

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 Department of Health and Human Services (“HHS”), and the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”) (collectively, the “United States”); Burlington County Eye Physicians II and Gregory H. Scimeca, M.D. (“Dr. Scimeca”) (collectively, the “defendants”); and Relator Tricia Lennox Thomas, M.D. (“Relator”) (hereafter the United States, the defendants, and the Relator are collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Burlington County Eye Physicians II, also known as Burlington County Eye Physicians, and doing business as The Eye Professionals (“BCEP”) is an ophthalmology practice with locations in New Jersey and Pennsylvania.

B. Dr. Scimeca is a resident of New Jersey. Dr. Scimeca is an ophthalmologist, and the owner of BCEP.

C. A transcranial doppler (“TCD”) test is a noninvasive diagnostic test that can be used to estimate the blood flow through certain blood vessels in the brain by bouncing high-frequency sound waves off blood cells.

D. Medicare has specific requirements to reimburse for TCD scans, which Medicare contractors have set forth in Local Coverage Determinations (“LCDs”) for non-invasive vascular studies. *See* LCDs 35753 and 35397.

E. Non-invasive vascular studies are not reimbursable under applicable Medicare LCDs unless (1) significant signs/symptoms of arterial or venous disease are present; (2) the information is necessary for appropriate medical and/or surgical management; and/or (3) the test

is not redundant of other diagnostic procedures that must be performed. In addition, TCD scans are medically unnecessary if the outcome will not potentially impact the clinical course of the patient.

F. A physician can use modifier 26 to bill for the professional component of a TCD test, when a physician interprets but does not perform the test. A physician is not permitted to use modifier 26 when they re-read another physician's interpretation of the TCD results.

G. On November 19, 2020, the Relator filed an action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Lennox-Thomas v. Burlington County Eye Physicians et al.*, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). On May 28, 2021, the Clerk of Court transferred the Civil Action to the District of Massachusetts. On July 30, 2021, the Relator filed an amended complaint in the Civil Action. The Civil Action alleges, among other things, that the defendants and other individuals and entities submitted or caused the submission of false claims to Medicare for medically unnecessary TCD testing and received kickbacks for the TCD referrals, in violation of the False Claims Act. The relator further alleged that BCEP referred patients for TCD testing based on conditions that the patients did not have, including Vertebro-Basilar Syndrome or Vertebrobasilar Insufficiency ("VBI"), a very rare condition that causes inadequate blood flow in the brain.

H. The United States contends that BCEP and Dr. Scimeca submitted and caused the submission of claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and the FEHBP, 5 U.S.C. §§ 8901-8914 for TCD tests.

I. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), prohibits health care providers from knowingly and willfully soliciting or receiving any remuneration for

referring a patient for a Medicare-reimbursed diagnostic test or for ordering any Medicare-reimbursed diagnostic test.

J. BCEP and Dr. Scimeca each admit, acknowledge, and accept responsibility for the following facts:

From May 13, 2019 through February 22, 2021 (the “Relevant Period”) BCEP submitted and caused the submission of claims for TCD tests, using Current Procedural Terminology (“CPT”) codes 93886, 93888, 93890, and 93892, to Medicare and FEHBP. During the Relevant Period Medicare and FEHBP collectively reimbursed BCEP \$118,953 for CPT codes 93886, 93888, 93890, and 93892.

During the Relevant Period, BCEP had a written contractual agreement with an independent medical diagnostics company (“TCD company”). The TCD company rented space from BCEP and provided an on-site technician to BCEP. The TCD technician conducted TCD tests on site using the TCD company’s equipment. The TCD company’s technician reviewed patient files and filled out order sheets for TCD tests at BCEP. BCEP physicians, including Dr. Scimeca, signed the order forms for TCD tests. BCEP physicians, including Dr. Scimeca, signed order forms for TCD tests that indicated that particular patients had VBI, when those patients did not have a diagnosis of VBI.

A radiology company associated with the TCD company (“radiology company”) read the TCD test results and sent summaries interpreting the results to BCEP. BCEP paid thirty dollars to either the TCD company or the radiology company to read each TCD test. BCEP physicians, including Dr. Scimeca, billed for the professional component of TCD tests using modifier 26 when the ordering physician was not the physician reading and interpreting the TCD results. BCEP retained the reimbursement it received from Medicare and FEHBP for the professional component of the TCD tests.

K. The United States contends that it has certain civil claims against BCEP and Dr. Scimeca arising from the conduct in Recital J during the period from May 13, 2019 through February 22, 2021 (hereafter the “Covered Conduct”). In particular, the United States contends that, as a result of the Covered Conduct, the defendants submitted and caused the submission of false claims to Medicare and FEHBP for TCD tests, in violation of the False Claims Act. The United States contends that the claims were false because (1) the TCD tests were medically unnecessary, (2) the defendants used modifier 26 to bill for professional services that they did not perform, and (3) the arrangement between BCEP and the TCD company violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

L. 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.

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

TERMS AND CONDITIONS

1. BCEP and Dr. Scimeca shall collectively pay to the United States \$469,232, plus interest at a rate of 4.375% per annum from March 25, 2024, and continuing through the date of payment (“Settlement Amount”), no later than 15 days after the Effective Date of this Agreement. Of the Settlement Amount, \$234,616 is restitution. BCEP and Dr. Scimeca are jointly and severally liable for the Settlement Amount.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$84,461.76 plus a pro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer (“Relator’s Share”).

3. Pursuant to 31 U.S.C. § 3730(d), BCEP and Dr. Scimeca shall collectively pay to Relator a total of \$105,000 for expenses, attorneys' fees, and costs no later than 15 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions provided by Relator.

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 BCEP and Dr. Scimeca 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 6 below, and upon the United States' receipt of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases BCEP and Dr. Scimeca and their current and former direct and indirect subsidiaries, affiliates, divisions, shareholders, directors, officers, and employees, from any and all actions, causes of action, debts, dues, claims and demands of every name and nature, without limitation at law, in equity, or as to administrative relief, which Relator and/or Relator's counsel may have had, now have, or may have, whether known or unknown, by reason of any matter or thing arising from the beginning of time through the Effective Date, and 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. Notwithstanding the releases given in Paragraph 4 of this, 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 other than Dr. Scimeca.

7. Relator and her 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 her 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. Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases Dr. Scimeca and BCEP, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

9. BCEP and Dr. Scimeca waive and shall not assert any defenses they 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.

10. BCEP and Dr. Scimeca 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 BCEP and Dr. Scimeca 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.

11. BCEP and Dr. Scimeca fully and finally release the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that BCEP and Dr. Scimeca have asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof.

12. 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), FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and BCEP and Dr. Scimeca agree not to resubmit to any Medicare contractor or FEHBP carrier 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.

13. BCEP and Dr. Scimeca 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 Dr. Scimeca or BCEP, 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 and any criminal investigation(s) of the matters covered by this Agreement;
- (3) BCEP's and Dr. Scimeca's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal 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(s) BCEP and Dr. Scimeca make to the United States pursuant to this Agreement and any payments that BCEP and Dr. Scimeca may make to Relator, 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 BCEP and Dr. Scimeca, and they 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 BCEP or Dr. Scimeca or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:
BCEP 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 Dr. Scimeca or BCEP 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. BCEP and Dr. Scimeca agree that the United States, at a minimum, shall be entitled to recoup from BCEP and Dr. Scimeca 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 Dr. Scimeca or BCEP or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Dr. Scimeca's or BCEP's 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 Dr. Scimeca's or BCEP's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

14. BCEP and Dr. Scimeca agree to cooperate fully and truthfully with any investigation by the United States of individuals and entities not released in this Agreement, including the TCD company, radiology company, and related individuals and entities in

connection with the Covered Conduct. Upon reasonable notice, BCEP and Dr. Scimeca shall encourage, and agree not to impair, the cooperation of BCEP's 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 and without waiver of the rights and privileges of such individuals.

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 Paragraph 16 (waiver for beneficiaries paragraph), below.

16. BCEP and Dr. Scimeca 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.

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). With respect to the United States, the dismissal shall be with prejudice as to the Covered Conduct and without prejudice as to the other conduct or causes of action. Relator's dismissal shall be with prejudice as to the Covered Conduct and all other conduct or causes of action concerning BCEP, its physicians, and Dr. Scimeca.

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 Dr. Scimeca's and BCEP'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 (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: 7/19/2024

BY: JESSICA WEBER Digitally signed by JESSICA WEBER
Date: 2024.07.19 08:14:25 -04'00'
JESSICA J. WEBER
CHRISTOPHER MORGAN
Assistant United States Attorneys
District of Massachusetts

DATED: _____

BY: _____
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

DATED: _____

BY: _____
EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations,
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

JESSICA J. WEBER
CHRISTOPHER MORGAN
Assistant United States Attorneys
District of Massachusetts

DATED: 07/15/24

BY: SUSAN GILLIN Digitally signed by SUSAN GILLIN
Date: 2024.07.15 16:36:57 -04'00'

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

DATED: _____

BY: _____

EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations,
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

JESSICA J. WEBER
CHRISTOPHER MORGAN
Assistant United States Attorneys
District of Massachusetts

DATED: _____

BY: _____

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

DATED: _____

BY: _____

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Date: 2024.07.18 13:27:18 -04'00'

EDWARD M. DEHARDE
Deputy Associate Director of Federal Employee
Insurance Operations,
Healthcare and Insurance
United States Office of Personnel Management

DATED: _____

BY: _____

PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

JESSICA J. WEBER
CHRISTOPHER MORGAN
Assistant United States Attorneys
District of Massachusetts

DATED: _____

BY: _____

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

DATED: _____

BY: _____

EDWARD M. DEHARDE
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United States Office of Personnel Management

DATED: _____

BY: _____

PAUL ST
HILLAIRE
PAUL ST. HILLAIRE
Assistant Inspector General
for Legal & Legislative Affairs
Office of the Inspector General
United States Office of Personnel Management

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HILLAIRE
Date: 2024.07.17 12:57:32
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BCEP AND DR. SCIMECA - DEFENDANTS

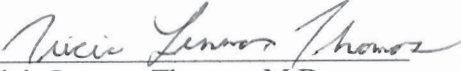
DATED: 7/16/24 BY: Gregory H Scimeca MD
Gregory H. Scimeca, M.D. owner of
Burlington County Eye Physicians

DATED: 7/16/24 BY: Gregory H Scimeca MD
Gregory H. Scimeca, M.D.


DATED: 7/17/24 BY: [Signature]
~~Daniella Gordon~~
Glenn A Mackinlay
McCarter & English, LLP
Counsel for BCEP and Dr. Scimeca

DR. LENNOX THOMAS - RELATOR

DATED: 7/13/24

BY: 
Tricia Lennox Thomas, M.D.

DATED: July 17, 2024

BY: 
Michael M. Mustokoff
Duane Morris LLP
Counsel for Tricia Lennox Thomas, M.D.