

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
YVONNE C. HINES, M.D., DERMATOPATH LAB, INC.,
AND HINES DERMATOLOGY ASSOCIATES, INC.**

I. PREAMBLE

Yvonne C. Hines, M.D. (Dr. Hines), Dermatopath Lab, Inc. (the “Lab”) and Hines Dermatology Associates, Inc. (the “Practice”) (hereinafter collectively referred to as “Hines Dermatology”) hereby enter 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, program requirements, 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). This IA applies to Dr. Hines, any entity in which Dr. Hines has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), at any time during the term of the IA, including, but not limited to, Hines Dermatology Associates, Inc. and Dermatopath Lab, Inc., and any other Covered Persons as defined in Section II.C. Contemporaneously with this IA, Hines Dermatology is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. The date on which the final signatory of this IA executes this IA shall be known as the Effective Date, unless otherwise specified. The period of compliance obligations assumed by Hines Dermatology under this IA shall be five years from the Effective Date. 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 from OIG’s receipt of: (1) Hines Dermatology’s final Annual Report; or (2) any additional materials submitted by Hines Dermatology pursuant to OIG’s request, whichever is later.

C. The scope of this IA shall be governed by the following definitions:

1. “Covered Persons” includes:

- a. all owners, officers, directors, and employees of Hines Dermatology; and
- b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Hines Dermatology, excluding vendors whose sole connection with Hines Dermatology is selling or otherwise providing medical supplies or equipment to Hines Dermatology and who do not bill the Federal health care programs for such medical supplies or equipment.
- c. all employees of any entity in which Dr. Hines has an ownership or control interest at any time during the term of this IA (as defined in 42 U.S.C. § 1320a-3(a)(3)) and any contractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes Covered Persons 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.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact. Within 30 days after the Effective Date, Hines Dermatology shall designate a Covered Person to be responsible for compliance activities (Compliance Contact) for the Lab and the Practice. Hines Dermatology shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) monitoring Hines Dermatology’s day-to-day compliance activities; (2) meeting all reporting obligations created under this IA; and (3) responding to questions and concerns from Covered Persons and the OIG regarding compliance with the IA.

Hines Dermatology shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this IA within 15 days after such change. The name, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice. Within the 90 days after the Effective Date, Hines Dermatology shall post in a prominent place accessible to all patients and Covered Persons a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business.

This notice shall include the following information: (i) a means (e.g., telephone number or address) by which billing concerns and other issues may be reported anonymously; (ii) Hines Dermatology's commitment to maintain the confidentiality of the report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by Hines Dermatology.

This notice shall also include 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. A copy of this notice shall be included in the Implementation Report.

C. Billing and Claims Submission and Medical Record Documentation Procedures. Within 120 days after the Effective Date, Hines Dermatology shall implement and distribute to all Covered Persons written procedures and requirements for (i) preparing and submitting claims to Federal health care programs on behalf of Hines Dermatology; and (ii) the proper documentation of medical records and billing information for services furnished on behalf of Hines Dermatology. Within 120 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by these procedures. New Covered Persons shall receive and review the written procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Hines Dermatology shall assess and update, as necessary, these billing and claims submission and medical record documentation procedures. Within 30 days after the effective date of any revisions, any such revised procedures shall be distributed to all Covered Persons.

Copies of the written billing and claims submission and medical record documentation procedures shall be included in the Implementation Report. Copies of any

such procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to the procedures required by this Section and the reason for each change.

D. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, all Covered Persons shall receive at least two hours of General Training. This training, at a minimum, shall explain:

- a. the IA requirements; and
- b. Hines Dermatology's Compliance Program (including Hines Dermatology's policies and procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. the Federal health care program requirements regarding the accurate coding and submission of claims;
- b. policies, procedures, and other requirements applicable to the documentation of medical records; including, but not limited to, the proper documentation of the medical necessity for items or services provided or ordered by Hines Dermatology;
- c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;

- e. the legal sanctions for violations of the Federal health care program requirements; and
- f. examples of proper and improper claims submission practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Hines Dermatology 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 the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least one hour of Specific Training in each subsequent Reporting Period.

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

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* The training required by this section shall be updated as necessary to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information.

6. *Computer-based Training.* Hines Dermatology may provide the training required under this IA through appropriate computer-based training approaches. If Hines Dermatology chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, the Lab shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist the Lab in assessing and evaluating its billing and coding practices and certain other obligations pursuant to this IA and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

The IRO shall evaluate and analyze the Lab’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review). The IRO requirement is not applicable to the Practice.

b. *Frequency of Claims Review.* The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

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

2. *Claims Review.* The Claims Review shall include a Discovery Sample of 50 Paid Claims and, if the Error Rate for the Discovery Sample is 5% or greater, a Full Sample and Systems Review. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this IA, which is incorporated by reference.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B.

4. *Repayment of Identified Overpayments.* In accordance with Section III.H.1, the Lab shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. The Lab shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

5. *Validation Review.* In the event OIG has reason to believe that: (a) the Lab's Claims Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate (Validation Review). The Lab shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of the Lab's final Annual Report shall be initiated no later than one year after the Lab's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify the Lab of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, the Lab may request a meeting with OIG to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review and/or to correct the inaccuracy of the Claims Review and/or (c) propose alternatives to the proposed Validation Review. The Lab agrees to provide any additional information as may be requested by OIG under this Section III.E.5 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with the Lab prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to the Lab a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review and that it has concluded that it is, in fact, independent and objective.

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, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

- i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
- ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>)

2. *Screening Requirements.* Hines Dermatology shall not hire, employ or engage as a Covered Person any Ineligible Person. Hines Dermatology shall ensure that all Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Hines Dermatology shall screen all prospective and current Covered Persons against the Exclusion Lists 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. Hines Dermatology shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Hines Dermatology shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

Hines Dermatology shall maintain documentation demonstrating that: (1) it has checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the responsibility of (or liability for) Hines Dermatology to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Hines Dermatology understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Hines Dermatology may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an

excluded person regardless of whether Hines Dermatology meets the requirements of Section III.F.

3. *Removal Requirement.* If Hines Dermatology has actual notice that a Covered Person has become an Ineligible Person, Hines Dermatology shall remove such Covered Person from responsibility for, or involvement with, Hines Dermatology's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services rendered, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Hines Dermatology 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, Hines Dermatology 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, 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 after discovery, Hines Dermatology shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Hines Dermatology conducted or brought by a governmental entity or its agents involving an allegation that Hines Dermatology 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. Hines Dermatology 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 proceedings, if any.

H. Repayment of Overpayments.

1. *Definition of Overpayments.* For purposes of this IA, an “Overpayment” shall mean the amount of money Hines Dermatology has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Reporting of Overpayments.*

a. If, at any time, Hines Dermatology identifies or learns of any Overpayment, Hines Dermatology shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Hines Dermatology shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, Hines Dermatology shall notify the payor at that time of its efforts to quantify the Overpayment amount and provide a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies.

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

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 Hines Dermatology.

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

2. Reporting of Reportable Events. If Hines Dermatology determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Hines Dermatology 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. For Reportable Events under Section III.I.1.a, the report to OIG shall be made at the same time as the repayment to the payor required in Section III.H, and shall include:

- a. a copy of the notification and repayment to the payor required in Section III.H.2;
- b. a description of the steps taken by Hines Dermatology to identify and quantify the Overpayment;
- c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- d. a description of Hines Dermatology's actions taken to correct the Reportable Event; and
- e. any further steps Hines Dermatology plans to take to address the Reportable Event and prevent it from recurring.

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Hines Dermatology's actions taken to correct the Reportable Event;
- c. any further steps Hines Dermatology plans to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Hines Dermatology to identify and quantify the Overpayment.

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

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Hines Dermatology changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Hines Dermatology shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Hines Dermatology purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Hines Dermatology shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the name and address of the contractor that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this IA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Hines Dermatology proposes to sell any or all of its business units or locations that are subject to this IA, Hines Dermatology shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This IA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Hines Dermatology 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, phone number, and a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Hines Dermatology posted in its office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the procedures required by Section III.C;
4. the following information regarding each type of training required by Section III.D:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. the following information regarding the IRO: (a) identity, address and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any current and prior engagements between Hines Dermatology and the IRO;

6. a certification from the IRO regarding its professional independence and objectivity with respect to Hines Dermatology;

7. a certification by Hines Dermatology that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by Section III.F;

8. a list of all of Hines Dermatology'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 number(s), provider identification number(s), and/or supplier number(s), and the name and address of each Medicare contractor to which Hines Dermatology currently submits claims;

9. a description of Hines Dermatology's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

10. if Dr. Hines becomes an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Hines shall inform OIG of the name, location, relationship, and her responsibilities with respect to her employment or contract; and

11. a certification by Dr. Hines and Hines Dermatology's Compliance Contact that: (a) they have reviewed the IA in its entirety, understand the requirements described within, and maintains a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Implementation Report, Hines Dermatology is in compliance with all of the requirements of this IA; and (c) they have reviewed the Implementation Report and have made a reasonable inquiry regarding its content and believe that the information is accurate and truthful.

B. Annual Reports. Hines Dermatology shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Hines Dermatology's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall, at a minimum, include:

1. any change in the name, phone number, or job responsibilities of the Compliance Contact;

2. any changes to the posted notice and the reason for such changes;

3. a summary of the reports received pursuant to the reporting mechanism required in Section III.B that relate to Federal health care programs;

4. a copy of any new or revised procedures required by Section III.C and the reason(s) for any revisions (e.g., change in contractor policies, etc.);

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.E;

7. Hines Dermatology's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

8. a summary and description of any current and prior engagements and agreements between the Lab and the IRO, if different from what was submitted as part of the Implementation Report;

9. a certification from the IRO regarding its professional independence and objectivity with respect to the Lab;

10. a certification by Hines Dermatology that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F;

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 summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

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

14. a description of all changes to the most recently provided list of Hines Dermatology's locations (including addresses) as required by Section V.A.9; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Hines Dermatology currently submits claims;

15. if Dr. Hines became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Hines shall inform OIG of the name, location, relationship, and her responsibilities with respect to Dr. Hines's employment or contract; and

16. a certification signed by Dr. Hines and Hines Dermatology's Compliance Contact certifying that: (a) they have reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Annual Report, Hines Dermatology is in compliance with all of the requirements of this IA; and (c) they have reviewed the Annual Report and have made a reasonable inquiry regarding its content and believe that the information is accurate and truthful.

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

C. Designation of Information. Hines Dermatology 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. Hines

Dermatology 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

Hines Dermatology's Compliance Contact:

Cheryl Farpelha
Hines Dermatology Associates, Inc.
555 Pleasant Street, Suite 106
Attleboro, MA 02703
Telephone: (508) 222-1976
Facsimile: (508) 222-8385

Unless otherwise specified, all notifications and reports required by this IA shall 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. Upon request by OIG, Hines Dermatology may be required to provide OIG with an electronic copy of each notification or report required by this IA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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 Hines Dermatology's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Hines Dermatology locations for the purpose of verifying and evaluating: (a) Hines Dermatology's compliance with the terms of this IA;

and (b) Hines Dermatology's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Hines Dermatology 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 Hines Dermatology'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. Hines Dermatology shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Hines Dermatology's employees may elect to be interviewed with or without a representative of Hines Dermatology present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Hines Dermatology 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, Hines Dermatology and OIG hereby agree that failure to comply with certain obligations set forth in this IA (unless a timely written request for an extension has been submitted and approved in accordance with Section B below) 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 \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Hines Dermatology fails to:

- a. designate a Compliance Contact in accordance with the requirements of Section III.A;
- b. establish and/or post a notice in accordance with the requirements of Section III.B;
- c. implement, distribute, or update the procedures required by Section III.C;
- d. establish and implement a training program in accordance with the requirements of Section III.D;
- e. engage an IRO in accordance with the requirements of Section III.E and Appendix A;
- f. submit the IRO's annual Claims Review Report in accordance with the requirements of Section III.E and Appendix B;
- g. obtain and/or maintain the following documentation: written procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;
- h. screen Covered Persons in accordance with the requirements of Section III.F; or require Covered Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F;
- i. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G; or

2. A Stipulated Penalty of \$1000 (which shall begin to accrue on the day after the date the obligation became due) for each day Hines Dermatology fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$750 for each day Hines Dermatology fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Hines Dermatology fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Hines Dermatology as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

5. A Stipulated Penalty of \$750 for each day Hines Dermatology fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to Hines Dermatology stating the specific grounds for its determination that Hines Dermatology has failed to comply fully and adequately with the IA obligation(s) at issue and steps the Hines Dermatology shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date Hines Dermatology 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 1-4 of this Section.

B. Timely Written Requests for Extensions. Hines Dermatology 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 Hines Dermatology 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 Hines Dermatology 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 Hines Dermatology 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 Hines Dermatology of: (a) Hines Dermatology's failure to comply; and (b) OIG's intent to exercise its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Hines Dermatology shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for 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 Hines Dermatology elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Hines Dermatology 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 Hines Dermatology 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 Hines Dermatology to report a Reportable Event, 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 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.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by Hines Dermatology constitutes an independent basis for Hines Dermatology's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Hines Dermatology has materially breached this IA

and that exclusion is the appropriate remedy, OIG shall notify Hines Dermatology of: (a) Hines Dermatology'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.* Hines Dermatology 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. Hines Dermatology is in compliance with the obligations of the IA cited by OIG as being the basis for the material breach;
- 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) Hines Dermatology has begun to take action to cure the material breach; (ii) Hines Dermatology is pursuing such action with due diligence; and (iii) Hines Dermatology has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Hines Dermatology fails to satisfy the requirements of Section X.D.3, OIG may exclude UMS from participation in the Federal health care programs. OIG shall notify Hines Dermatology in writing of its determination to exclude Hines Dermatology (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 Hines Dermatology's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Hines Dermatology 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 Hines Dermatology 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, UMS 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 the 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.

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 IA shall be: (a) whether Hines Dermatology was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Hines Dermatology 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 to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UMS 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 IA shall be:

- a. whether Hines Dermatology was in material breach of this IA;
- 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) Hines Dermatology had begun

to take action to cure the material breach within that period; (ii) Hines Dermatology has pursued and is pursuing such action with due diligence; and (iii) Hines Dermatology provided to OIG within that period a reasonable timetable for curing the material breach and Hines Dermatology 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 Hines Dermatology, only after a DAB decision in favor of OIG. Hines Dermatology's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Hines Dermatology 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 Hines Dermatology 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. Hines Dermatology 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 Hines Dermatology, Hines Dermatology shall be reinstated effective 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

Hines Dermatology 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 prior written consent of the parties to this IA.
- C. This IA shall be binding on the successors, assigns, and transferees of Hines Dermatology.
- D. OIG may agree to a suspension of Hines Dermatology's obligations under this IA in the event of Hines Dermatology's cessation of participation in Federal health care programs. If Hines Dermatology ceases to participate in Federal health care programs and is relieved of its IA obligations by OIG, Hines Dermatology shall notify OIG 30 days

in advance of Hines Dermatology's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the IA shall be reactivated or modified.

E. All requirements and remedies set forth in this IA are in addition to, and do not effect (1) Hines Dermatology'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 program requirements.

F. The undersigned Hines Dermatology signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatory represents that he is signing this IA in his official capacity and that he is authorized to execute this IA.

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

ON BEHALF OF YVONNE C. HINES, M.D., HINES DERMATOLOGY ASSOCIATES, INC., AND DERMATOPATH LAB, INC.

/Yvonne C. Hines, M.D./

—
YVONNE C. HINES, M.D.
Individually and as President of Hines Dermatology Associates, Inc., and Dermatopath Lab, Inc.

6/16/10
DATE

/Patricia K. Rocha/

—
PATRICIA K. ROCHA
Counsel for Yvonne Hines, M.D., Hines Dermatology Associates, Inc., and Dermatopath Lab, Inc.

6/16/10
DATE

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

/Gregory E. Demske/

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

2/2/10
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the IA. The IRO requirement applies to the Lab only and is not applicable to the Practice.

A. IRO Engagement.

Dermatopath Lab, Inc. (the “Lab”) 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 D. Within 30 days after OIG receives the information identified in Section V.A.5 and Section V.A.6 of the IA, OIG will notify the Lab if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Lab may continue to engage the IRO.

If the Lab engages a new IRO during the term of the IA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, the Lab shall submit the information identified in Section V.A.5 and Section V.A.6 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, OIG will notify the Lab if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Lab may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review engagement who have expertise in the billing, coding, reporting, and other requirements of claims for skin pathology services, including claims for immunoperoxidase stain testing under CPT code 88432, and in the general requirements of the Federal health care program(s) from which the Lab seeks reimbursement;

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

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

4. 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 Claims Review in accordance with the specific requirements of the IA;
2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the Claims Review;
3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
4. respond to all OIG inquiries 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. IRO Independence and Objectivity.

The IRO must perform the Claims Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and the Lab.

E. IRO Removal/Termination.

1. Provider. If the Lab terminates its IRO during the course of the engagement, the Lab must submit a notice explaining its reasons to OIG no later than 30 days after termination. The Lab must engage a new IRO in accordance with Paragraph A of this Appendix.

2. OIG Removal of IRO. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require the Lab to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring the Lab to engage a new IRO, OIG shall notify the Lab of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, the Lab may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. The Lab shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with the Lab prior to requiring the Lab to terminate the IRO. However, the final determination as to whether or not to require the Lab to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review.

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

a. Overpayment: The amount of money the Lab has received in excess of the amount due and payable under any Federal health care program requirements.

b. Paid Claim: A claim submitted by the Lab and for which the Lab has received reimbursement from the Medicare program.

c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at the Lab's office or under the Lab's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, the Lab should, as appropriate, further analyze any errors identified in the Discovery Sample.

The Lab recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at the Lab or under the Lab's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from the Lab to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

4. *Systems Review.* If the Lab's Discovery Sample identifies an Error Rate of 5% or greater, the Lab's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of the Lab's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);
- b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements.*

a. Supporting Documentation. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and the Lab shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from the Lab after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Documentation), the IRO shall identify in the Claims Review Report the Supplemental Documentation, the date the Supplemental Documentation was accepted, and the relative weight the IRO gave to the Supplemental Documentation in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Documentation was accepted and the IRO's reasons for accepting the Supplemental Documentation.

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

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) 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 Discovery Sample or Full Sample).

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

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

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

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

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

e. Supplemental Documentation. A description of any Supplemental Documentation as required by A.5.a., above.

2. *Statistical Sampling Documentation.*

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

b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

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

ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

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

ii. 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 the Lab.

iii. Total dollar amount of all Overpayments in the sample.

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

v. Error Rate in the sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct 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 the Lab's billing and coding system based on the findings of the Claims Review

4. *Systems Review.* The IRO shall prepare a report based on the Systems Review (Systems Review Report) that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in the Lab's billing systems and processes;

b. the strengths and weaknesses in the Lab's coding systems and processes;
and

c. possible improvements to the Lab's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *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.