

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, (collectively the “United States”); the State of Florida, acting through the Florida Office of the Attorney General (“State of Florida”); H. Lee Moffitt Cancer Center & Research Institute Hospital, Inc. and H. Lee Moffitt Cancer Center and Research Institute Lifetime Screening Center Inc. (d/b/a Moffitt Medical Group) (collectively “Moffitt”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

- A. Moffitt is a non-profit health care entity that provides patient care and conducts clinical research at numerous Moffitt hospital and clinics throughout the Tampa, Florida metropolitan area.
- B. On December 11, 2020, Moffitt disclosed to the United States that issues with its billing systems and practices had resulted in Moffitt billing federal health care programs for services provided during certain clinical research studies for which Moffitt should not have received payment. Moffitt conducted an independent investigation and compliance review of those issues and provided the United States with a detailed and thorough supplemental written self-disclosure.
- C. Moffitt cooperated with the United States’ and the State of Florida’s investigation, including by preserving, collecting, and disclosing relevant documents and information relating to the conduct, disclosing facts gathered during its investigation, and retaining an independent expert to assist in determining the amounts improperly billed to federal healthcare programs.

D. Moffitt took significant steps to remediate the issues with its billing systems and practices, including (1) establishing a new unit within its finance department responsible for ensuring compliant billing of services provided in clinical trials; (2) updating its policies and procedures relating to the billing of services provided in clinical trials; (3) hiring significant additional staff to implement these new policies and procedures; and (4) placing a blanket hold on all charges associated with clinical trials until it could ensure that the new policies and procedures were working effectively.

E. Moffitt received credit under the Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual §4-4.112.

F. The United States and the State of Florida contend that Moffitt 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 Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); and the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE").

G. The United States and the State of Florida contend that, between May 11, 2014 and May 10, 2020, Moffitt submitted claims to Medicare, Medicaid, and TRICARE for clinical trial services that were billed in violation of the Centers for Medicare and Medicaid Services National Coverage Determination 310.1 governing Routine Costs in Clinical Trials. Specifically, Moffitt billed federal health care programs for patient care items and services provided as part of clinical trial research that should have been billed to trial sponsors or, customarily, should have been provided free-of-charge for beneficiaries enrolled in clinical trials. This conduct is referred to below as the "Covered Conduct."

H. The United States and the State of Florida contend that they have certain civil and administrative claims against Moffitt arising from the Covered Conduct.

I. This Settlement Agreement is neither an admission of liability by Moffitt nor a concession by the United States or the State of Florida that their claims are not well founded.

J. 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. Moffitt shall pay to the United States and the State of Florida, collectively, a total of \$19,564,743, plus interest accrued at the annual rate of 5% from November 27, 2023 to the Effective Date of this Settlement Agreement (“Settlement Amount”), of which \$13,043,162 constitutes restitution as set forth below, no later than fifteen (15) days after the Effective Date of this Agreement. The Settlement Amount shall be paid as follows:

a. Moffitt shall pay to the United States \$18,244,242.54, plus accrued interest as set forth above (“Federal Settlement Amount”), of which \$12,162,828.40 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Middle District of Florida.

b. Moffitt shall pay to the State of Florida \$1,320,500.46, plus accrued interest as set forth above (“State Settlement Amount”), of which \$880,333.64 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the Florida Office of the Attorney General.

2. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and conditioned upon the United States’ receipt of the Federal Settlement Amount, the United States releases Moffitt, together with its current and former parent corporations; direct and indirect

subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of and assigns of any of them, 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 Moffitt's self-disclosure of this matter and Moffitt's obligations in this Agreement, and conditioned upon the United States' receipt of full payment of the Federal 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 Moffitt 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 reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Moffitt 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 Moffitt set forth in this Agreement, and conditioned upon the United States' receipt of full payment of the Federal Settlement Amount, DHA shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Moffitt under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6 (concerning

reserved claims), below. DHA expressly reserves authority to exclude Moffitt 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. Subject to the exceptions in Paragraph 7 below (concerning reserved claims), and conditioned upon the State of Florida's receipt of full payment of the State Settlement Amount, the State of Florida releases Moffitt, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of and assigns of any of them from any civil or administrative monetary claim the State of Florida has for any claims submitted or caused to be submitted to the State of Florida's Medicaid Program or its contracted Managed Care Organizations as a result of the Covered Conduct. Nothing in this Agreement precludes the State of Florida from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. Notwithstanding the releases given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory 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.

7. Notwithstanding the releases given in Paragraph 5 of this Agreement, or any other term of this Agreement, the following claims and rights of the State of Florida 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 administrative liability that any person or entity, including Moffitt, has or may have to Florida or to the individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in paragraph 5 above, including by not limited to, any and all of the following claims: (i) claims involving unlawful or illegal conduct based on State of Florida or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

- d. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Florida's Medicaid program;
- e. Any liability to the State of Florida (or its agencies) for any conduct other than the Covered Conduct;
- f. Any liability based upon obligations created by this Agreement;
- g. Any liability of individuals;
- h. Any liability for express or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- j. Any liability for failure to deliver goods or services due.

8. Moffitt waives and shall not assert any defenses Moffitt 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.

9. Moffitt fully and finally releases the United States and the State of Florida, along with their respective agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Moffitt has asserted, could have asserted, or may assert in the future against the United States, the State of Florida, or any of their respective agencies, officers, agents, employees, and servants,

related to the Covered Conduct and the United States' and the State of Florida's investigation and prosecution thereof.

10. 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 carrier or payer, or any state payer (including but not limited to the State of Florida's Medicaid program, or any other Florida program payor), related to the Covered Conduct; and Moffitt agrees not to resubmit to any Medicare contractor, TRICARE 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.

11. Moffitt 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 Moffitt, 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) Moffitt'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 attorneys' fees);
- (4) the negotiation and performance of this Agreement; and

(5) the payment Moffitt makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Moffitt 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 Moffitt 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. Moffitt agrees that the United States, at a minimum, shall be entitled to recoup from Moffitt 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 and the State of Florida reserve their rights to disagree with any calculations submitted by Moffitt or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Moffitt 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 or the State of Florida to audit, examine, or re-examine Moffitt's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

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. Moffitt 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 into this Agreement without any degree of duress or compulsion.

16. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the Middle District of Florida. 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 Moffitt's successors, transferees, heirs, and assigns.

21. All Parties consent to the United States' and the State of Florida's 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.

[Signature Pages Follow]

THE UNITED STATES OF AMERICA

DATED: 1/2/2024

BY: 
GARY R. DYAL
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1/3/2024

BY: 
CAROLYN B. TAPIE
Assistant United States Attorney
Middle District of Florida

DATED: 12/22/23

BY: SUSAN
GILLIN

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: _____
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
GARY R. DYAL
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
CAROLYN B. TAPIE
Assistant United States Attorney
Middle District of Florida

DATED: _____

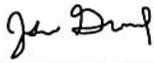
BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 12/19/2023

BY: BLEY.PAUL.NICHOLAS.1099873821
Digitally signed by
BLEY.PAUL.NICHOLAS.1099873821
Date: 2023.12.19 19:34:41 -05'00'
SALVATORE M. MAIDA
for General Counsel
Defense Health Agency
United States Department of Defense

STATE OF FLORIDA

DATED: Dec 21, 2023

BY: 
JOHN M. GUARD
Chief Deputy Attorney General
Office of the Attorney General
State of Florida

MOFFITT

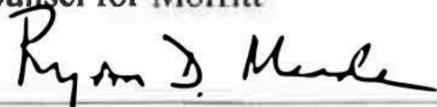
DATED: 12/20/23

BY: 
L. DAVID DE LA PARTE
General Counsel
Moffitt Cancer Center

DATED: 12/20/23

BY: 
GREGORY W. KEHOE
Greenberg Traurig, P.A.
Counsel for Moffitt

DATED: 12/20/25

BY: 
RYAN D. MEADE
Meade, Roach & Annulis, LLP
Counsel for Moffitt