



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

February 10, 2021

North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Tim Moore
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Danny Earl Britt, Jr.
Senator Warren Daniel
Representative James Boles, Jr.
Representative Allen McNeill
Representative Carson Smith
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Merit Medical
Systems, Inc.

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above referenced- matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A settlement has been executed between Merit Medical Systems, Inc. and the State of North Carolina.

The settlement resolves allegations that from September 1, 2010 through March 31, 2017, Merit Medical Systems, under an internal program known as the Local Advertising Program, offered and paid physicians, medical practices, and hospitals millions of dollars in free advertising assistance, practice development, practice support, and purported unrestricted "educational" grants to induce the Healthcare Providers to purchase and use Merit products in medical procedures performed on Medicaid beneficiaries, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$466,184.44. Of that amount, the federal government will receive \$235,732.40 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$40,074.76 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$89,541.88 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$83,626.08 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive \$17,209.32 for investigative costs and costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,



Seth Dearmin
Chief of Staff

SD:ng

cc: William Childs, NCGA Fiscal Research Division
Mark White, NCGA Fiscal Research Division
Morgan Weiss, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of North Carolina (“the State”) and Merit Medical Systems, Inc. (“Merit”), collectively, “the Parties.”

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Merit, a publicly-held corporation with its principal place of business in South Jordan, Utah, is a medical device manufacturer that markets and sells its products throughout the United States. Among other things, Merit markets and sells embolotherapeutic devices used to treat arteriovenous malformations, symptomatic uterine fibroids, and hypervascular tumors.

B. In April 2016, Relator filed a qui tam action in the United States District Court for the District of New Jersey captioned United States et al., ex rel. Wolf v. Merit Medical Systems, Inc., Civ. A. No. 16-1855 (D.N.J.), pursuant to the provisions of the False Claims Act, 31 U.S.C. § 3730(b) and corresponding provisions of analogous or other statutes of the states named (the “Civil Action”). The Relator filed an Amended Complaint on September 26, 2017. The United States intervened in the Civil Action on June 12, 2020.

C. Merit has entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the “United States of America” (the “United States”) as that term is defined in the Federal Settlement Agreement.

D. The State contends that Merit caused claims for payment to be submitted to the State’s Medicaid Program (“Medicaid”) (42 U.S.C. Chapter 7 Subchapter XIX), including “managed care entities” as defined by 42 U.S.C. § 1396u-2.

E. The State contends that it has certain civil and administrative causes of action against Merit for engaging in the following conduct from September 1, 2010 to March 31, 2017 (the “Covered Conduct”):

The State contends that under an internal program known as the Local Advertising Program, Merit offered and paid physicians, medical practices, and hospitals (collectively, “Healthcare Providers”) millions of dollars in free advertising assistance, practice development, practice support, and purported unrestricted “educational” grants to induce the Healthcare Providers to purchase and use Merit products in medical procedures performed on Medicaid beneficiaries, in violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b) and analogous or other statutes of the State.

The State further contends that Merit executives and sales personnel selected which Healthcare Providers would benefit from Merit’s Local Advertising Program payments, as reward for past sales, to induce future sales, and to steer business to Merit and away from Merit’s competitors. In its subsidized advertising, Merit promoted the targeted Healthcare Providers by name, provided contact information for those Healthcare Providers, and did not mention Merit or Merit products. The State contends that before agreeing to make the Local Advertising Program payments to benefit a targeted Healthcare Provider, Merit often estimated the “projected revenue” that it expected to receive from the Healthcare Provider’s purchase of Merit products, and after making the payments, Merit often tracked the return on investment (ROI) based on the Healthcare Provider’s purchase of Merit products.

Merit and its executives claimed that the purpose of the Local Advertising Program was to increase patient awareness of uterine fibroid embolization. In fact, the State contends that Merit used the Local Advertising Program payments to induce its targeted Healthcare Providers to use

Merit products by providing them financial support and patient referrals. In internal communications, Merit described using the Local Advertising Program payments as “leverage,” a “bargaining chip,” or as part of a “deal” to secure Merit business from Healthcare Providers. The State contends that Merit disregarded warnings that its conduct may violate the AKS, including from its Chief Compliance Officer. Merit knowingly submitted or caused to be submitted false or fraudulent claims to the State’s Medicaid Program.

F. This Agreement is neither an admission of facts or liability by Merit nor a concession by the State that its allegations are not well founded. Merit denies the allegations and contentions of the State.

G. The Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Merit agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of \$18,000,000.00 plus accrued interest (the “Total Settlement Amount”). The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) Merit shall pay to the United States the sum of \$15,210,000.00 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$5,580,000.00 consisting of \$2,790,000.00 for the states pursuant to this Agreement and \$2,790,000.00 for the United States

pursuant to the Federal Settlement Agreement. Merit shall pay to the Medicaid Participating States the sum of \$2,790,000.00 plus accrued interest on that amount of 0.75% per annum, calculated monthly, commencing on July 8, 2020, and continuing to and including the day payment is made under this Agreement (the “Medicaid State Settlement Amount”), subject to the non-participating state deduction provision of sub-paragraph (d) below (the “Medicaid Participating State Settlement Amount”), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid and immediately deposited by electronic funds transfer to the New York State Attorney General’s National Global Settlement Account pursuant to written instructions from the state negotiating team (the “State Team”), which written instructions shall be delivered to counsel for Merit.

(c) Merit shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Merit and the State Team have agreed or in a form otherwise agreed to by Merit and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Merit’s attorneys within 60 days of receiving this Agreement. Merit’s offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Merit and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Merit in settlement for the Covered Conduct for the State is \$465,650.70, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$229,918.30 plus applicable interest (the “State Amount”), of which \$114,959.15 is restitution. If the State does not execute this Agreement

within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Merit absent written agreement between counsel for Merit and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Merit in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator the amount of \$40,074.76 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Merit set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Merit, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively, the "Merit Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State's Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

- (a) any criminal, civil, or administrative liability arising under state revenue codes;
- (b) any criminal liability;

(c) any civil or administrative liability that any person or entity, including the Merit Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 3 above, including, but not limited to, any and all of the following claims: (i) claims involving unlawful or illegal conduct based on State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid Program;

(f) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. In consideration of the obligations of Merit set forth in this Agreement, and the Corporate Integrity Agreement (the "CIA") that Merit has entered into with the Office of the Inspector General of the United States Department of Health and Human Services in connection with this matter, and conditioned on the State's receipt of the State Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid Program against Merit for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State

from taking action against Merit in the event that Merit is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. Merit waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, the Merit Released Entities, waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Merit Released Entities have against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Merit must pay to the State pursuant to Paragraph 1 above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and Merit agrees not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

9. Merit shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors.

10. Merit expressly warrants that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

11. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

12. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. Upon receipt of the State Amount described in Paragraph 1, above, the State shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal pursuant to Rule 41(a)(1) that is consistent with and subject to the terms and conditions of this Settlement Agreement. The State Team will coordinate the State's participation in the filing of the Joint Stipulation of Dismissal.

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity.

15. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

16. In addition to all other payments and responsibilities under this Agreement, Merit agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Merit will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

17. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

18. The undersigned Merit signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. The facsimile, email or other electronically delivered signatures of the parties shall be deemed to constitute acceptable binding signatures for purposes of this Agreement, and facsimile or electronic copies shall be deemed to constitute duplicate originals.

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

21. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

23. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

Dated: 10/19/2020

By: 

Dave Richard

Name

Deputy Secretary, NC Medicaid

Title

Department of Health & Human
Services, Division of Health Benefits
Organization

Dated: 10/20/2020

By: 

F. Edward Kirby, Jr.

Name

Director


Title


NCDOJ, Medicaid Investigations Division
Organization

MERIT MEDICAL SYSTEMS, INC.


DATED: December 31, 2020

BY: 


Name

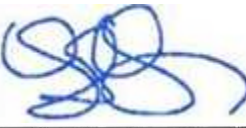

Title
Merit Medical Systems, Inc.

DATED: December 31, 2020

BY: 

MICHAEL R. PAUZÉ
King & Spalding LLP
Counsel for Merit Medical Systems, Inc.

DATED: 12/31/2020

BY: 

LAWRENCE S. LUSTBERG
Gibbons P.C.
Counsel for Merit Medical Systems, Inc.