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.

I. 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.

J. 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.

K. 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.

IV. 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.

V. 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.

VI. 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.

VII. 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.

VIII. 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.

IX. 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).

X. 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.

XI. 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/ 6/29/2022
JANE PINE WOOD DATE
Chief Legal Officer for BioReference Health, LLC

/Steven Rubin/ 6/29/2022
STEVEN RUBIN DATE
Executive Vice President, Administration
OPKO Health, Inc.

/Karen S. Lovitch/ June 29, 2022
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

/Lisa M. Re/ 7/1/2022
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/Tamar Terzian/ July 14, 2022
TAMAR TERZIAN DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. BioReference shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to BioReference as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by BioReference in response to a request by OIG, whichever is later, OIG will notify BioReference if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, BioReference may continue to engage the IRO.

2. If BioReference engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, BioReference shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by BioReference at the request of OIG, whichever is later, OIG will notify BioReference if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, BioReference may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes;

2. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. The Companies' Responsibilities

The Companies shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Relationship to the Companies

The IRO shall not (1) currently represent or currently be employed or engaged by the Companies or (2) have a current or prior relationship to the Companies or their owners, officers, or Board members that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Appendix B to this CIA.

F. Assertions of Privilege

The Companies shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement. BioReference's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

G. IRO Removal/Termination

1. *BioReference and IRO*. If BioReference terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, BioReference must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. BioReference must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, has a prohibited relationship as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify BioReference in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. BioReference shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, relationship or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by BioReference regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify BioReference in writing that BioReference shall be required to engage a new IRO in accordance

with Paragraph A of this Appendix. BioReference must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require BioReference to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of a Systems Review and a Transactions Review. If there are no material changes to BioReference's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If BioReference materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of BioReference's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. BioReference's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing, new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;

2. BioReference's systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

3. BioReference's systems, policies, processes, and procedures for 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;

4. BioReference's systems, policies, processes and procedures for 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 Arrangements Covered Person(s) who received or were otherwise involved with the fair market value determination(s);

5. BioReference's systems, policies, processes, and procedures for 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);

6. BioReference's systems, policies, processes, and procedures for 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);

7. BioReference's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

8. BioReference's systems, policies, processes, and procedures for the internal review and approval of existing, new, and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by BioReference, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

9. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, BioReference's internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. BioReference's systems, policies, processes, and procedures for 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; and

11. BioReference's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of BioReference's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;

3. findings and supporting rationale regarding weaknesses in BioReference's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and

4. recommendations to improve BioReference's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-11 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 100 randomly selected Focus Arrangements that were entered into or renewed by BioReference during the Reporting Period. The IRO shall assess whether BioReference has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

a. verifying that the Focus Arrangement is maintained in BioReference's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e, items or services actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);

b. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with BioReference's policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with BioReference's policies and procedures;

e. verifying that the service and activity logs are properly completed and reviewed (if applicable);

f. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

2. For any Focus Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Focus Arrangements subject to the Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Arrangements Transactions Review Report, the OIG may require the IRO to select an additional sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the IRO, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and submit to BioReference and OIG an Additional Transactions Review Report that includes the information specified in Section D below, within 60 days of the date the OIG notifies BioReference and its IRO that an Additional Transactions Review will be required.

D. Arrangements Transactions Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.

   a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.

   b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions Review.

   c. Supplemental Materials. The IRO shall request all documentation required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and BioReference shall furnish such documentation to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation from BioReference after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall include the following in the Arrangements Transactions Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.

2. *Review Findings*. The IRO's findings with respect to whether BioReference has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO, including findings for each item listed in Sections C.1.a-g above. In addition, as applicable, the Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials*. The names and credentials of the individuals who conducted the Arrangements Systems Review and the Arrangements Transactions Review.