INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SALVADOR RIBOT RUIZ
AND
POLICLINICA DR. SALVADOR RIBOT RUIZ, INC.

I. PREAMBLE

Salvador Ribot Ruiz and Policlinica Dr. Salvador Ribot Ruiz, Inc. (collectively "Ribot") hereby enters into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, 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 Salvador Ribot Ruiz and Policlinica Dr. Salvador Ribot Ruiz, Inc., any entity in which Salvador Ribot Ruiz has an ownership or control interest at any time during the term of the IA, as defined in 42 U.S.C. § 1320a-3(a)(3), and any other Covered Persons as defined in Section II.C. Contemporaneously with this IA, Ribot Ruiz and Policlinica Dr. Salvador Ribot Ruiz, Inc. are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

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

C. The term "Covered Persons" includes:

1. Ribot and all employees of Ribot;

2. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Ribot; and

3. all employees of any entity in which Ribot 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.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days after the Effective Date, Ribot shall designate a Covered Person to be responsible for compliance activities (Compliance Contact). Ribot shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) monitoring Ribot'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.

Ribot 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 five days after such change.

B. Posting of Notice; Disclosure Log

Within the 90 days after the Effective Date, Ribot shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his 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) Ribot'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 Ribot. The Compliance Contact shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the Compliance Contact's review of each disclosure, and any corrective action taken in response to the disclosure.

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.

C. Billing, Claims Submission and Medical Record Documentation Procedures

Within 90 days after the Effective Date, Ribot 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 Ribot and (ii) the proper documentation of medical records and billing information for services furnished on behalf of Ribot. Within 90 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 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Ribot 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.

D. Training and Education

1. *Training*. Within 90 days after the Effective Date and during each subsequent Reporting Period, all Covered Persons shall receive at least three hours of training from an individual or entity, other than Ribot or another Covered Person. Training may be received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors).

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. A new Covered Person shall work under the direct supervision of a Covered Person

who has received such training, 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 Covered Person completes the training.

At a minimum, the initial, annual, and new Covered Person training sessions shall include the following topics:

a. the requirements of Ribot's IA;

b. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;

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

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

e. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;

f. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements; and

g. examples of proper and improper coding and claims submission practices.

2. *Certification.* Each individual who is required to receive training shall certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training received and the date received. Ribot shall retain the certifications along with all training materials.

3. *Qualifications of Trainer(s).* Persons providing the training shall be knowledgeable about the subject area.

4. *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 the Claims Review, and any other relevant information.

5. *Computer-Based Training*. Ribot may provide the training required under this IA through appropriate computer-based training approaches. If Ribot chooses to provide computer-based training, he 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 90 days after the Effective Date, Ribot shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

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

2. *Claims Review*. The IRO shall review Ribot's coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference.

3. *Validation Review*. In the event OIG has reason to believe that: (a) Ribot'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). Ribot shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Ribot's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Ribot 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, Ribot may request a meeting with OIG to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Claims Review to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. Ribot agrees to provide any additional information requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with Ribot 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.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Ribot a certification or sworn affidavit that it has evaluated its professional independence and objectivity and 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 scope 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*. Ribot shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

b. Ribot shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Ribot shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

Ribot shall maintain documentation demonstrating that: (1) he 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 Ribot's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Ribot understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Ribot may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Ribot meets the requirements of Section III.F.

3. *Removal Requirement*. If Ribot has actual notice that a Covered Person has become an Ineligible Person, Ribot shall remove such Covered Person from responsibility for, or involvement with, Ribot'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 Ribot 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, Ribot 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, Ribot shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Ribot conducted or brought by a governmental entity or its agents involving an allegation that Ribot 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. Ribot 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 Ribot 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, Ribot identifies or learns of any Overpayment, Ribot shall repay the Overpayment to the appropriate 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. If not yet quantified within 30 days after identification, Ribot 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 Ribot.

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

2. *Reporting of Reportable Events.* If Ribot determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Ribot 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 Ribot 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 Ribot's actions taken to correct the Reportable Event; and

e. any further steps Ribot 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 III.I.1.c, the report to the 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 Ribot's actions taken to correct the Reportable Event; and

c. any further steps Ribot 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 Ribot to identify and quantify the Overpayment.

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

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Ribot to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 30 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

J. Third Party Billing

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

Ribot also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Ribot 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, Ribot 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, Ribot 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, Ribot 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 and state Medicaid program provider identification number and/or supplier number, and the name and address of each Medicare and state Medicaid program contractor to which Ribot currently submits claims. 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, Ribot proposes to sell any or all of his business units or locations that are subject to this IA, Ribot 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.

D. New Employment or Contractual Arrangement. Prior to Ribot becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ribot shall notify that party of this IA. This notification shall include a copy of the IA, a statement indicating the remaining term of the IA, and a summary of Ribot's obligations under the IA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Ribot 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 Ribot posted in his 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 made 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; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; (d) a summary and description of any and all current and prior engagements and agreements between Ribot and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Ribot;

6. a certification by Ribot that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F (the documentation supporting this certification shall be made available to OIG upon request);

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

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

9. if Ribot 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, Ribot shall inform OIG of the name, location, relationship, and his responsibilities with respect Ribot's employment or contract; and

10. a certification by the Ribot and the Compliance Contact that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Ribot is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports. Ribot shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Ribot'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. a description of any changes to the notice required by Section III.B, and the reason for such changes, along with a copy of the revised notice;

3. a summary of the disclosures received pursuant to the reporting mechanism required in Section III.B that relate to Federal health care programs (a complete copy of the disclosure log shall be made available to OIG upon request);

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.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 made available to OIG upon request.

6. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter;

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

8. a summary and description of any current and prior engagements and agreements between Ribot 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 Ribot;

10. a certification by Ribot that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F (the documentation supporting this certification shall be made available to OIG upon request);

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

15. a description of all changes to the most recently provided list of Ribot's locations (including addresses) as required by Section V.A.8; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider identification number(s), and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Ribot currently submits claims;

16. if Ribot 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, Ribot shall inform OIG of the name, location, relationship, and his responsibilities with respect to Ribot's employment or contract; and

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

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. Ribot shall clearly identify any portions of its submissions that he 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. Ribot 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

Compliance Contact: Jimmy Rivera-Viana, Administrator
Policlinica Dr. Salvador Ribot, PO Box 800, Carolina, PR 00986
Information to be provided by Ribot's counsel 787-776-3840

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

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Ribot 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, Ribot 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 Ribot fails to:

a. designate and maintain 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 and use an IRO in accordance with the requirements of Section III.E, Appendix A, and Appendix B;

f. submit the IRO's annual Claims Review Report in accordance with the requirements of Section III.E and Appendix B;

g. obtain and 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 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;

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

k. report a Reportable Event.

2. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Ribot 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 Ribot fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Ribot fails to grant access.)

4. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Ribot 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 Ribot fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to Ribot stating the specific grounds for its determination that Ribot has failed to comply fully and adequately with the IA obligation(s) at issue and steps the Ribot shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date Ribot 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. Ribot 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 Ribot 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 Ribot 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 Ribot 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 Ribot of: (a) Ribot's failure to comply; and (b) OIG's intent to exercise its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days of the receipt of the Demand Letter, Ribot 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 Ribot elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Ribot 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 Ribot 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 Ribot to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;

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, Appendix A, and Appendix B.

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

3. *Opportunity to Cure.* Ribot 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. Ribot 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) Ribot has begun to take action to cure the material breach; (ii) Ribot is pursuing such action with due diligence; and (iii) Ribot has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Ribot fails to satisfy the requirements of Section X.D.3, OIG may exclude Ribot from participation in the Federal health care programs. OIG shall notify Ribot in writing of its determination to exclude Ribot. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Ribot'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, Ribot 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 Ribot 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, Ribot 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 Ribot was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Ribot 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 Ribot to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Ribot 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 Ribot 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) Ribot had begun to take action to cure the material breach within that period; (ii) Ribot has pursued and is pursuing such action with due diligence; and (iii) Ribot provided to OIG within that period a reasonable timetable for curing the material breach and Ribot 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 Ribot, only after a DAB decision in favor of OIG. Ribot's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Ribot 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 Ribot 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. Ribot shall waive his 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 Ribot, Ribot 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

Ribot 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 Ribot.

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

E. All requirements and remedies set forth in this IA are in addition to, and do not effect (1) Ribot'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 Ribot 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 SALVADOR RIBOT RUIZ AND
POLICLINICA DR. SALVADOR RIBOT RUIZ, INC.

/Salvador Ribot Ruiz/

Salvador Ribot Ruiz

PO Box 800
Carolina, PR 00986

5/11/11
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 Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

5/25/11
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.

A. IRO Engagement

1. Ribot 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 of the IA or any additional information submitted by Ribot in response to a request by OIG, whichever is later, OIG will notify Ribot if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Ribot may continue to engage the IRO.

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of infusion and medication services and in the general requirements of the Federal health care program(s) from which Ribot 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 and Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

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

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

D. 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 Ribot.

E. IRO Removal/Termination

1. *Practitioner and IRO.* If Ribot terminates its IRO or the IRO withdraws from the engagement during the term of the CIA, Ribot must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Ribot must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Ribot to engage a new IRO in accordance with Paragraph A of this Appendix. Ribot must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

Prior to requiring Ribot to engage a new IRO, OIG shall notify Ribot 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, Ribot may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Ribot prior to requiring Ribot to terminate the IRO. However, the final determination as to whether or not to require Ribot to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

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

b. Paid Claim: A claim submitted by Ribot and for which Ribot has received reimbursement from the Medicare or Medicaid programs.

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 Items in the sample.

2. *Discovery Sample*. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of Ribot (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Ribot's office or under Ribot's control and applicable billing and coding regulations and guidance to determine whether the claim submitted 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, Ribot should, as appropriate, further analyze any errors identified in the Discovery Sample. Ribot 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 Ribot's office or under Ribot's control and applicable billing and coding regulations and guidance to determine whether the claim submitted 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 Ribot 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 Ribot's Discovery Sample identifies an Error Rate of 5% or greater, Ribot's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

a. a review of Ribot'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. Supplemental Materials. 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 Ribot 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 Ribot after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which Ribot cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Ribot 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).

6. *Repayment of Identified Overpayments.* Ribot 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. Ribot shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review Report performed. 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 Materials. A description of any Supplemental Materials 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 Ribot'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 Ribot (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 Ribot.

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, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Ribot's billing and coding system based on the findings of the Claims Review.

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

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

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

c. possible improvements to Ribot'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.