

**COMPLIANCE AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
HEALTHTEXAS MEDICAL GROUP OF SAN ANTONIO**

**I. PREAMBLE**

HealthTexas Medical Group of San Antonio (“HTMG”) hereby enters into this Compliance Agreement (“Agreement”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal health care program requirements”). Contemporaneously with this Agreement, HTMG is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

**II. TERM AND SCOPE OF THE AGREEMENT**

A. The period of the compliance obligations assumed by HTMG under this Agreement shall be three years from the effective date of this Agreement (“Effective Date”) (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this Agreement executes this Agreement. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (A) HTMG’s final annual report; or (B) any additional materials submitted by HTMG pursuant to OIG’s request, whichever is later.

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

1. “Covered Persons” includes:
  - a. all physicians and employees of HTMG; and
  - b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of HTMG at HTMG’s office locations.

2. "Covered Persons" does not include "Temporary Staff" as defined below in Section II.C.3.
3. "Temporary Staff" includes any physicians, employees, contractors, or agents who would otherwise be covered under Section II.C.1, engaged to work at HTMG office locations on a contractual basis or otherwise for 160 hours or less, out of any consecutive 52-week period during the term of this Agreement. Physicians, employees, contractors, or agents who work greater than 160 hours at HTMG office locations shall be required to fulfill all obligations required of Covered Persons.

### III. INTEGRITY OBLIGATIONS

HTMG shall maintain a Compliance Program that includes the following elements:

#### A. Compliance Contact

To the extent HTMG has not already done so, within 30 days of the Effective Date, HTMG shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, HTMG shall notify the OIG, in writing, within 30 days of such a change.

#### B. Posting of Notice

Within the 30 days of the Effective Date, HTMG shall post in a prominent place in its offices accessible to all patients and Covered Persons a notice detailing HTMG's commitment to comply with all Federal health care program requirements in the conduct of its business. This notice shall include a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report.

#### C. Written Policies and Procedures

To the extent not already done so, within 120 days of the Effective Date, HTMG shall develop, implement, and make available to all Covered Persons written policies that address the following:

1. HTMG's commitment to operate HTMG's business in full compliance with all Federal health care program requirements;
2. HTMG's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with HTMG's own Policies and Procedures as implemented pursuant to Section III.C (including the requirements of this Agreement);
3. The requirement that all of HTMG's Covered Persons shall be expected to report to HTMG or the Compliance Contact suspected violations of any Federal health care program requirements or HTMG's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect;
4. HTMG shall ensure that all Covered Persons and Temporary Staff are not Ineligible Persons. For purposes of this Agreement, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. To ensure that such persons are not Ineligible Persons, HTMG shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying 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://oig.hhs.gov>) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) HTMG to refrain from billing Federal health care programs for services of the Ineligible Person. In addition to prospective checks, HTMG shall conduct annual checks of all Covered Persons and Temporary Staff against the Exclusion Lists annually;
5. The commitment of HTMG to remain current with all Federal health care program requirements;
6. The proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements; and

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

At least annually (and more frequently, if appropriate), HTMG shall assess and update as necessary the Policies and Procedures. To the extent not already distributed, within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

Within 120 days of the Effective Date and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by HTMG's Policies and Procedures as described above. New Covered Persons shall review the Policies and Procedures as described above and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days of the Effective Date of the Agreement, whichever is later.

Copies of the written policies and procedures shall be included in the Implementation Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

#### D. Training and Certification

Within 120 days of the Effective Date and at least once each year thereafter, Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive appropriate and adequate training from an individual or entity with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for the types of services provided by HTMG.

New Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive the training described above within 30 days after becoming a Covered Person or within 120 days of the Effective Date, whichever is later. Until they have received the requisite training, such New Covered Persons shall work under the supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;
2. The written Policies and Procedures developed pursuant to Section III.C., above;
3. The legal sanctions for improper billing or other violations of the Federal health care program requirements; and
4. Examples of proper and improper billing practices.

Each Covered Person shall annually 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. HTMG shall retain the certifications, along with the training course materials. The certification may be completed at the training session or at some other point during each Reporting Period. The training course materials shall be made available to the OIG upon request.

Training provided to Covered Persons within 6 months prior to the Effective Date that satisfies the requirement of this Section III.D shall be deemed to meet the training requirements of Section III.D.

#### E. Third Party Billing

HTMG presently contracts with a third party billing company to submit claims to the Federal health care programs. HTMG represents that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If HTMG intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, HTMG shall notify the OIG 30 days prior to any such proposed involvement.

#### F. Review Procedures

##### 1. *General Description.*

- a. Retention of Independent Reviewer. HTMG has represented to OIG that it presently contracts with an independent reviewer through its third party billing company. HTMG shall continue to retain that reviewer or

another individual or entity (or entities), such as an accounting, auditing, or consulting firm or nurse reviewer (hereinafter "Independent Reviewer" or "IR"), to perform reviews to assist HTMG in assessing and evaluating its billing and coding practices. Each IR retained by HTMG shall have expertise in the billing, coding, reporting, and other requirements of physician practices and in the general requirements of the Federal health care program(s) from which HTMG seeks reimbursement. Each IR shall assess, along with HTMG, whether it can perform the IR review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. The IR(s) review shall address and analyze HTMG's billing and coding to the Federal health care programs ("Claims Review") and if applicable, shall analyze whether HTMG sought payment for certain unallowable costs ("Unallowable Cost Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IR(s) shall perform all components of each annual Claims Review; however, subject to approval from OIG, and subject to the conditions set forth in Section III.F.8, HTMG may elect to conduct an Internal Claims Review for one or more of the three Reporting Periods.

c. Frequency of Unallowable Cost Review. If applicable, the IR shall perform the Unallowable Cost Review for the first Reporting Period.

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

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

a. Discovery Sample. The IR or HTMG, subject to the conditions set forth in Section III.F.8, below, shall randomly select and review a sample of 10 Medicare Paid Claims submitted by or on behalf of HTMG per physician at HTMG who is a Covered Person as defined in Section II.C. The Paid Claims shall be reviewed based on the supporting documentation available at HTMG, under HTMG's control, or at health

care facilities where HTMG provides patient care items or services, 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 a 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, HTMG should, as appropriate, further analyze any errors identified in each Discovery Sample. HTMG recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in each Discovery Sample.)

ii. If a Discovery Sample indicates that the Error Rate is 5% or greater, the IR or HTMG, as applicable, shall perform a Full Sample and a Systems Review for the Medicare Paid Claims of the physician, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IR or HTMG, as applicable, shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. Each Full Sample shall be designed to (i) 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 (ii) 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 HTMG, under HTMG's control, or at health care facilities where HTMG provides patient care items or services, 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 each Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, HTMG may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 10 Items, as part of its Full Sample. OIG, in its full discretion, may refer the findings of each Full Sample (and any related workpapers) received from HTMG 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 one of HTMG's Discovery Samples identifies an Error Rate of 5% or greater, HTMG's IR or HTMG, as applicable, shall also conduct a Systems Review for such Discovery Sample. Specifically, for each claim in the Discovery Sample and the Full Sample that resulted in an Overpayment, the IR, or HTMG, as applicable, shall 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 IR or HTMG, as applicable, shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.

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

3. *Claims Review Report*. The IR or HTMG, as applicable, 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*. HTMG represents that it does not submit cost reports to any Federal health care program. In the event that HTMG does have occasion to submit such cost reports, the IR or HTMG, as applicable, shall conduct a review of HTMG's compliance with the unallowable cost provisions of the Settlement Agreement. The IR shall determine whether HTMG 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 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 HTMG 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 IR shall determine if such adjustments were proper. In making this determination, the IR may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* If applicable, the IR shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IR's findings and supporting rationale regarding the Unallowable Costs Review and whether HTMG 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 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. *Validation Review.* In the event OIG has reason to believe that: (a) HTMG's Claims Review or Unallowable Cost Review fails to conform to the requirements of this Agreement; or (b) the IR's findings, or HTMG's internal audit findings, as applicable, or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). HTMG shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after HTMG's final submission (as described in Section II) is received by OIG.

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

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

8. *Internal Claims Review Option.*

- a. Subject to approval from OIG and subject to the conditions set forth below, HTMG may, at its option, conduct an internal review of its

billings to the Federal health care programs in lieu of having an IR conduct the Claims Review. This internal review shall comply with all applicable requirements outlined in this Section III.F.2.

b. If HTMG chooses to exercise the Internal Claims Review Option, the results shall be validated by an IR for the first Reporting Period and one additional Reporting Period to be selected by the OIG (“Verification Review”). As part of any such Verification Review the IR shall review at least 20% of the claims reviewed by HTMG in its Internal Claims Review.

c. Prior to conducting its Internal Claims Review, HTMG agrees: i) to develop and adopt a written formal internal audit work plan consistent with the terms of this Agreement; ii) to devote sufficient resources and staff to enable it to accomplish an Internal Claims Review based on its internal work plan; and iii) that its Internal Claims Review staff shall at all times include persons qualified and experienced in accepted auditing and control processes, who possess expertise in billing, coding, and Medicare program requirements. In addition, HTMG agrees that its Internal Claims Review staff shall not include persons who were involved in the submission of bills or claims to the Medicare programs during the period to be audited and shall not include persons who are presently involved in such submissions.

d. If, in its sole discretion, OIG determines that such Internal Claims Review satisfactorily establishes the adequacy of HTMG’s billing and compliance practices pursuant to this Agreement, the OIG will allow HTMG to perform subsequent Internal Claims Reviews in lieu of the IR conducting the Claims Review. Consistent with the requirements of Section III.F.2, the Internal Claims Review shall include a Claims Review and the required respective reports of HTMG’s findings.

e. In the event that OIG determines, in its sole discretion, that HTMG is unable to satisfactorily implement an audit work plan, devote sufficient resources and appropriate qualified staff, or conduct the Internal Claims Review, HTMG agrees, at OIG’s discretion, to engage the IR to complete all remaining Claims Review requirements under this Agreement. To the extent that OIG permits HTMG to perform Internal Claims Reviews, HTMG shall submit all the information required in Section III.F.2 as well as the results of the IR’s verification. If HTMG decides not to exercise

its Internal Claims Review Option, the requirements of the IR Claims Review shall remain in effect for the term of the Agreement.

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

#### G. Notification of Government Investigation or Legal Proceedings

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

#### H. Reporting

##### 1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "Overpayment" shall mean the amount of money HTMG has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, HTMG identifies or learns of any Overpayment, HTMG shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after determining there is credible evidence of the Overpayment and take remedial steps within 60 days after such determination (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after determining that there is credible evidence of the Overpayment, HTMG shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after determining that there is credible evidence of the overpayment, HTMG shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the

payor shall be done in accordance with the payor's policies, and for Medicare contractors. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures. Routine adjustments to claims performed as part of the normal course of business at HTMG need not be reported as required by this Section III.J.1.b.

## 2. *Material Deficiencies.*

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

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

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

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

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

(B) the date of the check and identification number (or electronic transaction number) by 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 HTMG's actions taken to correct the Material Deficiency; and
- iv. any further steps HTMG plans to take to address the Material Deficiency and prevent it from recurring.

#### IV. NEW BUSINESS UNITS OR LOCATIONS

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

#### V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, HTMG shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This Implementation Report shall include:

1. The name, address, and phone number of HTMG's Compliance Contact;
2. A copy of the notice HTMG posted in HTMG's office as described in Section III.B;
3. A copy of the written policies and procedures required by Section III.C. of this Agreement;
4. A description of the training required by Section III.D, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held, and upon request, a copy of all materials used for the training;

5. A certification signed by HTMG's Compliance Contact attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;
7. the identity of the IR(s), a summary/description of all engagements between HTMG and the IR, as applicable, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the Claims Review, Unallowable Cost Review, or Systems Review;
8. a certification from the IR regarding its professional independence and/or objectivity from HTMG;
9. A list of all HTMG's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the name and address of the Medicare contractor to which HTMG currently submits claims; and
10. a certification from the HTMG's Compliance Contact stating that he or she has reviewed the Implementation Report, he or she has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports. HTMG shall submit to OIG Annual Reports with respect to the status of, and findings regarding, HTMG's compliance activities for each of the three Reporting Periods.

Each Annual Report shall include:

1. If revisions were made to the written policies and procedures developed pursuant to Section III.C, a copy of any policies and procedures that were revised;
2. A certification by HTMG's Compliance Contact that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C;

3. A schedule and topic outline of the training materials for the training programs attended in accordance with Section III.D, and upon request, copies of these training materials;
4. A certification signed by HTMG's Compliance Contact certifying that he or she is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D;
5. A complete copy of all reports prepared pursuant to the IR or HTMG's Internal Claims Review, including the Claims Review Report and Unallowable Cost Review Report, if applicable, along with a copy of the IR's engagement letter;
6. HTMG's response and corrective action plan(s) related to any issues raised or recommendations made by the IR;
7. A summary/description of all engagements between HTMG and the IR, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
8. A certification from the IR regarding its professional independence from HTMG;
9. A summary of Material Deficiencies (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
10. 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;
11. A certification signed by HTMG certifying that all Covered Persons and Temporary Staff are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and

12. A certification signed by HTMG's Compliance Contact certifying that he or she has reviewed the Annual Report, he or she has made a reasonable inquiry regarding its content, and he or she believes that, upon such inquiry, the information is accurate and truthful.

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

#### **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this Agreement shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies 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, S.W.  
Washington, D.C. 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

HealthTexas Medical Group of San Antonio:

Richard Reyna, M.D.  
HealthTexas Medical Group of San Antonio  
215 E. Quincy St. #500  
San Antonio, TX 78215

Unless otherwise specified, all notifications and reports required by this Agreement 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 HTMG's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of HTMG's locations for the purpose of verifying and evaluating: (a) HTMG's compliance with the terms of this Agreement; and (b) HTMG's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by HTMG 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 HTMG'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. HTMG shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. HTMG's employees may elect to be interviewed with or without a representative of HTMG present after being informed that they have the option to be interviewed with a HTMG representative present. Nothing in this Agreement, or any communication or report made pursuant to this Agreement, shall constitute a waiver of, or be construed to require HTMG to waive HTMG's attorney-client, work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect HTMG's obligation to comply with the provisions of this Agreement, e.g., by providing all documents necessary to determine whether HTMG is in compliance with the terms of this Agreement.

## **VIII. DOCUMENT AND RECORD RETENTION**

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

## **IX. DISCLOSURES**

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

**X. BREACH AND DEFAULT PROVISIONS**

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

**A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, HTMG and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day HTMG fails to:

- a. have in place a Compliance Contact as required in Section III.A;
- b. post the notice required in Section III.B;
- c. implement and make available the Policies and Procedures required in Section III.C;
- d. require that Covered Persons attend the training required by Section III.D. within the time frames required in that Section;
- e. submit the IR’s annual Claims Review Report as required in Section III.F and Appendix A; or
- f. meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day HTMG employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, HTMG’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 Section shall not be demanded for any time period during which HTMG can demonstrate that HTMG did not discover the person’s exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.4) as to the status of the person).

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

4. A Stipulated Penalty of \$750 for each day HTMG fails to comply fully and adequately with any obligation of this Agreement. In its notice to HTMG, OIG shall state the specific grounds for its determination that HTMG has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the HTMG must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date HTMG receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Subsections 1-3 of this Section.

#### **B. Timely Written Requests for Extensions**

HTMG 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 Agreement. 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 HTMG fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after HTMG 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 HTMG 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 HTMG of: (a) HTMG's failure to comply; and (b) 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, HTMG shall respond by either: (a) curing the breach to OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event HTMG elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HTMG 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 Agreement 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 HTMG has materially breached this Agreement, 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 Agreement**

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

- a. a failure by HTMG to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.F;
- b. a repeated or flagrant violation of the obligations under this Agreement, 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 Reviewer in accordance with Section III.F.

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

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, HTMG fails to satisfy the requirements of Section X.D.3, OIG may exclude HTMG from participation in the Federal health care programs. OIG will notify HTMG in writing of its determination to exclude HTMG (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 nonprocurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, HTMG wishes to apply for reinstatement, HTMG 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 HTMG of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, HTMG 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 Agreement. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (“DAB”), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days 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 Agreement shall be: (a) whether HTMG was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. HTMG shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders HTMG to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless HTMG 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 Agreement shall be:

- a. whether HTMG was in material breach of this Agreement;
- 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) HTMG had begun to take action to cure the material breach within that period;
  - (ii) HTMG has pursued and is pursuing such action with due diligence; and
  - (iii) HTMG provided to OIG within that period a reasonable timetable for curing the material breach and HTMG 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 HTMG, only after a DAB decision in favor of OIG. HTMG's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude HTMG upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that HTMG 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. HTMG agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of HTMG, HTMG will be reinstated effective on the date of the original exclusion.

#### **XI. 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, HTMG and the OIG agree as follows:

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

2. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
4. OIG may agree to a suspension of HTMG's obligations under this Agreement in the event of HTMG's cessation of participation in Federal health care programs. If HTMG withdraws from participation in Federal health care programs and is relieved from its Agreement obligations by the OIG, HTMG agrees to notify the OIG 30 days in advance of HTMG's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the Agreement should be reactivated or modified; and
5. The undersigned HTMG 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.

ON BEHALF OF HEALTHTEXAS MEDICAL GROUP OF SAN ANTONIO



Richard Reyna, M.D.  
HealthTexas Medical Group

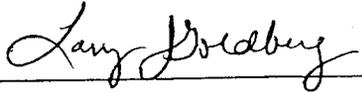
3/14/03  
DATE



Gary W. Eiland  
Counsel for HealthTexas Medical Group

3-17-2003  
DATE

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



\_\_\_\_\_  
Larry J. Goldberg  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

3/19/03  
DATE

## 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 HTMG 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 HTMG and for which HTMG has received reimbursement from the Medicare program.

d. Population: All Items for which HTMG has submitted a code or line item and for which HTMG 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 each Discovery Sample or each 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 HTMG cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by HTMG 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 a Discovery Sample or a 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 IR 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 each Discovery Sample and, if applicable, in each 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 IR.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in each 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 HTMG'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 IR's or HTMG's findings, as applicable, and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of each Discovery Sample, and the results of each 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 IR, or HTMG, as applicable, determined that the Paid Claims submitted by HTMG ("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 HTMG.

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: 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 IR), correct allowed amount (as determined by the IR), and 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: (a) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (b) performed the Claims Review.

C. Verification Review Report. The following information shall be included in the Verification Review Report generated by the IR:

1. *Claims Review Verification Methodology*

a. Verification Review Objective: A clear statement of the objective intended to be achieved by the IR's Verification Review.

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

c. Verification Review Population: A description of the Population subject to the IR's Verification Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of practitioners from which the IR's Verification Review 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. Sources of Data: A description of the documentation relied upon by the IR when performing the Verification 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 Verification Review was conducted by the IR and what was evaluated.

## 2. *Statistical Sampling Documentation*

a. The number of Items appraised in the IR's Verification Review Sample.

b. The Sampling Frame used in the IR's Verification Review Sample will be available to the OIG upon request

## 3. *Verification Review Results*

a. Total number and percentage of instances in which the IR determined that the IR's Paid Claim determinations differed from the HTMG's Paid Claim determinations.

b. Total number and percentage of instances in which HTMG's Paid Claim determinations differed from the IR's Paid Claim determinations and in which HTMG determined the Paid Claim to be reimbursed at a higher amount than the IR.

c. Total number and percentage of instances in which HTMG's Paid Claim determinations differed from the IR's Paid Claim determinations and in which HTMG determined the Paid Claim to be reimbursed at a lesser amount than the IR.

d. The dollar difference amounts, by paid claim, in which, HTMG's and the IR's reimbursement determination differed.

e. A spreadsheet of the IR Verification Review Results that includes the following information for each Paid Claim appraised: beneficiary health insurance claim number; date of service; procedure code submitted to payor; procedure code reimbursed by payor; allowed amount reimbursed by payor;

correct procedure code as determined by HTMG; correct procedure code as determined by the IR; correct allowed amount as determined by HTMG; correct allowed amount as determined by the IR; dollar difference between correct allowed amount as determined by HTMG; and correct allowed amount as determined by the IR. (See Attachment 2 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 Verification Review; and (2) performed the Verification Review.



