

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 United States Department of Health and Human Services, Office of Inspector General (OIG-HHS); the Health Resources and Services Administration (HRSA); the Defense Health Agency (DHA), acting on behalf of the TRICARE Program; and the Railroad Retirement Board (RRB), Office of Inspector General (OIG-RRB) (collectively, the “United States”); Capstone Healthcare, LLC, Capstone Diagnostics One, LP, Capstone Diagnostics, LLC, Capstone Genetics, ISPM GP, LLC, ISPM Laboratories, LP, and ISPM Labs, LLC (collectively, “Capstone Diagnostics” or “Capstone”), and Andrew Maloney (“Maloney”) (collectively, “Defendants”); and Jesse Allen (“Relator”), through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

RECITALS

A. Maloney, a resident of Roswell, Georgia, is the sole owner, CEO, and Chairman of Capstone Diagnostics. Capstone is a clinical laboratory in Atlanta, Georgia. Capstone provides, among other tests, toxicology tests (*i.e.*, urine drugs screens), COVID-19 tests, and respiratory pathogen panels (RPPs) to beneficiaries of: 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”); the HRSA’s Uninsured Program, administered under the authority of the Families First Coronavirus Response Act, P.L. 116-127, and the Paycheck Protection Program and Health Care Enhancement Act, P.L. 116-139, 134 Stat. 626 (“HRSA-UIP”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the Railroad Retirement Medicare Program (“RRMP”), administered under the Railroad Retirement Act of 1974, 45 U.S.C. §§ 231-231v, by the United States Railroad Retirement Board.

B. Pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), on [REDACTED], Jesse Allen filed a *qui tam* action in the United States District Court for the Northern District of Georgia captioned [REDACTED] [REDACTED] (the Civil Action) against Defendants. Relator filed an amended complaint on [REDACTED].

C. On February 28, 2024, Maloney will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(B) (the “Plea Agreement”) to an Information filed in *United States v. Drew Maloney*, Criminal Action No. 1:24-cr-00033 (N.D. Ga.) (the “Criminal Action”), charging Maloney with conspiring to pay unlawful health care kickbacks, in violation of 18 U.S.C. § 371 and 42 U.S.C. § 1320a-7b(b)(2)(B).

D. Defendants have entered or will be entering into separate settlement agreements, described in Paragraph 1.b., with certain states in settlement for the Covered Conduct (the “Medicaid State Settlement Agreements”). States with which Defendants execute a Medicaid State Settlement Agreement in the form to which Defendants and the National Association of Medicaid Fraud Control Units (“NAMFCU”) Negotiating Team have agreed, or in a form agreed to by Defendants and an individual State, shall be defined as “Medicaid Participating States.”

E. The United States contends that Capstone Diagnostics submitted, and Maloney caused to be submitted, claims for payment to Medicare, Medicaid, HRSA, TRICARE, and RRMP.

F. The United States contends that it has certain civil claims against Defendants arising from the following conduct, by which Capstone Diagnostics knowingly submitted, and Maloney knowingly caused the submission of, false or fraudulent claims to Medicare, Medicaid, HRSA, TRICARE, and RRMP:

(1) In 2017, Defendants hired independent contractor sales representatives to arrange for or recommend the ordering of toxicology tests on children participating in an after-school and youth mentoring program known as “Do-It-4-The-Hood.” With Defendants’ knowledge and approval, independent contractor sales representatives recruited at-risk youth, in particular children who were Medicaid eligible in Georgia, for their Do-It-4-The-Hood program. Once enrolled, children were required to submit urine specimens for drug testing. Defendants knew these tests were not medically necessary as the children did not need them, physicians did not order them, and the test results were disregarded. Defendants knowingly and willfully paid a commission for each toxicology test paid for by Georgia Medicaid (*i.e.*, a volume-based commission). Such payments violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2).

Between August 1, 2017, and November 30, 2018, Capstone knowingly submitted, and Maloney knowingly caused the submission of, false or fraudulent claims to Georgia Medicaid for medically unnecessary toxicology tests tainted by illegal volume-based commissions.

(2) In early 2020, the COVID-19 pandemic spread across the United States. As residents of senior living communities were especially vulnerable to the devastating effects of COVID-19, many states instituted emergency policies that required COVID-19 testing of residents in senior communities. Defendants sought to profit off the unfolding pandemic by directing independent contractor sales representatives to arrange for or recommend the ordering of RPPs to senior communities interested only in COVID-19 tests. RPPs are an expensive panel that tests for many different respiratory pathogens, some of which are very rare, do not cause overlapping clinical syndromes, and are found only in specific patient populations. With Capstone’s knowledge and approval,

independent contractor sales representatives agreed to perform COVID-19 tests at no cost to senior communities, but then also arranged for Capstone to perform and bill Medicare, Medicaid, HRSA, TRICARE, and RRMP for RPPs even though physicians had not ordered them. To make it appear as though physicians had ordered RPPs, Capstone directed independent contractor sales representatives to complete requisition forms (*i.e.*, orders) for physicians who had only authorized COVID-19 testing. On these forms, independent contractor sales representatives selected that senior community residents would receive both COVID-19 testing *and* RPPs, forged physician signatures, and added sham diagnosis codes that did not reflect the medical condition of the seniors who would receive testing. Defendants knowingly and willfully paid a volume-based commission for each RPP paid for by Medicare, Medicaid, HRSA, TRICARE, and RRMP. Such payments violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2).

Between April 1, 2020, and December 31, 2021, Capstone knowingly submitted, and Maloney knowingly caused the submission of, false or fraudulent claims to Medicare, Medicaid, HRSA, TRICARE, and RRMP for medically unnecessary RPPs that were tainted by illegal volume-based commissions.

The conduct set forth in Paragraph F is referred to below as the “Covered Conduct.”

G. On December 17, 2021, the Centers for Medicare & Medicaid Services (“CMS”) suspended certain Medicare payments to Capstone pursuant to 42 C.F.R. § 405.371(a)(2), and subsequently, RRB suspended Capstone’s Railroad Retirement Medicare Program payments (collectively, the “Suspensions”). The total amount held by the United States as of December 1, 2023, as a result of the Suspensions, a sum of \$2,308,474.57, shall be defined as the “Suspended Amount.”

H. 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. Defendants shall pay to the United States and the Medicaid Participating States, collectively, a total of \$14,308,474 (\$12,000,000 plus the Suspended Amount), of which \$7,227,554 is restitution, plus interest at a rate of 5.33% per annum from February 28, 2024, and continuing until and including the date of payment (the "Settlement Amount"), as follows:

a. Defendants shall pay to the United States \$11,577,120 (\$13,885,595 less the Suspended Amount), of which \$7,081,205 is federal restitution, plus accrued interest as set forth above ("Federal Settlement Amount"). Defendants shall pay the Federal Settlement Amount by electronic funds transfer pursuant to written instructions provided by the United States no later than seven (7) days after: (i) this Agreement is fully executed by the Parties and delivered to Defendants' attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(B) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action, whichever occurs later.

b. Defendants shall pay to the Medicaid Participating States \$422,880, of which \$146,349 is state restitution, plus accrued interest as set forth above, to be disbursed in accordance with written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the agreements that Defendants will enter into with the Medicaid Participating States.

c. Defendants hereby agree that the United States shall retain the Suspended Amount forevermore, which will be first applied to any outstanding Medicare overpayments determined by CMS or CMS contractor, including any interest, then to the Federal Settlement Amount. Defendants expressly relinquish any and all rights of any kind that it may have with respect to those funds, including, but not limited to: any and all claims or rights to have an overpayment determined under 42 C.F.R. § 405.372(c), any and all rights to payment of those funds, and any and all rights to appeal, whether formally or informally and whether administratively or judicially, the right of the United States, CMS, and/or RRB to retain those funds, and any other rights Defendants may have to challenge the Suspensions in any respect.

d. If Maloney's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(B) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court, this Agreement shall be null and void at the option of either the United States or Defendants. If either the United States or Defendants exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Defendants will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims, actions, or proceedings arising from the Covered Conduct that are brought by the United States within 120 calendar days of rescission, except to the extent such defenses were available on the day on which the *qui tam* complaint listed in Preamble Paragraph B was filed.

2. Conditioned upon the United States receiving the Federal Settlement Amount and as soon as feasible after receipt, the United States shall pay \$2,777,118 to Relator as Relator's

share of the proceeds pursuant to 31 U.S.C. § 3730(d). No other relator payments shall be made by the United States with respect to the matters covered by this Agreement.

3. Maloney shall pay \$150,000 to Relator's counsel for Relator's reasonable expenses, attorneys' fees, and costs within fifteen (15) calendar days of the Effective Date, pursuant to written instructions to be provided by Relator's counsel. This is intended to be a *pro tanto* settlement and is not evidence of Relator's actual fees, expenses, and costs.

4. Subject to the exceptions in Paragraph 6 and upon the United States' receipt of the Federal Settlement Amount, plus interest due under Paragraph 1.a., the United States releases Defendants, 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 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.

5. Subject to the exceptions in Paragraph 10, and upon the United States' receipt of the Federal Settlement Amount, plus interest due under Paragraph 1.a., Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Defendants from any civil monetary claim the Relator has on behalf of the United States alleged in the Civil Action under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. Notwithstanding the releases given in Paragraph 4, 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 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;
- f. Any liability of other 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; and,
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

7. Relator and his 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 Relator's Share, Relator and his 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 for the Covered Conduct to the extent it was performed by Defendants, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action recovered from Defendants. Relator expressly reserves all rights to claims against the United States for a share

of future proceeds arising from the Civil Action or under 31 U.S.C. § 3730 recovered from anyone except Defendants.

8. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Defendants from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs. Relator expressly reserves all rights relating to claims against anyone except Defendants, including for expenses, fees, and costs relating to the Civil Action.

9. Defendants waive and shall not assert any defenses Defendants 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.

10. Defendants 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 Defendants 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 or the United States' investigation or prosecution thereof.

11. Defendants fully and finally release the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the Relator, related to the Civil Action and the Relator's investigation and prosecution thereof.

12. The Federal 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), HRSA, RRMP, DHA, or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare contractor, HRSA, RRMP, DHA, 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.

13. Defendants agree 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 Maloney and Capstone, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement and any plea agreement;

- (5) the payment Defendants make to the United States pursuant to this Agreement and any payments that Defendants may make to Relator, including costs and attorneys fees; and

are unallowable costs for government contracting purposes and under the Medicare Program, the Medicaid Program, HRSA-UIP, TRICARE, and RRMP (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants 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 Defendants or any of its subsidiaries or affiliates to the Medicare Program, the Medicaid Program, HRSA-UIP, TRICARE, and RRMP.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare, HRSA, TRICARE, and RRMP fiscal intermediaries, carriers, and/or contractors, and Medicaid 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 Defendants 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. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants 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 Defendants or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Defendants 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 Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

14. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Defendants shall encourage, and agree 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. Defendants further agree 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.

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.

16. Defendants agree that they waive 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.

17. Upon receipt of the Federal Settlement Amount described in Paragraph 1.a., the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of Defendants from the Civil Action pursuant to Rule 41(a)(1). The Joint Stipulation of Dismissal shall be with prejudice as to the United States' and Relator's claims as to the Covered Conduct, and without prejudice to the United States and with prejudice as to Relator as to all other claims against Defendants in the Civil Action.

18. Except as discussed in Paragraph 3, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

20. 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 Northern District of Georgia. 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.

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

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

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

24. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

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

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

27. 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: Feb. 28, 2024

BY:



Paul R. Perkins
Deputy Director
Fraud Section, Civil Division
United States Department of Justice

DATED: _____

BY:

Neeli Ben-David
Assistant United States Attorney
United States Attorney's Office for the
Northern District of Georgia

DATED: _____

BY:

Susan Gillin
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: _____
Paul R. Perkins
Deputy Director
Fraud Section, Civil Division
United States Department of Justice

DATED: _____

BY: _____
NEELI BEN DAVID Digitally signed by NEELI BEN DAVID
Date: 2024.02.27 11:57:39 -05'00'
Neeli Ben-David
Assistant United States Attorney
United States Attorney's Office for the
Northern District of Georgia

DATED: _____

BY: _____
Susan Tamara Forys
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: _____

Paul R. Perkins
Deputy Director
Fraud Section, Civil Division
United States Department of Justice

DATED: _____

BY: _____

Neeli Ben-David
Assistant United States Attorney
United States Attorney's Office for the
Northern District of Georgia

DATED: _____

BY: _____

SUSAN GILLIN

Digitally signed by SUSAN
GILLIN
Date: 2024.02.28 11:05:29
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Susan Gillin
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: _____

Paul R. Perkins
Deputy Director
Fraud Section, Civil Division
United States Department of Justice

DATED: _____

BY: _____

Neeli Ben-David
Assistant United States Attorney
United States Attorney's Office for the
Northern District of Georgia

DATED: _____

BY: _____

Susan Tamara Forys
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: 02/21/2024

BY: BLEY.PAUL.NICHOLAS.10998738
LAS.1099873821

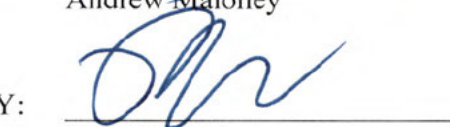
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for
Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

2/24/2024

Y: 

Andrew Maloney

Y: 

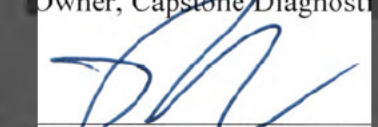
Brian Rafferty

2/28/2024



Andrew Maloney


Owner, Capstone Diagnosti




Brian Rafferty

JESSE ALLEN - RELATOR


DATED: 27 FEB 24

BY: 
Jesse Allen

DATED: 2/27/2024

BY: 
Julie Bracker
Counsel for Jesse Allen

DATED: 2/27/2024

BY: 
Jason Marcus
Counsel for Jesse Allen