

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 of the Department of Health and Human Services (“OIG-HHS”) (collectively, the “United States”); Massachusetts Eye and Ear Infirmary, Massachusetts Eye and Ear Associates, Inc., and the Foundation of the Massachusetts Eye and Ear Infirmary, Inc. (collectively the “Defendants”); and the Estate of Dr. Allan Goldstein (the “Relator’s Estate”) (hereafter collectively referred to as the “Parties”), through their authorized representatives.

RECITALS

A. Massachusetts Eye and Ear Infirmary (“MEEI”) is a not-for-profit teaching hospital that focuses on the treatment of diseases and medical conditions impacting the eye, ear, nose, throat, head, and neck. In addition to its principal location in Boston, MEEI also manages and maintains clinical locations throughout Massachusetts. Massachusetts Eye and Ear Associates, Inc. (“Associates”) is a physician group comprised, in large part, of ophthalmologists and otolaryngologists who provide medical services at all of MEEI’s clinical locations. The Foundation of the Massachusetts Eye and Ear Infirmary, Inc. (“Foundation”) is the parent corporation for MEEI, Associates, and other controlled organizations. On April 1, 2018, Partners HealthCare System (“Partners”) purchased the Defendants. On November 27, 2019, Partners HealthCare System changed its name to Mass General Brigham.

B. On October 19, 2018, the Relator filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States ex rel. John Doe v. Massachusetts Eye and Ear Infirmary, Massachusetts Eye and Ear Associates, Inc., and Foundation of the Massachusetts Eye and Ear Infirmary, Inc.*, 18-cv-12179-LTS, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The

Relator, a former otolaryngologist for Associates, alleged that the Defendants violated the Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b), and the physician self-referral law (commonly referred to as the “Stark Law”), 42 U.S.C. § 1395nn, by incentivizing Associates physicians to order outpatient services at MEEI outpatient departments by paying the Associates physicians bi-annual bonuses out of the facility fees MEEI received from insurers, including government healthcare payors. The Relator passed away on February 12, 2021. The Relator’s Estate substituted the Relator in this case, by order of the Court, on November 22, 2021.

C. The United States contends that the Defendants 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”).

D. The Medicare program pays for medically necessary professional services performed by physicians either in an office or facility setting, including a hospital or a clinic/site that operates as a provider-based hospital outpatient department (“HOPD”), under the Medicare Physician Fee Schedule. A hospital that participates in Medicare may also obtain reimbursement from Medicare under the Outpatient Prospective Payment System (“OPPS”) for facility fees, laboratory tests, x-rays and other radiological services, and various medical supplies, each time it furnishes outpatient services to a patient at the hospital or one of its HOPDs. A facility fee is intended to reimburse the hospital for overhead expenses it incurred in the treatment of a Medicare outpatient, including, for example, the costs incurred to maintain facilities or to pay non-clinical staff.

Unless an exception applies and its requirements are satisfied, the Stark Law prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship; and prohibits the entity from filing claims with Medicare (or billing another individual, entity, or

third-party payer) for any improperly referred designated health services. Hospitals are “entities” for purposes of the Stark Law, and all inpatient and outpatient hospital services are “designated health services” for purposes of the Stark Law.

E. The Defendants admit, acknowledge, and accept responsibility for the following facts:

1. The Defendants maintained numerous compensation arrangements with the approximately 240 physicians Associates employed. The government investigated these arrangements in conjunction with the Civil Action.

2. During the government’s investigation, the Defendants self-reported 7 compensation models involving 44 physicians that may have implicated the Stark Law. The Defendants executed these arrangements prior to Mass General Brigham’s acquisition in 2018. One arrangement ended before Mass General Brigham acquired the Defendants, and Mass General Brigham voluntarily terminated the remaining 6 arrangements on October 1, 2019.

3. MEEI operates HOPDs at various locations throughout the Commonwealth. At certain of these HOPDs, MEEI transferred a percentage of its operating margin at the applicable HOPD (ranging from 30-50%) to Associates at the end of each fiscal year. MEEI calculated the operating margin by subtracting the HOPD’s expenses from its fiscal year revenue, such that the operating margin included revenue from designated health services. Associates then included such funds in the overall revenue allocated to otolaryngologists and/or ophthalmologists affiliated with the HOPD location, against which Associates subtracted employment expenses. Associates paid any surplus to the physicians as a bonus as part of the physicians’ aggregate compensation. In most instances, Associates allocated the funds to each physician based on either personally performed services or time-based units for hours worked,

although in one instance, Associates allocated the funds in equal shares. The Defendants contend that the compensation of relevant physicians was consistent with fair market value.

4. In addition, MEEI similarly transferred a percentage of its operating margin to Associates with respect to 2 individual physicians who practiced at the main MEEI campus, and compensated those 2 physicians in a manner consistent with that described in paragraph 2.

5. Finally, with respect to 2 HOPDs, MEEI transferred 100% of the macular drug profit to Associates, which Associates then allocated to physicians based on personally performed injections.

6. The conduct described in this paragraph is referred to below as the “Covered Conduct.”

F. With the exception of the Covered Conduct, the Defendants expressly deny the allegations of the Relator’s Estate as set forth in the Civil Action.

G. The United States contends that it has certain civil claims against the Defendants arising from the facts described in Recital E. Specifically the United States contends that, as described in Recital E, MEEI’s incentive payments made through end of fiscal year money transfers to Associates which Associates then paid to the physicians employed by Associates, from October 1, 2008 until October 1, 2019, created a direct or indirect financial relationship between MEEI and the physicians employed by Associates; the physicians employed by Associates referred Medicare beneficiaries to MEEI for outpatient hospital services; and MEEI furnished outpatient hospital services ordered by the physicians employed by Associates and submitted the respective claims to Medicare for those services. The United States further contends that the financial relationships between MEEI and the physicians employed by Associates did not satisfy the requirements of any applicable exception to the Stark Law. The

United States further contends that referrals by physicians employed by Associates to MEEI for designated health services were, therefore, prohibited, and the submission of claims to the Medicare program for the improperly referred services violated the Stark Law and were false under the False Claims Act.

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

I. The United States recognizes and credits the Defendants for disclosure, cooperation, and remediation of the Covered Conduct under the Department of Justice's guidelines for False Claims Act cases embodied in the Justice Manual, §4-4.112.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. The Defendants shall pay to the United States \$5,700,111.10, plus interest at a rate of 4% per annum from January 1, 2023 ("Settlement Amount"), of which \$3,562,569.44 is restitution, no later than 15 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of Massachusetts.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay 17% of the Settlement Amount to Relator's Estate by electronic funds transfer ("Relator's Share").

3. The Defendants shall pay Relator \$375,000 for expenses, and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d)(1). Such payment shall be made no later than 10 days

after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided to Defendants by Relator's counsel.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States releases the Defendants, their predecessors, current and former parents, divisions, subsidiaries, successors, and assigns, 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; the civil monetary provisions of the Stark Law at 42 U.S.C. §§ 1395nn(g)(3) and (g)(4), or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 6 below, and upon the United States' receipt of the Settlement Amount under Paragraph 1 and Relator's Estate's receipt of amounts due under Paragraph 3, Relator's Estate, for and for its heirs, successors, attorneys, agents, and assigns, releases the Defendants, their predecessors, current and former parents, divisions, subsidiaries, successors, and assigns, from any and all liability, claims, allegations, demands, actions and causes of action whatsoever in law or equity, that Relator has or could have asserted against Defendants in the Civil Action, including but not limited to the civil monetary claim the Relator's Estate has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. 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 or permissive 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; and
- f. Any liability of individuals.

7. Relator's Estate and its 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 Estate's receipt of the Relator's Estate's Share, Relator's Estate and its 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.

8. The Defendants waive and shall not assert any defenses MEEI, Associates, and/or Foundation 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.

9. The Defendants fully and finally release 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 MEEI, Associates, and/or Foundation have

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.

10. The Defendants fully and finally release the Relator's Estate from any and all liability, claims, allegations, demands, actions and causes of action whatsoever in law or equity (including attorneys' fees, costs, and expenses of every kind and however denominated) that MEEI, Associates, and/or Foundation have asserted, could have asserted, or may assert in the future against the Relator's Estate, including but not limited to the Covered Conduct and the Relator's Estate's investigation and prosecution thereof.

11. 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 the Defendants agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

12. The Defendants agree 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 MEEI, Associates, and/or Foundation, their 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) The Defendants' 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; and
- (5) the payment the Defendants' make to the United States pursuant to this Agreement and any payments that the Defendants may make to Relator's Estate, including costs and attorneys' fees;

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).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the Defendants, and the Defendants 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 the Defendants or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: The Defendants further agree that within 90 days of the Effective Date of this Agreement they 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 the Defendants or any of their 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. The Defendants agree that the United States, at a minimum, shall be entitled to recoup from the Defendants 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 the Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on the Defendants or any of their 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 the Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. The Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, the Defendants shall encourage, and agree not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. The Defendants further agree to furnish to the United States,

upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

14. 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 Paragraph 15 (waiver for beneficiaries paragraph), below.

15. The Defendants agree that they waive 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.

16. 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).

17. Except as otherwise provided herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

19. 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.

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

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

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

23. This Agreement is binding on the Defendants' successors, transferees, heirs, and assigns.

24. This Agreement is binding on the Relator's Estate's successors, transferees, heirs, and assigns.

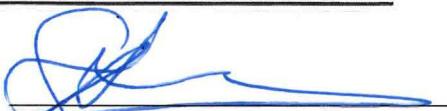
25. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement ("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: 5/24/2023

BY:



STEVEN SHAROBEM
CHARLES WEINOGRAD
Assistant United States Attorney
United States Attorney's Office, District of Massachusetts

DATED: _____

BY:

LISA RE

Digitally signed by LISA RE
Date: 2023.05.22 14:22:41
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LISA M. RE
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

MASSACHUSETTS EYE AND EAR INFIRMARY

DATED: 5/11/23 BY: Carolann Williams
CAROLANN WILLIAMS
Interim President, Massachusetts Eye and Ear Infirmary

DATED: 5/11/23 BY: Heather Price
LISA SCHLATZ
HEATHER PRICE
Counsel for Massachusetts Eye and Ear Infirmary

MASSACHUSETTS EYE AND EAR ASSOCIATES, INC.

DATED: 5/11/23 BY: Carolann Williams
CAROLANN WILLIAMS
Interim President, Massachusetts Eye and Ear Infirmary

DATED: 5/11/23 BY: Heather Price
LISA SCHLATZ
HEATHER PRICE
Counsel for Massachusetts Eye and Ear Associates, Inc.

FOUNDATION OF THE MASSACHUSETTS EYE AND EAR INFIRMARY, INC.

DATED: 5/11/23 BY: Carolann Williams
CAROLANN WILLIAMS
Interim President, Massachusetts Eye and Ear Infirmary

DATED: 5/11/23 BY: Heather Price
LISA SCHLATZ
HEATHER PRICE
Counsel for Foundation of the Massachusetts Eye and Ear Infirmary, Inc.

ESTATE of DR. ALLAN GOLDSTEIN

DATED: 5/8/23

BY:


DAVID KOPANS

Executor of Estate of Dr. Allan Goldstein

DATED: 5/8/23

BY:


LINDA C. SEVERIN

DAVID W. S. LIEBERMAN

Counsel for Estate of Dr. Allan Goldstein