INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LABTOX, LLC

I. PREAMBLE

LabTox, LLC (LabTox) hereby enters into this Integrity Agreement (IA) 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 IA, LabTox is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) LabTox's final annual report; or (2) any additional materials submitted by LabTox pursuant to OIG's request, whichever is later.

C. "Covered Persons" includes:

a. all owners and employees of LabTox; and

b. all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of LabTox.

III. INTEGRITY OBLIGATIONS

LabTox shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Chief Clinical Officer

1. *Compliance Officer.* Within 90 days after the Effective Date, LabTox shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the IA. The Compliance Officer shall be an employee and a member of senior management of LabTox, shall report directly to the Chief Executive Officer of LabTox, 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 LabTox. The Compliance Officer shall be responsible for, without limitation:

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

b. making periodic (at least quarterly) reports regarding compliance matters to the Chief Executive Officer of LabTox and shall be authorized to report on such matters to the Chief Executive Officer at any time. Written documentation of the Compliance Officer's reports to the Chief Executive Officer shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by LabTox as well as any reporting obligations created under this IA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this IA.

LabTox shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this IA, within five business days after such a change.

2. *Chief Clinical Officer*. Within 90 days after the Effective Date, LabTox shall appoint an employee to serve as its Chief Clinical Officer and shall maintain a Chief Clinical Officer for the term of the IA. The Chief Clinical Officer shall be a member of senior management of LabTox, shall report directly to the Chief Executive Officer of LabTox, and shall not be subordinate to the General Counsel or Chief Financial Officer. The Chief Clinical Officer shall be responsible for, without limitation:

a. reviewing and approving policies, procedures, and practices related to any clinical decision-making, including, but not limited to, reviewing standard order or requisition forms, reviewing and approving any clinical content included in any materials and information that may be distributed by LabTox regarding any of its items or services that may be paid for by any Federal health care program; and

b. making periodic (at least quarterly) reports regarding clinical matters directly to the Chief Executive Officer and Board of Directors of LabTox and shall be authorized to report on such matters to the Chief Executive Officer and Board of Directors at any time. Written documentation of the Chief Clinical Officer's reports to the Chief Executive Officer and Board of Directors shall be made available to OIG upon request.

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

B. Policies and Procedures

Within 90 days after the Effective Date, LabTox shall develop and implement written policies and procedures regarding appropriate billing, medical record documentation, the operation of its compliance program, including the compliance program requirements outlined in this IA, and LabTox's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (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;

b. the Federal health care program requirements regarding the accurate submission of claims for items or services. Specifically, LabTox shall develop and implement Policies and Procedures designed to:

i. prevent LabTox from submitting claims for items and services that are not medically reasonable and necessary given the patient's clinical condition, including a requirement that all orders for items or services must include diagnostic and other information sufficient to support the medical necessity of each item or service ordered; and

ii. prevent LabTox from submitting claims for items and services that are not covered services by the applicable Federal health care program to which the claim is being submitted. Such Policies and Procedures shall comply with all National Coverage Determinations, Local Coverage Determinations, manual provisions, and any other guidance, issued either publicly or directly to LabTox, by any Federal or State payor;

c. the use of order or requisition forms that include all appropriate information to inform ordering physicians of the importance of medical reasonableness and necessity of each available test. Specifically, LabTox's Policies and Procedures shall include the following requirements:

i. All requisition forms shall boldly state that Medicare and Medicaid will only pay for tests that are medically reasonable and necessary based on the clinical condition of each individual patient;

ii. Each requisition form shall list all potential tests, including the HCPSC and the current Medicare fee schedule amount of each test at the HCPCS unit level, clearly and distinctly, and the form must require the physician to request (by notation)

each ordered test individually and the corresponding number of units of testing; and

iii. Any tests that need to be repeated on the same beneficiary on the same date of service that exceed the relevant National Correct Coding Initiative Program Medical Unlikely Edit unit amount will require an additional physician signed requisition form requesting such repeat testing and stating the reason for needed repeat testing.

d. the materials and information distributed by LabTox, through its sales representatives (including any contract sales force) or otherwise, about available items or services and the manner in which LabTox and its sales representatives respond to requests for information about the medical reasonableness and necessity of available items or services. These Policies and Procedures shall require that sales representatives: (i) use only materials that have been reviewed and approved by LabTox; and (ii) refer all requests for information about the medical reasonableness and necessity of items or services to the Chief Clinical Officer;

e. the materials and information distributed by the Chief Clinical Officer and the mechanisms through, and manner in which, the Chief Clinical Officer receives and responds to requests for information about the uses of items or services; the form and content of information disseminated by LabTox in response to such requests; and the internal review process for the information disseminated; and

f. disciplinary policies and procedures, including corrective action plans as appropriate, for violations of LabTox's Policies and Procedures.

The Policies and Procedures shall be made available to all Covered Persons.

Throughout the term of this IA, LabTox shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), LabTox shall assess and update, as necessary, the Policies and Procedures. 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. Posting of Notice

Within 60 days after the Effective Date, LabTox shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the Compliance Officer and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training and Education

1. *Covered Persons Training*. All Covered Persons shall receive at least three hours of training during the first Reporting Period. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 90 days of becoming a Covered Person.

Training may be completed in-person or online. These training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), LabTox's Medicare contractor, or other training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

a. LabTox's IA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law.

b. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to the items or services furnished by LabTox;

c. the Federal health care program medical record documentation requirements relating to items or services furnished by LabTox; and

d. the personal obligation of each individual involved in the medical record documentation and claims submission processes to ensure that medical records and claims are accurate.

The OIG may, in its discretion, require that Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to LabTox of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records.* LabTox shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

E. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, LabTox shall engage an entity (or entities), such as an accounting, auditing or consulting firm, to perform the claims review described in Section III.E.2. The entity (or entities) engaged to perform the claims review is referred to hereinafter as the "Independent Review Organization" or "IRO." The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

b. *Retention of Records*. The IRO and LabTox shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and LabTox) related to the reviews.

c. *Access to Records and Personnel.* LabTox 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. *Claims Review.* The IRO shall conduct a review of LabTox's claims submitted to and reimbursed by the Medicare, Medicaid, and Medicaid Managed Care programs to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted, and reimbursed, for each three-month period during the term of this IA (Quarterly Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Independence and Objectivity Certification.* Prior to performing the first Quarterly Claims Review, and annually thereafter, the IRO shall submit to LabTox 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 IA. The IRO's certification shall include a summary of all current and prior engagements between LabTox and the IRO.

F. Ineligible Persons

1. *Definitions.* For purposes of this IA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in any Federal health care program; or

ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health

care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

2. *Screening Requirements*. LabTox shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. LabTox shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. LabTox shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.

c. LabTox shall require all Covered Persons to immediately disclose immediately if they become an Ineligible Person.

LabTox shall maintain documentation demonstrating that LabTox: (1) has checked the Exclusion List (e.g., print screens from search results) and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

Nothing in this Section III.F affects LabTox's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. LabTox understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that LabTox may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether LabTox meets the requirements of Section III.F.

3. *Removal Requirement*. If LabTox has actual notice that a Covered Person has become an Ineligible Person, LabTox shall remove such Covered Person from responsibility for, or involvement with, LabTox's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and 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).

4. *Pending Charges and Proposed Exclusions*. If LabTox has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, LabTox shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, LabTox shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to LabTox conducted or brought by a governmental entity or its agents involving an allegation that LabTox has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. LabTox shall also provide written notice to OIG within 30 days after the resolution of the matter and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

H. Overpayments

1. *Definition of Overpayments*. An "Overpayment" means any funds that LabTox receives or retains under any Federal health care program to which LabTox, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, LabTox shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments*. If, at any time, LabTox identifies any Overpayment, LabTox shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and guidance from the Centers for Medicare and Medicaid Services (CMS). LabTox should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

1. *Definition of Reportable Event*. For purposes of this IA, a "Reportable Event" means anything that involves:

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 penalties or exclusion may be authorized;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by LabTox.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If LabTox determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, LabTox shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a. and III.I.1.b.* For Reportable Events under Section III.I.1.a and b, 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. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

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

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

e. a description of LabTox'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, LabTox 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 a copy of the notification and repayment.

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, the report to OIG shall include:

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

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

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

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

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

5. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law*. Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by LabTox to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If LabTox identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then LabTox is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

J. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA LabTox contracts with a third party billing company to submit claims to the Federal health care programs on behalf of LabTox, LabTox must certify to OIG that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company.

LabTox also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded from participation in any Federal health care program to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its prospective and current employees against the Exclusion List; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in LabTox's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

In the event that, after the Effective Date, LabTox proposes to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. LabTox shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, LabTox wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, LabTox must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the location or business 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, IRO REPORTS, AND ANNUAL REPORTS

A. Implementation Report

Within 90 days after the Effective Date, LabTox shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

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

2. the name, business address, business phone number, and position description of the Chief Clinical Officer required by Section III.A.2;

3. a list of the Policies and Procedures required by Section III.B. and a copy of all current order and/or requisition forms in use by LabTox;

4. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

5. the following information regarding the IRO: (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 IA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to LabTox that includes a summary of all current and prior engagements between LabTox and the IRO;

6. a copy of the documentation (e.g. search result print screens) demonstrating that LabTox has screened all Covered Persons against the Exclusion List as required by Section III.F within 30 days of the Effective Date;

7. a copy of LabTox's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.H;

8. a copy of any certifications from LabTox and the third party billing company required by Section III.J (if applicable);

9. a list of all of LabTox's locations (including locations and 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

10. certifications by the Compliance Officer and Chief Clinical Officer that: (a) the Compliance Officer/Chief Clinical Officer has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, LabTox is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and (d) he or she understands that this certification is being provided to and relied upon by the United States.

B. IRO Claims Review Reports

Within 60 days following the end of each three-month period during the term of this IA, LabTox shall provide to OIG a copy of the Quarterly Claims Review Report prepared by the IRO for each Quarterly Claims Review performed, along with LabTox's

response and corrective action plan related to any recommendations made by the IRO in the Quarterly Claims Review Report. Each Quarterly Claims Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports

LabTox shall submit to OIG a written report on its compliance with the IA requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and/or Chief Clinical Officer described in Section III.A;

2. a list of any new or revised Policies and Procedures developed during the Reporting Period;

3. (in the first Annual Report) the following information regarding the training required by Section III.D: a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describes the content of the training program. A copy of all training materials shall be made available to OIG upon request;

4. a certification from the IRO regarding its professional independence and objectivity with respect to LabTox that includes a summary of all current and prior engagements between LabTox and the IRO;

5. a copy of the documentation demonstrating that LabTox screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.F;

6. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

7. a description of any changes to the Overpayment policies and procedures required by Section III.H, including the reasons for such changes;

8. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

9. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

10. a copy of any certifications from LabTox and the third party billing company required by Section III.J (if applicable);

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

12. a description of all changes to the most recently provided list of LabTox's locations (including addresses) as required by Section V.A.9; and

13. certifications signed by LabTox's Compliance Officer and Chief Clinical Officer that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, LabTox is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful, and (d) he or she understands that this 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.

D. Designation of Information

LabTox 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. LabTox 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

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this IA shall be submitted to the following entities:

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, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

LabTox:

Erica Baker
LabTox, LLC
2716 Old Rosebud Road; Suite 280
Lexington KY 40509
Telephone: (859) 303-4050
Facsimile: (859) 303-4051 fax
E-Mail: erica@labtoxlabs.com

Unless otherwise specified, all notifications and reports required by this IA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, LabTox may be required to provide OIG with an additional copy of each notification or report required by this IA, in OIG's requested format (electronic or paper).

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 LabTox's books, records, and other documents and supporting materials and conduct on-site reviews of any of LabTox's locations, for the purpose of verifying and evaluating: (a) LabTox's compliance with the terms of this IA and (b) LabTox's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by LabTox to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of LabTox's owners, employees, and contractors 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. LabTox shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. LabTox's owners, employees, and contractors may elect to be interviewed with or without a representative of LabTox present.

VIII. DOCUMENT AND RECORD RETENTION

LabTox shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four 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 LabTox prior to any release by OIG of information submitted by LabTox pursuant to its obligations under this IA and identified upon submission by LabTox as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, LabTox shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

LabTox is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, LabTox and OIG hereby agree that failure to comply with certain obligations set forth in this IA may lead to the imposition of the following

monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day LabTox fails to establish, implement or comply with any of the following obligations as described in Section III:

a. appoint a Compliance Officer and a Chief Clinical Officer as required by Section III.A;

b. written Policies and Procedures required by Section III.B;

c. post a notice in accordance with the requirements of Section III.C;

d. complete the training and education required for Covered Persons and maintain training records, in accordance with the requirements of Section III.D;

e. screen Covered Persons in accordance with the requirements of Section III.F or require Covered Persons to disclose if they are excluded in accordance with the requirements of Section III.F; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;

f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;

g. establish policies and procedures regarding the repayment of Overpayments;

h. repay any Overpayments as required by Section III.H and Appendix B;

i. report a Reportable Event in accordance with Section III.I; or

j. provide to OIG the certifications required by Section III.J relating to any third-party biller engaged by LabTox during the term of the IA.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day LabTox fails to engage and use an IRO, as required by Section III.E, or Appendices A and B.

3. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day LabTox fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day LabTox fails to submit any Quarterly Claims Review Report in accordance with the requirements of Section III.E and Appendix B, , or fails to repay any Overpayment identified by the IRO, as required by Appendix B.

5. A Stipulated Penalty of $1,000 for each day LabTox fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date LabTox fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of LabTox as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

7. A Stipulated Penalty of $1,000 for each day LabTox fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day LabTox fails to furnish to the IRO accurate and complete records, as required by Section III.E, Appendix A, and Appendix B.

8. A Stipulated Penalty of $1,000 for each day LabTox fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to LabTox stating the specific grounds for its determination that LabTox has failed to comply fully and adequately with the IA obligation(s) at issue and steps the LabTox shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 business days after the date LabTox receives this notice from OIG of the failure to comply.) A Stipulated

Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

LabTox 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 IA. Notwithstanding any other provision in this Section, 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 LabTox fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, 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 LabTox receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that LabTox has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify LabTox of: (a) LabTox's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 business days after the receipt of the Demand Letter, LabTox shall either: (a) cure the breach to OIG's satisfaction and 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. In the event LabTox elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until LabTox cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under Section X.D.

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.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that LabTox has materially breached this IA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this IA

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

a. a failure by LabTox to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;

b. repeated violations or a flagrant violation of any of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.E or Appendices A and B.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this IA by LabTox constitutes an independent basis for LabTox'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 three years per material breach. Upon a determination by OIG that LabTox has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify LabTox of: (a) LabTox's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure*. LabTox shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30 day period, but that: (i) LabTox has begun to take action to cure the material breach; (ii) LabTox is pursuing such action with due diligence; and (iii) LabTox has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, LabTox fails to satisfy the requirements of Section X.D.3, OIG may exclude LabTox from participation in the Federal health care programs. OIG shall notify LabTox in writing of its determination to exclude LabTox. (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 LabTox's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, LabTox 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 delivery to LabTox of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, LabTox 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 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this IA. 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 HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. 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 IA shall be: (a) whether LabTox was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. LabTox shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance,

if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders LabTox to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless LabTox requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 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 IA shall be whether LabTox was in material breach of this IA and, if so, whether:

a. LabTox cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following LabTox's receipt of the Notice of Material Breach: (i) LabTox had begun to take action to cure the material breach; (ii) LabTox pursued such action with due diligence; and (iii) LabTox provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for LabTox, only after a DAB decision in favor of OIG. LabTox's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude LabTox upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that LabTox may request review of the ALJ decision by the DAB. 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. LabTox 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 LabTox, LabTox 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. Consequently, the parties to this IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

XI. EFFECTIVE AND BINDING AGREEMENT

LabTox and OIG agree as follows:

A. This IA shall become final and binding on the date the final signature is obtained on the IA.

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

C. OIG may agree to a suspension of LabTox's obligations under this IA based on a certification by LabTox that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If LabTox is relieved of its IA obligations, LabTox shall be required to notify OIG in writing at least 30 days in advance if LabTox plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to and do not affect (1) LabTox'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.

E. The undersigned LabTox signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

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

ON BEHALF OF LABTOX, LLC

____/Ron Coburn/_____ _____16 Oct 2019_____
RON COBURN DATE
Chief Executive Officer
LabTox, LLC
2716 Old Rosebud Rd. Suite 280
Lexington, KY 40509

_____/Luke Morgan/_____ _____10-16-19_____
LUKE MORGAN DATE
Counsel for LabTox, LLC
McBrayer, PLLC
201 East Main Street, Suite 900
Lexington, KY 40507

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

_____/Lisa M. Re/_____ ____10/28/2019_____
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

_____/Andrea L. Treese Berlin/_____ ____10/25/2019_____
ANDREA L. TREESE BERLIN DATE
Senior Counsel
Administrative and Civil Remedies Branch
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Claims Review Independent Review Organization (IRO) required by Section III.D of the IA.

A. IRO Engagement

1. LabTox shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.5 of the IA or any additional information submitted by LabTox in response to a request by OIG, whichever is later, OIG will notify LabTox if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, LabTox may continue to engage the IRO.

2. If LabTox engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, LabTox shall submit the information identified in Section V.A.5 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by LabTox at the request of OIG, whichever is later, OIG will notify LabTox if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, LabTox may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Quarterly Claims Review who have expertise in the billing, coding, claims submission and other applicable Medicare, state Medicaid, and Medicaid Managed Care program requirements;

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

3. assign individuals to conduct the coding review portions of the Quarterly Claims Review who have a nationally recognized coding certification and who have

maintained this certification (e.g., completed applicable continuing education requirements);

4. 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 Quarterly Claims Review; and

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

C. IRO Responsibilities

The IRO shall:

1. perform each Quarterly Claims Review in accordance with the specific requirements of the IA;

2. follow all applicable Medicare, state Medicaid, and Medicaid Managed Care program rules and reimbursement guidelines in making assessments in the Claims Review;

3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare, state Medicaid, or Medicaid Managed Care 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 to the IA.

D. LabTox Responsibilities

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

E. IRO Independence and Objectivity

The IRO must perform the Quarterly 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 Removal/Termination

1. *LabTox and IRO*. If LabTox terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, LabTox 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. LabTox 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 the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify LabTox in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. LabTox shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by LabTox regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify LabTox in writing that LabTox shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. LabTox 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 LabTox to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

QUARTERLY CLAIMS REVIEW

A. Quarterly Claims Review. The IRO shall conduct a review of LabTox's claims submitted to and reimbursed by the Medicare, Medicaid, and Medicaid Managed Care programs, to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claims were correctly coded, billed, and reimbursed, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed. The first three-month period shall begin 30 days following the Effective Date of this IA.

1. *Definitions*. For the purposes of this Appendix B, the following definitions shall be used:

a. Overpayment: The amount of money LabTox has received in excess of the amount due and payable under any Medicare, state Medicaid, or Medicaid Managed Care program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.

b. Paid Claim: A claim submitted by LabTox and for which LabTox has received reimbursement from the Medicare program, a state Medicaid program, or a Medicaid Managed Care program.

c. Population: The Population shall be defined as all Paid Claims during the three-month period covered by the Quarterly Claims Review.

2. *Quarterly Claims Sample.*

a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of LabTox during the preceding three-month period (Quarterly Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp.

b. LabTox shall provide the IRO with a list of all LabTox's Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO.

c. The randomly selected 30 Paid Claims shall be reviewed by the IRO based on the supporting documentation available at LabTox's office or under LabTox's control and applicable Medicare, state 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.

d. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Repayment of Identified Overpayments.* LabTox shall repay within 60 days any Overpayments identified by the IRO in the Quarterly Claims Sample, 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 (the "CMS overpayment rule"). If LabTox determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, LabTox shall repay that amount at the mean point estimate as calculated by the IRO. LabTox shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Review Sample (and any related work papers) received from LabTox to the appropriate Medicare, state Medicaid, or Medicaid Managed Care program contractor for appropriate follow up by that payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.

a. Claims Review Population. A description of the Population subject to the Quarterly Claims Review.

b. Source of Data. A description of (1) the process used to identify claims in the Population, and (2) the specific documentation relied upon by the IRO when performing the Quarterly 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 contractor manual or bulletins (including issue and date), other policies, regulations, or directives).

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

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in each Quarterly Claims Sample and LabTox shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from LabTox after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation*. A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings*.

a. Narrative Results.

i. For the first Quarterly Claims Review Report only, a description of (a) LabTox's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing, and (b) a description of controls in place to ensure that all items and services billed to Medicare, state Medicaid, or a Medicaid Managed Care program by LabTox are medically necessary and appropriately documented. Subsequent Quarterly Claims Review Reports should describe any significant changes to items (a) and (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Claims Review Report.

ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by LabTox differed from what should have been the correct coding and in which such difference resulted in an Overpayment to LabTox.

ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to LabTox.

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 and resulted in an Overpayment to LabTox.

iv. Total dollar amount of all Overpayments in the Quarterly Claims Review Sample.

v. Total dollar amount of Paid Claims included in the Quarterly Claims Review Sample.

vi. Error Rate in the Quarterly Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Quarterly Claims Review Sample by the total dollar amount associated with the Paid Claims in the Quarterly Claims Review Sample.

vii. An estimate of the actual Overpayment in the Population at the mean point estimate.

viii. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), 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 LabTox's billing and coding system or to LabTox's controls for ensuring that all items and services billed to Medicare, state Medicaid, or a Medicaid Managed Care program are medically necessary and appropriately documented, based on the findings of the Quarterly Claims Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Other Requirements. The following requirements apply to any Quarterly Claims Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation.* Any Paid Claim for which LabTox cannot produce documentation shall be considered an error and the total reimbursement received by LabTox for such Paid Claim shall be deemed an

Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn*. For the purposes of all samples discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the sample).