UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 14, 2022

OPKO Health, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4400 Biscayne Blvd.	**Miami,**	**Florida**	**33137**
(Address of Principal Executive Offices)			(Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	OPK	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 1.01. Entry into a Material Definitive Agreement.

OPKO Health, Inc., a Delaware corporation (the "Company"), and BioReference Health, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company (formerly BioReference Laboratories, Inc. "BioReference"), entered into (i) a Settlement Agreement, effective July 14, 2022, with the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"), and the Defense Health Agency, acting on behalf of the TRICARE Program (collectively, the " United States"), the Commonwealth of Massachusetts (the "Commonwealth"), the State of Connecticut, ("Connecticut"), and the relator identified therein ("Relator"), and (ii) a Corporate Integrity Agreement, effective July 14, 2022 (the "CIA"), with the OIG-HHS, to resolve the investigation and related civil action concerning alleged fee-for-service claims for payment to the Medicare Program, the Medicaid Program, and the TRICARE Program (collectively, the "Federal Health Care Programs").

Under the Settlement Agreement, the Company and BioReference admitted only to having made payments to certain physicians and physicians' groups for office space rentals for amounts that exceeded fair market value, and that it did not report or return any such overpayments to the Federal Health Care Programs (the "Covered Conduct"). The Covered Conduct had commenced prior to the Company's acquisition of BioReference in 2015, which the Company and BioReference identified in internal audits conducted in 2017 and 2019. With the exception of the Covered Conduct, the Company and BioReference expressly deny the allegations of the Relator as set forth in her civil action. The Company has agreed to pay a total of $10,000,000 plus accrued interest from September 24, 2021 at a rate of 1.5% per annum (the "Settlement Amount"). The Settlement Amount consists of $9,853,958 payable to the United States, $141,041 payable to the Commonwealth and $5,001 payable to Connecticut, in each case plus interest and payable no later than July 24, 2022. Conditioned upon payment of the Settlement Amount, the United States, the Commonwealth and Connecticut have agreed to release the Company and BioReference from any civil or administrative monetarily liability arising from the Covered Conduct. Upon payment of the Settlement Amount and the amount due under a separate agreement with the Relator, the Relator has agreed to release the Company and BioReference from any and all claims and potential claims. Further, in consideration of the obligations of the Company and BioReference in the Settlement Agreement and the CIA, the OIG-HHS has agreed to release and refrain from instituting any administrative action seeking to exclude the Company or BioReference from participating in Medicare, Medicaid or other Federal health care programs as a result of the Covered Conduct.

Under the CIA, which has a term of 5 years, BioReference is required to, among other things: (i) maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; (ii) provide management certifications and compliance training and education; (iii) establish written compliance policies and procedures to meet federal health care program requirements; (iv) create procedures designed to ensure compliance with the Anti-Kickback Statute and/or Stark Law; (v) engage an independent review organization to conduct a thorough review of BioReference' s systems, policies, processes and procedures related to certain arrangements; (vi) implement a risk assessment and internal review process; (vii) establish a disclosure program for whistleblowers; and (viii) report or disclose certain events and physician payments. The Company's or BioReference's failure to comply with its obligations under the CIA could result in monetary penalties and the exclusion from participation in Federal Health Care Programs. The CIA does not apply to any of the Company's subsidiaries other than BioReference, and its scope is generally limited to "focus arrangements", which are those "arrangements" (as defined in the CIA) (i) between BioReference and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value, or (ii) is between BioReference and any physician (or a physician's immediate family member). Most of these measures have already been implemented at BioReference. Following its acquisition of BioRerefence, the Company and BioReference implemented robust compliance measures that substantially align with those actions required under the CIA.

The foregoing description of the Settlement Agreement and the CIA is only a summary and is qualified in its entirety by reference to the full text of such agreements, which are filed as Exhibits 10.1 and 10.2, respectively, to this Current Report on Form 8-K and are incorporated by reference in this Item 1.01.

ITEM 5.07. Submission of Matters to a Vote of Security Holders.

On July 14, 2022, the Company held its 2022 Annual Meeting of Stockholders (the "Annual Meeting"). Below is a summary of the proposals submitted to a vote of the Company's stockholders at the Annual Meeting and the corresponding votes.

1. All thirteen nominees were elected to the Board of Directors with each director receiving votes as follows:

Election of Directors	For	Withheld	Broker Non-Votes
Phillip Frost, M.D.	346,445,817	84,980,968	97,999,906
Jane H. Hsiao, Ph.D.	332,412,437	99,014,347	97,999,906
Steven D. Rubin	323,992,168	107,434,616	97,999,906
Elias A. Zerhouni, M.D.	364,910,176	66,516,609	97,999,906
Jon R. Cohen , M.D.	335,019,949	96,406,835	97,999,906
Gary J. Nabel, M.D., Ph.D.	368,161,695	63,265,089	97,999,906
Alexis Borisy	304,302,351	127,124,433	97,999,906
Richard M. Krasno, Ph.D.	374,406,829	57,019,955	97,999,906
Prem A. Lachman, M.D.	374,341,432	57,085,352	97,999,906
Roger J. Medel, M.D.	374,109,296	57,317,488	97,999,906
John A. Paganelli	345,249,107	86,177,677	97,999,906
Richard C. Pfenniger, Jr.	395,537,060	35,889,724	97,999,906
Alice Lin-Tsing Yu, M.D., Ph.D.	408,617,483	22,809,301	97,999,906

2. The stockholders voted to approve, on a non-binding advisory basis, the compensation of the named executive officers of the Company as disclosed in the Company's 2022 Proxy Statement for the Annual Meeting. The votes on this proposal were as follows:

For	Against	Abstain	Broker Non-Votes
402,336,412	28,153,806	936,566	97,999,906

3. The stockholders voted to amend the OPKO Health, Inc. 2016 Equity Incentive Plan to increase the number of shares issuable thereunder from 30,000,000 to 60,000,000. The votes on this proposal were as follows:

For	Against	Abstain	Broker Non-Votes
297,094,646	133,594,936	737,202	97,999,906

4. The stockholders voted to ratify the appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2022. The votes on this proposal were as follows:

For	Against	Abstain	Broker Non-Votes
522,909,259	5,802,347	715,084	—

No other matters were considered or voted upon at the meeting.

ITEM 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
10.1	Settlement Agreement, dated July 14, 2022, by and among OPKO Health, Inc., BioReference Health, LLC, the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, and the Defense Health Agency, acting on behalf of the TRICARE Program, the Commonwealth of Massachusetts, the State of Connecticut and Jean Marie Crowley.
10.2	Corporate Integrity Agreement, dated July 14, 2022, by and among OPKO Health, Inc., BioReference Health, LLC and the Office of Inspector General of the United States Department of Health and Human Services.
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OPKO Health, Inc.

By: /s/ Steven D. Rubin

Date: July 15, 2022

Name: Steven D. Rubin

Title: Executive Vice President-Administration

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"), the Commonwealth of Massachusetts (the "Commonwealth"), acting through the Medicaid Fraud Division of the Office of Attorney General and on behalf of the Executive Office of Health and Human Services ("EOHHS"), limited to its role as the single state agency for Medicaid ("MassHealth"), the State of Connecticut, acting through the Attorney General of the State of Connecticut (collectively, "Connecticut"), BioReference Health, LLC and OPKO Health, Inc. (together, the "Defendants"), and Jean Marie Crowley ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Defendant OPKO Health, Inc. ("OPKO") is a Delaware corporation with principal executive offices at 4400 Biscayne Blvd., Miami, FL 33137. OPKO Health 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 April 25, 2019, Relator filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Crowley v. BioReference Laboratories, Inc. and OPKO Health, Inc.*, No. 19-cv-10981, pursuant to the qui tam provisions

of the False Claims Act, 31 U.S.C. § 3730(b), the Massachusetts False Claims Act, M.G.L. c. 12, § 5A *et seq*., and the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, *et seq*. (the "Civil Action"). Relator alleges that Defendants violated the federal False Claims Act, the Connecticut False Claims Act, and the Massachusetts False Claims Act by: (1) paying unlawful remuneration to physician groups that referred testing to BioReference, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and (2) submitting claims for designated health services referred in violation of the federal physician self-referral law (commonly referred to as the "Stark Law,"), 42 U.S.C. § 1395nn.

D. The United States, the Commonwealth, and Connecticut contend that Defendants submitted or caused to be submitted fee-for-service 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") (collectively, "Federal Health Care Programs").

E. The United States contends that it has certain civil claims against Defendants 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), and/or the Stark Law, 42 U.S.C. § 1395nn.

F. The Commonwealth and Connecticut contend that they have certain civil claims against Defendants for submitting or causing the submission of false claims for payment to MassHealth and Connecticut Medicaid that were tainted by violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), the Stark Law, 42 U.S.C. § 1395nn, the Massachusetts Anti-Kickback Law, M.G.L. c. 175H § 3, and/or the Connecticut Anti-Kickback Law, Conn. Gen. Stat. § 53a-161d(a). The Commonwealth and Connecticut contend that MassHealth and Connecticut Medicaid require that enrolled providers comply with federal and state law, including the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), the Stark Law, 42 U.S.C. §

1395nn, the Massachusetts Anti-Kickback Law, M.G.L. c. 175H § 3, and/or the Connecticut Anti-Kickback Law, Conn. Gen. Stat. § 53a-161d(a).

G. Defendants admit, acknowledge, and accept responsibility for the following facts. For the physicians, physician groups, and time periods set forth in a separate letter dated June 29, 2022, which is incorporated herein by reference (the "Practice List"), BioReference made payments to the physicians and physicians' groups, from January 1, 2013 through March 31, 2021, for office space rentals for amounts that exceeded fair market value. BioReference used the rented office space for its Patient Service Centers ("PSCs"), where BioReference collected patients' blood samples. BioReference analyzed referrals from nearby health care providers—including many of the physician-lessors identified in the Practice List—when deciding whether to open, maintain, or close PSCs. When BioReference entered into the rental arrangements set forth in the Practice List and determined the payments it would make to physicians and physicians' groups for the office space rentals, in some cases BioReference (i) inaccurately measured the amount of space that BioReference would use exclusively, and (ii) included a disproportionate share of the common spaces in the calculations of office space for which BioReference made payments. OPKO and BioReference conducted internal audits between 2017 and 2019 that identified certain physician-lessors to whom BioReference made lease payments in excess of fair market value. Defendants did not report or return any overpayments to the Federal Health Care Programs. This conduct is referred to below as the "Covered Conduct." *

H. With the exception of the Covered Conduct, Defendants expressly deny the allegations of the Relator as set forth in the Civil Action.

* The Practice List also identifies the specific physicians/physician groups for which the Covered Conduct took place in the Commonwealth and Connecticut.

I. Relator claims entitlement under 31 U.S.C. § 3730(d), M.G.L. c. 12, § 5F, and Conn. Gen. Stat. § 4-278(e) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

J. 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 $9,853,958 ("Federal Settlement Amount"), of which $4,926,979 is restitution, and interest on the Settlement Amount at a rate of one-and-one-half percent (1.5%) per annum from September 24, 2021, 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 for the District of Massachusetts.

2. Defendants shall pay to the Commonwealth $141,041 ("Commonwealth Settlement Amount") and interest on the Commonwealth Settlement Amount at a rate of one-and-one-half percent (1.5%) per annum from September 24, 2021, 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 Massachusetts Attorney General's Office.

3. Defendants shall pay to Connecticut $5,001 ("Connecticut Settlement Amount") and interest on the Connecticut Settlement Amount at a rate of one-and-one-half percent (1.5%) per annum from September 24, 2021, 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 Connecticut Attorney General's Office.

4. Conditioned upon the United States receiving payment of the Federal Settlement Amount, and as soon as feasible after receipt, the United States shall pay $1,675,172.86 plus a ro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer ("Federal Relator's Share").

5. Conditioned upon the Commonwealth receiving the Commonwealth Settlement Amount, and as soon as feasible after receipt, the Commonwealth shall pay $23,976.97 plus a pro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer ("Commonwealth Relator's Share").

6. Conditioned upon Connecticut receiving the Connecticut Settlement Amount, and as soon as feasible after receipt, Connecticut shall pay $850.17 plus a pro rata share of the accrued interest at the rate set forth above to Relator by electronic funds transfer ("Connecticut Relator's Share").

7. Defendants have agreed to pay Relator's reasonable expenses, fees, and costs related to the Civil Action, as contemplated by 31 U.S.C. §§ 3730(d) and (h)(2) and comparable state law provisions, and will do so subject to terms set forth in a separate agreement being entered into by Relator and Defendants. Moreover, Defendants and Relator have resolved Relator's claims under 31 U.S.C. § 3730(h) and M.G.L. ch. 12 § 5J relating to the Civil Action subject to the terms set forth in a separate agreement.

8. Subject to the exceptions in Paragraph 14 (concerning reserved claims) below, and upon the United States' receipt of the Federal Settlement Amount plus interest due under Paragraph 1, the United States releases Defendants, their predecessors, their current and former parents, divisions, subsidiaries, 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; the civil onetary provisions of the Stark Law at 42 U.S.C. §§ 1395nn(g)(3) and (g)(4); or the common law theories of payment by mistake, unjust enrichment, and fraud.

9. Subject to the exceptions in Paragraph 14 below, and conditioned upon the Commonwealth's receipt of Defendants' full payment of the Massachusetts Settlement

Amount, the Commonwealth releases Defendant Releasees from any civil or administrative monetary claim the Commonwealth has for the Covered Conduct under the Massachusetts False Claims Act, M.G.L. c. 12, § 5A, *et seq*.; the Massachusetts Medicaid False Claims Act, M.G.L. c. 118E, §§ 40 and 44; the overpayment provisions of 130 C.M.R. §§ 450.237, 450.260(A), 450.260(I)); or the common law theories of payment by mistake, unjust enrichment, and fraud.

10. Subject to the exceptions in Paragraph 14 below, and conditioned upon Connecticut's receipt of Defendants' full payment of the Connecticut Settlement Amount, Connecticut releases Defendant Releasees from any civil or administrative monetary claim Connecticut has for the Covered Conduct under the Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274, *et seq*.; or the common law theories of payment by mistake, unjust enrichment, and fraud.

11. Upon Defendants' full payment of the Federal, Commonwealth, and Connecticut Settlement Amounts plus interest due under Paragraph 1, and amounts due under the separate agreements referenced in Paragraph 7, Relator, to the full extent of her legal authority to do so, for herself and for her heirs, successors, attorneys, agents, assigns, and any and all entities formerly, or now, or in the future owned in whole or in part by herself or her heirs, successors, partners, agents, and assigns (collectively with Relator, the "Relator Releasors"), jointly and severally, releases 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 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 her qui tam complaint filed in the Civil Action, (ii) any other claims Relator has on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-3733, or on

behalf of the Commonwealth or the State of Connecticut under their respective False Claims Acts, (iii) any employment claims, and (iv) 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. Relator represents and warrants that she is not currently aware of any legal claim that could lawfully be brought at this time against Defendant Releasee Entities other than those encompassed within the Covered Conduct and the Civil Action, for which a full release is herein granted.

12. In consideration of the obligations of Defendants in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between the OIG-HHS and OPKO and BioReference, and upon the United States' receipt of full payment of the Federal 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 Defendants 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 14 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Defendants 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 or practices, for which claims have been reserved in Paragraph 14, below.

13. In consideration of the obligations of Defendants in this Agreement, and upon the United States' receipt of full payment of the Federal Settlement Amount, plus interest due under Paragraph 1, DHA shall release and refrain from instituting, directing, or maintaining any

administrative action seeking exclusion from the TRICARE Program against Defendants under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in

Paragraph 14 (concerning reserved claims), below. DHA expressly reserves authority to exclude Defendants 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 or practices, for which claims have been reserved in Paragraph 14, below.

14. Notwithstanding the releases given in Paragraphs 8, 9, and 10 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States, the Commonwealth, and Connecticut are specifically reserved and are not released:

a) Any liability arising under Title 26, U.S. Code (Internal Revenue Code) or Title IX (Chapters 58 - 65C) of the Massachusetts General Laws;

b) Any liability arising under the laws and regulations that are administered and enforced by the State of Connecticut Department of Revenue Services;

c) Any criminal liability;

d) Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory exclusion from Federal health care programs;

e) Except as explicitly stated in this Agreement, any administrative liability to the State of Connecticut Department of Social Services ("DSS"), or enforcement right of the State of Connecticut (or its agencies), including suspension from Connecticut Medicaid;

f) Except as explicitly stated in this Agreement, any civil or administrative liability that any person or entity has or may have to the State of Connecticut or to individual consumers or state program payors under any statute, regulation or rule

not expressly covered by the release in Paragraph 10 above, including, but not limited to, any and all of the following claims: (i) State or federal antitrust violations; (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

g) Any liability to the United States, the Commonwealth or the State of Connecticut (or their agencies) for any conduct other than the Covered Conduct;

h) Any liability based upon obligations created by this Agreement;

i) Any liability of individuals;

j) Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

k) Any liability for failure to deliver goods or services due; and

l) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

15. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement, the Federal Settlement Amount, the Commonwealth Settlement Amount, and the Connecticut Settlement Amount are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and applicable state law. For the avoidance of doubt, Relator and her heirs, successors, attorneys, agents, and assigns hereby waive the right to challenge the fairness, adequacy, or reasonableness of the Agreement, the Federal Settlement Amount, the Commonwealth Settlement Amount, and the Connecticut Settlement Amount, and waive the opportunity for a hearing on any objection to this Agreement, the Federal Settlement Amount, the Commonwealth Settlement Amount, and the Connecticut Settlement Amount pursuant to 31 U.S.C. § 3730(c)(2)(B) and applicable state law. Conditioned upon Relator's receipt of the Relator's Share, Relator and her 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. Conditioned upon Relator's receipt of the Commonwealth Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the Commonwealth, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under M.G.L. c. 12, § 5A, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action. Conditioned upon Relator's receipt of the Connecticut Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge Connecticut, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under Conn. Gen. Stat. § 4-275, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

16. Conditioned upon Relator's execution of this Agreement and the separate agreements referenced in Paragraph 7, and dismissal with prejudice as to Relator of the Civil Action against Defendants as set forth more fully in Paragraph 25, Defendant Releasee Entities, to the full extent of their legal authority to do so, release Relator Releasors, 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 Relator's qui tam complaint in the Civil Action; (ii) claims against Relator under the False Claims Act, 31 U.S.C. §§ 3729-3733, or the False Claims Acts of the Commonwealth or the State of Connecticut; (iii) any employment claims; and (iv) 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. 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 Relator

Releasors other than those encompassed within the Covered Conduct and the Civil Action, for which a full release is herein granted.

17. 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.

18. 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.

19. Defendants fully and finally release the Commonwealth, 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 Commonwealth, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the Commonwealth's investigation or prosecution thereof.

20. Defendants fully and finally release Connecticut, 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 Connecticut, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the Connecticut's investigation or prosecution thereof.

21. The Federal, Commonwealth, or Connecticut Settlement Amounts 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, or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare contractor, TRICARE, 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.

22. 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 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 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 investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

4) the negotiation and performance of this Agreement**;**

5) the payments 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

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 22.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 Defendants.

b) Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers 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 their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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 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 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. 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.

d) 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 their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Defendants or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

e) 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.

23. 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 24 (waiver for beneficiaries paragraph), below.

24. 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.

25. Upon receipt of the payments described in Paragraphs 1, 2, and 3, above, and any payments required by the separate agreements referenced in Paragraph 7, above, the United States, the Commonwealth, Connecticut, and 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)(A). The dismissal shall be with prejudice as to Relator as to all claims and all parties in the Civil Action. With respect to the United States, the Commonwealth, and Connecticut, the dismissal shall be with prejudice as to the Covered Conduct and without prejudice as to any other conduct or causes of action.

26. Except as otherwise provided herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

28. 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 Massachusetts, except that disputes only between the State of Connecticut and Defendants will be resolved in the Superior Court for the Judicial District of Hartford, Connecticut. 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.

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

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

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

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

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

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

35. 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: 7/14/22 By: /s/ Alexandra Brazier
ALEXANDRA BRAZIER
CHARLES WEINOGRAD
Assistant United States Attorneys
District of Massachusetts

DATED: 7/14/22 By: /s/ Douglas Rosenthal
DOUGLAS ROSENTHAL
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 7/14/22 By: /s/ Lisa M. Re
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: 6/29/22 By: BLEY.PAUL.NICHOLAS.1099873821 Digitally signed by BLEY.PAUL.NICHOLAS.1099873821
SALVATORE M. MAIDA
for General Counsel Date: 2022.06.29 18:30:08 -04'00'
Defense Health Agency
United States Department of Defense

THE COMMONWEALTH OF MASSACHUSETTS

DATED: 7/12/22 By: /s/ Toby Unger
TOBY UNGER
Chief, Medicaid Fraud Division
Office of Attorney General
Commonwealth of Massachusetts

DATED: 7/11/22 By: /s/ Marylou Sudders
MARYLOU SUDDERS
Secretary
Executive Office of Health and Human Services
Commonwealth of Massachusetts

THE STATE OF CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

DATED: June 30, 2022 By: /s/ Gregory K. O'Connell
GREGORY K. O'CONNELL
Assistant Attorney
General State of
Connecticut

BIOREFERENCE

DATED: June 29, 2022 By: /s/ Jane Pine Wood
JANE PINE WOOD
Chief Legal Counsel, BioReference Health, LLC

DATED: June 29, 2022 By: /s/Karen S. Lovitch by Karen S. Lovitch
HOPE S. FOSTER
KAREN S. LOVITCH
Counsel for BioReference Health, LLC

OPKO

DATED: 6/27/2022 By: /s/ Steve Rubin
STEVE RUBIN
Executive Vice President, Administration
OPKO Health, Inc.

DATED: June 29, 2022 By: /s/Karen S. Lovitch by Karen S. Lovitch
HOPE S. FOSTER
KAREN S. LOVITCH
Counsel for OPKO Health, Inc.

JEAN MARIE CROWLEY - RELATOR

DATED: 7/1/2022 By: /s/ Jean Marie Crowley
JEAN MARIE CROWLEY

DATED: 7/1/2222 By: /s/ Linda C. Severin
LINDA C. SEVERIN
ERICA BLACHMAN HITCHINGS
SUZANNE E. DURRELL
Counsel for Jean Marie Crowley

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
OPKO HEALTH, INC. AND BIOREFERENCE HEALTH, LLC.

I. PREAMBLE

OPKO Health, Inc. (OPKO) and BioReference Health, LLC. (BioReference), (collectively, the "Companies") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). The obligations of this CIA apply to OPKO only with respect to its oversight of BioReference and only as specifically referenced below. The obligations of this CIA do not apply to any OPKO subsidiary, corporate affiliate, or related organization other than BioReference. Contemporaneously with this CIA, the Companies are entering into a Settlement Agreement with the United States.

The Companies represent that BioReference has implemented a compliance program, that includes a Chief Compliance Officer, Code of Conduct, written policies and procedures, a disclosure program, screening measures, regular compliance training for employees, and various compliance auditing and monitoring programs.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this CIA shall be the signature date of the final signatory of this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) the Companies' final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and the Companies comply with the decision.

C. Definitions.

1. "Arrangements" means:

   a every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between BioReference and (i) any actual or potential source of health care business or referrals to BioReference or (ii) any actual or potential recipient of health care business or referrals from BioReference; and

   b every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between BioReference and a physician (or a physician's

immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to BioReference for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

i. "Source of health care business or referrals" means any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

ii. "Recipient of health care business or referrals" shall mean any individual or entity (a) to whom BioReference refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom BioReference purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

2. "Arrangements Covered Persons" means each Covered Person who is involved with the development, approval, management, or review of BioReference Arrangements.

3. "Certifying Employees" means the following:

a Steven C. Allen, SVP, Chief Operating Officer, BioReference

b Natalie Cummins, SVP, Chief Commercial Officer, Payor Relations, BioReference

c Robert J. Rossi, SVP, Chief Compliance and Privacy Officer, BioReference

d Adam Logal, Chief Financial Officer, OPKO/BioReference

e Peter Sperger, Global Chief Compliance Officer, OPKO

f Susan M. Aveta, VP, Phlebotomy, BioReference

g Ellen G. Beausang, SVP, Advanced Diagnostics Oncology Franchise, BioReference

h Scott Fein, SVP, Business Development, Commercial, BioReference

i Joseph A. Gargiulo, Director, Operations Initiatives, BioReference

j Cynthia L. Jacke, SVP, Strategic Services, BioReference

k Ryan Kellogg, VP, National Sales, BioReference

4. “Covered Persons” means: (a) all owners of BioReference who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), (b) officers and employees of BioReference and any officers or employees of OPKO who are identified as Certifying Employees, (c) members of the OPKO board of directors (Board), and (d) all contractors who furnish patient care items or services or who perform billing or coding functions on behalf of BioReference.

5. “Disclosure Program” means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any potential violations of criminal, civil, or administrative law related to the Federal health care programs or any issues or questions associated with BioReference’s policies, conduct, practices, or procedures.

6. “Exclusion Lists” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.

7. “Focus Arrangements” means every Arrangement that:

a is between BioReference and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

b is between BioReference and any physician (or a physician’s immediate family member) (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to BioReference for designated health services (as defined at 42 U.S.C. §1395nn(h))(6)).

Any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests), 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits), 42 C.F.R. § 411.357(o) (compliance training), 42 C.F.R. § 411.357(q) (referral services), 42 C.F.R. § 411.357(s) (professional courtesy), or 42 C.F.R. § 357(u) (community-wide health information systems), shall not be considered a Focus Arrangement for purposes of this CIA, provided that BioReference maintains sufficient documentation to demonstrate compliance with the applicable exceptions to 42 U.S.C. § 1395nn (Stark Law). Such documentation shall be made available to OIG upon request.

8. “Ineligible Person” means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

9. “Overpayment” means any funds that BioReference receives or retains under any Federal health care program to which BioReference, after applicable reconciliation, is not entitled under such Federal health care program.

10. “Reportable Event” means: (a) a substantial Overpayment; (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal penalties or civil

monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with or having as a member of the active medical staff a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by BioReference.

11. "Reporting Period" means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

12. "Training Plan" means a written plan that outlines the steps BioReference will take to ensure that: (a) Covered Persons receive training on a periodic basis during the term of the CIA regarding the CIA requirements and BioReference's compliance program and the applicable Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and the Stark Law; and (b) Arrangements Covered Persons receive at least annual training regarding (i) Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes; (ii) BioReference's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of BioReference's Arrangements to know the applicable legal requirements and BioReference's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (v) examples of violations of the Anti-Kickback Statute and the Stark Law.

13. "Transition Plan" means a plan to address whether and how the BioReference compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA's term.

III. COMPLIANCE PROGRAM REQUIREMENTS

BioReference shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board Oversight, and Certifying Employees.

1. *Compliance Officer*. Within 90 days after the Effective Date, BioReference shall appoint a Compliance Officer who is an employee and a member of senior management of BioReference. The Compliance Officer shall report directly to the Chief Executive Officer or Executive Chairman of BioReference and shall not be or be subordinate to the BioReference or OPKO General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for BioReference or OPKO. The Compliance Officer shall be authorized to report to the Board regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:

a developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;

b making at least quarterly reports regarding compliance matters to the Board.

c monitoring the day-to-day compliance activities engaged in by BioReference; and

d all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

BioReference shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, BioReference shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.F below, and the development and implementation of the Transition Plan required by Section III.K below. The Compliance Committee shall meet at least quarterly.

BioReference shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Board Oversight.* The Audit Committee of the Board (Board Committee) shall be responsible for the review and oversight of BioReference's compliance with Federal health care program requirements and the requirements of this CIA. The Board Committee must include independent (i.e., non-employee and non-executive) members.

The Board Committee shall, at a minimum, be responsible for the following:

a meeting at least quarterly to review and oversee BioReference's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b submitting to the OIG a description of the materials the Board Committee received and reviewed and any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c for each Reporting Period of the CIA, adopting a resolution approved by each member of the Board Committee regarding its review and oversight of BioReference's compliance with Federal health care program requirements and the requirements of this CIA.

At minimum, the resolution shall include the following language:

"The Board Committee has made a reasonable inquiry into the operations of BioReference's compliance program including the performance of the Compliance

Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, BioReference has implemented an effective compliance program to meet Federal health care program requirements and the requirements of the Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

If the Board Committee is unable to adopt such a resolution, the Board Committee shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps the Board is taking to implement an effective compliance program at BioReference.

BioReference shall report to OIG, in writing, any changes in the membership of the Board Committee, within 15 business days after such a change.

4. *Management Certifications.* The Certifying Employees shall monitor and oversee compliance within the divisions or departments for which they are responsible and annually certify that the applicable BioReference division or department is in compliance with applicable Federal health care program requirements and the requirements of this CIA. For each Reporting Period, each Certifying Employee shall certify as follows:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of division or department], an area under my supervision. My job responsibilities include ensuring [insert name of division or department]'s compliance with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and BioReference's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide this certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, BioReference shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards. Within 90 days after the Effective Date, BioReference shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of BioReference's compliance program, including the compliance program requirements outlined in this CIA; (2) BioReference's compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law, and the regulations and other guidance documents related to these statutes, and business or financial arrangements that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; (3) the requirements set forth in Section III.D below; and (4) the identification, quantification, and repayment of Overpayments. BioReference shall enforce its Policies and Procedures and make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures, as necessary. Any revised or new Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Covered Persons and Arrangements Covered Persons Training.* Within 90 days after the Effective Date, BioReference shall develop a Training Plan that includes the following information: (a) training topics; (b) identification of Covered Persons and Arrangements Covered Persons required to attend each training session; (c) length of the training sessions(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Board Training*. Within 90 days after the Effective Date, members of the Board shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of the OIG's guidance on board member responsibilities. Each member of the Board also shall receive the training described in Section III.C.1.

New members of the Board shall receive the training described in this Section III.C.2 within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

3. *Training Records.* BioReference shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Compliance with the Anti-Kickback Statute and Stark Law.

1. *Focus Arrangements Procedures*. Within 90 days after the Effective Date, BioReference shall create procedures designed to ensure that each existing, new, or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

a creating and maintaining a centralized tracking system for all existing, new, or renewed Focus Arrangements and the information specified in Sections III.D.1.b-f below for each existing, new, or renewed Focus Arrangement (Focus Arrangements Tracking System);

b documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

c tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;

d documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);

e tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

f monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

g establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all existing, new, or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law; (ii) a process for specifying and documenting the business need or business rationale for all Focus Arrangements; and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;

h ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.D.1.g above;

i requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and

j implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate.

2. *New or Renewed Focus Arrangements*. No later than 90 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, BioReference shall comply with the following requirements (Focus Arrangements Requirements):

a ensure that all written Focus Arrangements are signed by BioReference and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;

b ensure that all Focus Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement, and that BioReference maintains appropriate documentation of the review and approval of such Focus Arrangement; and

c include in any written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. *Records Retention and Access.* BioReference shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures.

1. *General Description.*

a *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, BioReference shall engage a lawyer, law firm, or consulting firm (the "Independent Review Organization" or "IRO") that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.E.

b *Retention of Records.* The IRO and BioReference shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and BioReference related to the reviews described in this Section III.E.

c *Responsibilities and Liabilities*. Nothing in this Section III.E affects BioReference's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

d *Access to Records and Personnel.* BioReference shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *Arrangements Review*. The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Certification Regarding Prohibited Relationships*. The IRO shall include in its report(s) to BioReference a certification that the IRO (a) does not currently represent or is not currently employed or engaged by BioReference or OPKO and (b) does not have a current or

prior relationship to BioReference or its owners or officers, or to OPKO or its owners, officers, or Board members that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by this Section III.E. The IRO's certification shall include a summary of any current and prior relationships between BioReference or its owners or officers or OPKO or its owners, officers, or Board members and the IRO.

F. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, BioReference shall develop and implement a centralized annual risk assessment and internal review process to identify and address the Anti-Kickback Statute and Stark Law risks associated with Arrangements and BioReference's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require BioReference to: (1) identify and prioritize risks; (2) develop work plans or audit plans (as appropriate) related to the identified risk areas; (3) implement the work plans and audit plans; (4) develop corrective action plans in response to the results of any internal audits performed; and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

G. Disclosure Program. Within 90 days after the Effective Date, BioReference shall establish a Disclosure Program. BioReference shall appropriately publicize the existence of its Disclosure Program (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to the use of the Disclosure Program and BioReference shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not); (2) the date the disclosure was received; (3) the individual or department responsible for reviewing the disclosure; (4) the status of the review; (5) any corrective action taken in response to the review; and (6) the date the disclosure was resolved.

H. Ineligible Persons.

1. *Screening Requirements*. BioReference shall:

   a screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process or medical staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons;

   b screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter; and

c require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement.* If BioReference has actual notice that a Covered Person has become an Ineligible Person, BioReference shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that BioReference may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether BioReference meets the requirements of Section III.H.

IV. NOTIFICATION OF GOVERNMENT INVESTIGATION OR LEGAL PROCEEDING.

BioReference shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that BioReference has committed a crime or has engaged in fraudulent activities, within 30 days of BioReference receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, BioReference shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

A. Reportable Events. BioReference shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Substantial Overpayment*. The report to OIG shall include:

a a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b the Federal health care programs affected by the Reportable Event;

c a description of the steps taken by BioReference to identify and quantify the Overpayment; and

d a description of BioReference's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, BioReference shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance, and provide OIG with documentation of the repayment.

2. *Probable Violation of Law.* The report to OIG shall include:

a a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;

c the Federal health care programs affected by the Reportable Event;

d a description of the steps taken by BioReference to identify and quantify any Overpayments; and

e a description of BioReference's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, BioReference shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

3. *Ineligible Persons*. The report to OIG shall include:

a the identity of the Ineligible Person and the job duties performed by that individual;

b the dates of the Ineligible Person's employment or contractual relationship;

c a description of the Exclusion Lists screening that BioReference completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d a description of how the Ineligible Person was identified; and

e a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

4. *Bankruptcy*. The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

5. *Reportable Events Involving the Stark Law*. Any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by BioReference to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if BioReference identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then BioReference is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.

B. Transition Plan. Prior to the end of the fourth Reporting Period, BioReference shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's term. A copy of BioReference's approved Transition Plan shall be included in the fourth Annual Report.

V. SUCCESSOR LIABILITY

If, after the Effective Date, BioReference proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. If, after the Effective Date, OPKO proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of laboratory services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of laboratory services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. The Companies shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit, or location.

If the Companies wish to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, the Companies must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

VI. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, the Companies shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);

7. a description of (a) the Focus Arrangements Tracking System required by Section III.D.1.a; (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO that it does not have a prohibited relationship with the Companies or their owners, officers, or Board members (as set forth in Section III.E.3) that includes a summary of any current and prior relationships between the Companies or their owners, officers, or Board members, and the IRO;

9. a description of the risk assessment and internal review process required by Section III.F;

10. a description of the Disclosure Program required by Section III.G;

11. a description of the Ineligible Persons screening and removal process required by Section III.H;

12. a description of the Companies' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

13. a list of all of BioReference's locations (including mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and

14. a certification by the Compliance Officer and Chief Executive Officer that:

    a to the best of his or her knowledge, except as otherwise described in the report, BioReference is in compliance with all of the requirements of this CIA;

    b to the best of his or her knowledge, BioReference has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;

c to the best of his or her knowledge, BioReference has fulfilled the requirements for new or renewed Focus Arrangements under Section III.D.2 of the CIA;

d he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

e he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. The Companies shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the members of the Compliance Committee, a current list of the Board Committee members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committees, Board Committee, or Certifying Employees;

2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

4. the Board Committee resolution required by Section III.A.3 and a description of the materials reviewed by the Board Committee and any additional steps taken in its oversight of the compliance program and in support of making the resolution;

5. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

6. the certifications of Certifying Employees required by Section III.4;

7. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;

8. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons, Arrangements Covered Persons, and Board members during the Reporting Period;

9. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a complete copy of all reports prepared pursuant to Section III.E and BioReference's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

11. a certification from the IRO that it does not have a prohibited relationship with the Companies, as described in Section III.E.3 above, including a summary of any current and prior relationships between the Companies or their owners, officers, or Board members and the IRO;

12. a description of any changes to the risk assessment and internal review process required by Section III.F, including the reason(s) for such changes;

13. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified; (b) work plans and internal audit plans developed; (c) internal audits performed; (d) corrective action plans developed in response to internal audits; and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective actions plans shall be made available to OIG upon request;

14. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs or involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute, including at least the following information: (a) a description of the disclosure; (b) the date the disclosure was received; (c) the resolution of the disclosure; and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;

15. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reason(s) for such changes;

16. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a summary of all Reportable Events required to have been reported pursuant to Section III.J during the Reporting Period;

18. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.K;

19. a description of all changes to the most recently provided list of BioReference's locations (including addresses) as required by Section V.A.13;

20. a description of any changes to the Companies' corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. a certification by the Compliance Officer and Chief Executive Officer that:

    a to the best of his or her knowledge, except as otherwise described in the report, BioReference is in compliance with all of the requirements of this CIA;

    b to the best of his or her knowledge, BioReference has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark

Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;

c to the best of his or her knowledge, BioReference has fulfilled the requirements for new or renewed Focus Arrangements under Section III.D.2 of the CIA;

d he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

e he or she understands that the certification is being provided to and relied upon by the United States.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Designation of Information. The Companies shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. The Companies shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

All notifications and reports required under this CIA shall be submitted using the following contact information:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Email Address: officeofcounsel@oig.hhs.gov
BioReference Health, LLC:
Robert J. Rossi
SVP Chief Compliance and Privacy Officer
481 Edward H. Ross Drive
Elmwood Park, NJ 07407
Telephone: 800.229.5227, Ext. 8433
Email Address: rrossi@bioreference.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify BioReference in writing of any changes to the OIG contact information listed above. BioReference shall notify OIG in writing within two business days of any changes to the BioReference contact information listed above.

VIII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy the Companies' books, records, and other documents and supporting materials, and conduct on-site reviews of any of the Companies' locations for the purpose of evaluating: (a) the Companies' compliance with the requirements of this CIA and (b) the Companies' compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by the Companies to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of the Companies' owners, employees, contractors, and Board members who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. The Companies shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. The Companies' owners, employees, contractors, and Board members may elect to be interviewed with or without a representative of the Companies present.

IX. DOCUMENT AND RECORD RETENTION

BioReference shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

X. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify BioReference prior to any release by OIG of information submitted by BioReference pursuant to its requirements under this CIA and identified upon submission by BioReference as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, BioReference shall have the rights set forth at 45 C.F.R. § 5.42(a).

XI. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day BioReference or OPKO fails to comply with Section III.A;
2. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.B;
3. A Stipulated Penalty of up to $2,500 for each day BioReference or OPKO fails to comply with Section III.C;
4. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.D;
5. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day BioReference fails to\ comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section III.K;

12. A Stipulated Penalty of up to $2,500 for each day BioReference or OPKO fails to comply with Section IV;

13. A Stipulated Penalty of up to $2,500 for each day BioReference or OPKO fails to comply with Section V;

14. A Stipulated Penalty of up to $2,500 for each day BioReference or OPKO fails to comply with Section VII;

15. A Stipulated Penalty of up to $2,500 for each day BioReference fails to comply with Section VIII; or

16. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of BioReference or OPKO under this CIA.

B. Timely Written Requests for Extensions. BioReference may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. If OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after BioReference fails to meet the revised deadline set by OIG. If OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after BioReference receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify BioReference of: (a) its failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, BioReference shall either: (a) pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

D. Exclusion for Material Breach.

1. *Definition of Material Breach.* A material breach of this CIA means:

a failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

b failure to comply with Section III.A.1;

c failure to comply with Section III.D;

d failure to comply with Section III.E;

e failure to comply with Section III.J;

f failure to comply with Section V;

g failure to respond to a Demand Letter in accordance with Section X.C.;

h a false statement or false certification made to OIG by or on behalf of BioReference under this CIA;

i failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering BioReference to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

j failure to come into compliance with a requirement for which the OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by BioReference constitutes an independent basis for OPKO and/or BioReference's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that BioReference has materially breached this CIA, OIG shall notify OPKO and BioReference of: (a) BioReference's material breach; and (b) OIG's intent to exclude OPKO and/or BioReference. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. The Companies shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify OPKO and/or BioReference in writing of its determination to exclude OPKO and/or BioReference. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by OPKO and/or BioReference, including administrative and management services, except as stated in regulations found at 42 C.F.R. 1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, OPKO and/or BioReference may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights*. Upon OIG's issuing a Demand Letter or Exclusion Letter to OPKO and/or BioReference, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, OPKO and/or BioReference shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005.1: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter, and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether BioReference was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. BioReference shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that BioReference has breached this CIA and orders BioReference to pay Stipulated Penalties, BioReference must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless BioReference properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, BioReference must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether BioReference was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20

days after the DAB decision. OPKO and/or BioReference shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of OPKO and/or BioReference, OPKO and/or BioReference shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and the Companies agree not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XII. EFFECTIVE AND BINDING AGREEMENT

The Companies and OIG agree as follows:

A. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) BioReference's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

C. The undersigned OPKO and BioReference signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

D. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF OPKO HEALTH, INC. AND
BIOREFERENCE HEALTH, LLC

JANE PINE WOOD DATE
Chief Legal Officer for BioReference Health, LLC

STEVEN RUBIN DATE
Executive Vice President, Administration
OPKO Health, Inc.

HOPE S. FOSTER DATE
KAREN S. LOVITCH
Counsel for BioReference Health, LLC and
OPKO Health, Inc.

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

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TAMAR TERZIAN DATE
Senior Counsel
Office of Inspector General
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