

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among (i) the United States of America, acting through the United States Department of Justice (“DOJ”) and on behalf of the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”); the Centers for Medicare and Medicaid Services (“CMS”); the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program, 5 U.S.C. §§ 8901-8914 (“FEHBP”) (collectively, the “United States”); (ii) the Virginia Birth-Related Neurological Injury Compensation Program and its Board of Directors (the “Program”) and the Commonwealth of Virginia (“Virginia”), including the Department of Medical Assistance Services (“DMAS”) (collectively, “Virginia/DMAS”), and (iii) Relators Theodore Arven III and Veronica N. Arven (collectively, “Relators”) (the United States, Program, Virginia/DMAS, and Relators, collectively the “Parties”), through their authorized representatives.

RECITALS

A. In 1987, the Virginia legislature enacted the Virginia Birth-Related Neurological Injury Compensation Act (the “Act”), which established the Program and the Virginia Birth-Related Neurological Injury Compensation Fund (the “Fund”), which is administered by the Program. Va. Code Ann. §§ 38.2-5000, *et seq.* The Program makes payments from the Fund to reimburse qualified claimants for “medically necessary and reasonable” expenses resulting from birth-related neurological injuries subject to the terms and conditions of the Virginia Code, applicable regulations, and guidance documents. The Program Fund is financed by assessments paid by participating and non-participating physicians, other medical providers licensed in Virginia, and liability insurance carriers who do business in Virginia. Most civil actions arising

out of medical malpractice claims for birth-related neurological injuries are foreclosed against medical providers who participate in the Program.

B. Medicaid is a joint federal-state health program that provides coverage and benefits to individuals whose income is below a certain threshold as measured against the federal poverty line and/or individuals who may have certain disabilities. 42 U.S.C. §§ 1396 to 1396w-5 (“Medicaid”). In Virginia, Medicaid is administered by DMAS. Generally speaking, both federal and Virginia law establish Medicaid as the payer of last resort—meaning, Medicaid pays claims for covered medical items and services only after all other potential third party payers have made payments. 42 U.S.C. § 1396a(a)(25); Va. Code Ann. § 32.1-325.2.

C. Under the federal Medicaid statute, third parties are defined to include “health insurers, self-insured plans, group health plans... or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.” 42 U.S.C. §1396a(a)(25)(A).

D. Under the Medicaid statute, DMAS is obligated to “take all reasonable measures to ascertain the legal liability of third parties” to pay for care and services covered by Medicaid. *Id.* When such a third party is found, the Medicaid statute requires DMAS in most circumstances to seek full reimbursement from the third party of any medical claims DMAS has already paid. 42 U.S.C. §1396a(a)(25)(B).

E. Virginia’s Birth-Related Neurological Injury Compensation Act states that the Program will not pay for “[e]xpenses for items or services that the infant has received, or is entitled to receive, under the laws of any state or the federal government except to the extent prohibited by federal law.” Va. Code Ann. §38.2-5009(A)(1)(a).

F. On July 7, 2015, Relators filed a civil suit, pursuant to 31 U.S.C. § 3730(b), in the United States District Court for the Eastern District of Virginia captioned *United States ex rel. Arven v. Virginia Birth-Related Neurological Injury Compensation Program*, Civ. A. No. 15-0870 (E.D. Va.) (the “Civil Action”). Relators generally allege that the Program violated federal statutes by requiring participants to seek and obtain reimbursement from Medicaid before considering any disbursements from the Fund for the claimed medical services.

G. Based on its review of the Civil Action and its investigation undertaken therefrom, the United States contends that it has certain civil claims against the Program arising from the following alleged conduct, which occurred from January 1, 2006, through December 31, 2016 (the “Relevant Time Period”) and that despite federal and Virginia laws establishing Medicaid as the payer of last resort, the Program interpreted the Act to make the Program the payer of last resort. Specifically, the United States contends that the Program: (a) published literature and other documents saying it was “the payer of last resort;” (b) gave cards to admitted claimants’ parents or guardians, saying the Program was the “payer of last resort;” (c) caused admitted claimants’ parents or guardians to submit claims to Medicaid, TRICARE, and the FEHBP for payment before the Program paid them; and (d) did not prevent admitted claimants’ parents or guardians from submitting, and did not advise such parents or guardians not to submit, claims to Medicaid, TRICARE, and the FEHBP first.

Similarly, following its investigation, the United States contends that it could bring civil claims against Virginia/DMAS for erroneously interpreting the Act in a manner that contradicted federal law establishing Medicaid as the payer of last resort during the Relevant Time Period. Specifically, the United States contends that Virginia/DMAS: (i) did not “take all reasonable

measures to ascertain the legal liability of' the Program for medical claims DMAS had paid; and (ii) did not seek any third party reimbursement from the Program.

In sum, the United States contends that in submitting, or causing to be submitted, claims for payment to the Medicaid, TRICARE, and the FEHBP, the Program and Virginia/DMAS: (1) administered the Program as the payer of last resort when federal law specified that the Program could not be the payer of last resort; (2) failed to ascertain the Program's third party liability for payment of claims for Program beneficiaries who were also enrolled in Medicaid; and (3) failed to seek or recover third party reimbursements from the Program on behalf of Medicaid.

The conduct alleged in this Paragraph G is hereinafter referred to as the "Covered Conduct."

H. The Program and Virginia/DMAS expressly deny (i) that either is liable to the United States or Relators in any amount; (ii) that 31 U.S.C. §3729, *et seq.*, applies to either of them; and (iii) that either submitted, or caused to be submitted, a false claim to the United States. The Program and Virginia/DMAS specifically assert that each agency at all times acted in good faith in interpreting and applying the payer of last resort regulations and other provisions of state and federal law and operated in a transparent fashion. The Program and Virginia/DMAS assert that they relied upon an opinion of the Attorney General of Virginia and explicit acceptance of their interpretation by CMS personnel in formulating and maintaining their position that the Program does not meet the definition of a third party from which Virginia/DMAS could seek reimbursement and that the Program was the payer of last resort, not Medicaid. The Program and Virginia/DMAS assert that this position was consistently maintained throughout the relevant time period. The Program and Virginia/DMAS have been cooperative with the DOJ's investigation.

I. Indeed, this Agreement is neither an admission of liability by the Program or Virginia/DMAS nor a concession that their defenses to the Covered Conduct are not well founded. Similarly, this Agreement is not a concession by the United States that its claims are not well founded.

J. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement that are received by the United States, as agreed between the United States and Relators, and to payment for Relators' reasonable expenses, attorneys' fees and costs, as agreed between Relators' counsel and the Program.

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 Agreement, the Parties agree and covenant as set forth below.

TERMS AND CONDITIONS

1. This Agreement is subject to the provisions of Va. Code Ann. §2.2-514 and therefore has been approved by the Virginia Office of the Attorney General and by the Governor.

2. Within sixty (60) calendar days after the Effective Date of this Agreement, the Program shall pay to the United States \$20,707,965.13 (the "Settlement Amount") by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of Columbia.

3. Conditioned upon the United States receiving the payment of the Settlement Amount described in Paragraph 2 above, and as soon as feasible after receipt of that payment, the United States shall pay \$4,141,593.03 (the "Relators' Share") to Relators' counsel by electronic funds transfer, which shall fully satisfy Relators' claim to a relator share in this action.

4. Following the Effective Date of the Agreement and receipt of written instructions from counsel for Relators, the Program agrees to pay to Relators' counsel an agreed sum pursuant

to 31 U.S.C. § 3730(d) for expenses and attorneys' fees and costs arising from the filing of the Civil Action ("Attorneys' Fees Payment").

5. The Program and/or Virginia/DMAS, as applicable:
 - a. provided DOJ with a summary of the steps each has taken to demonstrate that the Program will not be operating as the "payer of last resort" vis-à-vis the Medicaid program, TRICARE, or the FEHBP concerning admitted claimants residing in Virginia;
 - b. sent a letter to the parents or guardians of admitted claimants in the Program who are also enrolled in Medicaid advising them that claims have been processed in a different manner beginning August 15, 2017; sent a letter to parents or guardians of admitted claimants which contains answers to frequently asked questions concerning the changes being implemented, a copy of the letter for insurance brokers or Marketplace Facilitators who will assist the parents or guardians of admitted claimants with obtaining private health insurance coverage for admitted claimants, and a copy of the Procedural Guidance Document that has been posted on the Program's website and on the Virginia regulatory Town Hall;
 - c. hired a facilitator to assist admitted claimants' parents or guardians with obtaining private insurance policies for admitted claimants, and hired a third party administrator to process certain claims on behalf of the Program for items prescribed and services performed on or after August 15, 2017;
 - d. clarified in all references in the Program's forms, website, literature, promotional materials, reports, and other documents, that the Program generally is

the “payer of last resort,” except with respect to Medicaid or sources prohibited by federal law from being a primary payer;

e. treat the Program as a third party from which it will seek reimbursement for claims paid by Medicaid for compensable expenses under the Virginia Birth-Related Neurological Injury Compensation Act that are incurred on behalf of Program beneficiaries after their admission into the Program and after the Effective Date of this Agreement;

f. does not operate as the payer of last resort vis-à-vis the Virginia Medicaid program, compensable medical expenses of admitted claimants residing in Virginia who are covered by the TRICARE program, or compensable medical expenses of admitted claimants residing in Virginia who are covered by the FEHBP program. If the Program becomes aware that an admitted claimant has moved outside the Commonwealth of Virginia to reside in another state, the Program shall notify the admitted claimant’s parent/s or legal guardian/s in writing that he, she, or they must notify the Medicaid agency, TRICARE, or FEHBP program, as applicable, in that state of the admitted claimant’s enrollment in the Program. The Parties agree that neither the Program, nor Virginia/DMAS, has any responsibility to monitor or enforce an admitted claimant’s parent/s’ or legal guardian/s’ compliance with this notice requirement and that neither the Program, nor Virginia/DMAS, may be liable for any resulting primary payer status of, or payments made by, the Medicaid, TRICARE, or FEHBP programs in any state other than the Commonwealth of Virginia. The Parties also agree that neither the Program, nor Virginia/DMAS, has any responsibility to ascertain any third-party liability of the Program for payment

of claims for Program admitted claimants who were enrolled in Virginia Medicaid prior to their filing petitions seeking admission into the Program, or prior to a moving party's referral for an eligibility determination pursuant to Virginia Code § 8.01-273.1, with respect to expenses that were incurred prior to a claimant's admission into the Program and that neither the Program, nor Virginia/DMAS, shall be required to seek or recover third party reimbursements from the Program on behalf of the Virginia or Federal Medicaid programs with respect to expenses that were incurred prior to a claimant's admission into the Program;

g. agree that this Agreement provides the United States at its election to inspect or audit the Program's and/or Virginia/DMAS's books, records, and documents to verify compliance. The Program and Virginia/DMAS agree to cooperate in any such inspection or audit and agree to provide the United States access to any and all of their respective books, records, and documents to facilitate such inspection or audit; and

h. shall report any violations of the provisions of this Agreement to the United States within thirty (30) days of learning of any such violation.

6. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon the full payment of the Settlement Amount, the United States, on behalf of HHS (including the OIG and CMS), DHA, and OPM, releases the Program and Virginia/DMAS from any civil or administrative monetary claim (including any claim for attorneys' fees, costs, and expenses of every kind and however denominated) the United States has or may have against the Program or Virginia/DMAS for the Covered Conduct under applicable federal Medicaid laws and

regulations; 31 U.S.C. § 3729, *et seq.*; 42 U.S.C. § 1320a-7a; 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

7. Subject to the exceptions in Paragraph 8 below, and conditioned upon the full payment of the Settlement Amount and the Attorneys' Fees Payment, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release the Program and Virginia/DMAS from any civil monetary claim (including any claim for attorneys' fees, costs, and expenses of every kind and however denominated) that Relators have, have asserted, could have asserted, or may assert in the future, or may have, on behalf of the United States for the Covered Conduct under 31 U.S.C. § 3729, *et seq.*

8. Notwithstanding the releases given in the foregoing Paragraphs, or any other term or provision 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 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.

9. Relators and their 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).

10. Conditioned upon Relators' receipt of the Relators' Share, Relators and their 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 or the Civil Action.

11. Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release the Program and Virginia/DMAS, and their officers, agents, and employees, from any liability to Relators arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

12. The Program and Virginia/DMAS 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 the Program and Virginia/DMAS, respectively, 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 and the United States' investigation and prosecution thereof.

13. The Program and Virginia/DMAS fully and finally release the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that the Program and Virginia/DMAS, respectively, have asserted, could have asserted, or may assert in the future against the Relators, related to the Civil Action and the Relators' investigation and prosecution thereof.

14. The Program waives and shall not assert any defenses that the Program may have to any criminal prosecution 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.

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. The Program and Virginia/DMAS agree that they waive and shall not seek payment for any of the health care claims and billings covered by this Agreement from any Program admitted claimants or their parents or legal guardians based on claims included in the Covered Conduct.

17. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any state Medicaid payer, TRICARE, or the FEHBP, related to the Covered Conduct. The Program and Virginia/DMAS agree not to resubmit or cause the resubmission to TRICARE, the FEHBP, or any federal 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.

18. Upon receipt of the payment of the Settlement Amount by the United States, Relators shall promptly file in the Civil Action a notice of dismissal pursuant to Federal Rule of Civil Procedure 41(a)(1), and the United States shall promptly thereafter file a notice indicating its consent to such dismissal pursuant to 31 U.S.C. § 3730(b)(1).

19. Except as otherwise provided in Paragraph 4 herein above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

21. 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 Eastern District of Virginia.

22. 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.

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

24. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below subject to the approval requirements established by Virginia state law and Federal law, respectively.

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

26. This Agreement is binding on the Program's and Virginia/DMAS's successors, transferees, heirs, and assigns.

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

28. All Parties consent to any Party's disclosure of this Agreement to the public.

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

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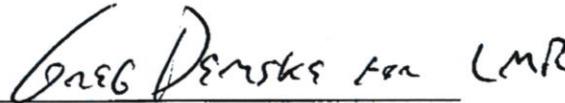
FOR THE UNITED STATES OF AMERICA, ACTING THROUGH THE UNITED STATES DEPARTMENT OF JUSTICE AND ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES; THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; THE DEFENSE HEALTH AGENCY; AND THE OFFICE OF PERSONNEL MANAGEMENT:

DATED: Sept. 12, 2018

BY: 

BRIAN PAUL HUDAK
Assistant United States Attorney
United States Attorney's Office for the District of Columbia

DATED: 9/7/18

BY:  for LMR

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

FOR 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; THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; THE DEFENSE HEALTH AGENCY; AND THE OFFICE OF PERSONNEL MANAGEMENT:

DATED: _____

BY: _____

BRIAN PAUL HUDAK
Assistant United States Attorney
United States Attorney's Office for the District of Columbia

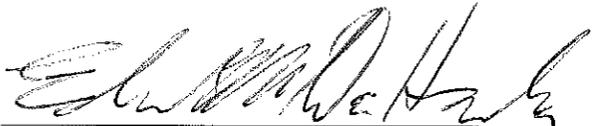
DATED: _____

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: 8/29/2016

BY: _____


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

**FOR THE VIRGINIA BIRTH-RELATED NEUROLOGICAL INJURY
COMPENSATION PROGRAM:**

DATED: Aug 31, 2018 BY: Vanessa Rakestraw
VANESSA RAKESTRAW, PH.D., C.R.C.
Chair of the Virginia Birth-Related
Neurological Injury Compensation
Program's Board of Directors

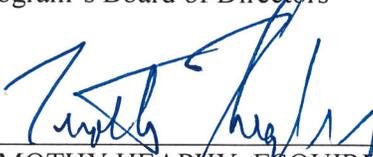
DATED: _____ BY: _____
TIMOTHY HEAPHY, ESQUIRE
Counsel for the Virginia Birth-Related
Neurological Injury Compensation Program

**FOR THE VIRGINIA BIRTH-RELATED NEUROLOGICAL INJURY
COMPENSATION PROGRAM:**

DATED: _____

BY: _____
VANESSA RAKESTRAW, PH.D., C.R.C.
Chair of the Virginia Birth-Related
Neurological Injury Compensation
Program's Board of Directors

DATED: _____

BY:  _____
TIMOTHY HEAPHY, ESQUIRE
Counsel for the Virginia Birth-Related
Neurological Injury Compensation Program

FOR THE COMMONWEALTH OF VIRGINIA:

DATED: 8/31/18

BY: Jennifer S. Lee, MD
JENNIFER S. LEE, M.D.,
Director of the Virginia Department of
Medical Assistance Services

FOR DMAS:

DATED: 8/31/18

BY: Jennifer S. Lee, MD
JENNIFER S. LEE, M.D.,
Director of the Virginia Department of
Medical Assistance Services

DATED: _____

BY: _____
TIMOTHY HEAPHY, ESQUIRE
Counsel for the Virginia Department of
Medical Assistance Services

FOR THE COMMONWEALTH OF VIRGINIA:

DATED: _____

BY: _____
JENNIFER S. LEE, M.D.,
Director of Virginia Department of
Medical Assistance Services

FOR DMAS:

DATED: _____

BY: _____
JENNIFER S. LEE, M.D.,
Director of Virginia Department of
Medical Assistance Services

DATED: _____

BY:  _____
TIMOTHY HEAPHY, ESQUIRE
Counsel for the Virginia Birth-Related
Neurological Injury Compensation Program

FOR RELATORS:

DATED:

8/31/18

BY:

Scott Austin

Scott Austin
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800 SunTrust Plaza
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BY:

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FOR RELATORS:

DATED: _____

BY: _____

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Roanoke, Virginia 24022

DATED: 8/31/2018

BY:  _____

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