#### CORPORATE INTEGRITY AGREEMENT

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

INTREPID USA HEALTHCARE SERVICES

#### I. PREAMBLE

Intrepid USA Healthcare Services and all entities owned, operated, managed, or administered by Intrepid that provide or perform home health care services ("Intrepid"), the purchaser of Meridian Corporation a/k/a Medshares, Inc., and their subsidiaries hereby enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Contemporaneously with this CIA, Intrepid is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

## II. TERM AND SCOPE OF THE CIA

- A. The period of the compliance obligations assumed by Intrepid under this CIA shall be 5 years from the effective date of this CIA ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."
- B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Intrepid's final annual report; or (2) any additional materials submitted by Intrepid pursuant to OIG's request, whichever is later.
  - C. The scope of this CIA shall be governed by the following definitions:
    - 1. "Covered Persons" includes all:

- a. 1) officers; 2) managers; 3) administrators; directors and 4) employees (including physicians);
- b. Covered Contractors": includes any contractor, agent, or other third party or individual who is engaged to participate directly in the preparation or submission of claims, reports, or other requests for payment on behalf of Intrepid for which Intrepid seeks payment from any Federal health care program; and/or directly furnish patient care items or services at any Intrepid facility for which Intrepid seeks payment from any Federal health care program; and
- c. "Temporary Staff": include any staff retained to work at Intrepid on a contractual basis or otherwise for 140 hours or less out of any consecutive 52-week period during the term of this CIA. Temporary staff who work greater than 140 hours are required to fulfill all obligations required of Covered Persons unless such persons meet the definition of Covered Contractors, in which case such persons are required to fulfill all obligations required of Covered Contractors.
- 2. "Relevant Covered Persons" includes all Covered Persons and Covered Contractors that provide patient care items or services to Federal health care program beneficiaries or that perform billing or coding functions for patient care items or services that are reimbursed by Federal health care programs on behalf of Intrepid.

# III. CORPORATE INTEGRITY OBLIGATIONS

Intrepid shall establish a Compliance Program that includes the following elements:

## A. Compliance Officer and Committee.

1. Compliance Officer. Within 120 days after the Effective Date, Intrepid 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 CIA and with Federal health care program requirements. The Compliance Officer shall be a senior-level employee of Intrepid, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Intrepid, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities in furtherance of the integrity obligations established under the Agreement.

Intrepid shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. Compliance Committee. Within 120 days after the Effective Date, Intrepid shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior level employees of relevant departments, 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).

Intrepid shall report to OIG, in writing, 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 CIA, within 15 days after such a change.

# B. Written Standards.

1. Code of Conduct. Within 120 days after the Effective Date, Intrepid shall establish a written Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons and Covered Contractors within 120 days after the Effective Date. Intrepid shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Intrepid's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Intrepid's requirement that all of its Covered Persons and Covered Contractors shall be expected to comply with all Federal health care program requirements and with Intrepid's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Intrepid's Covered Persons and Covered Contractors shall be expected to report to the Compliance Officer or other appropriate individual designated by Intrepid suspected violations of any Federal health care program requirements or of Intrepid's own Policies and Procedures;
- d. the possible consequences to Intrepid and Covered Persons and Covered Contractors of failure to comply with Federal health care program requirements and with Intrepid's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and Intrepid's commitment to maintain confidentiality, as appropriate, and nonretaliation with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person and Covered Contractor shall certify, in writing, that he or she has received, read, understood, and shall abide by Intrepid's Code of Conduct. New Covered Persons and Covered Contractors shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or Covered Contractor or within 120 days after the Effective Date, whichever is later.

Intrepid 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 after finalizing such changes. The requirement to distribute a revision shall be satisfied by publishing it on Intrepid's intranet system, coupled with an electronic message to Covered Persons notifying them of

the revisions and the requirement to read, understand, and abide by it. Each Covered Person and Covered Contractor shall certify that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of such revisions.

- 2. Policies and Procedures. Within 120 days after the Effective Date, Intrepid shall implement written Policies and Procedures regarding the operation of Intrepid's compliance program and its compliance with Federal health care 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 requirements that apply to physician signatures to certify care (including that they be genuine);
  - c. The requirement that medical records be maintained in their original state and not improperly altered or fabricated;
  - d. The requirement that items and services are to be billed to Medicare, Medicaid and other Federal health care program only once, unless re-billing is appropriate;
  - e. The circumstances under which re-billing to Federal health care programs is appropriate; and
  - f. The proper submission of cost reports to Federal Health Care Provider.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

Procedures. The requirement shall be satisfied by publishing the revised Policies and Procedures on Intrepid's intranet system, coupled with an electronic message to Covered Persons whose job functions related to those revised Policies and Procedures notifying them of the revisions.

# C. Temporary Staff Requirements

Within 5 business days of commencing work for Intrepid, Intrepid shall obtain written documentation from its Temporary Staff showing:

- 1. Code of Conduct. That the Temporary Staff has received and read Intrepid's Code of Conduct and that the Temporary Staff understands that Intrepid's Code of Conduct applies to the Temporary Staff.
- 2. Policies and Procedures. That the Temporary Staff received and read all Intrepid's Policies and Procedures, if any, applicable to the job functions for which the Temporary Staff has been engaged.
- 3. Disclosure Program. That the Temporary Staff has received notice of and education on the appropriate use of the Disclosure Program.
- 4. General and Specific Training. That the Temporary Staff received appropriate training for the services for which the Temporary Staff has been engaged by Intrepid. Temporary Staff are not required to receive either General or Specific training required by this CIA, provided Intrepid obtains and maintains all documentation evidencing compliance with this Section III.C.

# D. Training and Education.

- 1. General Training. Within 120 days after the Effective Date, Intrepid shall provide at least two hours of general training to each Covered Person and Covered Contractor (except as otherwise provided in section D.4). This training, at a minimum, shall explain Intrepid's:
  - a. CIA requirements; and
  - b. Compliance Program including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues,

including Intrepid's commitment to prepare and submit accurate claims consistent with Federal health care program requirements, including, but not limited to, the following:

- i. the requirement that home health care services be medically necessary; and
- ii. the requirements that beneficiaries receiving home health care services be homebound as determined by Medicare regulations then in effect.

New Covered Persons shall receive the general training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

- 2. Specific Training. Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least 6 hours of specific training in addition to the general training required above. This specific training shall include a discussion of the following:
  - a. the submission of accurate claims for services rendered to Federal health care program beneficiaries;
  - b. policies, procedures, and other requirements applicable to the documentation of medical records;
  - c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
  - d. applicable reimbursement statutes, regulations, and program requirements and directives;
  - e. the legal sanctions for improper claims
  - f. the requirements that apply to physician signatures to certify care (including that they be genuine);

- g. the requirement that medical records be maintained in their original state and not be fabricated or improperly altered; and
- h. examples of proper and improper claims submission practices.

Persons providing the training shall be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment, beginning to furnish services as Covered Contractors, becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An Intrepid employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, each Relevant Covered Person shall receive at least 4 hours of specific training annually. Intrepid shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

- 3. Certification. Each individual who is required to attend training shall certify, in writing (or in electronic form, if he or she has received computer-based training), that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.
- 4. Covered Contractor Requirements. Where a Covered Contractor is not a sole physician practitioner, Intrepid shall require the Covered Contractor to: (a) identify a point of contact who will attend Intrepid's general and specific training; (b) agree to provide training on the topics outlined in Section III.D.2 to employees working on Intrepid matters; and (c) certify to Intrepid that all employees working on Intrepid matters have received such training. Intrepid shall also make its general and specific training available to all Covered Contractor employees and shall use its best efforts to encourage their attendance and participation. The Compliance Officer shall keep a record of all

Covered Contractor certifications and Covered Contractors who are sole physician practitioners who attend the general and specific training.

#### E. Review Procedures.

- 1. General Description.
  - a. Retention of Independent Review Organization. Within 120 days after the Effective Date, Intrepid 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 Intrepid in assessing and evaluating its billing and coding practices and certain other obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by Intrepid shall have expertise in the billing, coding, reporting, and other requirements of home health care services and in the general requirements of the Federal health care program(s) from which Intrepid seeks reimbursement. Each IRO shall assess, along with Intrepid, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. The IRO(s) review shall address and analyze Intrepid's billing and coding to the Federal health care programs ("Claims Review") and shall analyze whether Intrepid sought payment for certain unallowable costs ("Unallowable Cost Review").
  - b. <u>Frequency of Claims Review</u>. The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.
  - c. <u>Selection of Facilities Subject to Claims Review</u>. The Claims Review shall consist of a review of a sample of Federal health care program claims from each of one-fifth (but in no event less than five Intrepid Facilities) of distinct Intrepid owned, operated, managed, or administered facilities providing home health services ("Intrepid Facilities"). Within 15 days after the first Reporting Period, and annually thereafter, Intrepid shall submit to the OIG a document (the

"List") listing all Intrepid Facilities. For each Intrepid Facility, the List shall identify the number of Federal health care beneficiaries treated during the immediately preceding Reporting Period [e.g., the first Reporting Period in the first year]. The List shall rank the Intrepid Facilities from highest to lowest Federal health care program billings. The OIG shall select the Intrepid Facilities to be subject to the Claims Review from the List. If, during the term of the CIA, either the OIG or Intrepid determines that a method other than selecting Intrepid Facilities from the List would identify a sample of more appropriate facilities for a Claims Review, the Parties agree to consider adopting that alternative method of selection. If, during the term of the CIA, the number of Intrepid Facilities increases and decreases, either OIG or Intrepid may propose an alternate percentage or population of such facilities to be subject to a Claims Review.

- c. <u>Frequency of Unallowable Cost Review</u>. The IRO shall perform the Unallowable Cost Review for the first Reporting Period.
- d. <u>Retention of Records</u>. The IRO and Intrepid shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Intrepid) related to the reviews.
- 2. Claims Review. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.
  - a. <u>Discovery Sample</u>. The IRO shall randomly select and review from each Intrepid Facility selected to be subject to a Claims Review a sample of 30 Federal health care program Paid Claims submitted by or on behalf of Intrepid or the Intrepid Facility. The Paid Claims shall be reviewed based on the supporting documentation available at Intrepid or under Intrepid'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, Intrepid and/or the Intrepid Facility should, as appropriate, further analyze any errors identified in the Discovery Sample. Intrepid recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)
- 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 shall be designed to (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Intrepid or under Intrepid'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, Intrepid may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 30 Items, as part of its Full Sample. OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Intrepid 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 a Discovery Sample identifies an Error Rate of 5% or greater in any of the Intrepid Facilities selected for a Claims Review, Intrepid's IRO shall also conduct a Systems Review of that Intrepid Facility. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.
- d. Repayment of Identified Overpayments. In accordance with Section III.I.1, Intrepid shall repay 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. Intrepid shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.
- 3. Claims Review Report. The IRO shall prepare a report based upon the Claims Review performed on each Intrepid Facility subject to the Claims Review (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 Intrepid's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Intrepid 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 Intrepid 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 shall 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 Intrepid has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.
- 6. Validation Review. In the event OIG has reason to believe that: (a) Intrepid's Claims Review(s) or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review(s) results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review(s) or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review(s) results are inaccurate ("Validation Review"). Intrepid shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Intrepid's final submission (as described in Section II) is received by OIG.

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

7. Independence/Objectivity Certification. The IRO shall include in its report(s) to Intrepid a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with

regard to the Claims Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

# F. Disclosure Program.

Within 120 days after the Effective Date, Intrepid shall establish a disclosure Program, which shall 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 Intrepid's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. Intrepid shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall publish and display in an obvious place a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure related to a Federal health care program or abuse or neglect of a patient 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, Intrepid shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

#### G. <u>Ineligible Persons</u>.

1. Definition. For purposes of this CIA, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise

ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

- 2. Screening Requirements. Intrepid shall ensure that all owners, officers, directors, employees, contractors and agents of Intrepid are not Ineligible Persons. To ensure that such persons are not Ineligible Persons, Intrepid shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) Intrepid to refrain from billing Federal health care programs for services of the Ineligible Person.
- 3. Review and Removal Requirement. Within 120 days after the Effective Date, Intrepid shall review its list of the persons identified in Section III.F.2 against the Exclusion Lists. Thereafter, Intrepid shall review its list of such persons against the Exclusion Lists semi-annually. In addition, Intrepid shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If Intrepid has actual notice that such person has become an Ineligible Person, Intrepid shall remove such person from responsibility for, or involvement with, Intrepid's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation 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 Intrepid has actual notice that a person identified in Section F.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, Intrepid shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care

rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

# H. Notification of Government Investigation or Legal Proceedings.

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

# I. Reporting.

## 1. Overpayments

- a. <u>Definition of Overpayments</u>. For purposes of this CIA, an "Overpayment" shall mean the amount of money Intrepid has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, Intrepid identifies or learns of any Overpayment, Intrepid shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Intrepid shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Intrepid shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors, shall include the information contained

on the Overpayment Refund Form, provided as Appendix B to this CIA Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

- 2. Material Deficiencies.
  - a. <u>Definition of Material Deficiency</u>. For purposes of this CIA, a "Material Deficiency" means anything that involves:
    - i. a substantial Overpayment;
    - ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

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

- b. <u>Reporting of Material Deficiencies</u>. If Intrepid determines through any means that there is a Material Deficiency, Intrepid shall notify OIG, in writing, within 30 days after making the determination that the Material Deficiency exists. The report to OIG shall include the following information:
  - i. If the Material Deficiency results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:
    - (A) the payor's name, address, and contact person to whom the Overpayment was sent; and

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

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

iii. a description of Intrepid's actions taken to correct the Material Deficiency; and

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

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>Implementation Report</u>. Within 150 days after the Effective Date, Intrepid shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

- 2. The names and positions of the members of the Compliance Committee required by Section III.A;
- 3. a copy of Intrepid's Code of Conduct required by Section III.B.1;
- 4. a copy of all compliance-related Policies and Procedures required by Section III.B.2 and a summary of all other Policies and Procedures required by Section III.B.2;
- 5. a description of all training materials used for the training required by Section III.D, a description of such training, 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. All training materials must be made available to the OIG upon request;
- 6. a certification by the Compliance Officer that:
  - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons and Covered Contractors;
  - b. all Covered Persons and Covered Contractors have completed the Code of Conduct certification required by Section III.B.1; and
  - c. all Covered Persons and Covered Contractors have completed the applicable training and executed the certification(s) required by Section III.D.

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

- 7. a description of the Disclosure Program required by Section III.F;
- 8. the identity of the IRO(s), a summary/description of all engagements between Intrepid and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and

completion dates of the Claims Review, Unallowable Cost Review, or Systems Review;

- 9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Intrepid;
- 10. a summary of personnel actions (other than hiring) taken pursuant to Section III.G.;
- 11. a list of all of Intrepid Facilities where either (i) patient care items or services are provided to Federal health care program beneficiaries; or (ii) claims are prepared for submission to any Federal health care program (including locations and mailing addresses), the corresponding name under which each Intrepid Facility is doing business, the corresponding phone numbers and fax numbers, each Intrepid Facility's Medicare provider identification number(s), and the contractor's name and address that issued each provider identification number;
- 12. a description of Intrepid's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
- 13. the certification required by Section V.C.
- B. <u>Annual Reports</u>. Intrepid shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Intrepid's compliance activities for each of the five Reporting Periods.

# Each Annual Report shall include:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
- 2. a certification by the Compliance Officer that:
  - a. all Covered Persons and Covered Contractors have completed any Code of Conduct certifications required by Section III.B.1;

- b. all Covered Persons and Covered Contractors have completed the applicable training and executed the certification(s) required by Section III.D;
- c. Intrepid 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 Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

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

- 3. 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) and copies of any compliance-related Policies and Procedures or the updates from such Reporting Period;
- 4. a copy of all training materials used for the training required by Section III.D shall be made available to the OIG upon request (to the extent it has not already been provided as part of the Implementation Report), a description of such training 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;
- 5. a complete copy of all reports prepared pursuant to the IRO's Claims Review(s), Unallowable Cost Review, and Systems Review, if applicable, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
- 6. Intrepid's response and corrective action plan(s) related to any issues raised by the IRO(s);

- 7. a revised summary/description of all engagements between Intrepid and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
- 8. a certification from the IRO regarding its professional independence and/or objectivity with respect to Intrepid;
- 9. a summary of Material Deficiencies (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;
- 11. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 12. a description of any personnel actions (other than hiring) taken by Intrepid as a result of the obligations in Section III.G, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G., and the actions taken in response to the obligations set forth in that Section;
- 13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;
- 14. a description of all changes to the most recently provided list (as updated) of Intrepid Facilities (including addresses) as required by Section

V.A.11, the corresponding name under which each Intrepid Facility is doing business, the corresponding phone numbers and fax numbers, each Intrepid Facility's Medicare provider identification number(s), and the contractor name and address that issued each Medicare provider number; and

15. the certification required by Section V.C.

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

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Intrepid is in compliance with all of the requirements of this CIA; 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. <u>Designation of Information</u>. Intrepid 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 potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Intrepid shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

#### VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, D.C. 20201

Telephone: 202.619.2078 Facsimile: 202.205.0604

Intrepid: Intrepid USA Healthcare Services

Attention: Todd J. Garamella, President 6600 France Avenue South, Suite 510

Edina, Minnesota 55435 Telephone: 952.285.7300 Facsimile: 952.928.9795

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

# VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Intrepid's books, records, and other documents and supporting materials and/or conduct on-site reviews of Intrepid for the purpose of verifying and evaluating: (a) Intrepid's compliance with the terms of this CIA; and (b) Intrepid's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Intrepid 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 Intrepid'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. Intrepid shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Intrepid's employees may elect to be interviewed with or without a representative of Intrepid present.

#### VIII. DOCUMENT AND RECORD RETENTION

Intrepid shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 years (or longer if otherwise required by law).

#### IX. DISCLOSURES

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

# X. Ownership, Control, or Sale Involving Former Chief Executive Officer, Stephen H. Winters

Intrepid shall take all reasonable steps to prevent Medshare's former Chief Executive Officer, Stephen H. Winters or any of his immediate family members, as defined by 42 U.S.C. § 1320a-7(j), from obtaining ownership or control of Intrepid or its successor corporations or from purchasing from Intrepid any health care assets, including but not limited to provider agreements, Certificates of Need, and home health care licenses. Breach of this provision shall constitute a material breach of this CIA. Intrepid shall submit a yearly certification in its annual report to the OIG that Intrepid has no connection, as described in this Paragraph, with Stephen H. Winters or any of his family members.

## XI. Breach and Default Provisions

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

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Intrepid and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.
- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Intrepid fails to have in place any of the obligations described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.
- 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 Intrepid fails to retain an IRO as required in Section III.E.
- 3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Intrepid fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.
- 4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Intrepid employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, Intrepid's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Intrepid can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.G) as to the status of the person).
- 5. A Stipulated Penalty of \$1,500 for each day Intrepid fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Intrepid fails to grant access.)
- 6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Intrepid as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.

- 7. A Stipulated Penalty of \$1,000 for each day Intrepid fails to comply fully and adequately with any obligation of this CIA. In its notice to Intrepid, OIG shall state the specific grounds for its determination that Intrepid has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Intrepid shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Intrepid receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.
- B. <u>Timely Written Requests for Extensions</u>. Intrepid may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Intrepid fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Intrepid receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

#### C. Payment of Stipulated Penalties.

- 1. Demand Letter. Upon a finding that Intrepid has failed to comply with any of the obligations described in Section XI.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Intrepid of: (a) Intrepid's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, Intrepid shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section XI.E. In the event Intrepid elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Intrepid cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter

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in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section XI.D.

- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.
- 4. Independence from Material Breach Determination. Except as set forth in Section XI.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Intrepid has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section XI.D, below.

#### D. Exclusion for Material Breach of this CIA.

- 1. Definition of Material Breach. A material breach of this CIA means:
  - a. a failure by Intrepid to report a Material Deficiency, take corrective action, and make the appropriate refunds, as required in Section III.I;
  - b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section XI.A;
  - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
  - d. a failure to retain and use an IRO in accordance with Section III.D.
  - e. A failure to take reasonable steps regarding Intrepid's involvement with Medshare's former Chief Executive Officer, Stephen H. Winters, in accordance with Section X.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Intrepid constitutes an independent basis for Intrepid's exclusion from participation in the Federal health care programs. Upon a determination

by OIG that Intrepid has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Intrepid of: (a) Intrepid's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

- 3. Opportunity to Cure. Intrepid shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
  - a. Intrepid is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
  - b. the alleged material breach has been cured; or
  - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Intrepid has begun to take action to cure the material breach; (ii) Intrepid is pursuing such action with due diligence; and (iii) Intrepid has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, Intrepid fails to satisfy the requirements of Section XI.D.3, OIG may exclude Intrepid from participation in the Federal health care programs. OIG shall notify Intrepid in writing of its determination to exclude Intrepid (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section XI.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Intrepid may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. <u>Dispute Resolution</u>

1. Review Rights. Upon OIG's delivery to Intrepid of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Intrepid shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part

1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Intrepid was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Intrepid shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Intrepid to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Intrepid requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:
  - a. whether Intrepid was in material breach of this CIA;
  - b. whether such breach was continuing on the date of the Exclusion Letter; and
  - c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Intrepid had begun to take action to cure the material breach within that period; (ii) Intrepid has pursued and is pursuing such action with due diligence; and (iii) Intrepid provided to OIG within that period a reasonable timetable

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for curing the material breach and Intrepid has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Intrepid, only after a DAB decision in favor of OIG. Intrepid's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Intrepid upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Intrepid may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Intrepid shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Intrepid, Intrepid shall be reinstated effective on the date of the original exclusion.

#### XII. EFFECTIVE AND BINDING AGREEMENT

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

- A. This CIA shall be binding on the successors, assigns, and transferees of Intrepid;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Intrepid's obligations under the CIA in the event of Intrepid's cessation of participation in Federal health care programs. If Intrepid withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Intrepid shall notify OIG at least 30 days in advance of Intrepid's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

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

# ON BEHALF OF INTREPID

Toda I. Garmella

President and CEO

Intrepid USA Healthcare Services

8/26/2003

DATE

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

Larry J. Goldberg

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

#### APPENDIX A

#### A. Claims Review.

- 1. Definitions. For the purposes of the Claims Review, the following definitions shall be used:
  - a. <u>Overpayment</u>: The amount of money Intrepid has received in excess of the amount due and payable under any Federal health care program requirements.
  - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
  - c. <u>Paid Claim</u>: A code or line item submitted by Intrepid and for which Intrepid has received reimbursement from the Medicare program.
  - d. <u>Population</u>: All Items for which Intrepid has submitted a code or line item and for which Intrepid has received reimbursement from the Medicare program (<u>i.e.</u>, 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. <u>Error Rate</u>: 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. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which

Intrepid cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Intrepid for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

- b. <u>Use of First Samples Drawn</u>. 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. <u>Claims Review Report.</u> 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. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review.
    - b. <u>Claims Review Population</u>. A description of the Population subject to the Claims Review.
    - c. <u>Claims Review Objective</u>. A clear statement of the objective intended to be achieved by the Claims Review.
    - d. <u>Sampling Frame</u>. 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. <u>Source of Data</u>. 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).

# Attachment 1

# **Claim Review Results**

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt
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Do you have a			Agreement	with OIO	G?	Yes	N	o
Reason Codes:	1							
Billing/Clerical E	rror N		Payer Involve		Miscellan	<u>eous</u>		
01 - Corrected Dat		08 - M	SP Group He	alth Plan I	nsurance	13 - Insufficier		
02 - Duplicate	T C 1		SP No Fault In			14 - Patient En		
03 - Corrected CF		10 - M	SP Liability I	nsurance		15 - Services I Medical Neces		rea
04 - Not Our Pati 05 - Modifier Ad			lack Lung	comp.(mc	17 - 10	Other (Please	Specify)	
06 - Billed in Erro		12 - V	eterans Admir	nistration				
07 - Corrected CI								

 	· · · · · · · · · · · · · · · · · · ·	 <del></del>	 
			<del>"</del>

Appendix B