

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”); OPKO Health, Inc. and BioReference Health, LLC (collectively “BioReference” or “the Defendants”); and Relator Omni Healthcare, Inc. (the “Relator”) (hereafter collectively the United States, the Defendants and the Relator are referred to as “the Parties”), through their authorized representatives.

RECITALS

- A. Defendant OPKO Health, Inc. (“OPKO”) is a Delaware corporation with its principal place of business at 4400 Biscayne Boulevard in Miami, Florida. OPKO is a publicly traded diversified health care company whose diagnostics business includes BioReference Health, LLC.
- B. Defendant BioReference Health, LLC (“BioReference”) is a Delaware limited liability company that provides laboratory services nationwide. BioReference was known as BioReference Laboratories, Inc., a New Jersey Corporation, until March 10, 2022. BioReference is a wholly owned subsidiary of OPKO. OPKO completed its acquisition of BioReference on August 20, 2015.
- C. On September 6, 2019, the Relator filed a *qui tam* action in the United States District Court for the District of Delaware captioned *United States et al. ex rel. Omni Healthcare, Inc. v. OPKO Health, Inc. and BioReference Laboratories, Inc.*, Civil Action No. 19-1670 (under seal) (the “Civil Action”), pursuant to the *qui tam* provisions of the False Claims Act, 31

U.S.C. § 3730(b). The Relator alleges that the Defendants violated the federal False Claims Act and the False Claims Act of each of the States of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New Hampshire, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia.

D. The United States contends that the Defendants submitted or caused to be submitted false claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III (Medicare), the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid), and the TRICARE Program, 10 U.S.C. §§1071-1110b (collectively, the “Federal Healthcare Programs”).

E. The United States contends that it has certain civil claims under the federal False Claims Act against the Defendants for knowingly submitting or causing the submission of claims to the Federal Healthcare Programs for Complete Blood Count laboratory tests with automated white blood cell differential (“CBC with WBC”) (which is billed using CPT code 85025), including in circumstances where the ordering provider hand-wrote “CBC” on a hard copy test requisition or order form (“TRF”) that were not medically reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Specifically, the United States contends that from January 1, 2012 until March 1, 2023, the Defendants at times performed CBC with WBC tests when, in fact, the patient’s medical provider had ordered CBC with no white blood cell differential (“CBC without WBC”) (which is billed using CPT code 85027), such as, for example, circumstances where the ordering provider hand-wrote “CBC” on a

hard copy TRF. The Defendants then billed Federal Healthcare Programs for the more expensive CBC with WBC. The foregoing claims and conduct described in this paragraph are referred to below as the “Covered Conduct.”

- F. The Defendants expressly deny the allegations of the Relator as set forth in the Civil Action. This Agreement is neither an admission of liability by the Defendants, nor a concession by the United States that its claims are not well founded.
- G. The Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to the 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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. The Defendants shall pay to the United States seven hundred and four thousand three hundred and forty-nine dollars and ninety cents (\$704,349.90) (“Federal Settlement Amount”), of which three hundred and fifty-two thousand one hundred and seventy-four dollars and ninety-five cents (\$352,174.95) is the Federal Restitution Amount, no later than 30 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.
2. Conditioned upon the United States receiving the Federal Settlement Amount and as soon as feasible after receipt, the United States shall pay \$112,694.64 of the Federal Settlement Amount to the Relator by electronic funds transfer (“Relator’s Share”).
3. As of the Effective Date of this Agreement, the Relator and the Defendants have not reached an agreement relating to claims by the Relator for reasonable expenses, attorneys’

fees, and costs under 31 U.S.C. § 3730(d). As an exception to Paragraphs 5 and 10 below, the Relator and the Defendants specifically reserve and do not release:

a. Any claims the Relator may have for reasonable expenses, attorneys' fees, and costs, pursuant to 31 U.S.C. § 3730(d); and

b. Any defenses that the Defendants may have to the Relator's claims for expenses, attorneys' fees, or costs.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the Federal Settlement Amount due under Paragraph 1, the United States releases the Defendants, their predecessors; their current and former parents; divisions; direct and indirect subsidiaries; brother or sister corporations; current or former corporate owners; and the corporate successors and assigns (collectively, the "Defendant Releasees") 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. Upon the United States' receipt of the Federal Settlement Amount due under Paragraph 1, and subject to the exceptions set forth in Paragraph 3 above, the Relator, to the full extent of its legal authority to do so, for itself and its directors, officers, owners, operators, heirs, successors, attorneys, agents, and assigns, and any and all entities formerly, or now, or in the future owned or operated in whole or in part by the Relator or its directors, officers, owners, operators, heirs, successors, partners, agents, and assigns (collectively with the Relator, the "Relator Releasers"), jointly and severally, releases the Defendant Releasees and their current and former affiliates, owners, directors, officers, employees, agents, shareholders, joint venturers, and

successors and assigns of any of these entities (together with the Defendant Releasees, the “Defendant Releasee Entities”), jointly and severally, from any and all claims and potential claims, whether known or unknown, from the beginning of time until the Effective Date of this Agreement, including but not limited to (i) all claims included in the Relator’s *qui tam* complaint filed in the Civil Action, (ii) any other claims the Relator has on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-3733, or on behalf of any state under their respective state false claims acts, and (iii) any common law and/or statutory claims, with the express exception of any potential claims concerning conduct that post-dates the Effective Date of this Agreement. The Relator Releasees represent and warrant that they are not currently aware of any legal claim that could lawfully be brought at this time against the Defendant Releasee Entities other than those encompassed within the Covered Conduct and the Civil Action, for which a full release is herein granted.

6. Notwithstanding the release given in Paragraph 4 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;

- 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; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. The Relator and its officers, directors, owners, operators, heirs, successors, attorneys, agents, and assigns do not object to this Agreement but agree and confirm that this Agreement and the Federal Settlement Amount are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). For the avoidance of doubt, the Relator and the Relator Releasers, jointly and severally, hereby waive the right to challenge the fairness, adequacy, or reasonableness of the Agreement and the Federal Settlement Amount, and waive the opportunity for a hearing on any objection to this Agreement or the Federal Settlement Amount pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon the Relator's receipt of the Relator's Share, the Relator and its 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, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. The Defendants waive and shall not assert any defenses they 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. The 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 the 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.

10. Conditioned upon the Relator's execution of this Agreement and dismissal with prejudice as to the Relator of the Civil Action against the Defendants as set forth more fully in Paragraph 15, and subject to the exceptions set forth in Paragraph 3 above, the Defendant Releasee Entities, to the full extent of their legal authority to do so, release the Relator Releasers, jointly and severally, from any and all claims and potential claims, whether known or unknown, from the beginning of time until the Effective Date of this Agreement, including but not limited to (i) all claims related to the Relator's *qui tam* complaint in the Civil Action; (ii) claims against the Relator under the False Claims Act, 31 U.S.C. §§ 3729-3733; and (iii) any common law and/or statutory claims, with the express exception of any potential claims concerning conduct that post-dates the Effective Date of this Agreement. The Defendant Releasee Entities represent and warrant that they are not currently aware of any legal claim that could lawfully be brought at this time against the Relator Releasers other than those encompassed within the Covered Conduct and the Civil Action, for which a full release is herein granted.

11. 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, or carrier) or TRICARE carrier or payer, or any

state payer, related to the Covered Conduct; and the Defendants agree not to resubmit to any Medicare contractor or TRICARE carrier or payer, or any state payer, any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

12. The 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. §§ 1395-1395*III* and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Defendants, their 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) the Defendants' 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 the Defendants make to the United States pursuant to this Agreement and any payments that the Defendants may make to the Relator, including costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, and TRICARE Program (the "Unallowable Costs").

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: The Defendants further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare, TRICARE 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 the Defendants or any of their 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. The Defendants agree that the United States, at a minimum, shall be entitled to recoup from the 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 the Defendants or any of

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

13. 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 14 (waiver for beneficiaries paragraph), below.

14. The 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.

15. Upon the United States' receipt of the payment described in Paragraph 1, above, the United States and the Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). The dismissal shall be with prejudice as to the Relator as to all claims and all parties in the Civil Action. With respect to the United States, the dismissal shall be with prejudice as to the Covered Conduct and without prejudice as to any other conduct or causes of action.

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

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

18. 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 District of Delaware. 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.

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

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

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

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

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

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

25. 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: 1/14/25

BY: Claire L. Norsetter
Claire L. Norsetter
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DAVID C. WEISS
United States Attorney
District of Delaware

DATED: 12/26/24

BY: Shamoor Anis
Shamoor Anis
Assistant United States Attorney
District of Delaware

DATED: 12/23/24

BY: SUSAN GILLIN
Digitally signed by
SUSAN GILLIN
Date: 2024.12.23
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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: _____

Claire L. Norsetter
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DAVID C. WEISS
United States Attorney
District of Delaware

DATED: _____

BY: _____

Shamoor Anis
Assistant United States Attorney
District of Delaware

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: 12/20/2024

BY: _____

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

BIOREFERENCE - DEFENDANT

DATED: 12/30/2024


BY: *Robert J. Rossi*
ROBERT J. ROSSI
Senior Vice President and Chief Legal Officer,
BioReference Health, LLC

DATED: 12/30/24


BY: *Karen S. Lovitch*
KAREN S. LOVITCH
SAMANTHA P. KINGSBURY
Counsel for BioReference Health, LLC

OPKO - DEFENDANT

DATED: 12/30/2024


BY: 
STEVE RUBIN
Executive Vice President, Administration,
OPKO Health, Inc.

DATED: 12/30/24

BY: 
KAREN S. LOVITCH
SAMANTHA P. KINGSBURY
Counsel for OPKO Health, Inc.

OMNI HEALTHCARE, INC. - RELATOR

DATED: 12/29/2024

BY: 
CRAIG DELIGDISH
Omni Healthcare, Inc.

DATED: 1/2/25

BY: David Harrison
DAVID HARRISON
Counsel for Omni Healthcare, Inc.