

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”), and the Defense Health Agency (DHA), acting on behalf of the TRICARE Program (collectively, the “United States”) and Inform Diagnostics, Inc. (“Inform”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Inform is a Delaware corporation with its headquarters in Irving, Texas. Inform provides anatomic pathology services to physician practices throughout the United States. Throughout the period referenced in this Agreement, certain of Inform’s anatomic pathology services were reimbursed by federal health care programs, including Medicare.

B. The United States contends that Inform submitted or caused to be submitted claims for payment for anatomic pathology services to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”), and the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”) (collectively, “Federal Health Care Programs”).

C. The United States contends that it has certain civil claims against Inform for submitting or causing the submission of false claims for payment to Federal Health Care Programs that were tainted by violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

D. Reimbursement for anatomic pathology (“AP”) laboratory services involves two components: a “technical” component, involving the physical preparation of the specimen for pathologist review, and a “professional” component, involving analysis of the slide by the pathologist.

E. Inform admits, acknowledges, and accepts responsibility for the following facts.

From January 1, 2018 through December 31, 2023, Inform had purchased test arrangements (“PTAs”) with a small number of its physician practice customers. Under these PTAs, the customer performed one component of an AP service, referred the other component of the AP service to Inform to perform, and Inform billed commercial insurers for both components, reimbursing the customer for the component the customer performed at a set price. Customers with PTAs usually also referred both components of other AP services to Inform, including services that Inform performed and billed to Federal Health Care Programs. In the fourth quarter of 2023, Inform initiated an internal investigation, and following its completion of that investigation, Inform terminated its eight then-active PTAs. These eight PTAs are set forth in a separate letter dated December 11, 2024, which is incorporated herein by reference (the “PTA List”). This conduct is referred to below as the “Covered Conduct.”

F. This Agreement credits Inform under the Department of Justice’s Guidelines for Taking Voluntary Disclosure, Cooperation and Remediation into Account in False Claims Act Matters, Justice Manual § 4-4.112. Inform voluntarily disclosed its conduct to the United States and cooperated with the United States’ investigation by identifying the claims that are described in the covered conduct and determining the amount of the losses.

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

TERMS AND CONDITIONS

1. Inform shall pay to the United States \$2,968,031.14 (“Settlement Amount”), of which \$1,978,687.43 is restitution, and interest on the Settlement Amount at a rate of 4.0% per annum from September 30, 2024, no later than 10 days after the Effective Date of this

Agreement by electronic funds transfer pursuant to written instructions to be provided by United States Attorney for the District of Massachusetts.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount plus interest, the United States releases Inform, 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. Notwithstanding the release 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 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.

4. Inform waives and shall not assert any defenses Inform 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.

5. Inform 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 Inform 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.

6. 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 DHA related to the Covered Conduct; and Inform agrees not to resubmit to any Medicare contractor or DHA 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.

7. Inform 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 Inform, 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) Inform'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 Inform makes to the United States pursuant to this Agreement

are unallowable costs for government contracting purposes and under the Federal Health Care Programs (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Inform, and Inform 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 Inform or any of its subsidiaries or affiliates to the Federal Health Care Programs.

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

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

8. 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 9 (waiver for beneficiaries paragraph), below.

9. Inform 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.

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

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

12. 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.

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

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

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

16. This Agreement is binding on Inform's successors, transferees, heirs, and assigns.

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

18. 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: 12/20/24

BY: ALEXANDRA BRAZIER
Digitally signed by ALEXANDRA
BRAZIER
Date: 2024.12.20 14:25:20 -05'00'

Alexandra Brazier
Abraham R. George
Assistant United States Attorneys
District of Massachusetts

DATED: 12/19/24

BY: SUSAN GILLIN
Digitally signed by SUSAN
GILLIN
Date: 2024.12.19 09:24:14
-05'00'

Susan E. 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: _____

Alexandra Brazier
Abraham R. George
Assistant United States Attorneys
District of Massachusetts

DATED: _____

BY: _____

Susan E. 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: 12/12/2024

BY: _____

for

BLEY.PAUL.NICHOLA  Digitally signed by
S.1099873821

Date: 2024.12.12 12:23:08 -05'00'

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

INFORM DIAGNOSTICS, INC.

DATED: 12/12/2024

BY: 
Inform Diagnostics, Inc.
Chris Wicker VP & GM

DATED: 12/12/2024

BY: 
Karen Lovitch
Grady Campion
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Counsel for Inform Diagnostics, Inc.