CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PRECISION TOXICOLOGY, LLC D/B/A PRECISION DIAGNOSTICS

I. PREAMBLE

Precision Toxicology, LLC d/b/a Precision Diagnostics (Precision)[1] hereby enters 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). Contemporaneously with this CIA, Precision is entering into a Settlement Agreement with the United States.

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) Precision's 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 Precision complies 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 Precision and (i) any actual or potential source of health care business or referrals to Precision or (ii) any

1 This CIA also applies to any subsidiaries of Precision that furnish items or services that are paid for by the Federal health care programs.

actual or potential recipient of health care business or referrals from Precision;

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" means any individual or entity (a) to whom Precision refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom Precision 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; and

b. every financial relationship (as defined in 42 C.F.R. § 411.354(a)) that is between Precision 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 Precision for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Arrangements Covered Persons" includes each Covered Person who is involved with the development, approval, management, or review of Precision's Arrangements.

3. "Certifying Covered Persons" means the following:

- Chief Executive Officer
- President
- Chief Technology Officer
- Counsel
- Production Manager
- Director of Clinical Operations
- Medical Director
- Chief Financial Officer
- Vice President of Sales
- Chief Compliance Officer
- Laboratory Director
- Production Manager

- Chief Scientific Officer
- Director of Non-Clinical Operations
- All members of senior management and the leaders of all business units, divisions or departments with operations that relate to the Federal health care programs.

4. "Covered Persons" means: (a) all owners who are natural persons, officers, board members, and employees of Precision; (b) all contractors who furnish patient care items or services or who perform billing or coding functions on behalf of Precision; and (c) all physicians and other non-physician practitioners who are members of Precision's active medical staff.

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 Federal health care programs or any issues or questions associated with Precision'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 Precision 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 Precision 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 Precision 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 Precision 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 US.C. §1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in the Federal health care programs.

9. "Ordering Provider" means any provider who orders Testing (as defined below) that is billed by or on behalf of Precision to any Federal health care program.

10. "Overpayment" means any funds that Precision receives or retains under any Federal health care program to which Precision, after applicable reconciliation, is not entitled under such Federal health care program.

11. "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 or contracting with a Covered Person, or having as a member of the active medical staff, someone who is an Ineligible Person; or (d) the filing of a bankruptcy petition by Precision.

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

13. "Testing" means any diagnostic testing, including, but not limited to, urine drug testing, which is billed by or on behalf of Precision to any Federal health care program.

14. "Training Plan" means a written plan that outlines the steps Precision will take to ensure that: (a) Covered Persons receive training on a periodic basis during the term of the CIA regarding Precision's CIA requirements and 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) Precision'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 Precision's Arrangements to know the applicable legal requirements and the

Precision'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.

15. "Transition Plan" means a plan to address whether and how Precision's 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

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

A. Compliance Officer, Medical Director, Compliance Committee, Board Oversight, and Management Certifications.

1. *Compliance Officer and Medical Director*:

a. *Compliance Officer*. Within 90 days after the Effective Date, Precision shall appoint a Compliance Officer who is an employee and a member of senior management of Precision. The Compliance Officer shall report directly to the Chief Executive Officer of Precision and shall not be or be subordinate to the 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 Precision. The Compliance Officer shall be authorized to report to the Board of Directors of Precision (Board) regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:

i. 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;

ii. making at least quarterly reports regarding compliance matters in person to the Board;

iii. monitoring the day-to-day compliance activities engaged in by Precision; and

iv. 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.

Precision 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.

b. *Medical Director*. Within 90 days after the Effective Date, Precision shall appoint an employee to serve as its Medical Director and shall maintain a Medical Director for the term of the CIA. The Medical Director shall be a member of senior management of Precision, shall report directly to the Chief Executive Officer of Precision, shall not be subordinate to the General Counsel or Chief Financial Officer, and shall be either an M.D. or a D.O. with experience in the field of pain management and urine drug testing. The Medical Director shall be responsible for, without limitation:

i. reviewing and approving policies, procedures, and practices related to any medical or clinical decision-making; and

ii. making periodic (at least quarterly) reports regarding medical/clinical matters directly to the Chief Executive Officer, Compliance Committee, and Board of Precision and shall be authorized to report on such matters to the Chief Executive Officer, Compliance Committee, and Board at any time. Written documentation of the Medical Director's reports to the Chief Executive Officer, Compliance Committee, and Board shall be made available to OIG upon request.

Precision shall report to OIG, in writing, any changes in the identity or position description of the Medical Director, or any actions or changes that would affect the Medical Director's ability to perform the duties necessary to meet the obligations in this CIA, within five business days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Precision shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the Medical Director and all 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 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.

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

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

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

a. meeting at least quarterly to review and oversee Precision'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 it 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;

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

d. for the first and fourth Reporting Periods, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of Precision's compliance program for each Reporting Period of the CIA. The Compliance Expert must not be employed or engaged by Precision and must not have a current or prior relationship to Precision that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review. The Compliance Expert shall prepare a written report that includes a description of the review and any recommendations with respect to Precision's compliance program. The Board shall review the compliance program review report as part of its review and oversight of Precision's compliance program. A copy of the report and the Board's response to the report, along with corrective action plan(s) related to any report recommendations, shall be provided to OIG in each Annual Report submitted by Precision, along with a certification from the

Compliance Expert that it does not have a prohibited relationship with Precision as set forth above and a summary of any current or prior relationships with Precision. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

> "The Board has made a reasonable inquiry into the operations of Precision'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, Precision has implemented an effective compliance program to meet Federal health care program requirements and the requirements of Precision's Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

If the Board is unable to adopt such a resolution, the Board 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 Precision.

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

4. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable 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 Covered Person 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 Precision'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 Covered Person is unable to provide this certification, the Certifying Covered Person 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, Precision shall develop and implement a written process for Certifying Covered Persons 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 Covered Person making the required certification).

B. Written Standards. Within 90 days after the Effective Date, Precision shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of Precision's compliance program, including the compliance program requirements outlined in this CIA; (2) Precision'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 or contracts 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. Precision 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, Precision 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 appropriate.

3. *Training Records.* Precision shall make available to OIG, upon request, training materials and records verifying 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, Precision 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, Precision shall comply with the following requirements (Focus Arrangements Requirements):

a. ensure that all written Focus Arrangements are signed by Precision 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 Precision 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*. Precision 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, Precision shall engage a lawyer, law firm, or consulting firm that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the arrangements review described in Section III.E.2. Within 90 days after the Effective Date, Precision shall engage an entity that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the claims review described in Section III.E.3. The entity (or entities) engaged to perform the claims review and the arrangements review are referred to hereinafter as the "Independent Review Organization" or "IRO."

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

c. *Responsibilities and Liabilities*. Nothing in this Section III.E affects Precision'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.* Precision 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. *Claims Review*. The IRO shall review fee-for service claims submitted by Precision and reimbursed by the Medicare program, or any Medicaid program, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted, and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

4. *Certifications*. The IRO for the Claims Review shall include in its report(s) to Precision a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between Precision and the IRO. The IRO for the Arrangements Review shall include in its report(s) to Precision a certification that the IRO (a) does not currently represent or is not currently employed or engaged by Precision and (b) does not have a current or prior relationship to Precision 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 Precision or its owners, officers, or Board members and the IRO.

F. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, Precision 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 Precision'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 Precision 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, Precision shall establish a Disclosure Program. Precision shall appropriately publicize the existence of the 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 use of the Disclosure Program and Precision 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 appropriate 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.* Precision 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 the medical staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons;

b. screen all 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 Precision has actual notice that a Covered Person has become an Ineligible Person, Precision 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 an excluded person are not payable by Federal health care programs and Precision may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Precision meets the requirements of Section III.H.

I. Notification of Government Investigation or Legal Proceeding. Precision shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Precision has committed a crime or has engaged in fraudulent activities, within 30 days of Precision 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, Precision shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

J. Reportable Events. Precision 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 Precision to identify and quantify any Overpayments; and

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

Within 60 days of identification of the substantial Overpayment, Precision 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 Violations 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 Precision to identify and quantify any Overpayments; and

   e. a description of Precision'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, Precision 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 or medical staff membership;

   c. a description of the Exclusion Lists screening that Precision completed before and/or during the Ineligible Person's employment or contract or medical staff membership and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with or credentialing 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 or credentialing 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 Precision to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if Precision identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Precision 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, Precision 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 Precision's approved Transition Plan shall be included in Precision's fourth Annual Report.

L. Testing Monitoring

Precision shall create and maintain a report of all orders for Testing by Ordering Providers (Testing Report). The Testing Report shall include at least the following information: (a) specific type of testing ordered, (b) patient's name, (c) Ordering Provider name (d) date the testing was ordered, and (e) reason the testing was ordered (including relevant diagnosis code). Order/requisition forms shall be modified to capture all information required for the Testing Report.

On a monthly basis, the Compliance Officer shall review the Testing Report with the Medical Director (Monthly Testing Review) to determine whether, by Ordering Provider: (a) the entries contain the required information and (b) the Ordering Provider does not exhibit patterns and practices that may be inconsistent with standards for the medical reasonableness and necessity of the testing ordered. The Compliance Officer shall prepare a written summary of the findings of each Monthly Testing Review that describes the methodology used to perform the Monthly Testing Review and the results of the Monthly Testing Review.

On a quarterly basis, the Compliance Officer, Medical Director, and Compliance Committee shall review the Testing Report to identify trends or outlier Ordering Providers for further review (Quarterly Testing Review), including but not limited to: (a) providers whose testing frequency, patterns, or practices appear to be beyond what is medically reasonable and

necessary and (b) providers who have not regularly and timely reviewed the results of testing ordered and acted, as appropriate, to modify patient care. The Compliance Officer shall also identify claims that have been billed to an inappropriate payer. The Compliance Officer shall prepare a written summary of the findings of each Quarterly Testing Review that describes the methodology used to perform the Quarterly Testing Review.

In each Annual Report, Precision shall include a summary of the Monthly Testing Reviews and the Quarterly Testing Reviews for the applicable Reporting Period, along with a response and corrective action plan to address any identified issues. Copies of each Monthly Testing Review and Quarterly Testing Review shall be available to OIG upon request.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, Precision 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. Precision 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 Precision wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, Precision 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, Precision 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 and the Medical Director 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 following information regarding the individual or entity retained by the Board to be the Compliance Expert: (a) identity, address, and phone number; (b) information to demonstrate the individual's or entity's expertise in compliance with Federal health care program requirements, and (c) a certification from the Compliance Expert that they do not have a current or prior relationship to Precision that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review.

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

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

7. 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);

8. 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;

9. 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; (d) (for the Claims Review) a certification from the IRO regarding its professional independence and objectivity with respect to Precision that includes a summary of all current and prior engagements between Precision and the IRO; and (e) (for the Arrangements Review) a certification from the IRO that it does not have a prohibited relationship with Precision or its owners, officers, or Board members (as set forth in Section III.E.4) that includes a summary of all current and prior relationships between Precision or its owners, officers, or Board members, and the IRO;

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

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

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

13. a description of the methodology that will be used to perform the Testing Monitoring required by Section III.L;

14. a description of Precision's corporate structure, including identification of any individual owners, parent and sister companies, subsidiaries, and their respective lines of business;

15. a list of all of Precision'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

16. a certification by the Compliance Officer, Medical Director, and Chief Executive Officer that:

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

b. to the best of his or her knowledge, Precision 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, Precision 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. Precision 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 or Medical Director; a current list of the Compliance

Committee members, a current list of the Board members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;

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

5. for the first and fourth Reporting Periods, a copy of the Compliance Expert's report, the Board's response to the report and corrective action plan(s) related to any report recommendations, and a certification from the Compliance Expert that they do not have a current or prior relationship to Precision that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review of Precision's compliance program.

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

7. the certifications of Certifying Covered Persons required by Section III.4;

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

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

10. 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;

11. a complete copy of all reports prepared pursuant to Section III.E and Precision's response to the reports, along with corrective action plan(s) related to any issues raised by the reports and documentation of Precision's refund of the Estimated Overpayment (as defined in Appendices B and C to this CIA);

12. (for the Claims Review) a certification from the IRO regarding its professional independence and objectivity with respect to Precision that includes a summary of all current and prior engagements between Precision and the IRO and (for the Arrangements Review) a certification from the IRO that it does not have a prohibited relationship with Precision or its owners, officers, or Board members (as set forth in Section III.E.4) that includes a summary of all current and prior relationships between Precision or its owners, officers, or Board members, and the IRO;

13. 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;

14. 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 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;

15. 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 or Stark law, 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;

16. 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;

17. 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;

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

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

20. a summary of the Monthly Testing Reviews and the Quarterly Testing Reviews for the applicable Reporting Period, along with a response and corrective action plan to

address any identified issues. The written summaries of each Monthly Testing Review and Quarterly Testing Review shall be made available to OIG upon request;

21. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Precision's response and corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

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

23. a description of any changes to Precision's corporate structure, including individual owners, any parent and sister companies, subsidiaries, and their respective lines of business; and

24. a certification by the Compliance Officer, Medical Director, and Chief Executive Officer that:

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

b. to the best of his or her knowledge, Precision 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, Precision 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. Precision 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. Precision 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

Precision:

Heather Kaufman
Precision Diagnostics
Chief Compliance Officer
4215 Sorrento Valley Blvd Ste. 100
San Diego, CA 92121
Telephone: 800.635.6901
Email Address: heather.kaufman@precisiondxlab.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify Precision in writing of any changes to the OIG contact information listed above. Precision shall notify OIG in writing within two business days of any changes to the Precision 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 Precision's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Precision's locations for the purpose of evaluating: (a) Precision's compliance with the requirements of this CIA and (b) Precision's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Precision 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 Precision's 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. Precision shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Precision's owners, employees, contractors, and Board members may elect to be interviewed with or without a representative of Precision present.

VIII. DOCUMENT AND RECORD RETENTION

Precision 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 Precision prior to any release by OIG of information submitted by Precision pursuant to its requirements under this CIA and identified upon submission by Precision as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Precision 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 Precision fails to comply with Section III.A;

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

3. A Stipulated Penalty of up to $2,500 for each day Precision fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day Precision fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day Precision fails to comply with Section III.E;

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

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

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

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

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

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

12. A Stipulated Penalty of up to $2,500 for each day Precision fails to comply with Section III.L;

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

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

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

15. A Stipulated Penalty of up to $2,500 for each day Precision 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 Precision under this CIA.

B. Timely Written Requests for Extensions. Precision 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 Precision 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 Precision 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 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 Precision of: (a) Precision's 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, Precision 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 upon 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 III.L;

g. failure to comply with Section V;

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

i. a false statement or false certification made to OIG by or on behalf of Precision under this CIA;

j. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Precision 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

k. 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 Precision constitutes an independent basis for Precision'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 Precision has materially breached this CIA, OIG shall notify Precision of: (a) Precision's material breach; and (b) OIG's intent to exclude Precision. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. Precision 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 Precision in writing of its determination to exclude Precision. (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 Precision, 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, Precision 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 Precision, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Precision 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 Precision was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Precision shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Precision has breached this CIA and orders Precision to pay Stipulated Penalties, Precision 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 Precision 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, Precision 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 Precision 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. Precision 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 Precision, Precision 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 Precision agrees 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

Precision 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) Precision'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 Precision 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 PRECISION TOXICOLOGY, LLC
D/B/A PRECISION DIAGNOSTICS

/Miguel Gallego/ 7/31/2024

MIGUEL GALLEGO
Chief Executive Officer
Precision Toxicology, LLC d/b/a Precision Diagnostics

DATE

/Robert Salcido/ 7/31/2024

ROBERT SALCIDO
Akin Gump
Counsel for Precision Toxicology, LLC
d/b/a Precision Diagnostics

DATE

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

/Susan Gillin/ 2024.08.07

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Andrea L. Treese Berlin/ 8/22/2024

ANDREA L. TREESE BERLIN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

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. Precision shall engage an IRO to perform the Claims Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the Claims Review in a professionally independent and objective fashion, as set forth in Paragraph E.

2. Precision shall engage an IRO to perform the Arrangements Review 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 Precision as set forth in Paragraph F.

3. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Precision in response to a request by OIG, whichever is later, OIG will notify Precision if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Precision may continue to engage the IRO.

4. If Precision 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, Precision 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 Precision at the request of OIG, whichever is later, OIG will notify Precision if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Precision 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;

3. assign individuals to conduct the Claims Review who have expertise in the Federal health care program requirements applicable to the claims being reviewed;

4. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

5. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

6. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

7. 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 and Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review;

3. request clarification from the applicable Federal health care program if in doubt of the application of a particular program policy or regulation;

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

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

D. Precision Responsibilities

Precision 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 Independence and Objectivity

The IRO engaged to perform the Claims Review must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Relationship to Precision

The IRO engaged to perform the Arrangements Review shall not (1) currently represent or currently be employed or engaged by Precision or (2) have a current or prior relationship to Precision or its owners, officers, or Board members that would cause a reasonable person to question the IRO's objectivity in performing the Arrangements Review.

G. Assertions of Privilege

Precision 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 to perform the Arrangements Review. Precision'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.

H. IRO Removal/Termination

1. Precision *and IRO*. If Precision terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Precision 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. Precision 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, is not independent and objective as set forth in Paragraph E or has a prohibited relationship as set forth in paragraph F (as applicable), or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Precision in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Precision shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence, relationship to Precision or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Precision regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Precision in writing that Precision shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Precision 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 Precision 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 Precision's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Precision 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 Precision's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Precision'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. Precision'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. Precision'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. Precision'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) involved with the fair market value determination(s);

5. Precision'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. Precision'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. Precision'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. Precision'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 Precision, 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, Precision's internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. Precision'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. Precision'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 Precision'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 Precision's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and

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

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus Arrangements that were entered into or renewed by Precision during the Reporting Period. The IRO shall assess whether Precision 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 Precision'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 Precision'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 Precision'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 Precision 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 Precision 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 Transactions 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 and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and Precision shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental

documentation from Precision 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 Precision 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.

APPENDIX C

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review for each of the five Reporting Periods.

1. *Definitions*.

a. "Paid Claim" means a fee-for-service claim submitted by Precision and for which Precision has received reimbursement from the Medicare program, any Medicare managed care program, any Medicaid program, or any Medicaid managed care program.

b. "Population" means all Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify Precision and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. Precision, or its IRO on behalf of Precision, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed at least 120 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by Precision or its IRO, (2) information furnished to OIG regarding the results of Precision's internal risk assessment and internal auditing, or (3) other information obtained by OIG. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

c. "Overpayment" means the amount of money Precision has received in excess of the amount due and payable under Medicare, Medicare managed care, Medicaid, or Medicaid managed care program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix.

d. "Error Rate" means the percentage of net Overpayments identified in the Claims Review Sample. The net Overpayment shall be calculated by subtracting all underpayments identified in the Claims Review Sample from all Overpayments identified in the Claims Review Sample. The Error Rate is calculated by dividing the net Overpayment by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

2. *Claims Review Sample.* The IRO shall select a random sample of 100 Paid

Claims (Claims Review Sample). The IRO shall review the Paid Claims based on Precision's documentation and the applicable Medicare, Medicare managed care, Medicaid, or Medicaid managed care program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. The documentation reviewed shall include, but not be limited to, new client registrations, requisition or order forms, and any applicable test results to identify patterns and practices that may be inconsistent with standards for the medical reasonableness and necessity of the testing ordered.

3. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation required for its review of the Paid Claims in the Claims Review Sample and Precision shall furnish such documentation to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation from Precision after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall include the following in the Claims 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.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which Precision cannot produce documentation shall be considered an error and the total reimbursement received by Precision for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims without documentation is not permitted.

c. Use of First Sample Drawn. The first set of Paid Claims selected shall be used for the Claims Review Sample (i.e., it is not permissible to generate more than one list of random samples and then select one for use).

4. *Repayment of Estimated Overpayment.* The findings of the Claims Review Sample shall be used by the IRO to estimate the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval. Within 60 days of receipt of the Claims Review Report, Precision shall repay the lower limit of the two-sided 90% confidence interval (Estimated Overpayment) to the applicable payor(s). Documentation of Precision's refund of the Estimated Overpayment to the applicable payor(s) shall be submitted to OIG with Precision's Annual Report. OIG, in its sole discretion, may refer the findings of the Claims Review Sample to the applicable payor(s) for appropriate follow up.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Claims Review that includes the following information:

1. *Claims Review Methodology.*

   a. Claims Review Objective. A statement of the objective intended to be achieved by the Claims Review.

   b. Claims Review Population. A description of the Population subject to the Claims Review.

   c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation and other information sources relied on by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

   d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

   e. Supplemental Materials. The information regarding any Supplemental Materials required by A.3.a., above.

2. *Statistical Sampling Documentation.*

   a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

   b. A description or identification of the statistical sampling software package used by the IRO.

3. *Claims Review Findings.*

   a. Narrative Results.

      i. A description of Precision's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A description of controls in place at Precision to ensure that all items and services furnished by Precision are correctly coded, appropriately documented, and medically necessary.

iii. A narrative explanation of the results of the IRO's review of the Claims Review Sample, including an explanation of all errors identified by the IRO.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by Precision differed from what should have been the correct coding.

ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented.

iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary.

iv. Total dollar amount of Paid Claims included in the Claims Review Sample and the net Overpayment associated with the Claims Review Sample.

v. Error Rate in the Claims Review Sample.

vii. An estimate of the actual Overpayment in the Population with the point estimate and a two-sided 90% confidence interval.

viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim:

1. Federal health care program billed;
2. Beneficiary health insurance claim number;
3. Date of service;
4. Code submitted (e.g., DRG, CPT code, etc.);
5. Code reimbursed;
6. Allowed amount reimbursed by payor;
7. Correct code (as determined by the IRO);
8. Correct allowed amount (as determined by the IRO);
9. Whether the item or service was medically necessary;
10. Whether the item or service was appropriately documented; and

11. The dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Precision's billing and coding system or to Precision's controls for ensuring that all items and services billed to the Medicare program by Precision are correctly coded, appropriately documented, and medically necessary, based on the findings of the Claims Review.

4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.