

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”) (collectively, the “United States”), and Radeas LLC (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Radeas LLC (“Radeas”) is a South Carolina limited liability company headquartered in Wake Forest, North Carolina. Radeas operates a clinical laboratory and offers clinical laboratory services to health care providers and patients, including, among other things, urine drug testing (“UDT”).

B. The United States contends that Radeas submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III (“Medicare”).

C. The United States contends that it has certain civil claims against Radeas for submitting false claims for medically unnecessary UDT to the Medicare Program (“Medicare”), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III and for submitting false claims for UDT to Medicare which were predicated on violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2).

D. Radeas admits, acknowledges, and accepts responsibility for the following facts. From May 10, 2013 through April 30, 2021, Radeas compensated sales organizations on a commission basis for their referrals of UDT to Radeas.

E. Radeas further admits, acknowledges, and accepts responsibility for the following facts. From January 1, 2016 through September 30, 2021, Radeas offered its health care

provider (“HCP”) clients the option to order both presumptive and definitive UDT. For those HCP clients who submitted orders to Radeas for both presumptive and definitive UDT, Radeas performed both presumptive UDT and definitive UDT on the same sample at or near the same time, for the same or similar substances, often providing overlapping information for presumptive and definitive UDT. Radeas then reported both the presumptive and definitive UDT results back to HCPs at the same time. Absent HCP-designated reflex orders in certain situations or clear orders from HCPs, this definitive testing was not medically necessary or reasonable. Yet, from January 1, 2016 through September 30, 2021, Radeas billed, or caused to be billed, Medicare for medically unnecessary definitive UDT that Radeas simultaneously reported with presumptive UDT results to HCP clients.

The conduct in paragraphs D and E is hereinafter referred to as the “Covered Conduct.”

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Radeas shall pay to the United States \$11,642,545.50 plus interest at the annual rate of 1.625% from January 17, 2022 (the “Settlement Amount”), of which \$7,761,697 is restitution, no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the District of Massachusetts.

2. Subject to the exceptions in Paragraph 4 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases Radeas, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the

Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of Radeas in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Radeas, and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1, the OIG-HHS shall 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 Radeas 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 4 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Radeas 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 4, below.

4. Notwithstanding the releases given in Paragraphs 2 and 3 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; and
- f. Any liability of individuals.

5. Radeas waives and shall not assert any defenses Radeas 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.

6. Radeas 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 Radeas has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. 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) or any state payer, related to the Covered Conduct; and Radeas agrees not to resubmit to any Medicare contractor 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.

8. Radeas 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 Radeas, 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) Radeas'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;
- (5) the payment Radeas makes to the United States pursuant to this Agreement; 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 8.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 Radeas.

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Radeas 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 Radeas 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. Radeas agrees that the United States, at a minimum, shall be entitled to recoup from Radeas 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 Radeas or any of

its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Radeas 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 Radeas' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

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

10. 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 11 (waiver for beneficiaries paragraph), below.

11. Radeas 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.

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

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

14. 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 District of Massachusetts. 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.

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

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

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

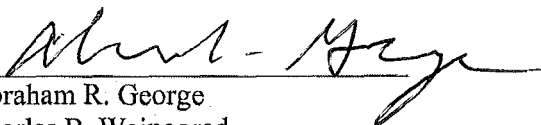
18. This Agreement is binding on Radeas' successors, transferees, heirs, and assigns.

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

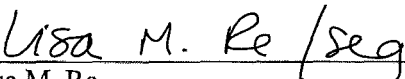
20. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 3/31/22


BY: 
Abraham R. George
Charles B. Weinograd
Assistant United States Attorneys
United States Attorneys
District of Massachusetts

DATED: 3/30/22

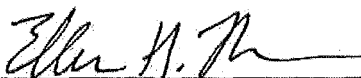
BY: 
Lisa M. Re
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

RADEAS LLC

DATED: 3/24/22

BY: 
Philip Radford
Owner and CEO, Radeas LLC

DATED: 3/24/22

BY: 
Ellen Persons
Brea Croteau
Counsel for Radeas LLC