CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PRINCETON BIOMEDICAL LABORATORY, INC.

I. PREAMBLE

Princeton Biomedical Laboratory Inc. ("Princeton") 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 by its officers, directors, employees, third parties engaged to bill and/or submit reimbursement claims, and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") 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, Princeton is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Princeton under this CIA shall be five years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Princeton pursuant to OIG's request.

III. CORPORATE INTEGRITY OBLIGATIONS

Princeton agrees to establish a Compliance Program that includes the following elements:

A. Compliance Officer

Within 90 days after the effective date of this CIA, Princeton shall appoint an individual to serve as its Compliance Officer. The Compliance Officer may be a part-time employee, or independent consultant. The Compliance Officer shall be responsible for 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. The Compliance Officer shall be responsible for monitoring compliance activities engaged in by Princeton as well as for reporting obligations created under this CIA. The Compliance Officer shall have direct access to the CEO and the Board of Directors, shall make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Princeton, and shall be authorized to report on such matters to the Board of Directors at any time.

Any changes in the identity or position description 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 CIA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct*. Within 90 days of the effective date of this CIA, Princeton shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. Princeton shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Princeton's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Princeton's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Princeton's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

c. the requirement that all of Princeton's Covered Persons shall be

expected to report to the Compliance Officer or other individual designated by Princeton suspected violations of any Federal health care program requirements or of Princeton's own Policies and Procedures;

d. the possible consequences to both Princeton and Covered Persons of failure to comply with all Federal health care program requirements and with Princeton's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Confidential Disclosure Program described in section III.E, and Princeton's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understands, and will abide by Princeton's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

Princeton shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understand and will abide by the revised Code of Conduct within 30 days of the finalization of such revisions.

2. *Policies and Procedures*. Within 90 days of the effective date of this CIA, Princeton shall implement written Policies and Procedures regarding the operation of Princeton's compliance program and its compliance with Federal health care program requirements. The Policies and Procedures shall reflect the principles and policies set forth in the HHS-OIG's Compliance Program Guidance for Clinical Laboratories. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1;

b. the requirement that Princeton take all reasonable steps to ensure that it is submitting claims for services that are reasonable,

necessary, and covered by the applicable Federal health care program;

c. the requirement that CPT or HCPCS codes used to bill accurately describe the clinical laboratory services ordered by the treating physician and performed;

d. the requirement that billing staff not record diagnostic information unless obtained from the test ordering physician or his or her qualified staff and that there be appropriate documentation of receipt of such information.

As part of its Implementation Report and Annual Report set forth in Section V *infra*, Princeton shall provide copies of all Policies and Procedures newly developed pursuant to Princeton's obligations under the CIA. All other Policies and Procedures shall be available to OIG upon request.

Within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Princeton shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training*. Within 90 days of the effective date of this CIA, Princeton shall provide at least two hours of general training to each Covered Person. This training shall explain Princeton's:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training*. Within 90 days of the effective date of this CIA, each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least four hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

a. policies, procedures and other requirements applicable to the submission of accurate bills for services rendered to Federal health care program patients;

b. policies, procedures and other requirements applicable to the documentation of medical records;

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

d. applicable reimbursement statutes, regulations, and program requirements and directives;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the effective date of this CIA, whichever is later. A Princeton employee who has completed the specific training shall review a new Relevant Covered Person's work, to

the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least four hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Princeton shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Princeton in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by Princeton shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Princeton seeks reimbursement.

b. Types of Engagements. The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address Princeton's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address Princeton's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Engagement").

c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO and Princeton shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

2. *Billing Engagement.* The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this CIA, which is incorporated by reference.

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Princeton to the Medicare program and all other Federal health care programs. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.

c. Systems Review. The IRO shall review Princeton's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

(i) Princeton's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and

(ii) Princeton's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).

d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:

(i) the strengths and weaknesses in Princeton's billing systems and/or operations;

(ii) the strengths and weaknesses in Princeton's coding systems and/or operations; and

(iii) any recommendations the IRO may have to improve any of these systems, operations, and processes.

3. *Compliance Engagement.*

a. Compliance Review. The IRO shall conduct a review of Princeton's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Princeton's compliance with the obligations set forth in each section of this CIA, and a review of Princeton's compliance with certain provisions of the Settlement Agreement. The IRO shall evaluate Princeton's compliance with the obligations set forth in each section of this CIA.

b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Princeton's compliance with the terms of each section of the CIA, as applicable.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Princeton's Billing or Compliance Engagement fails to conform to the requirements of

this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Princeton agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in section II) is received by the OIG.

E. Confidential Disclosure Program.

Within 90 days after the effective date of this CIA, Princeton shall establish a Confidential Disclosure Program, which must include a mechanism (*e.g.,* a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Princeton's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. Princeton shall publicize the existence of the confidential disclosure mechanism (*e.g.*, via periodic e-mails to employees or by posting the information in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Princeton shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs as a result of being listed on the General Services Administration's List of Parties Excluded from Federal Programs or the HHS/OIG List of Excluded Individuals/Entities; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* Princeton shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Princeton shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 90 days of the effective date of this CIA, Princeton shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Princeton shall review the list semi-annually. In addition, Princeton shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Princeton has notice that an employee or contractor has become an Ineligible Person, Princeton shall remove such person from responsibility for, or involvement with, Princeton's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Princeton has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract,

Princeton shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, Princeton shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Princeton 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. Princeton shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Princeton has received in excess of the amount due and payable under any Federal health care program requirements. Princeton may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, Princeton identifies or learns of any overpayments, Princeton shall notify the payor (*e.g.*, Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:

(i) a substantial overpayment; or

(ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. Reporting of Material Deficiencies. If Princeton determines that there is a Material Deficiency, Princeton shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of Princeton's actions taken to correct the

Material Deficiency; and

(iv) any further steps Princeton plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, Princeton changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Princeton shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (*e.g.,* completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this CIA, Princeton shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;

2. a copy of Princeton's Code of Conduct required by section III.B.1;

3. a copy of all Policies and Procedures newly developed pursuant to Princeton's obligations under the CIA as required by section III.B.2, and a summary of all other Policies and Procedures required by section III.B.2;

4. a description of the training required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a certification by the Compliance Officer that:

a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been made available to all appropriate Covered Persons;

b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and

c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

The documentation supporting this certification shall be available to OIG upon request.

6. a description of the Confidential Disclosure Program required by section III.E;

7. the identity of the IRO(s) and the proposed start and completion dates of the first annual review;

8. a summary of personnel actions taken pursuant to section III.F.;

9. a list of all of Princeton's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number;

10. to the extent not already furnished to OIG, or if modified, a description of Princeton's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

11. the certification required by section V.C.

B. Annual Reports. Princeton shall submit to OIG Annual Reports with respect to the status of and findings regarding of Princeton's compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

c. Princeton has complied with its obligations under the Settlement Agreement not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims;

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (*e.g.*, change in contractor policy);

4. a description of the training required by section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. Princeton's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and

preventative action relating to all such Material Deficiencies;

8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

9. a summary of the disclosures in the confidential disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by Princeton as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;

11. 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;

12. a description of all changes to the most recently provided list (as updated) of Princeton's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

13. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than one year and 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. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Princeton is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: Princeton 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 exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Princeton 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 of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit
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
Phone 202.619.2078
Fax 202.205.0604

Princeton:

Iqbal Haider
President
Princeton BioMedical Laboratories, Inc.
2000 Hartel Street
Levittown, PA 19057
Phone: 215.943.0700
Fax: 215.785.3100

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Princeton prior to any release by OIG of information submitted by Princeton pursuant to its obligations under this CIA and identified upon submission by Princeton as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Princeton shall have the rights set forth at 45 C.F.R. § 5.65(d). Princeton shall refrain from identifying any information as exempt from release if that

information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Princeton shall fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Princeton and OIG agree that failure to comply with certain obligations set forth in this CIA 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 $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Princeton fails to have in place any of the following:

a. a Compliance Officer as described by section III.A.1;

b. a written Code of Conduct as described by section III.B.1;

c. written Policies and Procedures as described by section III.B.2;

d. a requirement that Covered Persons be trained as described in section III.C; and

e. a Confidential Disclosure Program as described in section III.E.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Princeton fails to retain an IRO, as required in section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Princeton fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Princeton employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Princeton's business operations related to the Federal health care programs; or (ii) is in a

position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Princeton can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of $1,500 for each day Princeton fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date Princeton fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Princeton fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs 1-5. In its notice to Princeton, OIG shall state the specific grounds for its determination that Princeton has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Princeton must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Princeton of the failure to comply.)

B. Timely Written Requests for Extensions. Princeton 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. 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 Princeton 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 two business days after Princeton 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 Princeton 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 Princeton of: (a) Princeton's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the

Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Princeton 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 Princeton elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Princeton 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 CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

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 Princeton has materially breached this CIA, 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 CIA

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

a. failure by Princeton to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.H;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;

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

d. failure to retain and use an Independent Review Organization in

accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Princeton constitutes an independent basis for Princeton's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Princeton has materially breached this CIA and that exclusion should be imposed, OIG shall notify Princeton of: (a) Princeton's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

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

a. Princeton is in full compliance with this CIA;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Princeton fails to satisfy the requirements of section X.D.3, OIG may exclude Princeton from participation in the Federal health care programs. OIG will notify Princeton in writing of its determination to exclude Princeton (this letter shall be referred to hereinafter 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 exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Princeton wishes to apply for reinstatement, Princeton must submit 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 Princeton of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Princeton 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 CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Princeton was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Princeton shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Princeton to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Princeton 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 Chapter 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:

a. whether Princeton was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) Princeton had begun to take action to cure the material breach within that period;

(ii) Princeton has pursued and is pursuing such action with due diligence; and

(iii) Princeton provided to OIG within that period a reasonable timetable for curing the material breach and Princeton has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Princeton, only after a DAB decision in favor of OIG. Princeton's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Princeton upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Princeton 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.

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 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.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Princeton and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Princeton. However, on a case-by-case basis, OIG, in its sole discretion, may waive this successor liability provision upon proof that Princeton has wholly divested itself of any interest or involvement, direct or indirect, in the entity, that the successor is an independent entity unrelated in any manner to Princeton, that the successor has acquired its interest at fair market value in an arms' length transaction, and that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs.

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned Princeton signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF PRINCETON BIOMEDICAL LABORATORIES, INC:

Syed Iqbal Haider

IQBAL HAIDER
President

01/12/00
DATE

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

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

7/20/00
DATE

APPENDIX A

A. Claims Review.

1. ***Definitions***. For the purposes of the Claims Review, the following definitions shall be used:

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (*e.g.,* code, line item, beneficiary, patient encounter, etc.).

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Princeton has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, Princeton shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by Princeton and for which Princeton has received reimbursement from the Medicare program and all other Federal health care programs.

e. Population: All Items for which Princeton has submitted a code or line item and for which Princeton has received reimbursement from the Medicare program and all other Federal health care programs (*i.e.,* a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number of Items to be included in the Claims Review Sample.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".

2. ***Description of Claims Review***. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Confidence and Precision Requirements. The Claims Review Sample must contain a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (*i.e.*, semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Claims Review Sample Size. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items*. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Princeton for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a

zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of the Population (based on the amount of Overpayments received by Princeton for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items*. The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Princeton for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B, below).

c. <u>Calculation of Claims Review Sample Size and Selection of the Claims Review Sample</u>. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located

under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

d. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

e. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which Princeton cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Princeton for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

B. Claims Review Report. The following information shall be included in each Claims Review Report:

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the

3. ***Claims Review Results***

a. Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by Princeton ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Princeton.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to Princeton, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

d. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: 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. (See Attachment 1 to this Appendix.)

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.