ATTACHMENT B

COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND INLAND PHYSICIANS' SERVICE, PHYSICIANS MANAGEMENT SERVICE, THOMAS A. WOODBURY, D.O., AND JAMES M. LALLY, D.O.

I. PREAMBLE

Inland Physicians' Service, Physicians Management Service, Thomas A. Woodbury, D.O., and James M. Lally, D.O. (hereinafter individually and/or collectively referred to as "IPS") hereby agree to enter into this Compliance Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to provide for the establishment of a Compliance Program to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs") by IPS, by any physician group billing Medicare, Medicaid or any other Federal health care program in which IPS has a direct or indirect ownership or control interest as defined in 42 U.S.C. § 1320a-3(a)(3), and by all individuals or entities responsible for providing patient care or billing services on behalf of IPS.

IPS's compliance with the terms and conditions in this Agreement shall constitute an element of IPS's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, IPS is entering into a separate and distinct Settlement Agreement with the OIG.

II. TERMS OF THE AGREEMENT

Unless otherwise specified, the period of compliance obligations assumed by IPS under this Agreement shall be five years from the date of execution of this Agreement, unless IPS pays in full the settlement amount sooner than five (5) years, in which case the period of compliance obligations will be the date of full payment, but which period

cannot be less than three (3) years. The effective date of this Agreement will be the date on which the final signatory to this Agreement executes this Agreement.

III. COMPLIANCE OBLIGATIONS

IPS agrees to implement a Compliance Program (the "Program"), which shall include the following provisions:

A. COMPLIANCE CONTACT

Within thirty (30) days of the effective date of this Agreement, IPS shall designate a person to serve as the contact person for purposes of the compliance obligations herein (hereinafter referred to as the "Compliance Contact"). In the event a new Compliance Contact is appointed during the term of this Agreement, IPS shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. WRITTEN STANDARDS

1. *Posted Notice.*

Within the first thirty (30) days following the effective date of this Agreement, IPS shall post in a prominent place accessible to all patients and employees a notice detailing its commitment to comply with all applicable statutes, regulations and directives applicable to the Federal health care programs in the conduct of its business. This notice shall include a description of IPS's obligations under this Agreement, and a method by which instances of misconduct can be reported anonymously (e.g., telephone number, address, etc.) to IPS's Compliance Contact.

2. *Policies and Procedures.*

Policies and Procedures. Within ninety (90) days of the effective date of this Agreement, IPS shall develop and initiate implementation of written Policies and Procedures regarding the operation of IPS's compliance program and its compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address:

a. The proper submission of claims to the Federal health care programs to the correct Medicare carrier;

b. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;

c. The accurate billing of claims for services rendered by physicians' assistants and nurse practitioners, including but not limited to, procedures to ensure the appropriate supervision of physicians' assistants and nurse practitioners by a physician or the proper use of a modifier;

d. The proper coding of Evaluation and Management services in compliance with federal requirements or guidelines then in effect; and

e. The commitment of IPS not to hire or engage as contractors with respect to the delivery of health care services any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

IPS shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to the OIG in the Implementation Report, as discussed in Section VI.A. below. The Policies and Procedures will be available to the OIG upon request.

Within ninety (90) days of the effective date of the Agreement, the relevant portions of the Policies and Procedures shall be distributed to: (i) all contractors and agents with direct involvement in the preparation or submission of claims for reimbursement on behalf of IPS; (ii) all individuals with direct involvement in the provision of patient care or the

documentation of medical services on behalf of IPS; and (iii) all employees of IPS and all employees of any physician group billing Medicare, Medicaid or any other Federal health care program in which IPS has a direct or indirect ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)). The individuals described in (i) (ii) and (iii) of this subparagraph shall be hereinafter collectively referred to as the "Covered Persons.") An individual knowledgeable in the subject matter shall be available to explain any and all Policies and Procedures.

C. TRAINING AND CERTIFICATION

Within ninety (90) days following the effective date of this Agreement, IPS and all personnel involved in preparing or submitting to the Federal health care program bills for services and items provided by IPS or any of its agents shall be trained in the proper billing standards, methods, and procedures to ensure accurate billing for services rendered to the Federal health care programs. The training shall be designed to ensure that IPS and all of its employees and agents are aware of all applicable health care statutes, regulations, and program guidelines and with the standards of business conduct that such individual is expected to follow and the consequences (i.e., termination, legal sanctions, etc.) both to the individual and IPS that will ensue from any violation of such requirements. This initial training program shall provide for no less than four (4) hours of training. In the second through fifth years of this Agreement, an additional two (2) hours of training shall be required annually.

In addition, IPS will arrange for all new personnel involved in billing for services to participate in such training no later than thirty (30) days after they begin working for IPS. Until they have completed the requisite training, such new employees will work under the direct supervision of an employee who has received such training.

At a minimum, the training sessions shall cover the following topics:

1. The submission of accurate bills for services rendered to Federal health care program beneficiaries;

2. Policies, procedures and other requirements applicable to the documentation of medical records;

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

4. Applicable reimbursement statutes, regulations, and program requirements and directives, including, where appropriate, the rules governing services rendered by physician's assistants;

5. The legal sanctions for improper billings; and

6. Examples of proper and improper billing practices.

All Covered Persons will sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the Policies and Procedures and all applicable Federal health care laws, including Medicare and Medicaid statutes, regulations and standards of business conduct. These certifications will be maintained by IPS and shall be made available for inspection by OIG or its duly authorized representatives.

D. INDEPENDENT AUDITS

Within one hundred and twenty (120) days of the effective date of this Agreement, IPS agrees to retain a third-party reviewer (e.g., audit or health care consulting firm) to undertake an annual review of a statistically valid sample of the paid claims submitted by IPS, its agents, contractors, and/or employees to the Federal health care programs to determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of federal health care statutes, regulations, program requirements, billing policies and procedures. These reviews shall be undertaken after the completion of each year in which this Agreement is in effect, at a time when claims submitted by the anniversary date of this Agreement will have been paid. The review shall cover the preceding one (1) year period and shall seek to determine that the claims submitted to and paid by Federal health care programs were covered services under applicable program guidelines and that the claims were appropriately coded and billed. The results of this review, including the amounts of any overpayments shall be submitted with the Annual Report, as discussed below in Section VI.B., along with a corrective action plan for correcting any deficiencies found.

1. ***Overpayments.***

   a. *Definition of Overpayments.* For purposes of this Agreement, an "overpayment" shall mean the amount of money IPS has received in excess of the amount due and payable for any claim or claims under the Federal health care programs' statutes, regulations or guidelines, including carrier instructions.

b. *Reporting of Overpayments.* If, at any time, IPS identifies or learns of any billing, coding or other policies, procedures and/or practices that result in overpayments, IPS shall notify the contractor (e.g., Medicare fiscal intermediary or carrier) and repay any overpayments in accordance with the Medicare contractor's policies within thirty (30) days of identification and take remedial steps within sixty (60) days of identification (or such additional time as may be agreed to by the contractor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, may be done pursuant to a form similar to the Overpayment Refund Form, provided as Attachment B.1 to this Agreement.

2. ***Material Deficiencies.***

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

      (1) A substantial overpayment relating to any Federal health care program; or

      (2) A matter that a reasonable person based upon credible evidence would consider a violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized.

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

a. *Reporting of Material Deficiencies.* If IPS determines that there is a Material Deficiency, IPS shall notify OIG within thirty (30) days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(1) 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 contractor required in Section D.1.b., and shall include all of the information on the Overpayment Refund Form, as well as:

(a) The contractor's name, address, and contact person to whom the overpayment was sent; and

(b) The date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded.

(2) A complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and program authorities implicated;

(3) A description of IPS's actions to correct the Material Deficiency; and

(4) Any further steps IPS plans to take to address such a Material Deficiency and prevent it from recurring.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, IPS will report to OIG any reliable evidence of actions occurring after the effective date of this Agreement that IPS believes constitute a probable violation of any state or federal civil, criminal or administrative statute or regulation governing a Federal health care program. IPS must make the required

disclosure no later than thirty (30) calendar days after determining that there is reliable evidence of a probable violation. This disclosure shall include only conduct by any of IPS's personnel and any Covered Person.

IPS will certify to OIG that any disclosures made under this Paragraph have been investigated and that appropriate corrective actions have been taken to attempt to ensure that IPS is in compliance with all state and federal civil, criminal, and administrative statutes, regulations and rules governing all Federal health care programs. Nothing in this Paragraph waives OIG's right to enforce any and all statutes and regulations governing any Federal health care program, subject to the release provisions of the Settlement Agreement signed this same date.

V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine IPS's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (i) IPS's compliance with the terms of this Agreement; and (ii) IPS's compliance with the requirements of the Federal health care programs. OIG or its designee(s) may conduct on-site visits at any time to review Federal health care program patient medical records and other related documentation for the purpose of verifying and evaluating IPS's compliance with the terms of this Agreement.

VI. REPORTS

A. IMPLEMENTATION REPORT

Within one-hundred and twenty (120) days of the effective date of this Agreement, IPS shall provide the OIG with a written report demonstrating that IPS has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

1. A copy of the notice IPS posted in its office as described in Section III.B.

2. A certification signed by IPS attesting that all Covered Persons have completed the initial training required by Section III.C. as well as a

summary of what the training included. The training materials will be made available to OIG upon request.

3. A copy of the written Policies and Procedures required by Section III.B. of this Agreement.

4. A certification signed by IPS's Compliance Contact attesting that he/she has reviewed the Implementation Report, he/she has made a reasonable inquiry regarding its content and believes that, upon his/her inquiry, the information is accurate and truthful.

B. ANNUAL REPORTS

Within ninety (90) days of the anniversary date of the effective date of this Agreement, IPS shall submit annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures IPS has taken to implement and maintain the Compliance Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

1. Any change in the identity of the Compliance Contact.

2. A certification signed by IPS attesting that all Covered Persons have completed the training required by Section III.C. as well as a summary of what the training included. The training materials will be made available to OIG upon request.

3. A description, schedule and topic outline of the training programs implemented pursuant to Section III.C. of this Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in Section III.C. of this Agreement.

4. A copy of the audit findings for reviews conducted pursuant to Section III.D. of this Agreement relating to the year covered by the Annual Report, with supporting documents submitted upon request; a complete description of the audit findings made during the reviews and audits; copies of the disclosure or notice documents made by IPS

pursuant to this section; and any future corrective actions IPS plans to initiate and when.

5. An aggregate listing of all overpayments relating to the year covered by the Annual Report.

6. A certification signed by IPS's Compliance Contact attesting that he/she has reviewed the Annual Report, he/she has made a reasonable inquiry regarding its content and believes that, upon its inquiry, the information is accurate and truthful.

7.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

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

All correspondence to IPS shall be sent to:

Thomas A. Woodbury, D.O.
Suite 201
4950 San Bernadino Avenue
Montclair, CA 91763
Ph. 909.625.4846
Fax 909.624.2258

VIII. NEW BUSINESS UNITS OR LOCATIONS

In the event that IPS changes locations or purchases or establishes new business units related to the furnishing of items or services that will be reimbursed by Federal health care programs after the effective date of this Agreement, IPS shall notify OIG of this fact as soon as possible, but no later than within thirty (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 Agreement (e.g., completing certifications and undergoing training).

IX. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by IPS shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by IPS.

A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If IPS engages in conduct that OIG considers to be a material breach, as defined below in subparagraph VIII.B., of this Agreement, OIG may seek exclusion of IPS from participation in the Federal health care programs. Upon making its determination, OIG shall notify IPS of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). IPS shall have thirty-five (35) days from the date of the letter to:

1. Cure the alleged material breach; or

2. Demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that IPS has begun to take action to cure the material breach and that IPS will pursue such action with due diligence. IPS shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If, at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and IPS), IPS fails to act in accordance with

provisions 1 and 2 above, OIG may exclude IPS from participation in the Federal health care programs. OIG will notify IPS in writing of its determination to exclude IPS (this letter shall be referred to hereinafter as the "Exclusion Letter").

B. DISPUTE RESOLUTION

Upon OIG's delivery to IPS of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, the OIG may initiate proceedings to undertake appropriate administrative action, including exclusion, for a material breach of this Agreement. IPS shall be entitled to certain due process rights afforded in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005. Specifically, the OIG's determination to seek exclusion shall be subject to review by an HHS Administrative Law Judge ("ALJ") in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2 *et seq*. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. However, IPS agrees that the decision by the DAB, if any, shall constitute the final decision and no appeal right shall be afforded to Federal court.

For purposes of this section, a "material breach" shall mean: (i) a failure to comply with the requirements of Sections III.D and IV of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section VI of this Agreement; or (iii) a failure to retain and use an independent reviewer for review purposes in accordance with Section III.D.

X. EFFECTIVE AND BINDING AGREEMENT

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

1. This Agreement shall be binding on the successors, assigns and transferees of IPS;

2. This Agreement shall become final and binding only upon signing by each respective party hereto;

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

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

IPS

3/10/2000
Date

Inland Physicians' Service
Suite 201
4950 San Bernardino Avenue
Montclair, CA 91763
909-625-4846

3/10/2000
Date

Physicians Management Service
Suite 201
4950 San Bernardino Avenue
Montclair, CA 91763
909-625-4846

3/10/2000
Date

Thomas A. Woodbury, D.O.
Suite 201
4950 San Bernardino Avenue
Montclair, CA 91763
909-625-4846

3-9-2000
Date

James M. Lally, D.O.
Suite 201
4950 San Bernardino Avenue
Montclair, CA 91763
909-625-4846

Date

Counsel for IPS

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

3-27-07
Date

D. McCarty Thornton, Esquire
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

AMENDMENT TO THE COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND INLAND PHYSICIANS' SERVICE, PHYSICIANS MANAGEMENT SERVICE, THOMAS A. WOODBURY, D.O., AND JAMES M. LALLY, D.O.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Inland Physicians' Service, Physicians Management Service, Thomas A. Woodbury, D.O., and James M. Lally, D.O. ("IPS") entered into a Compliance Agreement ("Agreement") on March 27, 2000.

A. Pursuant to section X.3. of the Agreement, modifications to the Agreement may be made with the prior written consent of both the OIG and IPS. Therefore, the OIG and IPS hereby agree that IPS' Agreement will be amended as follows:

The first paragraph of Section III.D., Independent Audits, of the Agreement is hereby superceded by the attached new section III.D., Review Procedures.

Section III.D.1 (Overpayments) III.D.2 (Material Deficiencies) are re-numbered Section III.E.1 and 2.

The attached Appendix A is hereby added to IPS' Agreement.

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

C. The undersigned IPS signatories represent and warrant that they are 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. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF IPS

Thomas A. Woodbury, D.O.
(on behalf of himself and Inland Physicians' Service and Physicians Management Service)

10/18/2002
DATE

James M. Lally, D.O.
(on behalf of himself and Inland Physicians' Services and Physicians Management Service)

10/18/02
DATE

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

Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

12/4/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the effective date of this Agreement, IPS shall retain an entity, such as an auditing or health care consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist IPS in assessing and evaluating its billing and coding practices and systems. The IRO retained by IPS shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this Agreement and in the general requirements of the Federal health care program(s) from which IPS seeks reimbursement. The IRO shall assess, along with IPS, 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 review shall address and analyze IPS's billing and coding to the Federal health care programs ("Claims Review").

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

c. Retention of Records. The IRO and IPS 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 IPS) 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 Agreement, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of IPS to Federal heath care programs. The Paid Claims shall be reviewed based on the supporting documentation available at IPS or under IPS'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, IPS should, as appropriate, further analyze any errors identified in the Discovery Sample. IPS 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 IPS or under IPS'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, IPS 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 IPS 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 IPS's Discovery Sample identifies an Error Rate of 5% or greater, IPS'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 IPS 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 E of the Agreement, IPS 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. IPS 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. *Validation Review.* In the event the OIG has reason to believe that: (a) IPS's Claims Review fails to conform to the requirements of this Agreement; 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 complied with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). IPS 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 IPS'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 IPS 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, IPS may request a meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. IPS 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 issues with IPS 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.

5. *Independence Certification.* The IRO shall include in its report(s) to IPS a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims 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 IPS 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 IPS and for which IPS has received reimbursement from a Federal health care program.

d. Population: All Items for which IPS has submitted a code or line item and for which IPS has received reimbursement from a Federal health care 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 IPS cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by IPS 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 IPS'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 IPS ("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 IPS.

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.

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 Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt