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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) and 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”); Anne Arundel Medical Center, Inc. (hereafter “AAMC” or the “Defendant”), and Barbara McHenry (hereafter “Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. AMMC is a non-profit regional hospital headquartered in Annapolis, Maryland. In June 2007, AAMC opened an Anticoagulation Clinic (“the Clinic”) to provide outpatient testing to monitor oral anticoagulation therapy for patients taking Coumadin, or warfarin. Prothrombin testing is typically undertaken at least monthly for patients who are under warfarin therapy.

B. On April 30, 2015, Relator filed a qui tam action in the United States District Court for the District of Maryland, captioned *United States ex rel. Barbara McHenry v. Anne Arundel Medical Center*, Civil No. ELH-15-1256, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The Complaint alleges that AAMC billed every Clinic patient for both the blood test necessary for warfarin management and a Level 1 evaluation and management (“E/M”) office visit for every Clinic visit. The Complaint also alleged that frequently the E/M claim was not medically necessary.

C. The United States contends that AAMC submitted or caused to be submitted claims for payment to: the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C.

§§ 1395-1395kkk-1 (“Medicare”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the FEHBP, 5 U.S.C. §§ 8901-8914.

D. The United States contends that it has certain civil claims against AAMC, during the period from January 1, 2010, through December 31, 2017, as follows:

1. Patients who take Coumadin, or the generic warfarin, to prevent blood clots undergo regular blood tests to measure the time necessary for the patient’s blood to clot (international normalized ratio, or “INR”). Claims for an INR blood test are submitted under Current Procedural Terminology Code (“CPT”) 85610. If blood test results indicate the need to adjust a patient’s anticoagulation therapy, the provider may perform, and submit a claim for, an Evaluation and Management (“E/M”) service, typically CPT 99211.

2. On July 27, 2009, Novitas Solutions, the Centers for Medicare and Medicaid Services (“CMS”) Maryland Medicare administrative contractor, issued its position on the necessity of evaluation and management (“E/M”) services submitted as a component of anti-coagulation management:

The billing of an E/M service in addition to obtaining the clinical specimen (phlebotomy or finger stick) is not medically reasonable and necessary if the following conditions are met: If the INR is within therapeutic range, and the documentation does not support 1. a need for adjustment of warfarin dosage, or 2. that the patient is symptomatic, or 3. the presence of a new medical co-morbidity or dietary change.

3. Effective January 1, 2014, CMS updated the outpatient prospective payment system for hospitals by replacing clinic E/M visit levels with code G0463, which had the effect of bundling payment for most laboratory tests with an E/M code. Hospitals could bill separately for a laboratory test if the hospital only provided a laboratory test, but no other hospital outpatient services, to the patient. In that case, the hospital could not submit a claim for both G0463 and a lab test.

4. In or about June 2007, AAMC opened its Anticoagulation Clinic (“the Clinic”) for the purpose of outpatient monitoring of anticoagulation therapy. Between January 1, 2010 and December 31, 2013, AAMC submitted claims to Medicare, TRICARE, and FEHBP for CPT 85610 with claims for CPT 99211 that were not medically reasonable and necessary. Between January 1, 2014 and December 31, 2017, AAMC submitted claims to Medicare for code G0463 with CPT 85610, despite the fact that CMS included reimbursement for outpatient services that included laboratory tests with G0463.

5. A substantial percentage of the claims for CPT 99211 submitted by AAMC were not medically reasonable and necessary when submitted with CPT 85610.

All of the claims submitted by AAMC for CPT 85610 represented medically unnecessary billing when submitted with G0463.

The conduct described above is referred to as the "Covered Conduct."

E. This Settlement Agreement is neither an admission of liability by AAMC nor a concession by the United States that its claims are not well founded.

F. AAMC denies the United States' allegations in Paragraph D.

G. 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. AAMC shall pay to the United States Three Million One Hundred Fifty-Four Thousand Dollars, (\$3,154,000.00) ("Settlement Amount"), plus interest at a rate of 2.625% from February 27, 2019, of which \$1,577,000.00 is restitution, 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 District of Maryland.

2. Conditioned upon the United States receiving the Settlement Amount from AAMC and as soon as feasible after receipt, the United States shall pay \$473,100 plus interest to Relator by electronic funds transfer to Relator's counsel pursuant to written instructions to be provided by Relator's counsel.

3. The Defendant agrees to pay Relator and Relator's counsel Seventy One Thousand, Two Hundred and Fifty Dollars (\$71,250.00) in full satisfaction of their claims for expenses, attorneys' fees, and costs incurred in connection with the Civil Action under 31 U.S.C.

§ 3730(d), by electronic funds transfer to Relator's counsel pursuant to written instructions no later than five (5) days after the Effective Date of this Agreement. No additional attorneys' fees and costs shall be paid or claimed by Relator or her counsel. The Defendant agrees to pay Relator Eighty Thousand Dollars (\$80,000) in full and final settlement of Relator's employment claim brought under the Age Discrimination in Employment Act, 29 U.S.C. §§ 621 *et seq.* ("ADEA"), by electronic funds transfer to Relator's counsel pursuant to written instructions no later than five (5) days after the Effective Date of this Agreement.

4. Subject to the exceptions in Paragraph 9 (concerning excluded claims) below, and conditioned upon AAMC's full payment of the Settlement Amount, the United States releases AAMC 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 common law theories of payment by mistake, unjust enrichment, and fraud; or any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, 0.45(d).

5. Subject to the exceptions in Paragraph 9 below, and conditioned upon AAMC's full payment of the Settlement Amount, her attorney's fees, and her employment claim settlement amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases AAMC 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 and the ADEA.

6. In consideration of the obligations of AAMC in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and AAMC, and conditioned upon

AAMC'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 AAMC 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 9 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude AAMC 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 9, below.

7. In consideration of the obligations of AAMC set forth in this Agreement, and conditioned upon AAMC'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 AAMC under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 9 (concerning excluded claims), below. DHA expressly reserves authority to exclude AAMC 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 9, below.

8. In consideration of the obligations of AAMC in this Agreement, and conditioned upon AAMC'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 AAMC 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 90 (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 AAMC 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 9, below.

9. Notwithstanding the releases given in paragraphs 4 through 8 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;
- 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;

10. 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 payment described in Paragraph 2, 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.

11. Conditioned upon Relator's receipt of the payment described in Paragraphs 2 and 3, Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases AAMC, and its officers, agents, and employees, from any and all claims, counts, causes of action, liability, losses, damages, legal fees, or costs that the Relator has asserted, could have asserted, or may assert in the future against AAMC, known or unknown, reasonably discoverable or not, accrued or unaccrued, asserted or unasserted, whether legal, statutory, or equitable, arising out of or related to the Civil Action, the Covered Conduct, expenses or attorney's fees and costs under 31 U.S.C. § 3730(d), and her employment with AAMC.

12. AAMC waives and shall not assert any defenses AAMC 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.

13. AAMC 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 AAMC 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 and the United States' investigation and prosecution thereof.

14. AAMC fully and finally releases the Relator from any and all claims, counts, causes of action, liability, losses, damages, legal fees, or costs that AAMC has asserted, could have asserted, or may assert in the future against Realtor, known or unknown, reasonably discoverable or not, accrued or unaccrued, asserted or unasserted, whether legal, statutory, or equitable, arising out of or related to the Civil Action or the Covered Conduct (including attorney's fees, costs, and expenses of every kind and however denominated) and the Relator's investigation and prosecution thereof.

15. 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 any state payer, related to the Covered Conduct; and AAMC agrees not to resubmit to any Medicare contractor or TRICARE 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.

16. AAMC 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official

program directives promulgated thereunder) incurred by or on behalf of AAMC, 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) AAMC'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 attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment AAMC makes to the United States pursuant to this Agreement and any payments that AAMC may make to Relator, including costs and attorney's 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 16.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 AAMC.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers by AAMC, and AAMC

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 AAMC or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

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

17. AAMC agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, AAMC 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. AAMC 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 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.

18. 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 19 (waiver for beneficiaries paragraph), below.

19. AAMC 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.

20. Upon receipt of the payments described in Paragraphs 1 and 3, 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).

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

22. 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.

23. 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 Maryland. 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.

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

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

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

27. This Agreement is binding on AAMC's successors, transferees, heirs, and assigns.

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

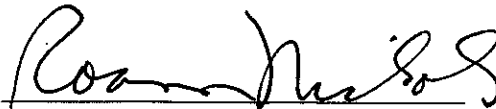
29. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

30. 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

Robert K. Hur
United States Attorney

DATED: 6/26/19

BY: 

Roann Nichols
Assistant United States Attorney
District of Maryland

DATED: 06/24/2019

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 of Federal Employee Insurance
Operations
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

Robert K. Hur
United States Attorney

DATED: _____


BY: _____
Roann Nichols
Assistant United States Attorney
District of Maryland

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: 06/19/2019

for

BY: 

Leigh A. Bradley
General Counsel
Defense Health Agency
United States Department of Defense

DATED: _____

BY: _____
Edward M. DeHarde
Assistant Director of Federal Employee Insurance
Operations
Healthcare and Insurance
United States Office of Personnel Management

THE UNITED STATES OF AMERICA

Robert K. Hur
United States Attorney

DATED: _____

BY: _____

Roann Nichols
Assistant United States Attorney
District of Maryland

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: 6/26/2019

BY: 

Edward M. DeHarde
Assistant Director of Federal Employee Insurance
Operations
Healthcare and Insurance
United States Office of Personnel Management

DATED _____

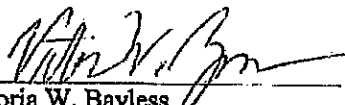
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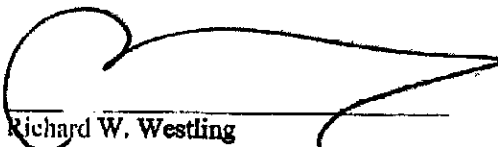
PAUL ST HILLAIRE

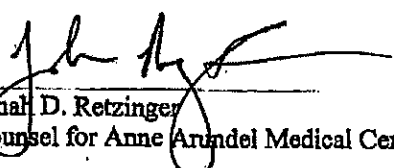
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Management, cn=PAUL ST HILLAIRE,
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Paul N. St. Hillaire
Senior Counsel/Debarring Official
Office of the Inspector General
United States Office of Personnel Management

ANNE ARUNDEL MEDICAL CENTER - DEFENDANT


DATED: 6/25/19 BY: 
Victoria W. Bayless
President and Chief Executive Officer
Anne Arundel Medical Center

DATED: 6/25/2019 BY: 
Richard W. Westling
Counsel for Anne Arundel Medical Center

DATED: 6/25/2019 BY: 
Jonah D. Retzinger
Counsel for Anne Arundel Medical Center

BARBARA McHENRY - RELATOR

DATED: 06/25/19 BY: 
Barbara McHenry
Relator

DATED: 06/25/2019 BY: 
R. Scott Oswald
Counsel for Barbara McHenry