are also federal health care programs. *See* 42 U.S.C. § 1320a-7b(f)(2).

D. Provider Agreement

30. Medicare providers, including AHS, AMG and AHC are required to enter into provider agreements with the federal government.

31. Hospitals that meet Medicare requirements enter into provider agreements pursuant to forms CMS 1450-UB-04 and CMS-855(A). Hospitals must also reconcile payments made throughout the year by the submission of a year-end cost report identified as CMS-2552. Physicians and their corporate entities that meet Medicare requirements enter into provider agreements through the use of forms CMS-1500s, CMS-855(B), and CMS-855(1).

E. Legally False Claims

32. The FCA generally prohibits private parties from knowingly submitting a false or fraudulent claim for reimbursement. *See* 31 U.S.C. §3729(a)(1)(A).

33. Under the terms of the provider agreements referred to in Paragraph 31, a Medicare provider certifies that it will comply with all laws and regulations concerning Medicare and the FCA in connection with claims submitted for payment relating to services provided to patients in which reimbursement is sought from a federal health care program.

34. False or fraudulent claims include both factually false and legally false requests for payment. *United States ex rel Polukoff v. St. Mark’s Hospital*, 895 F.3d 730, 741 (10th Cir.2018).

35. Claims arising from legally false requests generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment.

Id.

36. The submission of claims that do not comply with Medicare's reasonable and necessary requirement constitute legally false requests for payment. *Id.*

37. Claims of legal falsity are either categorized as express false certification or implied false certification. *Id.*

38. Claims for implied false certification occur when a payee, through the act of submitting a claim, knowingly and falsely implied that it was entitled to payment. *Id.*

39. In connection with the false claims that are the subject of this Complaint, Defendants certified that they had complied with Medicare and the FCA and that all of the claims presented for medical services that were rendered by the parties were reasonable and necessary.

40. Certification of compliance of the reasonableness and necessity of the medical procedures for which presentment of a claim is made to the United States is a prerequisite for hospitals, physicians, and their corporate entities to obtain a government benefit such as Medicare, Medicaid, TRICARE/Champus program, and other payments from federal health care programs. An action for the presentation of claims seeking reimbursement for services and items that are medically unnecessary is viable under the FCA. *Id.* at 743.

41. A Medicare claim is false if it is not reimbursable. A Medicare claim is not reimbursable if the services provided were not medically necessary. For a claim to be reimbursable, it must meet the United States' definition of reasonable and necessary as found in the Medicare Program Integrity Manual. *Id.* at 741-42; see Amicus Brief of the United States in *United States ex rel v. Polukoff, supra* (Attached as Exhibit 1)

42. Each time a false claim is submitted, that claim is a separate illegal claim that is actionable under the FCA. See *United States ex rel Augustine v. Century Health Services*, 289 F.3d 409, 415 (6th Cir. 2002).

F. Federal and State Whistleblower Protection

43. The FCA also provides whistleblower protection, including but not limited to, reinstatement, an award of liquidated damages, and attorney fees, to any employee who is demoted, suspended, threatened, harassed or in any manner discriminated against for reporting an employer's fraudulent actions under the FCA. This protection applies to employees who internally report or share their concerns with management. See 31 U.S.C. § 3730(h).

44. Ohio's whistleblower protection statute is codified in O.R.C. § 4113.52 and prohibits an employer from taking disciplinary or retaliatory action against an employee for reporting the employer's unlawful violations likely to cause imminent risk of physical harm or a hazard to public health or safety. See O.R.C. § 4113.52(A) and (B).

V. DEFENDANTS' ILLEGAL ACTIONS

A. Defendants Submitted False Claims for TAVRS

45. No payments may be made under Medicare for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. See 42 U.S.C. §1395y(a)(1)(A).

46. The determination of whether a medical service is reasonable and necessary has been delegated in the first instance to the Secretary of the HHS. HHS decides whether to exclude payment for medical services by promulgating National Coverage Determinations ("NCDs"). See 42 U.S.C. §§1395y, 1395ff(a)(1)(A), 42 CFR 405.1060(a); *United States ex rel Polukoff v. St. Mark's Hospital*, 895 F.3d 730, 735 (10th Cir.2018); *United States ex rel Ryan v. Lederman*, 2014 WL 1910096, *1 (E.D.N.Y. May 13, 2014)

47. NCDs are national payment policies relating to the payment of covered items and services by medical providers and are binding on both Medicare contractors and administrative law judges who preside over medical coverage appeals. *United States ex rel Groat v. Boston Heart*

Diagnostic Group, 255 F. Supp.3d 13, 18 (D.D.C. 2017); *Almy v. Sebeleus*, 679 F.3d 297, 299 (6th Cir. 2012).

48. An NCD is a determination by the United States of whether payment for a particular item or service is covered under Medicare. 42 CFR §405.1060(a)(1), 68 Fed. Reg. 187, pp. 55634, 55635 (Sept. 26, 2013). NCDs are controlling authorities for payments by Medicare contractors. 78 Fed. Reg. 152, pp. 48164, 48165 (Aug. 7, 2013)

49. An institutional provider such as AHS or AHC must present a claim for payment pursuant to CMS Form 1450 or UB-04. *See* 42 CFR §424.32. The form requires a certification by Defendants that each did not knowingly or recklessly misrepresent or disregard or conceal material facts to the claim submission. Additionally, each Defendant, in its Medicare Enrollment Form 855(A), certifies compliance with Medicare laws such as 42 U.S.C. §1395y(a)(1)(A). When AHS and/or AHC requests reimbursement for services it provides, it does so by submitting Annual Hospital Cost Reports identified as CMS 2252-10. These Reports require the hospital to certify, “I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in the cost report were provided in compliance with such laws and regulations.”

50. By submitting Forms UB-40, 855(A), and its Hospital Cost Report for 2022, AHS and/or AHC expressly certified that every procedure for which it sought reimbursement complied with Medicare requirements. *United States ex rel Polukoff v. St. Mark's Hospital*, 895 F.3d 730, 743-44 (10th Cir.2018).

51. A physician or health care supplier such as AMG when seeking reimbursements for treatment and services provided to Medicare patients must submit a CMS 1500 Form to the Medicare Contractor. *See United States Ex Rel Hobbs. v. Medquest Assoc. Inc.*, 771 F.3d 707, 711

(6th Cir. 2012). The CMS Form reflects the treatment or services provided and identifies the entity that provided them. Tests, supplies, and services are correlated to a series of unique numbers called CPT codes. *Id.* at 711. CPT codes identify the procedures for which AHS, AHC and AMG are presenting claims seeking reimbursement for the procedures performed at AHS, AHC and AMG.

52. The CMS 1500 Form requires the entity to certify that, in part, the services performed by the physicians are identified on the form were medically necessary. *Groat*, 255 F. Supp. 3d at 18.

53. Under the Medicare regulations, it is a condition of payment that services that are billed must be medically necessary procedures. *United States ex rel Polukoff v. St. Mark's Hospital*, 895 F.3d 730, 734 (10th Cir.2018).

54. Billing a health care benefit program for medically unnecessary procedures is one way in which a medical care provider can commit health care fraud. *United States v. Persaud*, 866 F.3d 371, 380-81 (6th Cir, 2017).

55. As pled herein, Defendants have and, upon information and belief, continue to present claims for reimbursement relating to TAVR procedures that do not meet HHS's NCDs. Therefore, the medical services for which the claims are being presented are not reasonable and necessary and constitute false claims for which reimbursement of millions of dollars have been knowingly sought and received by Defendants.

B. Transcatheter Aortic Valve Replacement ("TAVR")

56. Defendants are submitting false claims relating to Part A (Facility Fees) and Part B (Physician Fees) for treatment provided to Medicare, Medicaid, and Champus patients who are undergoing TAVR Procedures.

57. A TAVR is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve. The procedure is performed in a cardiac catheterization lab or a hybrid operating room/cardiac catheterization lab. An interventional cardiologist and cardiothoracic surgeon jointly participate in the intra-operative technical aspects of TAVR.

58. TAVR is a major surgical procedure with considerable morbidity and mortality, and intensivists caring postoperatively for TAVR patients must be able to treat the immediate postoperative complications. Postoperative neurologic events, cardiac arrhythmias, renal failure, vascular complications and hemorrhage are common postoperative complications of a TAVR.

59. In May 2012, the CMS first issued an NCD covering TAVR under Coverage with Evidence Development (“CED”)(Attached as Exhibit 2 is Chapter 20.32 of the Medicare National Coverage Determination Manual) (“MNCD Manual”). It has been reissued on a number of occasions with the same volume criteria. The NCD lists criteria for the physician operators and hospitals that must be met prior to beginning a TAVR program or after a TAVR program is established. *United States Ex Rel. Lynch v. Univ. of Cincinnati Med. Ctr., LLC*, 2020 WL 1322790 at *18 (S.D. Ohio Mar. 20, 2020).

60. In the MNCD Manual, it describes the purpose for the enactment of NCDs. According to the Secretary of HHS, the purpose of NCDs:

A. Purpose

The statutory and policy framework within which National Coverage Determinations (NCDs) are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The NCD Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. NCDs have been made on the items addressed in this manual. Decisions that items/services are not covered are generally based on §1862(a)(1) of the Act (the

“not reasonable and necessary” exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the authority for denial. Where an item/service is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items/services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item/service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item/service is not mentioned at all in the Centers for Medicare & Medicaid Services (CMS) NCD Manual and the Medicare Administrative Contractor (MAC) has the discretion to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings, and general program instructions. (Emphasis added)

(Attached as Exhibit 2)

C. NCD for TAVR Coverage

61. CMS covers TAVR under the following conditions:

- A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (“FDA”)-approved indication and when all of the following conditions are met:
 - 1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (“PMA”) for that system's FDA approved indication.
 - 2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team includes the following:
 - a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
 - i. independently examined the patient face-to-face, evaluated the patient’s suitability for surgical aortic valve replacement, TAVR or medical or palliative therapy;

- ii. documented and made available to the other heart team members the rationale for their clinical judgment.
- b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.
- 3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
- 4. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
 - a. On-site heart valve surgery and interventional cardiology programs;
 - b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures;
 - c. Appropriate volume requirements per the applicable qualifications below.

62. There are two sets of qualifications for a health care entity to be entitled to bill for TAVR procedures. The first set outlined below is for a hospital program, such as Defendants, and heart teams without previous TAVR experience.

63. Before Defendants are entitled to bill for a TAVR procedure, they must have had the following:

- a. ≥ 50 open heart surgeries in the previous year prior to TAVR program initiation, and;
- b. ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
- c. ≥ 2 physicians with cardiac surgery privileges, and;
- d. ≥ 1 physician with interventional cardiology privileges, and;
- e. ≥ 300 percutaneous coronary interventions (“PCIs”) per year.

64. Additionally, qualifications to begin a TAVR program for heart teams without TAVR experience:

The heart team must include:

- a. Cardiovascular surgeon with:
 - i. ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related; and,
- b. Interventional cardiologist with:
 - i. Professional experience of ≥ 100 career structural heart disease procedures; or, ≥ 30 left-sided structural procedures per year; and,
 - ii. Device-specific training as required by the manufacturer.

(See Exhibit 2)

D. AHC, AMG And AHS Have Submitted And Continue to Submit Or Cause To Be Submitted Claims for TAVR Procedures Without Meeting CMS' NCD Requirements

65. In October 2017, Relator began working as AHS's Vice President of Quality and Safety. In this role, Relator worked to operationalize high quality evidence-based care that was safe, accessible, and data-driven. The scope of Relator's duties and responsibilities included, but were not limited to, oversight of medical staff, quality, safety and infection to ensure Defendants complied with safety rules, regulations, procedures and protocols as well as to investigation allegations of noncompliance made against Defendants.

66. In late 2021 or early 2022, Defendants hired Dr. Atiq Rehman, a thoracic cardiovascular surgeon, to work in its cardiology department. In early 2022, AHS's Board of Trustees approved the implementation of a TAVR program in its cardiology department. At the time the Board approved implementation of TAVR program, AHS had not fulfilled the NCD

prerequisite that 20 or more aortic valve related procedures must be conducted in the hospital in the two years prior to the TAVR program initiation.

67. Despite this fact, AHS's Board of Trustees approved funding for the TAVR program and new equipment required for the surgery was purchased, including the valves for the procedure. AHS' Board of Trustees also approved funding to build a new hybrid operating room where the procedures were to be performed.

68. Prior to 2022, AHS had transferred cases requiring aortic valve procedures to other hospitals because AHS and AMG did not have the availability of trained specialists and staff to provide care for the patients after an aortic valve procedure.

69. In early 2022, Drs. Atiq Rehman, Mario Matos-Cruz, and Jerrod Betz were preliminarily approved by AHS' credentialing committee to perform the TAVR procedures subject to approval by AHS' Board of Trustee committee. In an email, AHS' Missy Brenner, Director of Medical Staff Services and Provider Enrollment, instructed Drs. Rehman, Matos-Cruz and Betz that TAVR procedures were not to be performed until final approval by committee of the Board of Trustees.

70. Without final Board of Trustee committee approval and confirmation of AHS' operational ability to commence TAVR procedures as required by the NCD, Defendants began conducting TAVR procedures. Three (3) procedures were completed without final Board approval. The fourth TAVR procedure, because the patient was too ill to transfer, was also performed without Board approval of physician privileges.

71. Prior to any TAVRs being performed by Defendants, Relator was concerned, among other things, with the issue of whether AHS and AHC qualified for Medicare/Medicaid reimbursement for TAVAR procedures under the applicable NCD. In or about January 2022,

Relator met with certain members of AMG, including Dr. Rehman, as well as AHS' Chief Compliance Officer, Kristin Boggs, and Nathan Montgomery, AHS' Director of Cardiology, and advised them that: Defendants did not meet the qualifications set forth in CMS' NCD rules to perform TAVR procedures and, further, that until those requirements were met, Defendants could not seek reimbursement from any government health benefit program, including but not limited to Medicare, for any such procedures. Relator further advised that TAVR procedures performed before qualifying under CMS' NCD rules could not be counted toward meeting the requirement that 20 or more aortic valve related procedures had to be completed prior to performing TAVRs subject to payment under a government health benefit program. Relator memorized his concerns in email communications and other writings to Defendants.

72. AHS and AMG began performing TAVR procedures in January 2022. At that time, AHS lacked the operational support and capacity to perform the procedures safely and the new hybrid operating room where the procedures were to be performed was not completed. Furthermore, Defendants' heart team, as described in the NDS, did not have adequate post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures. The heart team had inexperience dealing with aortic valve related surgeries and their post-operation concerns.

73. Throughout 2022 and early 2023, Relator conducted multiple internal investigations related to TAVR patient safety concerns. Relator reported the results of his investigations, including his finding that TAVRs could not be performed until all CMS' NCD requirements were fulfilled, to AHS's Chief Executive Officer, Jeff Graham, its Chief Executive Officer, Kathi Edrington, Chief Operations Officer, and Kristin Boggs. Relator's investigative findings were documented in written reports and communications.

74. In March 2023, Relator learned that AHS and AMG had performed in excess of 20 TAVRs in violation of the NCD. As previously stated, in order for AHS, AMG and AHC to bill or cause bills to be presented to Medicare, Medicaid, and/or TRICARE/Champus for TAVR procedures, the NCD requires that AHS and/or AHC, as an institution, must have performed at least 20 aortic valve procedures in the 2 years prior to the TAVR program implementation before any patient billings were reimbursable under any government benefit program. Therefore, billing any governmental benefit program for TAVRs would be illegal because the threshold requirements of the NCD had not been met.

75. Relator also learned, in March 2023, that, after Defendants completed 20 TAVR procedures (the number of which procedures then qualified Defendants to be reimbursed for future TAVR procedures under government benefit program), AHS, AMG and AHC then retroactively billed and/or caused to be billed the qualifying TAVR procedures. More specifically, Defendants held or delayed billing 17 of its initial TAVR procedures until 20 procedures had been performed and, then unlawfully caused bills to be issued for the qualifying procedures. Restated, Defendants unlawfully submitted claims for TAVR procedures conducted prior to AHS and/or AHC's qualification for reimbursement under NCD.

76. In March 2023, Relator reported his concerns that Defendants' TAVR billings were unlawful and, further, his concerns regarding TAVR patient safety to AHS' executive leadership. In response, AHS began a workplace investigation of Relator, placed him on leave and, shortly thereafter, terminated his employment on April 12, 2023.

77. Per the NCD, AHS and AHC were required to complete more than 20 aortic valve procedures prior to qualifying for TAVR program initiation and prior to any patient billings were

reimbursable under any government benefit program. Therefore, Defendants performed TAVRs that were not reasonable and necessary pursuant to 42 U.S.C. § 1395y(a)(1)(A).

78. From 2022 through the present, AHS, AHC and AMG have knowingly submitted and/or caused to be submitted false claims for Medicare Part A facility fees and Part B physician fees related to TAVRs in violation of the FCA. AHC has used AMG to bill and describe Part B physician fees, and used AHS to submit Part A facility fees and other required CMS forms. At no time has AHS, AHC and/or AMG met all qualifications to perform TAVRs and to submit or cause to be submitted claims for payment of TAVR procedures.

79. The names of the physicians, advanced practice providers, nurses, surgical techs- any caregiver involved in each procedure, and each procedure identified by medical record number, CPT/billing code, date performed, date the charges were posted, complications CPT/billing codes, length of the procedure, length of stay prior to and after the procedure, preoperative evaluations dates, and government funded claims are available and in the possession Defendants.

E. AHC, AMG, and AHS Submitted Or Caused To Be Submitted False Claims

80. The submission of claims by AHC, AMG, and AHS identified herein for reimbursement of the expenses incurred for TAVR procedures are false claims.

81. In AHS and/or AHC's application to participate in Medicare, it certified in CMS Form 855(A) and CMS 1450 its compliance with all Medicare laws. Additionally, in its year-end CMS form submission for 2021 and 2022, it certified that "the services identified in the cost reports were provided in compliance with [the laws and regulations regarding the provision of healthcare services]. Similarly, Defendants submitted CMS 1500 forms and, in doing so, certified that the

medical services, i.e., TAVRs, its physicians were providing to the patients being treated were medically necessary.

82. Under federal law, a claim presented by AHC, AMG, and/or AHS for a TAVR procedure must comply with an applicable NCD for it to be considered a reasonable and necessary procedure eligible for reimbursement. Unless the claims submitted by AHC, AMG, and AHS for the TAVR procedures during the period from January 2022 to the present met the NCD as set forth in Chapter 20.32 of the MNCD Manual, they cannot be considered to represent medical services which are reasonable and necessary for purposes of obtaining reimbursement from a government sponsored program.

83. Prior to their submission of Part A claims by AHC and AHS for reimbursement of facility expenses incurred in performing TAVRs beginning in January 2022, AHC and AHS had not met the minimal prerequisite volume of aortic valve procedures in the prior two years as mandated by the CMS-NCD, and therefore, the request for reimbursement of Part A facility expenses for medical services related to TAVR procedures is not reasonable or necessary under federal law. Similarly, prior to the submission of Part B professional services claims by AHS, AHC and AMG, they were aware that the minimal prerequisite volume of aortic valve procedures in the prior two years as mandated by the CMS-NCD had not been met and, therefore, any request for reimbursement of the Part B professional expenses for medical services relating to TAVR procedures is not reasonable or necessary under federal law.

84. Notwithstanding that knowledge, AHC, AMG, and AHS have knowingly violated the FCA by submitting claims under Part A and Part B for reimbursement by the United States, Medicaid or Champus and/or other government sponsored benefit programs relating to the performance of TAVRs in violation of the NCD. By definition, these billings are medical

procedures which are not reasonable and necessary under 42 U.S.C. §1395y(a)(1)(A). Accordingly, they constitute false claims.

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85. Under Rule 9(b) of the Federal Rules of Civil Procedure, allegations of malice, intent, knowledge, and other conditions of a person's state of mind are exempt from its heightened pleading standards.

86. As pled herein, from January 2022 through present, AHC, AMG, and AHS and their executives as well as AHS' Board of Trustees were informed that billing for TAVR procedures, which did not meet the requirements set forth in the applicable NCD, was unlawful.

87. Nevertheless, AHS and AHC knowingly submitted or caused to be submitted or cause to be submitted false claims to the United States for the reimbursement of Part A facility expenses incurred in the performance of TAVR procedures. Additionally, AHS, AHC and AMG knowingly submitted or caused to be submitted Part B professional fees to the United States incurred in the performance of TAVR procedures. AHC, AMG, and AHS knew that the presentation of a claim for TAVRs did not meet the NCD minimum volume requirement and, therefore, the submission of Part A or Part B claims was illegal and in violation of federal law.

G. Materiality

88. Under the FCA, a misrepresentation about compliance with a statutory, regulatory, or contractual requirement such as an NCD must be material to the government's payment decision. *United Health Services, Inc. v. United States ex rel. Escobar*, 136 S.Ct 1989 (2016).

89. The materiality analysis is holistic and considers several factors including: "(1) 'the Government's decision to expressly identify a provision as a condition of payment;'" (2) whether the Government refuses to pay noncompliant claims, or "with actual knowledge of non-

compliance, it consistently pays such claims” and it does not intend to stop payments; and (3) “whether the ‘noncompliance is minor or insubstantial’ or if it goes ‘to the very essence of the bargain.’” *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018).

90. For the first factor, Congress has expressly determined in 42 U.S.C. §1395y(a)(1)(A) that a condition of payment by Medicare is that the services provided by the health care entity are reasonable and necessary. In order to meet this express statutory condition of payment for reimbursement of the TAVR procedure, the procedure must meet the qualifying criteria set forth under the applicable NCD. AHS and ACH’s presentation of claims or causing the presentation of claims for payment for the Part A facility fees for the procedures described herein are false. AMG, AHS and ACH’s presentation of claims or causing the presentation of claims for payment of the Part B professional fees for the procedures are false. Failure to comply with the NCD 20.32 minimal volume requirements means that the TAVR procedures performed by AMG, including but not limited to, Drs. Rehman, Mario Matos-Cruz, and Betz, were not reasonable and necessary, therefore, Defendants have failed to comply with an express condition of payment. The Defendants’ actions are material to the United States, Medicare, Medicaid, and Champus’ decision to pay the claim.

91. For the second factor, if the United States had known of Defendants’ unlawful behavior, it would not have paid Defendants’ claims for reimbursement of the TAVR procedures performed at AHS.

92. Under the third factor, Defendants’ non-compliance goes to the very essence of the bargain between the United States, Medicare, Medicaid, and Champus. Whether the Defendants have complied with the applicable minimal volume requirements in the NCD is something a

reasonable person and, in this case, the United States, Medicare, Medicaid and Champus, would want to know before it paid Defendants' claims. The United States agrees to pay claims by medical providers that are reasonable and necessary pursuant to 42 U.S.C. §1395y(a)(1)(A). Submission of medical expenses that meet the standard go to the very essence of the bargain between the United States and medical providers because the United States does not reimburse medical providers for expenses that are either unreasonable or unnecessary. NCD constitutes an express condition of payment.

93. The United States has taken the position that under Medicare a claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services issued were not medically necessary. (Exhibit 2, pp. 8, 22 citing to 42 U.S.C. §1395y(a)(1)(A)) Thus, if a defendant seeks federal reimbursement for procedures that they knew or had reason to know were not medically necessary, they defrauded the government and should be liable for that fraud. (Exhibit 2, p. 22) By submitting claims for services that are defined as reasonable and necessary by the applicable statutory authority, AHC, AMG, and AHS have breached the bargain between themselves and the United States, entitling the United States to recoup the amounts previously paid and refusing to make payments on any future TAVR requests.

H. Presentment and Fed.R.Civ.P. 9(b)

94. The Relator can satisfy the pleading requirements necessary to assert a claim of fraud under Fed.R.Civ.P. 9(b), "[s]o long as a relator pleads sufficient detail—in terms of time, place and content, the nature of a defendant's fraudulent scheme, and the injury resulting from the fraud—to allow a defendant to prepare a responsive pleading, the requirements of Rule 9(b) will generally be met." *United States Ex Rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 504 (6th Cir.2008).

95. An FCA claim may be deemed to have complied with the pleading requirements of Fed.R.Civ.P. 9(b) “if it includes allegations showing ‘specific personal knowledge’ supporting a ‘strong inference that a [false] claim was submitted.’ ” *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017) (quoting *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc. (Prather I)*, 838 F.3d 750, 769 (6th Cir. 2016)). As set forth *supra*, including but not limited to Paragraphs 66-78, Relator has sufficiently pled facts setting forth his specific personal knowledge which facts support a strong inference that Defendants submitted and/or caused false claims to be submitted.

96. In early 2022, Relator personally informed AHS’ Board of Trustees and its executive leadership that Defendants could not submit or cause to be submitted patient billing for reimbursement of TAVRs until all NCD requirements had been satisfied. Relator, based upon his direct and independent knowledge, alleges that from 2022 through present, AHC, AMG, and AHS submitted or caused to be submitted false claims which claims included Part A facility fees and Part B professional fees to the United States for TAVR procedures.

97. Relator has alleged specific personal knowledge which supports a strong inference that false claims were submitted. Relator has documented through his investigations, communications with Defendants, invoices, billing codes, etc. unlawful claims for reimbursement and payments received for TAVRs. In response, AHS retaliated against Relator and terminated his employment. Consequently, all documentation evidencing Defendants’ unlawful actions remains in their possession, custody and control.

VI. CAUSES OF ACTION

1. AHC, AMG, and AHS's Actions Are A Violation of 31 U.S.C. §3729(a)(1)(A)

98. Relator realleges and incorporates by reference all the foregoing paragraphs as if fully rewritten herein.

99. From January 2022 to the present, AHC, AMG, and AHS have knowingly, or with reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented or caused to be presented, false or fraudulent TAVR claims to the United States Government for payment of Part A facility fees and Part B professional fees by federally funded health insurance programs in violation of 31 U.S.C. §3729(a)(1)(A).

100. AHC, AMG, and AHS falsely certified that, before presenting a claim for payment or causing the presentation of a claim from a federally funded health insurance program, they had complied with federal laws which was untrue.

101. The false representations were material to the United States' decision to pay the claims presented by AHC, AMG, and AHS. By presenting claims that were in violation of federal laws, they are in violation of the FCA for which the United States seeks reimbursement from Adena for three times the amount of money paid by the United States, plus civil penalties.

2. AHC, AMG, and AHS' Actions Are A Violation of 31 U.S.C. §3729(a)(1)(B)

102. Relator realleges and incorporates by reference all the foregoing paragraphs as if fully rewritten herein.

103. From January 2022 to the present, AHC, AMG, and AHS have knowingly, or with reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be used, false or fraudulent records or statements or statements material to a

false statement to the United States for the purpose of having a false or fraudulent TAVR claim paid or approved in violation of 31 U.S.C. §3729(a)(1)(B).

104. The representations referred to above were material to the United States' decision to pay the claims presented by AHC, AMG, and AHS.

105. The United States was unaware of the falsity of the claims or statements made, or caused to be made by AHC, AMG, and AHS and, in reliance of the accuracy of these claims and/or statements, paid for procedures provided to individuals by Defendants insured by federally funded health insurance programs.

106. By presenting claims that were in violation of the FCA, the United States seeks reimbursement from AHC, AMG, and AHS for three times of the amount of the money paid, plus civil penalties.

3. AHS, AHC And AMG's Actions Are A Violation of 31 U.S.C. §3729(a)(1)(C)

107. Relator realleges and incorporates by reference all the foregoing paragraphs as if fully rewritten herein.

108. Upon information and belief, AHC and AMG are owned and operated by AHS. As set forth herein, executives at these entities conspired among themselves in a single plan to cause or submit false claims to United States federal health programs for TAVR procedures that violated the applicable NCD and, therefore, the reimbursement for these procedures were not reasonable or necessary.

109. Defendants shared in the general conspiratorial objective to get these false claims paid. At least one or more of the conspirators performed the act of submitting a false claim in furtherance of a conspiracy in order to get the claims paid. The foregoing actions are a violation of 31 U.S.C. §3792(a)(1)(c).

4. AHC, AMG, And AHS' Actions Are A Violation of 31 U.S.C. §3729(a)(1)(G)

110. Relator realleges and incorporates by reference all the foregoing paragraphs as if fully rewritten herein.

111. 31 U.S.C. §3729(a)(1)(G) provides that any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the United States, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the United States, has committed a violation of the FCA.

112. The term obligation means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee based or similar relationship, from statute regulation, or from the retention of any over-payment.

113. Defendants have an obligation to submit cost reports under CMS-2552 reconciling payments made to Adena throughout the calendar year. If an overpayment has been made to a Defendant, it has an obligation to repay the amount to the United States.

114. Due to Defendants' illegal conduct, they have been overpaid by the United States an amount equal to the sums presented for all Part A facility fees for TAVRs from January 2022 to the present, including costs of the hospital stay.

115. From January 2022 to the present, Defendants have failed to identify to the United States that they been overpaid the Part A facility and TAVRs performed by Defendants in violation of federal law.

116. Defendants are obligated to report to the United States these overpayments and return the overpayments within 60 days of the date the yearly CMS-2552 reports were due from Defendants to their fiscal intermediaries.

117. Defendants' retention of these overpayments is a violation of the FCA and subjects Defendants to liability under 31 U.S.C. §3729(a)(1)(G).

5. AHS's Termination Of Relator Is In Violation of 31 U.S.C. §3730(h)

118. Relator realleges and incorporates by reference all the foregoing paragraphs as if fully rewritten herein.

119. Relator was employed by AHS as the Vice President of Quality and Safety. Relator was an employee protected from retaliation under 31 U.S.C. §3730(h).

120. Throughout 2022 and 2023, Relator raised concerns, informed and reported Defendants noncompliance with the NCD and its violations when performing TAVR procedures. Relator also reported issues of patient health and safety related to Defendants TAVR procedures. Relator informed Defendants that billing or causing to be billed for TAVR procedures for federal government benefits when the NCD requirements were not met would be and/or was unlawful.

121. AHS responded to Relator's concerns by instructing him to cease investigations related to TAVR procedures. After Relator raised additional concerns regarding patient health and safety related to TAVR procedures in March 2023, AHS placed Relator on leave pending investigation and, thereafter, on April 12, 2023, AHS terminated Relator's employment.

122. AHS unlawfully retaliated against Relator by placing him on leave, failing to conduct a good faith investigation and terminating his employment in retaliation for his reports of fraud and patient safety concerns related to Defendants' implementation and operation of its TAVR program.

123. As a direct a proximate result of AHS's wrongful actions, Relator has sustained damages, including but not limited to backpay, front pay, loss of fringe benefits, compensatory damages and attorney fees.

124. Relator seeks recovery of damages from AHS for the above, which amount includes but is not limited to, liquidated damages, interest, costs of litigation and reasonable attorney's fees, witness fees, and fees for experts who testify at trial, in an amount the court determines appropriate pursuant to 31 U.S.C. §3730(h).

6. AHS Actions Are In Violation of O.R.C. §4113.52

125. Relator restates and incorporates by reference all the foregoing paragraphs as if fully rewritten herein.

126. Relator was an employee protected from retaliation under O.R.C. §4113.52.

127. Throughout 2022 and 2023, in the course of his employment, Relator raised concerns and reported Defendants' unlawful acts of non-compliance with CMS' NCD requirements. Relator informed Defendants that billing or causing to be billed for TAVR procedures for federal government benefits when the NCD requirements were not met would be and/or was unlawful. Relator also reported issues of patient health and safety related to Defendants TAVR procedures. Relator orally notified AHS' executive leadership of the violations and subsequently filed a written report(s) with sufficient detail identifying and describing the violations.

128. Relator made a reasonable and good faith effort to determine the accuracy of any information reported regarding the NCD, TAVRs, and the unlawful billing procedures. Relator investigated and reported the issues over the span of months as part of his duties as the Vice President of Quality and Safety.

129. Relator continued to report his concerns regarding Defendants' TAVR program. AHS unlawfully retaliated against Relator by placing him on leave, failing to conduct a good faith

investigation and terminating his employment in retaliation for his reports of fraud and patient safety concerns related to Defendants' implementation and operation of its TAVR program.

130. As a direct a proximate result of AHS's wrongful actions, Relator has sustained damages, including but not limited to, backpay, front pay, loss of fringe benefits, compensatory damages and attorney fees.

WHEREFORE, Relator Rhett Holland, requests judgment to be entered against AHS, AMG, and AHC, jointly and severally as follows:

I. AHS, AMG, and AHC be enjoined and ordered to cease and desist from submitting or causing the submission of any further false claims;

II. Judgment be entered in the United States' favor against AHS, AMG, and AHC in the amount of each and every false or fraudulent claim submitted pursuant to the unlawful scheme described herein and tripled by 31 U.S.C. §3729(a), and that a civil penalty of not less than \$5,500 nor more than \$11,000 per claim submitted since January of 2022, as provided by 31 U.S.C. §3729 be imposed;

III. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d), including up to 25 percent of the proceeds of the action or settlement of the claim in the event the United States intervenes, or 30 percent of the recovery in the event the United States declines to intervene;

IV. Relator be awarded the payment of two times the amount of back wages, interest on the back pay, and all or a portion of the costs of litigation and reasonable attorney's fees, witness fees, and fees for experts who testify at trial, in an amount the court determines appropriate pursuant to 31 U.S.C. §3730(h), 31 U.S.C. §3730(d)(1), and O.R.C. §4113.52(E);

V. Relator be awarded further compensatory damages; and,

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

Respectfully submitted,

/s/ Judith E. Galeano
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Trial Attorneys for Relator

JURY DEMAND

Relator hereby demands that a jury decide all claims in this Complaint.

CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2023, a true and accurate copy of the foregoing was electronically filed with the Clerk of Courts using the CM/ECF system. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ Judith E. Galeano
Judith E. Galeano (0048366)
Trial Attorney for Plaintiff/Relator