

EXHIBIT A

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES
AND
SHASTA COUNTY**

I. PREAMBLE

Shasta County (“Shasta”) hereby agrees to enter into this Integrity Agreement (the “IA”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance by Shasta’s Mental Health Department (“MHD”) and all departments and entities within MHD’s control, its physicians, employees, officers, directors, contractors, agents, third parties engaged to bill or submit reimbursement claims, and all other individuals responsible for the provision, marketing, or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services 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)) (hereinafter collectively referred to as the “Federal health care programs”). Contemporaneously with this IA, Shasta is entering into a Settlement Agreement with the United States, and this IA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE IA AND DEFINITIONS

A. Term of the IA

The period of compliance obligations assumed by Shasta under this IA shall be five (5) years from the date of execution of this IA (unless otherwise specified). The effective date of this IA will be the date on which the final signatory of this IA executes this IA.

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

B. Definitions

1. *Covered Individuals.* Except as otherwise provided within this IA, the term "Covered Individuals" shall refer to all of MHD's employees, and all of MHD's contractors and individuals with responsibilities pertaining to the ordering, provision, documentation, coding or billing of services payable by a Federal health care program for which MHD seeks reimbursement from the Federal health care programs.

2. *Off-Site Contractor Providers.* The term "Off-Site Contractor Providers" refers to Covered Individuals who contract with MHD (or who are employed by or sub-contract with a person or entity who contracts with MHD) to provide services at locations that are not owned or leased by MHD. This term does not include Covered Individuals with responsibilities for coding or billing of services for which MHD seeks reimbursement from the Federal health care programs.

3. *Pre-Existing Contractors.* The term "Pre-Existing Contractors" refers to Covered individuals who are independent contractors with whom MHD has an existing contract on the effective date of this IA that has not been renewed or modified after the effective date of this IA. Once MHD renegotiates, modifies, or renews a contract with an existing contractor, that contractor ceases to be a Pre-Existing Contractor as that term is used for the purposes of this IA, and MHD will have full responsibility for the certification and training compliance obligations as pertain to that contractor.

III. INTEGRITY OBLIGATIONS

MHD hereby agrees to establish a Compliance Program that includes the following elements.

A. Compliance Officer and Committee

1. *Compliance Officer.* Within 90 days after the effective date of this IA, MHD shall appoint an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this IA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of MHD, shall make periodic (at least quarterly) reports regarding compliance matters directly to the County Administrative Officer and shall be authorized to report on such matters to both the County Administrative Officer and the Board of Supervisors of Shasta at any time. The Compliance Officer shall be responsible for

monitoring the day-to-day activities engaged in by MHD as well as for any reporting obligations created under this IA.

Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this IA, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* Within 90 days of the effective date of this IA, MHD shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers necessary to meet the requirements of this IA within MHD's organizational structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this IA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards

1. *Code of Conduct.* Within 90 days of the effective date of this IA, MHD shall establish a Code of Conduct. Except as further provided below, the Code of Conduct shall be distributed to all Covered Individuals within 90 days of the effective date of this IA. The Code of Conduct shall, at a minimum, set forth:

- a. MHD's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. MHD's requirement that all Covered Individuals shall be expected to comply with all Federal health care program requirements and with MHD's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of

this IA);

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

d. the possible consequences to MHD and to any Covered Individual of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with MHD's own Policies and Procedures or of failure to report such non-compliance; and

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

Except as otherwise provided in section III.B.1, within 90 days of the effective date of the IA, each Covered Individual shall certify, in writing, that he or she has received, read, understood, and will abide by MHD's Code of Conduct. New Covered Individuals shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Individual or within 90 days of the effective date of the IA, whichever is later.

MHD shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Individuals shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the finalization of such revisions.

For Off-Site Contractor Providers, MHD shall require in its contracts with the contracting individuals or entities through which the Off-Site Contractor Providers are associated with MHD that (1) the contractors acknowledge MHD's Compliance Program and Code of Conduct; (2) the Code of Conduct (including the toll-free telephone number) will be provided (either by MHD or the contracting entity) to all Covered Individuals who are employees of MHD contractors; and (3) the contractors obtain and retain (subject to review by MHD and/or OIG) signed certifications that each such individual has received,

has read, and understands the MHD Code of Conduct and agrees to abide by the requirements of MHD's Compliance Program. MHD shall make a good faith effort to ensure that the above obligations are met by the Off-Site Contractor Providers. If an Off-Site Contractor Provider is also a Pre-Existing Contractor, then the exceptions for Pre-Existing Contractors, as set forth in section III.C.6, below, may be applied to that MHD contractor.

MHD shall distribute the Code of Conduct to all Pre-Existing Contractors (as defined in section II.B.3, above). Within 90 days of the effective date of the IA, MHD shall use its best efforts to obtain written certification from each Pre-Existing Contractor that he, she, or it has received, has read, understands, and will abide by MHD's Code of Conduct. Any revisions to the Code of Conduct shall be distributed to each Pre-Existing Contractor within 30 days of initiating the changes. MHD shall use its best efforts to obtain on an annual basis written certification from each Pre-Existing Contractor that he, she, or it has received, read, understands, and will abide by MHD's Code of Conduct. MHD shall maintain records of the percentage of Pre-Existing Contractors who provide such certifications.

Within 30 days of the effective date of this IA, MHD shall commence making the promotion of and adherence to the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees.

2. *Policies and Procedures.* Within 90 days of the effective date of this IA, MHD shall implement written Policies and Procedures regarding the operation of MHD's compliance program and its compliance with Federal health program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in section III.B.1;
- b. the requisite qualifications required by a health care professional to render mental health services and treatments under the Medicare program;
- c. the requirement that MHD staff review mental health services and treatments to be billed to the Federal health care programs to ensure that the claims for such services as coded accurately reflect the level of service provided to its patients;
- d. the development, documentation, and operation of medically necessary individualized treatment plans as a requirement for Medicare

reimbursement for mental health services and treatments; and

e. the requirement that MHD staff review mental health services and treatments to be billed to Federal health care programs to determine they are properly documented as being medically necessary under the relevant program requirements.

The Policies and Procedures shall be available to OIG, upon request.

Within 90 days of the effective date of the IA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), MHD shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education

1. *General Training.* Within 90 days of the effective date of this IA, MHD shall provide at least two (2) hours of training to each Covered Individual. This General Training shall explain MHD's:

- a. Integrity Agreement requirements; and
- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues)

These training materials shall be made available to the OIG, upon request.

New Covered Individuals shall receive the General Training described above within 30 days of the beginning of their employment or contract, or within 90 days after the effective date of this IA, whichever is later. After the first year, each Covered Individual shall receive at least one hour of general training annually.

2. *Reimbursement Training.* Within 90 days of the effective date of this IA, each

Covered Individual who has responsibility for, or who supervises any person who has responsibility for, the preparation or submission (including, but not limited to, coding and billing) of claims (other than cost reports) for reimbursement for patient care, either provided on MHD's premises or for which MHD seeks reimbursement from the Federal health care programs, shall receive at least four (4) hours of Reimbursement Training in addition to the General Training required above. This Reimbursement Training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program patients;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

These training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Affected new Covered Individuals shall receive the Reimbursement Training within thirty (30) days of the beginning of their employment or contract, or within 90 days of the effective date of this IA, whichever is later. If a new Covered Individual has responsibility for, or supervises any person who has responsibility for, the preparation or submission of claims for reimbursement for patient care (including, but not limited to, coding and billing) for any Federal health care programs prior to completing this Reimbursement Training, a Covered Individual who has completed the Reimbursement Training shall review all of the untrained person's work regarding the preparation or submission of claims.

Each year, each Covered Individual who has responsibility for, or who supervises any person who has responsibility for, the preparation or submission of claims for reimbursement for patient care (including, but not limited to, coding and billing) for any

Federal health care programs shall receive an additional four (4) hours of such Reimbursement Training.

3. *Patient Care Training.* Each Covered Individual who has responsibility for, or who supervises any person who has responsibility for, the ordering, prescribing, provision or documentation of patient care or medical items or services at MHD or for which MHD seeks reimbursement shall receive at least four (4) hours of Patient Care Training in addition to the General Training required above. The Patient Care Training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program patients;
- b. MHD's billing process and an explanation of the role provider documentation plays in this process;
- c. policies, procedures and other requirements applicable to the documentation of medical records;
- d. the personal obligation of each individual involved in the documentation and billing process to ensure that such documentation and billings are accurate;
- e. applicable reimbursement statutes, regulations, and program requirements and directives, including any regulations related to medical necessity;
- f. the legal sanctions for improper documentation and billings; and
- g. examples of proper and improper patient file documentation.

These training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Affected new Covered Individuals shall receive this Patient Care Training within thirty (30) days of the beginning of their employment or contract, or within 90 days of the effective date of this IA, whichever is later. If a new Covered Individual has responsibility for, or supervises any person who has responsibility for, the ordering, prescribing, provision or documentation of patient care or medical items or services prior to completing this Patient Care Training, a Covered Individual who has completed the

Patient Care Training shall review all of the work of the untrained persons related to those responsibilities.

Each year, each Covered Individual who has responsibility for, or supervises any person who has responsibility for, the ordering, prescribing, or provision of patient care or medical items or services shall receive an additional four (4) hours of such Patient Care Training.

4. *Exception for Off-Site Contractor Providers.* Notwithstanding any other provision of this IA, the following are MHD's only obligations with respect to training and certification of Off-Site Contractor Providers. MHD shall make the General Training and the Patient Care Training, where appropriate, available to all Off-Site Contractor Providers, and shall use its best efforts to encourage their attendance and participation. MHD shall maintain records of the Off-Site Contractor Providers who attend such training. Such records shall be available for inspection by OIG.

5. *Exception for Pre-Existing Contractors.* Notwithstanding any other provision of this IA, the following are MHD's only obligations hereunder with respect to training and certification for Pre-Existing Contractors. MHD shall attempt to renegotiate contracts with Pre-Existing Contractors to require such contractors to meet all of the certification and training requirements of this IA. MHD shall make the General Training, the Reimbursement Training, and the Patient Care Training, where appropriate, available to all Pre-Existing Contractors, and shall use its best efforts to encourage their attendance and participation. The Compliance Officer shall keep a record of all Pre-Existing Contractors who do and do not attend such training.

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

D. Review Procedures

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1. General Description.

a. **Retention of Independent Review Organization.** Within 90 days of the effective date of this IA, MHD shall retain an entity (or

entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform review engagements to assist MHD in assessing and evaluating its billing and coding practices and its compliance obligations pursuant to this IA and the Settlement Agreement. Each Independent Review Organization retained by MHD shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this IA and in the general requirements of the Federal health care program(s) from which MHD seeks reimbursement. Each IRO shall assess, along with MHD, whether it can perform the IRO engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

b. *Types of Engagements.* The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address MHD’s billing and coding to the Federal health care programs (“Billing Engagement”). The second engagement shall address MHD’s compliance with the obligations assumed under this IA and the Settlement Agreement (“Compliance Engagement”).

c. *Frequency of Billing and Compliance Engagements.* The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this IA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this IA.

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

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

a. *Claims Review.* The IRO shall perform a Claims Review to

identify any overpayments through an appraisal of Paid Claims submitted by MHD to the Medicare program. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this IA.

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

c. Systems Review. The IRO shall review MHD’s billing and coding systems and/or operations and cost report preparation process (the “Systems Review”). The Systems Review shall consist of a thorough review of the following:

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

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

iii. MHD’s cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps MHD takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

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

- i. the strengths and weaknesses in MHD's billing systems and/or operations;
- ii. the strengths and weaknesses in MHD's coding systems and/or operations;
- iii. the strengths and weaknesses in MHD's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs; and
- iv. any recommendations the IRO may have to improve any of these systems, operations, and processes.

3. *Compliance Engagement.*

a. **Compliance Review.** The IRO shall conduct a review of MHD's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Shasta's compliance with the obligations set forth in each section of this IA, and a review of Shasta's compliance with certain provisions of the Settlement Agreement.

i. **IA Obligations Review.** The IRO shall evaluate Shasta's compliance with the obligations set forth in each section of this IA.

ii. **Unallowable Costs Review.** The IRO shall determine whether MHD 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 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 Shasta or any of its departments, and to request, and agree, that such cost reports, cost statements, information reports or payment requests,

even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year of the Settlement Agreement, as well as from previous years.

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

- i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Shasta's compliance with the terms of each section of the IA, as applicable; and
- ii. the IRO's findings and supporting rationale regarding whether Shasta 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

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Shasta's Billing or Compliance Engagement fails to conform to the requirements of this IA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the IA and/or the findings or Claims Review results are inaccurate. Shasta 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 Shasta's final submission (as described in section II) is received by the OIG.

E. Disclosure Program

Within 90 days after the effective date of this IA, MHD shall establish a Disclosure Program, which must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with MHD's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be inappropriate. MHD shall

publicize the existence of the disclosure mechanism (e.g., e-mail to employees or post hotline number in prominent common areas).

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

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

F. Ineligible Persons

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

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

3. *Review and Removal Requirement.* Within 90 days of the effective date of this IA, MHD will review its list of current employees and contractors against the Exclusion Lists. Thereafter, MHD will review the Exclusion Lists semi-annually. In addition, MHD shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

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

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

G. Notification of Proceedings

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

H. Reporting

1. Overpayments

a. Definition of Overpayments. For purposes of this IA, an "overpayment" shall mean the amount of money MHD has received in excess of the amount due and payable under any Federal health

care program requirements. MHD may not subtract any underpayments for purposes of determining the amount of relevant “overpayments” for IA reports.

b. Reporting of Overpayments. If, at any time, MHD identifies or learns of any overpayments, MHD shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, MHD shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, MHD 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 contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. Material Deficiencies.

a. Definition of Material Deficiency. For purposes of this IA, a “Material Deficiency” means anything that involves:

- (i) a substantial overpayment;
- (ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or
- (iii) a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in

high-risk situations.

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

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

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

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

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

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

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

(iv) any further steps MHD 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 of this IA, MHD changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Shasta shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location,

purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Individuals at such locations shall be subject to the applicable requirements in this IA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this IA, MHD shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. a copy of MHD's Code of Conduct required by section III.B.1;
4. the summary of the Policies and Procedures required by section III.B.2;
5. a description of the training programs required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been distributed to all pertinent Covered Individuals;
 - b. all Covered Individuals have completed the Code of Conduct certification required by section III.B.1; and
 - c. all appropriate Covered Individuals have completed the General Training, Reimbursement Training, and Patient Care Training, and executed the certification required by section III.C;

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

7. a description of the efforts made to amend contracts with Pre-Existing Contractors and to provide training to Pre-Existing Contractors and encourage their attendance, and a report of the percentage of Pre-Existing Contractors who have: (a) completed the Code of Conduct certification; and (b) attended the training described in section III.C.

8. a description of the Disclosure Program required by section III.E;

9. the identity of the IRO and the proposed start and completion dates of the first review;

10. a summary of personnel actions taken pursuant to section III.F;

11. a list of all of Shasta'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 contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of Shasta's organizational structure, including identification of any departments and divisions, and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. MHD shall submit to OIG Annual Reports with respect to the status of and findings regarding of MHD's compliance activities for each of the five one-year periods beginning on the effective date of the IA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

- a. all Covered Individuals have completed the annual Code of Conduct certification required by section III.B.1;
- b. all Covered Individuals have completed the training and executed the certification required by section III.C; and
- c. MHD has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims, and (ii) 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 and adjust any past charges of unallowable costs;

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
4. a description of the efforts made to amend contracts with Pre-Existing Contractors and to provide training to Pre-Existing Contractors and encourage their attendance, and a report of the percentage of Pre-Existing Contractors who have: (a) completed the Code of Conduct certification; and (b) attended the training described in section III.C;
5. a description of the training required by section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
7. MHD's response and corrective action plan to any issues raised by the IRO(s);

8. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
9. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
10. a copy of the disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
11. a description of any personnel actions (other than hiring) taken by MHD as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the name, title, and responsibilities of any person that falls within that ambit of section III.F.4 and the actions taken in response to the obligations set forth in that section;
12. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that MHD has committed a crime or has engaged in fraudulent activities which 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;
13. a description of all changes to the most recently provided list (as updated) of MHD's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and
14. the certification required by section V.C.

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

Report.

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

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this IA, all notifications and reports required under this IA shall be submitted to the entities listed below:

OIG:

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

MHD:

Clarice Gay, R.N.
Shasta County Mental Health Services
P.O. Box 496048
2640 Breslauer Way

Redding, CA 96049-6048
Phone 530.225.5200
Fax 530.225.5977

Unless otherwise specified, all notifications and reports required by this IA 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 MHD's books, records, and other documents and supporting materials and/or conduct an on-site review of any of MHD's locations for the purpose of verifying and evaluating: (a) MHD's compliance with the terms of this IA; and (b) MHD's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by MHD 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 MHD'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. MHD agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. MHD's employees may elect to be interviewed with or without a representative of MHD present.

VIII. DOCUMENT AND RECORD RETENTION

MHD shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this IA, for one year longer than the term required of the IA (or longer if otherwise required by law).

IX. DISCLOSURES

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

shall have the rights set forth at 45 C.F.R. § 5.65(d). MHD shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Shasta is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Shasta and OIG hereby agree that failure to comply with certain obligations set forth in this IA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 90 days after the effective date of this IA and concluding at the end of the term of this IA, MHD fails to have in place any of the following:

- a. a Compliance Officer as described by section III.A.1;
- b. a Compliance Committee as described by section III.A.2;
- c. a written Code of Conduct as described by section III.B.1;
- d. written Policies and Procedures as described by section III.B.2;
- e. a requirement that Covered Individuals be trained as described in section III.C; and
- f. a Disclosure Program as described by section III.E.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MHD fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day MHD:

a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which MHD can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, MHD'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 (this Stipulated Penalty shall not be demanded for any time period during which MHD can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the MHD fails to grant access) for each day MHD fails to grant access to the information or documentation as required in section VII of this IA.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to MHD of the failure to comply) for each day MHD fails to comply fully and adequately with any obligation of this IA. In its notice to MHD, OIG shall state the specific grounds for its determination that the MHD has failed to comply fully and adequately with the IA obligation(s) at issue.

B. Payment of Stipulated Penalties

1. *Demand Letter.* Upon finding that MHD has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Shasta by personal service or certified mail of (a) MHD's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, MHD shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below

in section X.D. In the event MHD elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until MHD cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions.* MHD may submit a timely written request for an extension of time to perform any act or file any notification or report required by this IA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after MHD fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after MHD receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

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 otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Shasta has materially breached this IA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this IA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that, consistent with the procedures set forth in this IA, a material breach of this IA by MHD constitutes an independent basis for MHD's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that MHD has materially breached this IA and that exclusion should be imposed, the OIG shall notify MHD by certified mail of (a) MHD'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").

2. *Opportunity to cure.* MHD shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

- a. MHD is in full compliance with this IA;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 35-day period, but that: (i) MHD has begun to take action to cure the material breach, (ii) MHD is pursuing such action with due diligence, and (iii) MHD has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, MHD fails to satisfy the requirements of section X.C.2, OIG may exclude MHD from participation in the Federal health care programs. OIG will notify MHD in writing of its determination to exclude MHD (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If MHD is excluded under the provisions of this IA, MHD may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this IA means:

- a. a failure by MHD to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;
- b. repeated or flagrant violations of the obligations under this IA, including, but not limited to, the obligations addressed in section X.A of this IA;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
- d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to MHD of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this IA, MHD shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this IA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within ten (10) days of MHD's receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this IA shall be (a) whether MHD was in full and timely compliance with the obligations of this IA for which OIG demands payment; (b) the period of noncompliance; and (c) with respect to a stipulated penalty authorized under section X.A.5 only, whether the failure to comply could not be cured within the 10-business-day period, but that by the end of that period (i) MHD had begun to take action to cure the failure to comply, (ii) MHD was and is pursuing such action with due diligence, and (iii) MHD had provided to OIG a reasonable timetable for curing the breach which is being followed. MHD shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this IA and orders MHD to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that MHD may request review of the ALJ decision by the DAB.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be (a) whether MHD was in material breach of this IA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that (i) MHD had begun to take action to cure the material breach within the 35 day period, (ii) MHD is pursuing such action with due diligence, and (iii) MHD provided to OIG within the 35 day period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. MHD's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude MHD upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that MHD may request review of the ALJ decision by the DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This IA shall be binding on the successors, assigns, and transferees of Shasta or MHD;

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

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

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

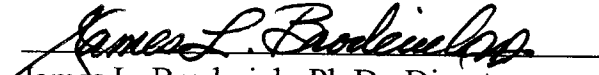
ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



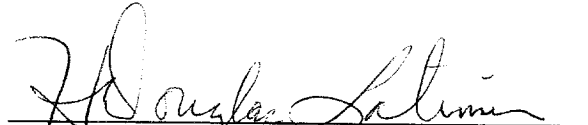
LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

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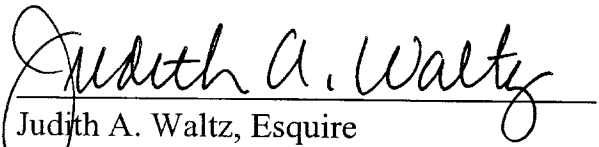
ON BEHALF OF SHASTA COUNTY


James L. Broderick, Ph.D., Director
(530) 225-5200

1-30-01
DATE


H. Douglas Latimer
County Administrative Officer
(530) 225-5550

1-30-01
DATE


Judith A. Waltz, Esquire
Counsel for Shasta County
(415) 438-6412
Approved as to Form and Content

3-12-01
DATE

APPENDIX A

A. Claims Review.

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

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

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

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

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

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

f. **Probe Sample:** A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of Overpayments in the Population. The estimated mean and standard deviation of Overpayments in the Population are to be used to calculate the minimum number of Items that shall be included in the Claims Review Sample in order to achieve the required confidence and precision levels.

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

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

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

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

i. ***Probe Sample with a Minimum Size of Thirty Items.*** The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by MHD for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in

the Population, and entering this information into the “Variable Appraisals”, “Difference Values Only” function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of Overpayments in the Population (based on the amount of Overpayments received by MHD for each sample Item) shall be determined from this Probe Sample, using RAT-STATS’ “Difference Values Only” function located under the “Variable Appraisals” component. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

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

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Claims Review Sample. In order to estimate the number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. Whereas the Claims Review Sample size is estimated from the results of the probe sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer will not be required to examine additional items.

The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

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

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

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the

Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

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

1. *Claims Review Methodology*

- a. Claims Review Objective: A clear statement of the objective intended to be achieved by the Claims Review.
- b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).
- c. Claims Review Population: A description of the Population subject to the Claims Review.
- d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.
- e. Sources of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation*

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

Review Sample.

- b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.
- c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.
- d. A copy of the RAT-STATS printout of the "Variable Appraisals", "Difference Values Only" function results for the Probe Sample, including a copy of the data file.
- e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. *Claims Review Results*

- a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by MHD ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to MHD.
- c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to MHD, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.
- d. The level of precision achieved by the Claims Review at a 90% confidence level.

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

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

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____
 AMOUNT OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

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

**AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SHASTA COUNTY**

The Office of Inspector General (“OIG”) of the Department of Health and Human Services and Shasta County (“Shasta”) entered into an Integrity Agreement (“IA”) on March 12, 2001.

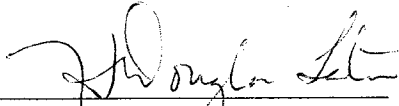
- A. Pursuant to Section XI.C. of Shasta’s IA, modifications to the IA may be made with the prior written consent of both the OIG and Shasta. Therefore, the OIG and Shasta hereby agree that Shasta’s IA will be amended as follows:

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

Appendix A of Shasta’s IA is hereby superceded by the attached new Appendix A.

- B. The OIG and Shasta agree that all other sections of Shasta’s IA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Shasta.
- C. The undersigned Shasta signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.
- D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF SHASTA COUNTY



H. Douglas Latimer
County Administrative Officer

3-12-02

DATE

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



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

3/6/02

DATE

D. Review Procedures.

1. *General Description.*

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

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

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

d. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of this IA.

e. Frequency of Cost Report Review. The Cost Report Review shall be performed annually and shall cover each of the one-year periods of the IA

beginning with the effective date of the IA. The IRO(s) shall perform all components of each annual Cost Report Review.

f. Retention of Records. The IRO and MHD 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 MHD) 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 IA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of MHD. The Paid Claims shall be reviewed based on the supporting documentation available at MHD or under MHD'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, MHD should, as appropriate, further analyze any errors identified in the Discovery Sample. MHD 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 MHD or under MHD'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, MHD 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 MHD 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 MHD's Discovery Sample identifies an Error Rate of 5% or greater, MHD'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 MHD the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

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

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

4. *Unallowable Cost Review*. The IRO shall conduct a review of MHD's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether MHD 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 MHD or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO will determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether MHD 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. *Compliance Review.* The IRO shall conduct a review of MHD's compliance activities. The Compliance Review shall consist of a review of MHD's compliance with the obligations set forth in each section of this IA.

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

8. *Cost Report Review.* The IRO shall conduct a review of MHD's cost report preparation process. The Cost Report Review shall consist of a thorough review of MHD's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps MHD takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

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

10. *Validation Review.* In the event the OIG has reason to believe that: (a) MHD's Claims Review, Unallowable Cost Review, Compliance Review, or Cost Report Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Unallowable Cost Review, Compliance Review, or Cost Report Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). MHD 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 MHD'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 MHD 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, MHD may request a meeting with the OIG to discuss the results of any Claims Review, Unallowable Cost Review, Compliance Review, or Cost Report Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, Unallowable Cost Review, Compliance Review, or Cost Report Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. MHD agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review, Compliance Review, or Cost Report Review issues with MHD prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

11. *Independence Certification.* The IRO shall include in its report(s) to MHD a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review, Unallowable Cost Review, Compliance Review, and Cost Report Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

- a. Overpayment: The amount of money MHD 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 MHD and for which MHD has received reimbursement from the Medicare program.
- d. Population: All Items for which MHD has submitted a code or line item and for which MHD has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

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

2. **Other Requirements.**

- a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which

MHD cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by MHD 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 MHD’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 MHD (“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 MHD.

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.