

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“HHS-OIG”) of the Department of Health and Human Services (“HHS”) (collectively, the “United States”), Cape Cod Hospital (“CCH”), and Richard B. Zelman, M.D. (“Relator”) (hereafter collectively referred to as the “Parties”), through their authorized representatives.

### RECITALS

- A. CCH is a Massachusetts not-for-profit corporation that operates a hospital in Hyannis, Massachusetts. CCH is a subsidiary of Cape Cod Healthcare, Inc.
- B. Relator is an interventional cardiologist who CCH employed during the relevant time period.
- C. On July 26, 2022, Dr. Zelman filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Richard Zelman v. Cape Cod Hospital*, No. 1:22-cv-11204, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action). Following the Effective Date of this Agreement, the United States will file a notice of intervention in part for purposes of settlement.
- D. The United States contends that CCH knowingly submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”).
- E. CCH admits, acknowledges, and accepts its responsibility for the following facts:
  - 1. In 2015, CCH began offering transcatheter aortic valve replacement (“TAVR”) services. TAVR procedures treat aortic stenosis—a condition where a person's aortic valve narrows, restricting blood flow from the heart to rest of the body—by

replacing the patient's damaged valve with an artificial one. Until approximately May 2022, CCH contracted with Hospital-1 to provide cardiac surgeons to CCH for various services, including TAVR procedures. Under this arrangement, as to the TAVR procedure, CCH billed Medicare for the facility fee and the professional services fees for its staff, and Hospital-1 billed Medicare for the professional services fees for the contracted cardiac surgeons.

2. CMS set forth the conditions for Medicare coverage for TAVRs in National Coverage Determination 20.32 (the "NCD"). Before June 21, 2019, the NCD required that, prior to performing a TAVR procedure, two cardiac surgeons independently examine the patient face-to-face and evaluate the patient's suitability for TAVR. The two cardiac surgeons were additionally required to document the rationale for their clinical judgment and make the rationale available to the team of medical professionals responsible for the TAVR procedure. After June 21, 2019, the NCD required that an interventional cardiologist and only one cardiac surgeon perform the independent examination. The documentation requirement did not change.
3. From November 1, 2015, through December 31, 2022 (the "Relevant Period"), CCH submitted approximately 800 claims to Medicare for TAVR procedures. Government counsel identified these claims to CCH through a separate letter to protect patient privacy.
4. In or about November 2021, Hospital-1 contacted CCH about conducting a review of TAVR procedures performed at CCH. Shortly thereafter, both CCH and Hospital-1 began independently reviewing records from a sample of 90 patients

selected by Hospital-1, on whom TAVR procedures were performed at CCH between November 12, 2015, and November 11, 2021.

5. In or about June 2022, Hospital-1 informed CCH that it would be issuing a full refund to Medicare on all TAVR cases performed at CCH and that it would be making a disclosure to its Medicare Administrative Contractor.
6. CCH, on the other hand, did not issue a full refund in part due to flaws in its review. For example, although CCH's review included procedures performed before June 21, 2019, CCH applied only the NCD in effect on or after June 21, 2019—not the more restrictive NCD in effect before that period. CCH also failed to identify as noncompliant certain records that did not comply with either NCD. At the end of this review, CCH determined that six of the 90 claims in the sample, four of which were Medicare claims, did not comply with the NCD for Medicare reimbursement. On January 4, 2023, CCH provided a voluntary refund to Medicare for those four Medicare claims.
7. In fact, significantly more of the TAVR procedures performed at CCH from November 1, 2015, to December 31, 2022, failed to comply with applicable NCD requirements. A review of a more extensive set of medical records for an expanded sample of 105 procedures reflected that nearly half of the sample did not comply with the applicable NCD requirements. More specifically, in some of these cases, CCH failed to comply with the NCD requirement that two cardiac surgeons (before June 21, 2019) or an interventional cardiologist and one cardiac surgeon (on or after June 21, 2019) independently examine the patient face-to-face and evaluate the patient's suitability for TAVR. In other cases, CCH failed to comply with the NCD requirement that the interventional cardiologist and/or

surgeon(s) document the rationale for their clinical judgment and make the rationale available to the team of medical professionals responsible for the TAVR procedure.

8. Extrapolating the conclusions from the expanded review to all of the approximately 800 claims that CCH submitted to Medicare during the Relevant Period, renders nearly half of those claims non-compliant with the NCDs. Accordingly, those claims should not have been billed to Medicare.

F. The United States contends that it has certain civil claims against CCH for engaging in the conduct described in Recital E during the period of November 1, 2015 through December 31, 2022 (hereinafter referred to as the “Covered Conduct”). In particular, the United States contends that CCH knowingly submitted hundreds of claims to Medicare for TAVR procedures that did not comply with the applicable NCD requirements. This resulted in CCH submitting millions of dollars of false claims to Medicare in violation of the False Claims Act.

G. CCH received credit under the Department of Justice’s guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual §4-4.112. Among other actions, CCH voluntarily produced materials, identified documents most relevant to the United States’ investigation, implemented appropriate remedial measures, and accepted responsibility for its wrongdoing.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

## TERMS AND CONDITIONS

1. CCH shall pay to the United States twenty-four million, three hundred ninety three thousand, five hundred seven dollars (\$24,393,507) (“Settlement Amount”) and interest on the Settlement Amount at a rate of 4.375% per annum from March 20, 2024, of which \$14,075,982.91 is restitution; the payment shall be made in two installments as follows (“Settlement Payment Schedule”):

- a. Initial Payment. CCH shall pay the sum of twelve million, one hundred ninety-six thousand, seven hundred and fifty-three dollars, and fifty cents (\$12,196,753.50), plus accrued interest as set forth above, within 30 days of the Effective Date of this Agreement.
- b. Second Payment. CCH shall pay the sum of twelve million, one hundred ninety-six thousand, seven hundred and fifty-three dollars, and fifty cents (\$12,196,753.50), plus accrued interest as set forth above, within 360 days of the Effective Date of this Agreement.
- c. Both payments shall be via electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

The Settlement Amount may be prepaid, in whole or in part, without penalty or premium.

2. Conditioned upon the United States receiving each payment pursuant to the Settlement Payment Schedule, and as soon as feasible after receipt, the United States shall pay 17.5% of each such payment, to Relator by electronic funds transfer (“Relator’s Share”).

3. CCH agrees to pay \$121,163 to Relator and Relator’s counsel, within 30 days of the Effective Date of this Agreement, in full satisfaction of their claims for expenses, attorney’s

fees, and costs incurred in connection with the Civil Action, by electronic funds transfer. No additional attorney's fees, expenses, or costs shall be paid or claimed by Relator or his counsel.

4. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases CCH from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 7 below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases CCH, its parent, and their respective trustees, officers, agents, employees, counsel, and insurers, from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733.

6. In consideration of the obligations of CCH in this Agreement and the Corporate Integrity Agreement (“CIA”), entered into between HHS-OIG and CCH, and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1, the HHS-OIG shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against CCH under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 7 (concerning reserved claims), below. The HHS-OIG expressly

reserves all rights to comply with any statutory obligations to exclude CCH from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the HHS-OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

8. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

9. Relator, for himself and his heirs, successors, attorneys, agents, and assigns, fully and finally releases CCH from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Relator has asserted, could have asserted, or may assert in the future against CCH, and its parent, and their respective trustees, officers, agents, employees, counsel, and insurers related to the Civil Action and Relator's investigation and prosecution, and CCH's defense thereof.

10. CCH waives and shall not assert any defenses CCH may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

11. CCH, its parent, and their respective trustees, officers, agents, employees, counsel and insurers, fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that CCH has asserted, could have asserted, or may assert



in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

12. CCH, its parent, and their respective trustees, officers, agents, employees, counsel and insurers, fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that CCH has asserted, could have asserted, or may assert in the future against the Relator, his agents, employees, counsel and insurers, related to the Civil Action and the Relator's investigation and prosecution thereof.

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and CCH agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

14. CCH agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of CCH, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) CCH's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in

connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement;
- (5) the payment CCH makes to the United States pursuant to this Agreement and any payments that CCH may make to Relator, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 14.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to CCH.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in non-reimbursable cost centers by CCH, and CCH shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by CCH or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: CCH further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and

Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by CCH or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. CCH agrees that the United States, at a minimum, shall be entitled to recoup from CCH any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by CCH or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on CCH or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine CCH's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 5 and 9 (Relator's release of CCH and others) and 16 (waiver for beneficiaries).

16. CCH agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors,

legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

17. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

20. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

22. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

24. This Agreement is binding on CCH's successors, transferees, heirs, and assigns.

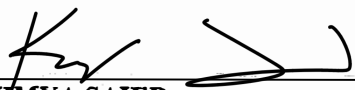
25. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

26. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


27. This Agreement is effective on the date of signature of the last signatory to the Agreement (the “Effective Date” of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: 5/16/2024

BY:   
**KIMYA SAIED**  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 5/16/2024

BY:   
**ANDREW A. CAFFREY, III**  
Assistant United States Attorney  
United States Attorney's Office for the  
District of Massachusetts

DATED: 05/14/24

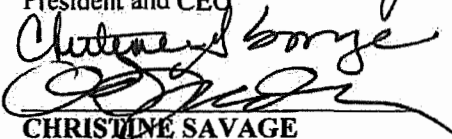
BY: **SUSAN GILLIN** Digitally signed by SUSAN GILLIN  
Date: 2024.05.14 18:01:49 -0400  
**SUSAN E. GILLIN**  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**Cape Cod Hospital - DEFENDANT**

DATED: 5.14.2024

BY:   
**MICHAEL K. LAUF**  
President and CEO

DATED: 5.14.2024

BY:   
**CHRISTINE SAVAGE**  
**ADAM BOOKBINDER**  
Counsel for Cape Cod Hospital

**Dr. Richard Zelman - RELATOR**

DATED: 5/13/2024 BY:   
RICHARD B. ZELMAN, M.D.

DATED: 5/14/24 BY:   
GREGG SHAPIRO  
Counsel for Dr. Richard Zelman