

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 (OIG-HHS) of the Department of Health and Human Services (HHS); the Defense Health Agency (DHA), acting on behalf of the TRICARE program; and the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP) (collectively, the “United States”), and Northwest ENT Associates, P.C. (“Northwest ENT”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Northwest ENT is a Georgia corporation that is owned by and that employs physicians who performed the procedures that are the subject of this Agreement at facilities owned by Northwest ENT in Atlanta and other locations in northwest Georgia.

B. The United States contends that Northwest ENT 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”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the FEHBP, 5 U.S.C. §§ 8901-8914.

C. The United States contends that it has certain civil claims against Northwest ENT arising from the following conduct in violation of the False Claims Act, 31 U.S.C. § § 3729, 3733 (“FCA”): Northwest ENT submitted and caused to be submitted claims to Medicare, Tricare and FEHBP for balloon sinus dilation procedures (CPT codes 31295, 31296 and 31297) that took place between January 1, 2011 and March 31, 2012 and that re-used balloon sinus dilation devices that were cleared by the Food and Drug Administration as intended for single-

use only, on multiple patients, which the United States alleges was an improper use of the device. That conduct is referred to below as the “Covered Conduct.”

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. Northwest ENT shall pay to the United States \$1,195,361.00 (“Settlement Amount”), of which \$398,454.00 is restitution, and interest on the Settlement Amount at an annual rate of 2.75% from May 30, 2018, no later than five (5) days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Northern District of Georgia.

2. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Northwest ENT’s full payment of the Settlement Amount, the United States releases Northwest ENT 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.

3. In consideration of the obligations of Northwest ENT in this Agreement and the Integrity Agreement (IA), entered into between OIG-HHS and Northwest ENT, and conditioned upon Northwest ENT’s full payment of the Settlement Amount, the OIG-HHS agrees to 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 Northwest ENT 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 6 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Northwest ENT 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 OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

4. In consideration of the obligations of Northwest ENT set forth in this Agreement, and conditioned upon Northwest ENT's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Northwest ENT under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 6 (concerning excluded claims), below. DHA expressly reserves authority to exclude Northwest ENT from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

5. In consideration of the obligations of Northwest ENT in this Agreement, and conditioned upon Northwest ENT's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the FEHBP against Northwest ENT under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 Subpart J or Part 919 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 6 (concerning excluded claims), below, and except if excluded by the OIG-HHS

pursuant to 42 U.S.C. § 1320a-7(a). OPM expressly reserves all rights to comply with any statutory obligation to debar Northwest ENT from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding the release given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims 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, 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; or
- g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Northwest ENT waives and shall not assert any defenses it 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.

8. Northwest ENT fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Northwest ENT has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. 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), TRICARE or FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and Northwest ENT agrees not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer, 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.

10. Northwest ENT 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 Northwest ENT, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Northwest ENT'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 attorney's fees);

- (4) the negotiation and performance of this Agreement and any Plea Agreement;
- (5) the payment Northwest ENT makes to the United States pursuant to this Agreement; and
- (6) the negotiation of, and obligations undertaken pursuant to the IA to: (i) retain an independent review organization to perform quarterly reviews as described in Section III of the IA; 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 10.a.(6) that may apply to the obligations undertaken pursuant to the IA affects the status of costs that are not allowable based on any other authority applicable to Northwest ENT.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers by Northwest ENT, and Northwest ENT 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 Northwest ENT or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

11. Northwest ENT agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Northwest ENT shall encourage, and agrees 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. Northwest ENT further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

12. 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 13 (waiver for beneficiaries paragraph), below.

13. Northwest ENT 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.

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

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

16. 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 Northern District of Georgia. 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.

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

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

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

20. This Agreement is binding on Northwest ENT's successors, transferees, heirs, and assigns.

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

22. 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: 7/26/2018

BY: 
NEELI BEN-DAVID
Assistant United States Attorney
Northern District of Georgia

DATED: 7/16/2018

BY: 
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

DATED: _____

BY: _____
LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
EDWARD M. DEHARDE
Assistant Director, Federal Employee Insurance Operations
Healthcare and Insurance

DATED: _____

BY: _____
ROBIN M. RICHARDSON
Acting Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

NEELI BEN-DAVID
Assistant United States Attorney
Northern District of Georgia

DATED: _____

BY: _____

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

DATED: 7/26/2018

BY:  _____

for

LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____

EDWARD M. DEHARDE
Assistant Director, Federal Employee Insurance Operations
Healthcare and Insurance

DATED: _____

BY: _____

ROBIN M. RICHARDSON
Acting Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

NEELI BEN-DAVID
Assistant United States Attorney
Northern District of Georgia

DATED: _____

BY: _____

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

DATED: _____

BY: _____

LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DATED: 7/19/2018

BY: 

EDWARD M. DEHARDE
Assistant Director, Federal Employee Insurance Operations
Healthcare and Insurance

DATED: _____

BY: _____

ROBIN M. RICHARDSON
Acting Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
NEELI BEN-DAVID
Assistant United States Attorney
Northern District of Georgia

DATED: _____

BY: _____
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

DATED: _____

BY: _____
LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
EDWARD M. DEHARDE
Assistant Director, Federal Employee Insurance Operations
Healthcare and Insurance

DATED: 7/18/18

BY: 
ROBIN M. RICHARDSON
Acting Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

NORTHWEST ENT ASSOCIATES, P.C. -DEFENDANT

DATED: 7/18/18 BY: 
SHATUL L. PARIKH, M.D.
Partner

DATED: 7/18/18 BY: 
AVANI PATEL INGLE, M.D.
Partner

DATED: 7/18/18 BY: 
RYAN M. KAUFFMAN, M.D.
Partner

DATED: 7/18/18 BY: 
DREW LOCANDRO, M.D.
Partner

DATED: 7/18/18 BY: 
RICHARD E. GLAZE, Jr.
Balch & Bingham, LLP
Counsel for Northwest ENT Associates, P.C.