UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES *ex rel.* RICHARD ZELMAN, Plaintiff, v. CAPE COD HOSPITAL, Defendant.	Civil Action No. FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

FALSE CLAIMS ACT COMPLAINT

Richard Zelman ("Relator") brings this action as a *qui tam* relator on behalf of the United States against Cape Cod Hospital ("CCH"), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729-33, to recover damages, penalties, attorneys' fees and costs, and other relief.

I. PRELIMINARY STATEMENT

1. Relator, an interventional cardiologist at CCH, alleges that CCH violated the False Claims Act, 31 U.S.C. § 3729, by submitting claims for transcatheter aortic valve replacement ("TAVR") procedures without complying with the National Coverage Determination ("NCD") conditions for Medicare reimbursement of TAVR procedures.

2. Since 2012, in order for a TAVR procedure to be reimbursable, the NCD has imposed a number of requirements, including (1) that an interventional cardiologist and one or more cardiac surgeons independently examine the patient face-to-face and evaluate the patient's suitability for TAVR, and (2) that an interventional cardiologist and cardiac surgeon "jointly participate in the intra-operative technical aspects of TAVR."

3. Since 2015, CCH has performed nearly 1000 TAVR procedures, but it has rarely complied with these conditions of payment.

4. In the vast majority of these cases, only an interventional cardiologist independently examined the patient and evaluated the patient's suitability for TAVR. During the subsequent procedures, at least one interventional cardiologist scrubbed in and performed the intra-operative technical aspects of TAVR, but a cardiac surgeon almost never scrubbed in or touched the patient; typically, the cardiac surgeon appeared in the procedure room only briefly, if at all, to observe.

5. Consequently, the vast majority of CCH's Medicare reimbursement claims for TAVR have not complied with the NCD and have been false.

6. Moreover, since at least as early as October 2021, senior CCH executives have been well aware that CCH's Medicare claims for TAVR procedures were false, but, on information and belief, CCH has not returned any of the overpayments it received on those claims.

7. Prior to the filing of this Complaint, Relator made substantive disclosures to the government of facts and evidence underlying the allegations in this Complaint, in accordance with the requirements of the False Claims Act, 31 U.S.C. § 3730(b)(2).

8. Relator is an original source of the information underlying this Complaint and of the information provided to the United States prior to the filing of this Complaint. *See* 31 U.S.C. § 3730(e)(4)(B). To Relator's knowledge, the information underlying the allegations and transactions in this Complaint has not been publicly disclosed.

9. This action is filed *in camera* and under seal pursuant to the requirements of the False Claims Act, 31 U.S.C. § 3730(b)(2).

II. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. § 3732, which confers jurisdiction over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

11. This Court may exercise personal jurisdiction over CCH, and venue is appropriate in this Court, under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)(2), because CCH can be found in this District, transacts business in this District, and engaged in acts proscribed by 31 U.S.C. § 3729 in this District.

III. THE PARTIES

12. Relator, a resident of Barnstable, Massachusetts, is an interventional cardiologist. Since 1990, Relator has practiced at CCH. Since 2006, he has been an employee of CCH. During his time at CCH, Relator has had various titles, including Medical Director of Interventional Cardiology within the Cardiac Catheterization Laboratories at CCH, Medical Director for Cardiovascular Services, Medical Director of Interventional Cardiology, Director of the CCH Inpatient Cardiology Program, and Administrative Medical Director of Cape Cod Healthcare's Heart and Vascular Institute. Relator's current employment contract with CCH expires on September 30, 2022. On June 13, 2022, CCH's Chief Executive Officer ("CEO"), Michael Lauf, informed Relator that CCH would not be renewing or extending Relator's contract.

13. Defendant CCH is a Massachusetts corporation that operates a hospital in Hyannis, Massachusetts. CCH is a subsidiary of Cape Cod Healthcare, Inc.

IV. BACKGROUND ON TAVR PROCEDURES

14. Physicians perform TAVR procedures on patients with severe aortic stenosis, a condition in which the aortic valve, which leads from the main pumping chamber of the heart

(the left ventricle) to the aorta (the main artery of the body), has narrowed and does not open fully, with a consequent reduction of blood flow from the heart to the rest of the body.

15. Traditionally, cardiac surgeons treated severe aortic stenosis through open-heart surgery to replace the aortic valve. As the Centers for Medicare and Medicaid Services ("CMS") explained in a 2019 Decision Memo:

> For decades, the only available treatment for aortic stenosis was surgical aortic valve replacement (SAVR)(Bonow, 2006). It is a major operation that requires opening the chest and using a heart-lung bypass machine, but the risks associated with SAVR are far less than those of leaving severe aortic valve stenosis untreated (Bakaeen, 2010). In this open-heart operation, the damaged valve is removed and replaced with a new artificial valve.

16. Because open-heart surgery is a complex and invasive procedure, it often is not suitable for patients who are elderly or have comorbidities.

17. In the early 2000s, trials of an alternative, less-invasive procedure, TAVR, began.

18. In a TAVR procedure, physicians do not open the chest cavity, but instead implant an artificial valve utilizing a catheter tube that they typically insert through the femoral artery from an insertion point in the groin.

19. On November 2, 2011, the Food and Drug Administration ("FDA") approved the Edwards Sapien Transcatheter Heart Valve ("THV") "for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis." In other words, the initial approval was for patients not eligible for open-heart surgery.

20. Since then, FDA has progressively expanded the approval of THVs for patients. On October 19, 2012, FDA approved the Edwards THV not only for inoperable patients, but also for patients who would be at high risk during open-heart surgery, specifically "operative

candidates for aortic valve replacement but who have a Society of Thoracic Surgeons predicted operative risk score ≥8% or are judged by the heart team to be at a ≥15% risk of mortality for surgical aortic valve replacement." On August 18, 2016, FDA expanded the Edwards THV indication to include patients "at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator)." On August 16, 2019, FDA further expanded the Edwards THV indication "to include patients at low risk for surgical aortic valve replacement."

21. Since 2015, FDA also has issued parallel approvals for a competing Medtronic THV.

V. LEGAL BACKGROUND

A. National Coverage Determinations

22. Congress has prohibited Medicare from reimbursing "any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

23. While the Medicare statute does not define "reasonable and necessary," Congress empowered CMS to issue NCDs "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. § 405.1060(a)(1) ("An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare."). CMS regulations explain that "NCDs are made under [42 U.S.C. § 1395y(a)(1)]," *i.e.*, the statutory "reasonable and necessary" requirement. 42 C.F.R. § 405.1060(a)(3).

B. The 2012 And 2019 NCDs For TAVR Procedures

24. On September 22, 2011, the Society of Thoracic Surgeons and the American College of Cardiology made a joint request to CMS for a NCD for TAVR procedures. Among other things, they proposed that Medicare cover TAVR procedures only when "joint cardiology and cardiac surgeon clinical judgment will be used to reach a final decision regarding the appropriate use of TAVR," and that "[c]overage is limited to facilities/providers where both the cardiologist and cardiac surgeon participate jointly in the intra-operative technical aspects of TAVR (the 'team approach')."

25. In 2012, CMS adopted many of the recommendations from the joint specialty society request and issued the first NCD for TAVR procedures. The 2012 NCD provided for reimbursement of TAVR procedures for patients who were "(preoperatively and postoperatively) . . . under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals" that included a "cardiovascular surgeon" and an "interventional cardiologist." The NCD set forth a number of conditions for TAVR coverage, including the following two conditions:

1. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

2. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

26. In June 2019, CMS issued a revised NCD with an implementation date of June 12, 2020. The revised NCD continues to require that "[t]he patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals" that includes a "cardiac surgeon" and an "interventional cardiologist." Among the coverage conditions in the revised NCD are that:

1. [A c]ardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis . . . have:
    i. independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy; [and]
    ii. documented and made available to the other heart team members the rationale for their clinical judgment.

2. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

27. Thus, prior to June 12, 2020, Medicare covered a TAVR procedure only if, among other things, prior to the procedure, *two* cardiac surgeons and an interventional cardiologist independently examined the patient and evaluated the patient's suitability for TAVR.

28. Since June 12, 2020, under the revised NCD, CMS has relaxed this requirement and now requires that only *one* cardiac surgeon and an interventional cardiologist perform independent examinations and evaluations of the patient prior to a TAVR procedure.

29. As CMS explained in its 2019 Decision Memo, "TAVR is a technically complex procedure with an evolving evidence base, and patients benefit from the multidisciplinary review, rather than a single physician. . . . [T]o ensure the best patient health outcomes an interventional cardiologist as well as a cardiac surgeon should evaluate the patient suitability for TAVR. . . . [T]his approach integrates multiple perspectives into a balanced, patient-centered care plan and encourages evidence-based medical care."

30. Meanwhile, throughout the period from 2012 through the present, CMS also has conditioned Medicare coverage for TAVR procedures on having both an interventional cardiologist and a cardiac surgeon "jointly participate in the intra-operative technical aspects of TAVR." In its 2019 Decision Memo, CMS specifically rejected "various suggestions including only requiring two operators when needed (for example, non-transfemoral access sites), allowing

an interventional cardiologist to perform TAVR without a cardiac surgeon in the room and allowing either a cardiothoracic surgeon or interventional cardiologist to perform TAVR alone." CMS reasoned that "During our evidence review there was not any data demonstrating equivalent or improved outcomes with a single operator or alternate operator combination."

C. Medicare Reimbursement For TAVR Procedures

31. After performance of a TAVR procedure, the hospital submits a facility claim under Medicare Part A, and the employer of the participating physicians submits medical service claims under Medicare Part B.

32. For the hospital, the applicable diagnosis-related groups ("DRGs") are 266 (endovascular cardiac valve replacement and supplement procedures with a major complication or comorbidity) or 267 (endovascular cardiac valve replacement and supplement procedures without a major complication or comorbidity).

33. In 2021, the reimbursement for DRG 266 was $45,617, and the reimbursement for DRG 267 was $36,000.

34. For the physicians, the applicable CPT codes include the range from 33361 to 33366, typically with Modifier 62, which applies "[w]hen two surgeons work together as primary surgeons performing distinct part(s) of a procedure." *See* National Government Services, *Modifiers*, available at https://www.ngsmedicare.com/modifiers?selectedArticleId=1410904&lob=96664&state=97224&region=93623. In 2021, the Medicare reimbursement for each physician under these circumstances ranged from $771 to $1001.

D. The False Claims Act

35. The False Claims Act provides, in pertinent part, that any person who:

> (A) knowingly presents, 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; [or] . . .
>
> (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,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

36. For purposes of the False Claims Act, "the terms 'knowing' and 'knowingly' mean that a person, with respect to information[,] (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B).

37. The False Claims Act defines the term "obligation," in pertinent part, as "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 or regulation." 31 U.S.C. § 3729(b)(3).

38. For purposes of the False Claims Act, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

E. The Medicare Advantage Program

39. In lieu of original Medicare, a person eligible for Medicare may subscribe to a Medicare Advantage plan offered by a private insurer through Medicare Part C. Medicare Advantage plans include the benefits of Medicare Parts A and B, but may impose additional limitations on that coverage.

40. CMS pays Medicare Advantage plans a per-patient per-month fee to provide health benefits to Medicare beneficiaries.

41. In 2009, Congress amended the False Claims Act to make clear that it applies to claims submitted to entities such as Medicare Advantage plans that are funded by the government. Specifically, the False Claims now provides that:

> the term "claim"—
> (A) means any request or demand . . . that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) *is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest*, and if the United States Government—
>
> (I) provides or has provided any portion of the money or property requested or demanded; or
>
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. . . .

31 U.S.C. § 3729(b)(2) (emphasis added).

42. The Senate Report for the 2009 False Claims Act amendments explained that this "section of the bill clarifies that liability under section 3729(a) attaches whenever a person

knowingly makes a false claim to obtain money or property, any part of which is provided by the Government without regard to whether the wrongdoer deals directly with the Federal Government; with an agent acting on the Government's behalf; or with a third party contractor, grantee, or other recipient of such money or property." S. Rep. 111-10, 11, 2009 U.S.C.C.A.N. 430, 438.

43. Thus, if a party submitted, or caused the submission of, false claims to a Medicare Advantage plan, that party also caused the submission of false claims to Medicare.

VI. FACTUAL ALLEGATIONS

A. CCH's Reliance On Cardiac Surgeons From BWH

44. In April 2001, the Massachusetts Department of Public Health approved CCH to perform open-heart surgeries. The first open-heart surgery at CCH occurred in August 2002.

45. CCH did not (and still does not) employ any cardiac surgeons. Instead, BWH generally supplied CCH with two cardiac surgeons. BWH paid the salaries of these surgeons and billed third-party payers, including Medicare, for the surgeons' services at CCH. CCH paid BWH an annual fee to administer the cardiac surgery program at CCH.

46. Dr. Robert Rizzo was CCH's first Chief of Cardiac Surgery, and he remained there until 2013.

47. Dr. Paul Pirundini joined the CCH cardiac surgery program in 2007, and he became Chief when Dr. Rizzo stopped practicing.

48. In or about January 2014, BWH hired Dr. Daniel Loberman to join Dr. Pirundini on the CCH cardiac surgery staff. In or about January 2020, Dr. Pirundini left CCH and joined the staff of Beth Israel Lahey Health. In or about August 2020, Dr. Anastasios Konstantakos joined the CCH cardiac surgery staff.

49. During the period from January to June 12, 2020, when the original TAVR NCD was still in effect, CCH could not have complied with that NCD's requirement that two cardiac surgeons independently examine and evaluate each patient's suitability for open aortic valve replacement, because CCH did not have two cardiac surgeons on staff.

50. In February 2022, CCH barred Dr. Loberman from its campus after determining that he had carried a rifle into the hospital campus.

51. Meanwhile, in or about December 2021, CCH gave notice that it was terminating its arrangement with BWH. At approximately the same time, CCH arranged for Beth Israel Lahey Health to supply cardiac surgeons to CCH beginning in or about April 2022.

B. CCH's Failure To Comply With The NCD Requirements For TAVR Procedures

52. CCH began offering TAVR procedures in 2015. Since then, physicians at CCH have performed nearly 1,000 TAVR procedures, mostly on Medicare beneficiaries. CCH, however, never required its cardiac surgeons to become trained to perform TAVR procedures.

53. Consequently, from 2015 through 2021, cardiac surgeons scrubbed in and performed jointly as operators in less than five percent of the TAVR procedures at CCH. Instead, a surgeon typically entered the procedure room only briefly to observe, usually just prior to insertion of the "big sheath" through which a THV is placed into a patient's heart. Sometimes, a surgeon did not even enter the procedure room during the procedure and appeared only briefly in the control area outside the procedure room.

54. Dr. Pirundini scrubbed in for approximately 5 TAVR procedures at CCH.

55. Dr. Loberman scrubbed in for approximately 20 TAVR procedures at CCH.

56. Dr. Konstakos never scrubbed in for a TAVR procedure at CCH.

57. In sum, although cardiac surgeons sometimes were present during parts of TAVR procedures at CCH, they almost never "jointly participate[d] in the intra-operative technical aspects of TAVR," notwithstanding the NCD requirement.

58. Cardiac surgeons at CCH also rarely performed independent examinations of patients to evaluate their suitability for TAVR prior to these procedures. In some cases, a cardiac surgeon prepared a short note concerning a potential TAVR candidate, but the surgeon typically did not conduct an independent history and physical examination that would enable the surgeon to evaluate the patient's suitability for TAVR or an alternative treatment. In many cases, the surgeons did not document an examination or evaluation at all.

59. On information and belief, CCH falsely billed Medicare for facility fees for TAVR procedures as if it had complied with the NCD, that is, as if cardiac surgeons had independently examined and evaluated the patients in advance of the procedures and then had jointly participated in the intra-operative technical aspects of the procedures. CCH also submitted medical service claims for the work of its interventional cardiologists and other physicians during TAVR procedures.

60. BWH submitted medical service claims representing that its cardiac surgeons, too, participated in the intra-operative aspects of the procedures, even though they rarely did.

C. CCH's Knowledge That Its Claims For TAVR Procedures Were False

61. Since at least as early as 2017, Relator has raised concerns multiple times with CCH management about poor outcomes and excessive mortality from surgeries that BWH cardiac surgeons have performed at CCH.

62. In 2017, for example, Relator expressed to the CCH CEO, Mr. Lauf, and the then-Chief Medical Officer ("CMO"), his concerns about cardiac surgeries Dr. Loberman recently had

performed at CCH. In response, Mr. Lauf and the CMO essentially told Relator that supervision of the cardiac surgeons at CCH was BWH's responsibility.

63. In 2021, Relator and the other two CCH interventional cardiologists, Alanna Coolong and David Leeman, met with Mr. Lauf to discuss poor outcomes from cardiac procedures Dr. Konstantakos recently had performed.

64. Shortly thereafter, BWH initiated a review of the work of its cardiac surgeons at CCH. In the course of this review, senior BWH surgeons traveled to Hyannis to observe cardiac surgeries and TAVR procedures at CCH.

65. On October 29, 2021, Relator met with Mr. Lauf and William Agel, CCH's Chief Medical Officer, concerning BWH's review. They told him that, the day before, they had spoken with Rafael Bueno, the Chief of the Division of Thoracic and Cardiac Surgery at BWH, to discuss BWH's review of the work of cardiac surgeons at CCH. According to Mr. Lauf and Dr. Agel, Dr. Bueno told them that the involvement (or lack of involvement) of cardiac surgeons in TAVR at CCH had to change: that surgeons had to examine and evaluate TAVR candidates more than a day before TAVR procedures, and that the surgeons had to participate in key aspects of the procedures, including when the sheath is inserted and the valve is deployed.

66. During Relator's meeting with Mr. Lauf and Dr. Agel, Dr. Agel provided Relator with a two-page set of polices to which the CCH heart team should adhere. As Dr. Agel subsequently explained to Relator in a text message, "[t]he first part is essentially cut and pasted from B+W, with some edits for grammar and redundancy. The second part is how I would operationalize it…." With respect to TAVR procedures, the document stated:

> As per CMS rules patients under consideration for Aortic Valve replacement will:
>
> - have a face-to-face consult with both an Attending cardiothoracic surgeon and an interventional cardiologist. These consults can be conducted either

concurrently or separately. Results of these consultations will be documented separately by each physician in the medical record.

- In either case the Heart Team will confer no later than the day prior to the planned procedure. This conference will include at least one attending CT surgeon, the consulting CT surgeon from B+W and one attending Interventional cardiologist. In addition, every effort will be made to include the patient[']s referring community cardiologist.
- Options will include
    - Continued medical management
    - SAVR
    - TAVR
    - Hospice/palliative care
- During TAVR the covering CT surgeon will be present *in the room* prior to placement of the TAVR sheath and remain until after deployment of the valve.

67. In providing these policies, Dr. Agel implicitly acknowledged the determination of both BWH and CCH that TAVR procedures at CCH previously had not occurred in a manner consistent with the policies.

68. In November 2021, Relator learned that BWH intended to self-report to CMS that BWH had billed inappropriately for the services of its cardiac surgeons during TAVR procedures at CCH, because the surgeons had not jointly participated in the intra-operative aspects of the procedures.

69. More recently, on July 6, 2022, Mr. Lauf informed Relator that CCH had decided not to renew Relator's employment agreement in part because, "on Thursday, May 26, 2022, Mass General Brigham informed [CCH] that the Brigham would make disclosure to its Medicare Administrative Contractor and issue a full refund on all TAVR cases performed at Cape Cod Hospital over the last six years. They then confirmed back to [CCH] on June 2nd that the Brigham had completed both tasks."

70. In an e-mail to Relator's attorney on January 25, 2022, CCH's general counsel, Michael Jones, acknowledged that CCH lacked documentation of compliance with the TAVR NCDs:

> One thing I likely will need to talk about more with Dr. Zelman is element #3 [the NCD requirement that the "interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR], as it does not appear that we have much in the way of documentation to confirm the surgeon's presence (at least not in the historic cases most germane to the present review), and we will need Dr. Zelman's help in how best to substantiate that that criterion indeed was met at the time of the given procedure.

D. Exemplar Procedures

Patient 1[1]

71. As of May 2015, Patient 1 was 89 years old and suffering from aortic stenosis.

72. On information and belief, Patient 1 was a Medicare beneficiary.

73. On May 1, 2015, Relator and Dr. Loberman, a cardiac surgeon, examined Patient 1 to evaluate his suitability for TAVR. A second cardiac surgeon did not independently examine Patient 1 and evaluate his suitability for TAVR.

74. On June 1, 2015, Patient 1 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

75. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 1's TAVR procedure.

Patient 2

76. As of May 2015, Patient 2 was 89 years old and suffering from aortic stenosis.

[1] For each patient that this complaint references by number, Relator has provided the patient's name to the government, and Relator will do the same for CCH and/or the Court upon request.

77. On information and belief, Patient 2 was a Medicare beneficiary.

78. On May 13, 2015, Patient 2 was admitted to CCH. On May 19, 2015, Relator performed a balloon aortic valvuloplasty on Patient 2, and she was discharged from the hospital the following day.

79. On June 28, 2015, Relator examined Patient 2 in person to evaluate her suitability for TAVR.

80. Two cardiac surgeons did not independently examine Patient 2 in person and evaluate her suitability for TAVR.

81. On June 29, 2015, Patient 2 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

82. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 2's TAVR procedure.

Patient 3

83. As of June 2020, Patient 3 was 75 years old and suffering from aortic stenosis.

84. On information and belief, Patient 3 was a Medicare beneficiary.

85. On June 16, 2020, Relator consulted with Patient 3 via telephone (in light of the Covid virus) to evaluate his suitability for TAVR.

86. A cardiac surgeon did not independently examine Patient 3 and evaluate his suitability for TAVR.

87. On July 23, 2020, Patient 3 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

88. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 3's TAVR procedure.

Patient 4

89. As of December 2020, Patient was 88 years old and suffering from aortic stenosis.

90. On information and belief, Patient 4 was a Medicare beneficiary.

91. On December 28, 2020, Relator examined Patient 4 in person to evaluate her suitability for TAVR.

92. A cardiac surgeon did not independently examine Patient 4 and evaluate her suitability for TAVR.

93. On January 21, 2021, Patient 4 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

94. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 4's TAVR procedure.

Patient 5

95. As of May 2021, Patient 5 was 76 years old and suffering from aortic stenosis.

96. On information and belief, Patient 5 was a Medicare beneficiary.

97. On May 26, 2021, Patient 5 was admitted to CCH through its emergency department.

98. After Patient 5's admission to CCH, Relator examined Patient 5 in person to evaluate his suitability for TAVR.

99. A cardiac surgeon did not independently examine Patient 5 and evaluate his suitability for TAVR.

100. On June 2, 2021, Patient 5 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

101. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 5's TAVR procedure.

Patient 6

102. As of May 2021, Patient 6 was 86 years old and suffering from aortic stenosis.

103. On information and belief, Patient 6 was a Medicare beneficiary.

104. On May 25, 2021, Dr. Coolong, a CCH interventional cardiologist, consulted with Patient 6 via telephone (in light of the Covid virus) to evaluate his suitability for TAVR.

105. A cardiac surgeon did not independently examine Patient 6 and evaluate his suitability for TAVR.

106. On July 1, 2021, Patient 6 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

107. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 6's TAVR procedure.

Patient 7

108. As of August 2021, Patient 7 was 79 years old and suffering from aortic stenosis.

109. On information and belief, Patient 7 was a Medicare beneficiary.

110. On August 2, 2021, Patient 7 was admitted to the emergency department at CCH's affiliate, Falmouth Hospital. He was subsequently transferred to CCH in Hyannis.

111. After Patient 7's admission to CCH, Relator examined Patient 7 in person to evaluate his suitability for TAVR.

112. A cardiac surgeon did not independently examine Patient 7 and evaluate his suitability for TAVR.

113. On August 5, 2021, Patient 7 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

114. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 7's TAVR procedure.

Patient 8

115. As of August 2021, Patient 8 was 80 years old and suffering from aortic stenosis.

116. On information and belief, Patient 8 was a Medicare beneficiary.

117. On August 3, 2021, Dr. Coolong, a CCH interventional cardiologist, consulted with Patient 8 via telephone (in light of the Covid virus) to evaluate her suitability for TAVR.

118. A cardiac surgeon did not independently examine Patient 8 and evaluate her suitability for TAVR.

119. On August 12, 2021, Patient 8 underwent a TAVR procedure at CCH. Relator participated in all of the intra-operative technical aspects of this procedure, but a cardiac surgeon did not participate in any of the intra-operative technical aspects of the procedure.

120. On information and belief, CCH billed Medicare or a Medicare Advantage Plan for Patient 8's TAVR procedure.

E. Even After CCH And BWH Recognized That BWH Cardiac Surgeons Had Not Performed The Services Necessary To Comply With The NCD Requirements, BWH Cardiac Surgeons Continued Not To "Jointly Participate" In TAVR Procedures At CCH.

121. On Monday, January 10, 2022, Relator performed an emergency TAVR procedure on Patient 9, an 80-year-old woman who had come into the hospital the weekend before suffering from cardiogenic shock due to severe aortic stenosis and who had sustained a myocardial infarction (heart attack) shortly after she was admitted. On the day before the procedure, Relator examined Patient 9 and evaluated her suitability for TAVR. On the morning of January 10, 2022, he requested that Dr. Loberman, a cardiac surgeon, examine Patient 9 and evaluate her suitability for TAVR. Both Relator and Dr. Loberman agreed that TAVR was Patient 9's only hope for survival, and her TAVR procedure was scheduled for that afternoon. There was an earlier TAVR procedure that day, and Dr. Loberman was present for it. Patient 9 was brought into the procedure room at 2:37 p.m. Dr. Loberman was not present, even though he knew the procedure was scheduled for that afternoon. Relator consulted with Dr. Coolong and other members of the heart team on whether to proceed. Relator decided to proceed because of the severity of Patient 9's condition. At the beginning of the procedure, Relator asked that Dr. Loberman be paged, but Dr. Loberman did not appear. During the course of the procedure, Relator learned that Dr. Loberman had left the hospital and that Dr. Konstantakos was covering in his absence. Relator asked that Dr. Konstantakos be paged, but learned that Dr. Konstantakos, too, was out of the hospital and was at least 10-20 minutes away. In light of Patient 9's critical condition, the rest of the procedure went forward. After the valve was deployed, Relator briefly observed Dr. Konstantakos in the control area outside the procedure room.

122. On March 17, 2022, Relator began a TAVR procedure on Patient 10. Again, no cardiac surgeon was present. As Relator explained to Dr. Agel and Mr. Lauf in a subsequent e-mail, the following then occurred:

> During placement of the smaller sheaths and preclosure of the vessel there was concern that an injury to the femoral vessel might have caused retroperitoneal bleeding. The remedy for this would be to immediately place the "big sheath" to seal any bleeding. Despite the cardiac surgeon knowing that the case was being performed he was not present and when called he informed the staff that he would "need at least ten minutes". I have been instructed that for "regulatory" and "compliance" reasons I am not to place the big sheath until the surgeon is present. I waited several minutes but with the blood pressure trending down I was clinically bound to place the big sheath. The patient stabilized and remained stable. The surgeon arrived 7 minutes later and the procedure was completed without complication.

VII. CAUSES OF ACTION

COUNT I
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

123. Relator re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

124. CCH knowingly presented or caused to be presented to Federal health care programs false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). Specifically, CCH presented or caused to be presented claims for payment to Federal health care programs for TAVR procedures that did not occur as CCH reported them to have occurred, as described herein.

125. By virtue of the false or fraudulent claims CCH knowingly presented or caused to be presented, the United States has suffered actual damages in an amount to be proven at trial. The United States is entitled to recover treble damages plus a civil monetary penalty for each and every false claim.

COUNT II
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

126. Relator re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

127. CCH knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to Federal health care programs, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B). These false records and statements included false entries in medical records concerning the role of cardiac surgeons in TAVR evaluations and procedures at CCH, and misleading representations on claim forms submitted to Federal health care programs concerning the role of cardiac surgeons in TAVR evaluations and procedures at CCH.

128. By virtue of the false records or statements CCH made, used or caused to be made or used, the United States has suffered actual damages in an amount to be proven at trial. The United States is entitled to recover treble damages plus a civil monetary penalty for each and every false claim.

Count III
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G)

129. Relator re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

130. Since at least as early as October 2021, CCH has been on notice that it had submitted claims to Federal health care programs for TAVR procedures that did not comply with the TAVR NCD conditions of payment, and that, as a result, it has had an obligation to report and return overpayments pursuant to 42 U.S.C. § 1320a-7k(d). Instead, CCH knowingly concealed or knowingly and improperly avoided its obligations to pay or transmit money or property to the Government, in violation of 31 U.S.C. § 3729(a)(1)(G).

131. By virtue of CCH's knowing failure to return overpayments, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each instance in which it knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money or property to the Government.

Count IV
Federal False Claims Act, 31 U.S.C. § 3730(h)

132. Relator re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

133. CCH refused to renew Relator's employment contract because his expression of concerns about the performance of cardiac surgeons at CCH led BWH to self-disclose to the government that TAVR cases at CCH were not performed in accordance with the TAVR NCD, thus exposing that CCH, too, had submitted false Medicare claims for TAVR procedures.

134. CCH's termination of Relator's employment with CCH is in retaliation for Relator's lawful acts.

135. As a result of CCH's wrongful actions, Relator has suffered and continues to suffer substantial damage in an amount to be determined at trial.

VIII. PRAYER FOR RELIEF

WHEREFORE, Relator demands and prays for the following relief:

1. That judgment be entered in favor of the United States for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper;
2. An award to the Relator of a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730(d);

3. An award of lost earnings, lost benefits, loss of future earning capacity, punitive damages, damages for emotional distress, liquidated damages, and pre-judgment and post-judgment interest;

4. An award to the Relator of his costs and reasonable attorney's fees for prosecuting this action; and

5. All other relief as may be required or authorized by law and in the interests of justice.

IX. DEMAND FOR JURY TRIAL

Relator hereby demands a trial by jury.

Dated: July 26, 2022

Respectfully submitted,

RICHARD ZELMAN

By his attorney

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