REVISED CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
STRAUB CLINIC & HOSPITAL, INC.

I. PREAMBLE

Straub Clinic & Hospital, Inc. ("Straub") hereby enters into this revised Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors, agents, and physicians with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). This CIA will supersede (i) the CIA executed on August 14, 1998, by Straub and the OIG, which was incorporated by reference into the settlement agreement executed on August 14, 1998, by Straub, PhyCor, Inc., the OIG, the Department of Justice, Department of Defense, and the State of Hawaii ("1998 Settlement Agreement") and (ii) the corporate integrity provisions in sections B.5-11 of the Settlement Agreement executed on April 17, 2000, by Straub and the OIG ("2000 Settlement Agreement").

Straub's compliance with the terms and conditions in this CIA shall constitute an element of Straub's present responsibility with regard to participation in the Federal health care programs. Straub agrees to adapt its existing compliance operations insofar as that may be necessary to ensure that the requirements and goals of this CIA are met.

II. TERM OF THE CIA AND DEFINITIONS

A. Term. The period of the compliance obligations assumed by Straub under this CIA shall be six (6) years from August 14, 1998, the effective date of the original CIA (unless otherwise specified). The effective date of this revised CIA shall be the date on which the final signatory of this CIA executes this CIA.

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

B. Definitions. For the purposes of this CIA, the following terms have the following meanings.

1. *Covered Person*: (a) any officer, director, or employee of Straub or any of its subsidiaries; or (b) any other person who (i) furnishes health care items or services at a facility owned or operated by Straub or any of its subsidiaries for which Straub or any of its subsidiaries claims reimbursement from any Federal health care program, or (ii) participates in the preparation or submission of claims, cost reports, or other requests for reimbursement from any Federal health care program on behalf of Straub or any of its subsidiaries (regardless of where such activity takes place).

2. *Subsidiary*: any corporation or other entity that provides items or services for which payment may be made by any Federal health care program, or prepares or submits requests for such payment, and in which Straub holds an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)).

III. CORPORATE INTEGRITY OBLIGATIONS

Straub warrants and represents that it currently operates and maintains a compliance program ("Compliance Program"). Pursuant to and for the duration of this CIA, Straub shall maintain its current Compliance Program, and, as required below, amend the Compliance Program to adhere to or include the following obligations or elements. Straub hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committees.

1. *Compliance Officer*. Straub currently has a Compliance Officer. Straub shall ensure that the Compliance Officer has sufficient management responsibility so as to permit the effective performance of all assigned duties. The Compliance Officer shall be responsible for implementation and oversight of the Compliance Program and for Straub's compliance with the requirements of this CIA and of the Federal health care programs. The Compliance Officer shall continue to be a member of senior management of Straub and make periodic (at least quarterly) reports regarding compliance matters directly to the Chief Executive Officer and/or to the Board of Directors of Straub (or relevant subcommittee of the Board), and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Straub as well as for any reporting

obligations created under this CIA. Straub shall make proper execution of Compliance Officer duties a major component of the performance evaluations of the Compliance Officer. Straub shall make periodic (at least yearly) assessments of the effectiveness of the Compliance Officer and the methods and findings of any such assessments shall be made available to the OIG upon request.

Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within thirty (30) days of such a change.

2. *Executive Compliance Committee.* Straub currently has an Executive Compliance Committee ("ECC") that is responsible for the review of matters related to its Compliance Program, this CIA, and compliance with the requirements of Federal health care programs. The ECC shall, at a minimum, include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, medical, human resources, audit, and operations). The Compliance Officer shall chair the ECC and the ECC shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Any changes in the composition of the ECC, or any actions or changes that would affect the ECC's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within thirty (30) days of such a change.

B. Written Standards.

1. *Standards of Conduct.* Straub currently has Standards of Conduct and has provided copies of the Standards of Conduct to all Covered Persons, who have certified that they have received, read, understood, and will abide by the Standards of Conduct. Straub shall maintain Standards of Conduct that contain at least the minimum elements set forth below:

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

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

c. the requirement that all of Straub's Covered Persons shall be expected to report to the Compliance Officer, or other individual designated by Straub, suspected violations of any Federal health care program requirements or of Straub's own Policies and Procedures;

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

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

On an annual basis, Straub shall review its Standards of Conduct and, where appropriate, make revisions to ensure that the Standards of Conduct contain at least the minimum elements set forth above. Any revised Standards of Conduct shall be distributed to all Covered Persons as part of their annual general compliance training required under section III.C.1. of this CIA. Covered Persons shall certify that they have received, read, understood, and will abide by the revised Standards of Conduct within 30 days of receiving such revisions.

2. *Policies and Procedures*.

a. *Standards of Conduct*. Straub has and shall maintain policies and procedures for the subjects relating to the Standards of Conduct identified in section III.B.1;

b. *Credit Balances*. Straub has and shall maintain policies and procedures regarding credit balances designed to ensure that overpayments from Federal health care programs are identified promptly and refunded to the appropriate payor in accordance with Federal health care program requirements. At a minimum, such policies and procedures shall address the following areas:

(1) Straub shall make adequate provisions for timely and accurate reporting of Federal health care program credit balances;

(2) Straub shall address the Health Care Financing Administration ("HCFA") requirements for reporting credit balances through the filing of credit balance reports (FORM HCFA-838);

(3) Straub shall retain an audit trail of patient account transactions involving Federal health care program payors for a period of seven years from the date that a claim for payment was submitted;

(4) Straub shall track accounts with credit balances involving Federal health care programs so that it can determine the status of refund requests and the payment of refunds;

(5) Straub's actions with regard to credit balances shall be in accordance with Federal health care program requirements; and

(6) Straub shall designate at least one individual for each of its business segments as having responsibility for the tracking, recording, reporting and refunding of credit balances.

c. *Clinical Laboratory Services*. Straub has and shall maintain policies and procedures for its clinical laboratory billing system that are designed, to the fullest extent possible, to properly and accurately bill clinical laboratory services to Federal health care programs. The billing system(s) and any attendant policies and procedures generally reflect those principles and policies set forth in the HHS-OIG's Compliance Program Guidance for Clinical Laboratories. The policies and procedures address the proper submission of clinical laboratory claims to the Medicare and Medicaid programs. These written policies and procedures have been distributed to all Covered Persons involved with Straub's clinical laboratory services, including those involved in preparing or submitting Straub's Medicare and Medicaid bills or claims, including any third parties contracting with Straub to provide clinical laboratory services or billing. At a minimum, the policies and procedures shall require that:

(1) Straub not engage in any conduct or activities that cause the submission of claims to Federal health care programs for clinical

laboratory tests and/or services that are not reasonable and necessary, as defined in 42 U.S.C. § 1395y(a)(1)(A). Straub shall communicate to physicians that claims submitted for services will only be paid if the services are covered, reasonable and medically necessary for the beneficiary, given his or her clinical condition;

(2) the CPT or HCPCS billing codes used by Straub accurately describe the clinical laboratory services ordered and performed;

(3) Straub's billing staff not record diagnostic information unless obtained from the test ordering physician or his or her qualified staff;

(4) where diagnostic information is obtained from a physician or his or her qualified staff after receipt of the specimen and request for services, documentation of the receipt of such information be created and retained for a period of at least five (5) years along with the laboratory service and billing records; and

(5) to the extent Straub's clinical laboratory permits physicians to order tests by panels, the laboratory fully discloses the contents of its panels on its test ordering forms or other test ordering system and gives physicians the option of ordering each test in a panel individually. If Straub permits tests to be ordered as panels, procedures shall be in place to assure that the tests that compose the panels are properly billed to Federal health care programs.

d. *Cost Reports*. Straub has and shall maintain written policies and procedures specifically aimed at ensuring that Straub will prepare and submit Medicare cost reports in a manner consistent with all applicable Federal health care program requirements.

At least annually (and more frequently, if appropriate), Straub shall review and, where appropriate, revise its written Policies and Procedures addressing each of the areas set forth above in sections III.B.2.a-d. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of any written Policies and Procedures that are revised shall be included in the Annual Report.

C. Training and Education.

1. *General Compliance Training.* Straub shall maintain and further develop its compliance training program to provide necessary training and information to Covered Persons about applicable Federal health care program requirements and related Straub Policies and Procedures. The objective of the general compliance training program shall be to enable Straub to operate in conformity with Federal health care program requirements and to satisfy the requirements of this CIA. At a minimum, the general compliance training program shall include the following elements:

a. *Corporate Integrity Agreement.* Straub shall take steps to inform Covered Persons of the existence of, and obligations imposed by, this CIA.

b. *Compliance Program.* Straub shall take steps to inform Covered Persons of the obligation imposed by Straub's Compliance Program (including the Standards of Conduct and Policies and Procedures pertaining to general compliance issues).

Each Covered Person shall receive at least one (1) hour of general compliance training annually. New Covered Persons shall receive the general compliance training described above within 30 days of becoming a Covered Person.

2. *Specific Training.* In addition to the general compliance training described in paragraph 1, each Covered Person who is involved in documenting the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program and not described in paragraph 3 or 4 below shall receive at least two (2) hours of specific training annually in addition to the general compliance training required above. This specific training shall include a discussion of:

a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;

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

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

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

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

3. *Cost Report Training.* In addition to the general compliance training described in paragraph 1, each Covered Person who is involved directly or indirectly in the preparation and/or submission of Medicare cost reports shall receive at least two (2) hours of training on an annual basis regarding the proper preparation and submission of Medicare cost reports.

For purposes of this Section, Covered Persons who are "indirectly" involved in the preparation and/or submission of Medicare costs reports are those Covered Persons who are not involved with the actual preparation of the cost report, but who, in the course of their normal duties, review and/or approve the draft cost report before filing with the Medicare program.

4. *Clinical Laboratory Training.* In addition to the general compliance training described in paragraph 1, each Covered Person who is involved in ordering outpatient clinical laboratory services or preparing or submitting Straub's claims for reimbursement for outpatient clinical laboratory services to the Medicare and Medicaid programs shall receive at least two (2) hours of training on an annual basis regarding the proper ordering and billing for outpatient clinical laboratory services. Straub must also provide training (either as part of or distinct from the aforementioned training) for all physicians on the active medical staff involved in ordering outpatient clinical laboratory services or preparing or submitting claims for reimbursement for outpatient clinical laboratory claims to the Medicare and Medicaid programs.

5. *Training Materials.* All training materials shall be made available to OIG, upon request.

6. *Trainers.* Persons providing the training discussed in paragraphs C.1 through 4 above must be knowledgeable about the applicable subject area.

7. *Time frames*. Straub currently provides training to Covered Persons in a number of areas on an ongoing basis. Training that satisfies, in whole or in part, the requirements under sections III.C.1 through 4 and is provided during the current CIA year (i.e., since August 14, 2000) shall be deemed to satisfy the relevant training requirements for the current CIA year.

8. *New Covered Persons*. Affected new Covered Persons shall receive the applicable training required by this CIA within the following time frames: General Compliance Training pursuant to paragraph III.C.1 within 30 days of commencing work; Specific Training pursuant to paragraph III.C.2 within 60 days of commencing work; Cost Report Training pursuant to paragraph III.C.3 within 60 days of commencing work; and Clinical Laboratory Training pursuant to paragraph III.C.4 within 30 days of commencing work or within 90 days of the effective date of this CIA, whichever is later. If a new Covered Person is in a position for which training is required under paragraphs III.C.2, C.3, or C.4 of this CIA and begins to perform his/her position responsibilities prior to receiving all the training required for that position, a Straub employee who has completed all the necessary training shall take appropriate steps to supervise that untrained person's work related to that substantive area in such a manner as to ensure that the person's work is performed in accordance with the applicable Federal health care program requirements, this CIA, and Straub's own Policies and Procedures.

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

10. *Contractors*. To the extent that Straub contracts with individuals or entities to provide services for which training is otherwise required under paragraphs III.C.1, C.2, C.3, or C.4 of this CIA, they may certify in writing to Straub that their personnel have undergone appropriate training applicable to the services provided to Straub. Such a certification would be in lieu of requiring the contractors' personnel to attend Straub's formal training programs.

11. *Courtesy Medical Staff*. Currently, a number of non-employed physicians maintain courtesy medical staff privileges at Straub. These courtesy medical staff physicians bill Federal health care programs for the professional component of services they provide while at Straub under their own names and provider numbers. Straub bills Federal health care programs for the technical

component of services ordered by these physicians and provided at Straub under its own name and provider number. Straub reviews courtesy medical staff privileges every two (2) years.

Physicians with courtesy medical staff privileges at Straub are required to comply with Straub's policies and procedures and this CIA. Straub shall provide sufficient supervision to ensure that courtesy medical staff physicians act in compliance with Straub's policies and procedures and this CIA and, in particular, to ensure that bills submitted to Federal health care programs under Straub's name and provider number for services ordered by courtesy medical staff physicians are accurate and appropriate.

Straub shall make available and encourage courtesy medical staff physicians to attend the General Compliance Training provided by Straub pursuant to section III.C.1 of this CIA. As part of the biennial credentialing process, courtesy medical staff physicians are required either to attend specific training provided by Straub pursuant to section III.C.2 of this CIA or to certify in writing to Straub that they have undergone such training at another hospital or institution and that such training is consistent with the applicable requirements of sections III.C.2. of this CIA. Notwithstanding any other provision of this CIA, the requirements of section III.C.11 are Straub's only obligations with respect to training of courtesy medical staff physicians.

D. Review Procedures.

1. *General Description.*

a. *Retention of Independent Review Organization.* Straub shall annually retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Straub in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA, the 1998 Settlement Agreement, and the 2000 Settlement Agreement. Each Independent Review Organization retained by Straub shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care programs from which Straub seeks reimbursement.

b. *Types of Engagements*. The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address Straub's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address Straub's compliance with the obligations assumed under this CIA, the 1998 Settlement Agreement, and the 2000 Settlement Agreement. ("Compliance Engagement").

c. *Frequency of Billing and Compliance Engagements.* The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning on August 14, 2000, the anniversary of the effective date of the original CIA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first and last one-year periods following the effective date of this revised CIA.

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

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

a. *Claims Review*. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Straub to the Medicare program. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

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

c. *Systems Review*. The IRO shall review Straub's billing and coding systems and/or operations and cost report preparation process (the

"Systems Review"). The Systems Review shall consist of a thorough review of the following:

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

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

iii. Straub's systems and/or operations relating to the preparation and submission of any cost reports to Federal health care programs (including, but not limited to, the steps Straub takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

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

i. the strengths and weaknesses in Straub's billing systems and/or operations;

ii. the strengths and weaknesses in Straub's coding systems and/or operations;

iii. the strengths and weaknesses in Straub's systems and/or operations for preparing and submitting cost reports to Federal health care programs; and

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

3. *Compliance Engagement.*

a. *Compliance Review.* The IRO shall conduct a review of Straub's compliance activities ("Compliance Review").

i. *CIA Obligations Review.* The IRO shall evaluate Straub's compliance with the obligations set forth in each section of this CIA and Straub's compliance with certain provisions of the 1998 Settlement Agreement and the 2000 Settlement Agreement.

ii. *Unallowable Costs Review.* The IRO shall determine whether Straub has complied with its obligation not to charge to, or otherwise seek payment from, any Federal health care program for unallowable costs (as defined in the 1998 Settlement Agreement and the 2000 Settlement Agreement).

b. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:

i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Straub's compliance with the terms of each section of the CIA, as applicable; and

ii. the IRO's findings and supporting rationale regarding whether Straub has complied with its obligation not to charge to, or otherwise seek payment from, any Federal health care program for unallowable costs (as defined in the 1998 Settlement Agreement and the 2000 Settlement Agreement).

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Straub's Billing or Compliance Engagement fails to conform to the requirements of this CIA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagements comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Straub agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in section II) is received by the OIG.

E. Confidential Disclosure Program.

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

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

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

F. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible.

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

3. *Review and Removal Requirement.* Straub shall review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists at least semi-annually. In addition, Straub shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee or contractor an Ineligible Person.

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

4. *Pending Charges and Proposed Exclusions.* If Straub has actual notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Straub shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Overpayments.*

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

b. Reporting of Overpayments. If, at any time, Straub identifies or learns of any overpayments, Straub shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of identification and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. The term "identification" as used in this paragraph refers to the existence of an overpayment, but not the exact amount of the overpayment. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

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

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

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

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

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

(iii) a description of Straub's actions taken to correct the Material Deficiency; and

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

IV. NEW BUSINESS UNITS OR LOCATIONS

Within 60 days of the effective date of this CIA, Straub shall provide OIG with a list of all of Straub's locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each Straub identification number. In the event that, after OIG receives the list mentioned above, Straub changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Straub shall notify OIG of this fact as soon

as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. ANNUAL REPORTS

A. Annual Reports. Straub shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Straub's compliance activities for each of the one-year periods beginning on August 14, 2000, the anniversary of the effective date of the original CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period.")

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Standards of Conduct certifications required by section III.B.1;

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

c. Straub has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Released Acts addressed in the 1998 Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from any Federal health care program payors for unallowable costs (as defined in the 1998 Settlement Agreement and the 2000 Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

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

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

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

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

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

7. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

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

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

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

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

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

13. the certification required by section V.C.

The first Annual Report under this revised CIA shall be received by the OIG no later than 60 days after August 14, 2001. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Annual Report shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Straub is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: Straub shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Straub shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Straub:

Compliance Officer
Straub Clinic and Hospital, Inc.
888 South King Street
Honolulu, Hawaii 96813
Phone 808.522.4114
Fax 808.522.4038

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

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Straub's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Straub's locations for the purpose of verifying and evaluating: (a) Straub's compliance with the terms of this CIA; and (b) Straub's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Straub 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 Straub'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. Straub agrees to assist OIG or its duly authorized representative(s) in contacting and

arranging interviews with such individuals upon OIG's request. Straub's employees may elect to be interviewed with or without a representative of Straub present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. PRIVILEGE AND DISCLOSURES

Nothing contained in this CIA shall constitute or be construed as a waiver by Straub of its attorney-client privilege, the attorney work product doctrine, or other applicable privileges.

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Straub prior to any release by OIG of information submitted by Straub pursuant to its obligations under this CIA and identified upon submission by Straub as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Straub shall have the rights set forth at 45 C.F.R. § 5.65(d). Straub shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Straub is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Straub and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Straub fails to have in place any of the following:

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

b. a Compliance Committee as described by section III.A.2;

c. written Standards of Conduct as described by section III.B.1;

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

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

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

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

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

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Straub employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Straub's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded or paid for any time period during which Straub can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

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

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

Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Straub of the failure to comply.)

B. Timely Written Requests for Extensions. Straub may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Straub fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after Straub 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 Straub 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 Straub of: (a) Straub's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Straub shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event Straub elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Straub cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

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

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

D. Exclusion for Material Breach of this CIA

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

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

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

c. 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 retain and use an Independent Review Organization in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Straub constitutes an independent basis for Straub's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Straub has materially breached this CIA and that exclusion should be imposed, OIG shall notify Straub of: (a) Straub'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.* Straub 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. Straub is in full compliance with this CIA;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Straub fails to satisfy the requirements of section X.D.3, OIG may exclude Straub from participation in the Federal health care programs. OIG shall notify Straub in writing of its determination to exclude Straub (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Straub wishes to apply for reinstatement, Straub must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Straub of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Straub shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Straub was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance.

Straub shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Straub to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Straub requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

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

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

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

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

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

(iii) Straub provided to OIG within that period a reasonable timetable for curing the material breach and Straub 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 Straub, only after a DAB decision in favor of OIG. Straub's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Straub upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Straub 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.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the 1998 Settlement Agreement and the 2000 Settlement Agreement, Straub and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Straub;

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

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

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

ON BEHALF OF STRAUB CLINIC & HOSPITAL, INC.

Kenneth Robbins MD

Kenneth Robbins, M.D.
President of Board of Directors
Straub Clinic & Hospital, Inc.

11/29/00
DATE

Sanford Teplitzky
Counsel for Straub Clinic & Hospital, Inc.
Ober, Kaler, Grimes & Shriver

12/5/00
DATE

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

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

12/13/00
DATE

APPENDIX A

A. Claims Review.

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

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

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

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

d. Paid Claim: A code or line item submitted by Straub and for which Straub has received reimbursement from the Medicare program

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

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

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

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

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

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

i. *Probe Sample with a Minimum Size of Thirty Items.* The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Straub for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of the Population (based on the amount of Overpayments received by Straub for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with

the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

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

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

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

under the Claims Review Report.

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

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

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

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Sources of Data: A description of the 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, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.

d. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.

e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. ***Claims Review Results***

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

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

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to

Straub, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

d. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

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

Attachment 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____ Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____
AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		_____
07 - Corrected CPT Code		

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND STRAUB CLINIC & HOSPITAL INC.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Straub Clinic & Hospital, Inc. ("Straub") entered into a revised Corporate Integrity Agreement ("CIA") on December 13, 2000.

A. Pursuant to section XI.C. of Straub's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Straub. Therefore, the OIG and Straub hereby agree that Straub's CIA will be amended as follows:

Section III.D., Review Procedures, of the CIA is hereby superceded by the attached new section III.D., Review Procedures.

Appendix A of Straub's CIA is hereby superceded by the attached new Appendix A.

B. The OIG and Straub agree that all other sections of Straub's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Straub.

C. The undersigned Straub signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF STRAUB CLINIC & HOSPITAL INC.

Raymond Vara
~~President and Chief Executive Officer~~ Chief Operating Officer
Straub Clinic and Hospital ~~Inc.~~

8/13/02
DATE

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

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

8/1/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Straub shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Straub in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the 1998 Settlement Agreement and 2000 Settlement Agreement. Each IRO retained by Straub shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Straub seeks reimbursement. Each IRO shall assess, along with Straub, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Straub's billing and coding to the Federal health care programs ("Claims Review"), shall analyze whether Straub sought payment for certain unallowable costs ("Unallowable Cost Review"), shall analyze Straub's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Review"), and shall conduct a review of Straub's cost report preparation and submission process ("Cost Report Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the effective date of this CIA.

d. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first and last one-year periods beginning with the effective date of this revised CIA.

e. Frequency of Cost Report Review. The Cost Report Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of the CIA. The IRO(s) shall perform all components of each annual Cost Report Review.

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

2. *Claims Review.* The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

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

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

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should 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 shall be reviewed based on supporting documentation available at Straub or under Straub'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, Straub may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Straub 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.

c. Systems Review. If Straub's Discovery Sample identifies an Error Rate of 5% or greater, Straub's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Straub the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, Straub agrees to 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. Straub agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

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

4. *Unallowable Cost Review.* The IRO shall conduct a review of Straub's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Straub has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the 1998 Settlement Agreement and 2000 Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Straub or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO will determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the 1998 Settlement Agreement and 2000 Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Straub has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the 1998 Settlement Agreement and 2000 Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

6. *Compliance Review.* The IRO shall conduct a review of Straub's compliance activities. The Compliance Review shall consist of a review of Straub's compliance with the obligations set forth in each section of this CIA.

7. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding Straub's compliance with the terms of each section of the CIA, as applicable.

8. *Cost Report Review.* The IRO shall conduct a review of Straub's systems and/or operations relating to the preparation and submission of any cost reports to Federal health care programs (including, but not limited to, the steps Straub takes to ensure that the proper information is being recorded on submissions to Federal health care programs

and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

9. *Cost Report Review Report.* The IRO shall prepare a report based upon the Cost Report Review performed. The Cost Report Review report shall include the IRO's finding and supporting rationale regarding the rationale regarding the strengths and weaknesses in Straub's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs.

10. *Validation Review.* In the event the OIG has reason to believe that: (a) Straub's Claims Review, Unallowable Cost Review, Compliance Review, and Cost Report Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Unallowable Cost Review, Compliance Review, and Cost Report Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Straub agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Straub's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Straub of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Straub may request a meeting with the OIG to discuss the results of any Claims Review, Unallowable Cost Review, Compliance Review, or Cost Report Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, Unallowable Cost Review, Compliance Review, Cost Report Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. Straub agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review, Compliance Review, Cost Report Review issues with Straub 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 the OIG.

11. *Independence Certification.* The IRO shall include in its report(s) to Straub a certification or sworn affidavit that it has evaluated its professional independence with

regard to the Claims Review, Unallowable Cost Review, Compliance Review, and Cost Report Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

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

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

c. Paid Claim: A code or line item submitted by Straub and for which Straub has received reimbursement from the Medicare program.

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

e. 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 or Full Sample (as applicable) 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. **Other Requirements.**

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

b. 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 associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, 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. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

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

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

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data. A description of the 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, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Statistical Sampling Documentation.**

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

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

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

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

a. Narrative Results.

i. A description of Straub'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) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Straub ("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 Straub.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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.