CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

ROTECH MEDICAL CORPORATION

I. PREAMBLE

Rotech Medical Corporation ("Rotech") hereby enters 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 ensure compliance by Rotech and each of its subsidiaries that provides items or services for which payment may be made by any Federal health care program and by all of Rotech's officers, directors, employees, contractors, and agents, with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs"). Rotech's compliance with the terms and conditions in this CIA shall constitute an element of Rotech's present responsibility with regard to participation in the Federal health care programs. Rotech is also entering into a Settlement with the United States, as embodied in the Plan of Reorganization soon to be filed in the Integrated Health Services, Inc.("IHS") Chapter 11 proceeding (In re IHS), Jointly Administered (the "Bankruptcy Court")) (hereafter referred to as "Settlement Agreement") and this CIA is incorporated by reference into the Settlement Agreement.

A. Definitions

1. "Covered Person": any (i) officer, director, or employee of Rotech; or (ii) agent or other individual who furnishes health care items or services at a Rotech owned or operated location for which Rotech claims reimbursement from any Federal health care program or who participates in the preparation or submission of claims for payment on behalf of Rotech with respect to items or services for which Rotech claims reimbursement from any Federal health care program (regardless of where such activity takes place).

2. "Contractor": any individual or entity whose work is performed at a location neither owned nor operated by Rotech, with whom Rotech has entered into a contract or other arrangement to furnish health care items or services for which Rotech claims reimbursement from any Federal health care program.

II. TERM OF THE CIA

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

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

III. CORPORATE INTEGRITY OBLIGATIONS

Rotech warrants and represents that it currently operates and maintains a compliance program ("Program"). Pursuant to and for the duration of this CIA, Rotech shall maintain, and as necessary, amend its current Program such that it adheres to or includes the following obligations or elements.

A. Compliance Officers and Committee

1. Corporate Compliance Officer. For the duration of this CIA, Rotech shall continue to maintain an individual to serve as Corporate Compliance Officer, in adherence with the following requirements. The Corporate Compliance Officer shall be responsible for ensuring the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Corporate Compliance Officer shall be a member of senior management of Rotech, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Rotech and shall be authorized to report to the Board of Directors at any time. The Corporate Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Rotech to further its compliance objectives, as well as any reporting obligations created under this CIA.

2. Compliance Liaisons.

Within 90 days of the execution of this CIA, Rotech shall also appoint a Compliance Liaison for each of its six Divisions. The Compliance Liaison will cooperate with the Corporate Compliance Officer to ensure the development and implementation of policies, procedures, and practices designed to ensure compliance with applicable Federal health care program requirements and with the requirements of this CIA. The Compliance Liaisons shall serve on the Compliance Committee on a rotating basis. The Compliance Liaisons also shall be responsible for assisting the Corporate Compliance Officer in meeting the reporting obligations created by this Agreement and shall report to the Compliance Officer at least quarterly.

- 3. Changes in Compliance Officer. In the event a new Corporate Compliance Officer is appointed during the term of this CIA, Rotech shall notify the OIG, in writing, within 15 days of such a change. Changes in Compliance Liaisons will be reported annually.
- 4. Corporate Compliance Committee. For the duration of this CIA, Rotech shall continue to maintain its "Corporate Compliance Committee" and, to the extent necessary, shall amend the Program within 90 days after the effective date of this CIA to ensure that the Corporate Compliance Committee meets the following requirements. The Corporate Compliance Committee shall, at a minimum, include the Compliance Officer, at least one of the six Compliance Liaisons, and any other member of senior management within the provider's corporate structure as necessary to meet the requirements of this CIA (e.g., senior executives responsible for major functions, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Corporate Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. Code of Conduct. For the duration of this CIA, Rotech shall continue to maintain its "Code of Conduct" or similar code however denominated (hereinafter referred to as "Code of Conduct") and, to the extent necessary, shall amend the Program and/or Code of Conduct within 120 days of the effective date of this CIA to ensure that the Code of Conduct meets the following requirements. The Code of Conduct shall be distributed within 120 days of the effective date of this CIA to all Covered Persons who

have not already received the Code of Conduct. Rotech shall make adherence to Company policies and procedures designed to ensure compliance with Federal health care program requirements an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

- a. Rotech's commitment to full compliance with Federal health care program requirements, including its commitment to prepare and submit accurate billings;
- b. a requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and with Rotech's own policies and procedures;
- c. a requirement that all Covered Persons shall be expected to report to Rotech suspected violations of any Federal health care program requirements or of Rotech's own policies and procedures;
- d. the possible consequences to both Rotech and Covered Persons of their failure to comply with the Federal health care program requirements or with Rotech's own policies and procedures, or of their failure to report such non-compliance; and
- e. the right of all Covered Persons to use the Confidential Disclosure Program, as well as Rotech's commitment to confidentiality and non-retaliation with respect to disclosures.

Within 120 days of the effective date of the CIA, each Covered Person shall certify, in writing, or electronically, that he or she has received, read, understood, and will abide by Rotech's Code of Conduct. New Covered Persons shall receive the Code of Conduct within 30 days after becoming a Covered Person and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days of the effective date of the CIA, whichever is later.

Rotech 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 45 days of finalizing such changes. Covered persons shall certify that they have received, read, understand and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

- 2. Policies and Procedures. For the duration of this CIA Rotech shall continue to maintain its current written policies and procedures regarding the operation of Rotech's compliance program and its compliance with Federal health care program requirements. Within 120 days of the effective date of this CIA, Rotech shall review its existing policies and procedures and, amend them if necessary, to ensure that they at a minimum address the following specific risk areas identified below associated with the provision and reimbursement of home oxygen and other durable medical equipment and supplies under Federal health care programs.
 - a. Coverage rules and criteria;
 - b. Medical Necessity requirements;
 - c. Certificates of Medical Necessity;
 - d. Physician's Orders;
 - e. Qualification of Patients for Oxygen Therapy;
 - f. Billing;
 - g. Selection of HCPCS Codes;
 - h. Capped rentals;
 - h. Collection of Medicare co-pay and deductibles; and
 - i. Kickbacks and Self-Referrals.

Within 120 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all 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), Rotech shall assess and update as necessary the Policies and Procedures. Within 45 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. <u>Training and Education</u>. For the duration of this CIA, Rotech shall continue to maintain its Training and Education program and further develop its compliance training program to provide necessary training and information to Covered Persons about applicable Federal health care program requirements and related Rotech policies and procedures. At a minimum, the compliance training program shall include the following elements:

- 1. <u>General Compliance Training</u>. Within 120 days of the effective date of this CIA, Rotech shall provide at least 1 hour of general training to each Covered Person. This training, at a minimum, shall explain Rotech's:
 - a. Corporate Integrity Agreement requirements; and
 - b. Compliance Program (including the Code of Conduct and the policies and procedures pertaining to general compliance issues)

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

- 2. Specialized Training. In addition to the general compliance training described above, all Covered Persons who participate in the delivery of patient care items or services or participate in the preparation or submission of claims for reimbursement, (either in paper or electronic format) to any Federal health care program shall receive at least 3 hours additional training relating to legal and regulatory issues specifically affecting their billing-related responsibilities. This training shall cover relevant Federal health care program requirements, and the specifically identified policies and procedures risk areas identified in Section III.B.2 above. Additionally, the training shall address:
 - a. the submission of correct and accurate bills for services rendered to all Federal health care program beneficiaries;
 - b. the personal obligation of each individual to make reasonable efforts to ensure that information provided in support of a submission for reimbursement for items or services furnished to beneficiaries of the Federal health care programs is accurate;
 - c. applicable Federal health care program requirements;
 - d. examples of improper billing and documentation practices; and e. the legal, regulatory, and internal Rotech sanctions for improper billings.

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

Rotech shall conduct regional specialized training sessions on a quarterly basis. Those individuals who are Relevant Covered Persons upon the effective date of this CIA shall receive this training at the first available training session in their region or within 120 days of the effective date of this CIA, which ever is later. New Relevant Covered Persons shall receive this training at the first available training session in their region following the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the effective date of this CIA, whichever is later. A Rotech 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 in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

Any training that has been provided by the Rotech Compliance Department within the 6 months prior to the effective date of this CIA and that satisfies the requirement with respect to Relevant Covered Persons shall be deemed to have satisfied the requirements of this provision, so long as such training can be documented to the OIG.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least 2 hours of specialized training annually.

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

D. Review Procedures.

- 1. General Description.
- a. <u>Internal Claims Review Option</u>. For the first Reporting Period (as defined in Section III.D.1.d), Rotech may conduct an internal review of its billing and coding practices with respect to the Federal health care programs. The review shall comply with all of the requirements outlined in Section III.D and in Appendix A to this CIA ("Claims Review"). Rotech will continue to perform the internal Claims Review in conformance with

the requirements of Section III.D and Appendix A to this CIA for the next Reporting Period of this CIA, unless the OIG, in its sole discretion, determines that Rotech's internal Claims Review has not been performed satisfactorily. To the extent that OIG permits Rotech to perform internal Claims Reviews, Rotech shall submit all information required by the provisions outlined in Section III.D and in Appendix A to this CIA.

b. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Rotech shall retain an entity such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Rotech in assessing and evaluating its billing and coding practices and systems pursuant to this CIA and the Settlement Agreement. Prior to performing any review engagements required under this CIA, the IRQ and Rotech shall design agreed upon procedures as defined in the AICPA "attest standards" for Agreed Upon Procedures Engagements (hereafter "agreed upon procedures") outlining the specific work to be performed by the IRO, and the agreed upon procedures shall be submitted to the OIG for review. Each IRO retained by Rotech shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Rotech seeks reimbursement. Each IRO shall assess, along with Rotech, 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.

c. IRO Verification or Claims Review

- i. For the first Reporting Period, the IRO shall perform an agreed upon procedures Verification Review of 7 of the Lawson Units reviewed by Rotech in its internal Claims Review ("Verification Review"). Such review shall consist of an assessment of 25 claims for each Lawson Unit.
- ii. For any Lawson Units reviewed by Rotech in its internal Claims Review which are subject to a full sample, the IRO shall perform a Verification Review of 10% of the sampling units in each full sample. These sampling units shall be randomly selected.

- iii. If the IRO's Verification Review, for the previous year, if applicable, results in (i) no more than a 5% sampling unit variance from Rotech's internal review; or (ii) neither Rotech's primary compliance staff nor its internal audit policies and procedures substantially change, then the IRO shall perform a Verification Review for the fourth year of the CIA only.
- iv. If the IRO's Verification Review, for the previous year, if applicable, results in (i) more than a 5% sampling unit variance from Rotech's internal review; or (ii) either Rotech's primary compliance staff or its internal audit policies and procedures substantially change; and if Rotech is permitted to perform the internal Claims Review, the IRO shall, at a minimum, perform a Verification Review for the next year Reporting Period and for the fourth year of the CIA.
- v. If the OIG does not allow Rotech to perform the Claims Review internally for any year after the first Reporting Period, the IRO shall perform a Claims Review for each successive year of the CIA, unless the OIG in its sole discretion allows Rotech to recommence internal claims review.

As part of Rotech's Annual Report, the IRO shall submit a report that verifies that the requirements outlined in Section III.D and in Appendix A to this CIA have been satisfied and shall report the results, sampling unit by sampling unit, of any Verification Review or Claims Review performed.

- d. <u>Frequency of Claims Review</u>. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA ("Reporting Period"). Rotech and/or the IRO shall conduct the Claims Review in accordance with Section III.D and Appendix A to this CIA.
- e. <u>Frequency of Unallowable Cost Review</u>. To the extent applicable, the Unallowable Cost Review shall be performed by the IRO for the first one-year Reporting Period beginning with the effective date of the CIA.
- f. <u>Retention of Records</u>. Rotech and the IRO(s) shall retain and make available to the OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports exchanged between the IRO and Rotech related to the Claims Review.

- 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>. With respect to each facility selected pursuant to the facility selection methodology set forth in Appendix A, Rotech or the IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Rotech. The Paid Claims shall be reviewed based on the supporting documentation available at Rotech or under Rotech's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.
 - i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) 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, Rotech should, as appropriate, further analyze any errors identified in the Discovery Sample. Rotech 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, Rotech or the IRO shall perform a Full Sample and a Systems Review, as described below.
 - b. <u>Full Sample</u>. If necessary, as determined by procedures set forth in Sections III.D.1 and III.D.2.a, Rotech or 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 (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 Rotech or under Rotech'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, Rotech 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 Rotech 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 the Discovery Sample identifies an Error Rate of 5% or greater, Rotech or the IRO, as determined by the procedures set forth in section III.D.1, shall also conduct a Systems Review. Specifically, for each Item in the Discovery Sample and Full Sample that resulted in an Overpayment, Rotech or 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. Rotech or the IRO shall generate a report summarizing its 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.I.1 of the CIA, Rotech 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. Rotech agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.
- 3. *Unallowable Cost Review*. If applicable, the IRO shall conduct a review of Rotech's compliance with the unallowable cost provisions of the Settlement Agreement during the first year of this CIA only.
 - a. The IRO shall determine whether Rotech 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 Rotech or any of its subsidiaries. To the extent 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.

- 4. Unallowable Cost Review Report. If applicable, 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 Rotech 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.
- 5. Claims Review Report. Depending on whether Rotech conducted an internal Claims Review with an IRO Verification Review or the IRO conducted the Claims Review, Rotech and/or 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 to this CIA.
- 6. Validation Review. In the event the OIG has reason to believe that: (a) Rotech's Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) Rotech's and/or 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 or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Rotech 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 Rotech's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Rotech 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, Rotech may request a meeting with the 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 to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Rotech 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 or Unallowable Cost Review with Rotech 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.

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

E. Acquisition Compliance Assessment

In the event that during the term of this CIA, Rotech acquires, merges with, purchases the stock or assets of, or otherwise gains an ownership or control interest of 5% or more in an entity that delivers health care items or services for which Federal health care program reimbursement is sought (hereinafter, "Acquisition" or "Acquisition Entity"), Rotech shall complete the following Acquisition Compliance Assessment ("ACA") procedures prior to finalizing the Acquisition in order to ensure the appropriateness of Rotech's consummating the proposed transaction.

Rotech warrants and represents that as part of its Compliance Program it currently has in place an Acquisition Due Diligence review process, including an Acquisition Committee. For the duration of this CIA, Rotech shall continue to maintain as part of its Compliance Program its Acquisition Due Diligence review process, including the Acquisition Committee, subject to the additional requirements set forth below. In fulfilling the obligations of the ACA as set forth below, Rotech may continue to use its current Due Diligence review process to the extent that it satisfies and/or is consistent with the ACA procedures set forth below.

- 1. Scope of ACA. In the event that the Acquisition Entity consists of more than a single business and/or operating facility (e.g., a corporate headquarters, five storefronts or facilities, and one billing center -- hereinafter collectively referred to as "facilities" regardless of composition), the ACA shall be performed, in the following manner: For any Acquisition Entity that consists of 2 to 10 total facilities, an ACA of 100% of the facilities shall be performed. For any Acquisition Entity that consists of 11 to 25 facilities, an ACA of 50% of the facilities shall be performed; but in no event more than 10. For any Acquisition Entity that consists of 26 to 50 facilities, an ACA of 25% of the facilities shall be performed, but in no event more than 10. For any Acquisition Entity that consists of more than 50 facilities, an ACA of 10% of the facilities shall be performed; however, no less than ten and no more than fifteen total facilities shall be included. For any less than 100% review of an Acquisition Entity, the facilities shall be randomly selected. All the ACA steps described below shall be performed at all the facilities required to be included in the ACA by the aforementioned provisions
- 2. Responsibility of Acquisition Committee and Compliance Officer. The Acquisition Committee shall review all potential Rotech Acquisitions. The Acquisition Committee shall, at a minimum, include the Rotech Corporate Compliance Officer and members of his or her staff as deemed appropriate. The Compliance Officer and his or her Compliance Department shall have primary responsibility for performing any ACA. An Acquisition shall only be consummated when approved by Rotech's Chief Executive Officer, Chief Operating Officer, Chief Legal Officer, Chief Financial Officer, and Chief Compliance Officer.
- 3. Compliance Program Infrastructure Evaluation. Rotech shall undertake a comprehensive review of the Acquisition Entity's existing compliance program (to the extent that such program exists) in order to assess whether it is operating in compliance with Federal health care program requirements. Such review shall include, at a minimum, an evaluation of the entity's compliance officer and compliance committee structure and personnel; compliance policies and procedures, the training and education program; the reporting system; the disciplinary mechanisms, employee screening process and its overall commitment to compliance as evidenced by involvement of the board of directors and/or senior management in the compliance program. The Diligence Questionnaire attached hereto at Appendix C sets forth the criteria to be used for such an assessment.

¹ To the extent that the required percentage of operational facilities is not a whole number, Rotech shall round up to the next whole number as the number of facilities subject to the ACA.

- 4. ACA Operational Review. Rotech shall undertake a comprehensive review of the Acquisition Entity's operations and participation in Federal health care programs in order to assess whether it is operating in compliance with Federal health care program requirements. At a minimum, such review shall focus on eliciting information about the Acquisition Entity's operations that are associated with the risk areas set forth in the Office of Inspector General's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry (June 1999) (published in 64 Fed. Reg. 36368) and any updates to this document. At a minimum, such review shall include the following:
 - a. interviews of key personnel (including managerial or supervisory as well as front line employees) available to Rotech who are involved in the provision of health care items or services for which the entity seeks reimbursement from any Federal health care program or who participate in the preparation or submission of claims for payment on behalf of the entity with respect to items or services for which the entity seeks reimbursement from any Federal health care program;
 - b. review of documents, including policies and procedures and third party contracts, relevant to the operations of the Acquisition Entity and its participation in Federal health care programs; and
 - c. completion of the Due Diligence Questionnaire (attached as Appendix C), including a certification as to truthfulness and accuracy of the responses by the owner.
- 5. ACA Chart Review. At a minimum, Rotech shall perform a chart review consisting of at least 50 Medicare oxygen charts and at least 50 DME charts, for any facility covered by the ACA. For any facility with less than 50 oxygen or 50 DME charts, Rotech shall review all the charts. For multi-facility entities, pursuant to section III.E.5 above regarding scope of the ACA, the chart reviews shall be performed at each facility required to be included in the ACA. Such reviews shall be selected randomly. Nothing in this provision precludes Rotech from performing as many chart reviews (at as many locations if a multi-facility entity) as it deems appropriate as part of its acquisition due diligence process.

- 6. ACA Final Report. Within 60 days of closing an Acquisition subject to an ACA as described above, Rotech shall submit in writing a report to the OIG, indicating that it performed the steps required under this section of the CIA and providing an enumeration and description of the procedures performed as well as a description and timetable for any corrective actions, if needed, being taken to address compliance issues at the Acquisition Entity, including the process for assimilating the Acquisition Entity into Rotech's own compliance program.
- 7. Validation Review. In the event the OIG has reason to believe that:
 (a) Rotech's ACA fails to conform to the requirements of this CIA; or (b) the ACA Final Report(s) are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the ACA complies with the requirements of the CIA and/or the ACA Final Report(s) are inaccurate. Rotech 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 Rotech's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Rotech of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Rotech may request a meeting with the OIG to discuss the results of any ACA submissions or any ACA Final Report(s); present any additional or relevant information to clarify the results of the ACA or to correct the inaccuracy of the ACA Final Report(s); and/or propose alternatives to the proposed Validation Review. Rotech 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 issues related to the ACA with Rotech 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.

F. <u>Disclosure Program</u>.

For the duration of this CIA, Rotech shall continue to maintain its "Compliance Hotline" or similar reporting mechanism however denominated (hereinafter referred to as "Disclosure Program") and, to the extent necessary, shall amend the Program and/or Disclosure Program within 90 days of the effective date of this CIA to ensure that the Disclosure Program meets the following requirements. The Disclosure Program 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 Rotech'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. Rotech 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 non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Rotech 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 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 any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.
- 2. Screening Requirements. Rotech shall not hire as employees or engage as Contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Rotech 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://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

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

If Rotech has notice that an employee or Contractor has become an Ineligible Person, Rotech shall remove such person from responsibility for, or involvement with, Rotech'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 Rotech 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 Rotech shall take all appropriate actions to ensure that the responsibilities of that employee or Contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, Rotech 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 Rotech 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. Rotech 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.

I. Reporting.

1. Overpayments

- a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Rotech 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, Rotech identifies or learns of any overpayments, Rotech 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, Rotech 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, Rotech 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, unless otherwise approved by the payor. 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. Definition of Material Deficiency. 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 potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized..

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

- b. Reporting of Material Deficiencies. If Rotech determines through any means that there is a Material Deficiency, Rotech 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, or the offset date;
 - (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 Rotech's actions taken to correct the Material Deficiency; and
 - (iv) any further steps Rotech plans to take to address the Material Deficiency and prevent it from recurring.

IV. <u>New Business Units or Locations</u>

In the event that, after the effective date of this CIA, Rotech 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, Rotech shall notify OIG of this fact as soon as possible, but no later than within 60 days of the date of a purchase and no less than annually with respect to changes of existing locations or establishments. This notification shall include the location of the new operation(s), phone number, fax number, Medicare Rotech number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare Rotech number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within 150 days after the effective date of this CIA, Rotech 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, position description, and summary of other non-compliance job responsibilities of the Compliance Officer and Compliance Liaisons 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 Rotech's Code of Conduct required by section III.B.1, in the event it was revised pursuant to the CIA;
 - 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, in the event they were revised or newly created pursuant to the CIA;
 - 5. a representative sample of training materials used for the training required by section III.C, 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. A copy of all training materials used for the training required by section III.C shall be made available to 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;
 - b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
 - c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

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

- 7. a description of the Disclosure Program required by section III.F, in the event it was revised pursuant to the CIA;
- 8. the identity of the IRO(s), a summary/description of all engagements between Rotech and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
- 9. a certification from the IRO regarding its professional independence from Rotech;
- 10. a summary of personnel actions (other than hiring) taken pursuant to section III.G.;
- 11. a list of all of Rotech'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 Rotech identification number(s) and the contractor's name and address that issued each Rotech identification number;

- 12. to the extent not already furnished to OIG, or if modified, a description of Rotech'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>. Rotech shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Rotech's compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

- 1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and Compliance Liaisons and any change in the membership of the Compliance Committee described in section III. A or the Acquisition Committee described in section III. E.;
- 2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;
 - c. Rotech 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;

d. for all Acquisitions, Rotech has complied with its obligations to perform an Acquisition Compliance Assessment and submit an ACA Final Report to the OIG in accordance with section III.E.

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;
- 4. a representative sample of training materials used for the training required by section III.C (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. A copy of all training materials used for the training required by section III.C shall be made available to OIG upon request.;
- 5. 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;
- 6. Rotech'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 Rotech 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 copy of Rotech's and/or the IRO's Claims Review reports;
- 9. a summary of Material Deficiencies (as defined in 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 should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
- 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 Rotech as a result of the obligations in section III.G, and the name, title, and responsibilities of any person that falls within the ambit of section III.G.4, 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 Rotech's locations (including locations and mailing addresses) as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program Rotech identification number(s), and the contractor name and address that issued each Rotech identification number; and
- 15. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 90 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 Acquisition Compliance Assessment Reports, the Implementation Report, and the Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report,

Rotech is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. <u>Designation of Information</u>: Rotech 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. Rotech shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

Rotech:

Robin Menchen Chief Compliance Officer Rebecca Myers Chief Legal Officer Rotech Medical Corporation 2600 Technology Drive Suite 300 Orlando, FL 32804 Phone 407.822.4600 Fax 407.297.8568

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

VIII. DOCUMENT AND RECORD RETENTION

Rotech 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, the OIG shall make a reasonable effort to notify Rotech prior to any release by OIG of information submitted by Rotech pursuant to its obligations under this CIA and identified upon

submission by Rotech as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Rotech shall have the rights set forth at 45 C.F.R. § 5.65(d). Rotech 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

Rotech 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, Rotech 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 Rotech fails to have in place any of the obligations described in section III:
 - a. a Compliance Officer and Compliance Liaisons;
 - 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 Rotech fails to retain an IRO, as required in section III.D.
- 3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Rotech fails to meet any of the

deadlines for the submission of the Acquisition Compliance Assessment Reports, 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 Rotech employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Rotech's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Rotech 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 Rotech fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date Rotech fails to grant access.)
- 6. A Stipulated Penalty of \$1,000 for each day Rotech fails to comply fully and adequately with any obligation of this CIA. In its notice to Rotech, OIG shall state the specific grounds for its determination that Rotech has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Rotech must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Rotech of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.
- B. <u>Timely Written Requests for Extensions</u>. Rotech 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 Rotech 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 Rotech 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 Rotech has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Rotech of: (a) Rotech's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Rotech shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event Rotech elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Rotech cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.
- 4. Independence from Material Breach Determination. Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Rotech has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

- 1. Definition of Material Breach. A material breach of this CIA means:
 - a. a failure by Rotech to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.H;

- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or
- d. a failure to retain and use an Independent Review Organization in accordance with section III.D; or
- e. a failure to perform an Acquisition Compliance Assessment as required in section III.E.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Rotech constitutes an independent basis for Rotech's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Rotech has materially breached this CIA and that exclusion should be imposed, OIG shall notify Rotech of: (a) Rotech'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. Rotech 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. Rotech is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Rotech has begun to take action to cure the material breach; (ii) Rotech is pursuing such action with due diligence; and (iii) Rotech has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, Rotech fails to satisfy the requirements of section X.D.3, OIG may exclude Rotech from participation

in the Federal health care programs. OIG will notify Rotech in writing of its determination to exclude Rotech (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Rotech wishes to apply for reinstatement, Rotech must submit 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 Rotech 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, Rotech 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Rotech was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Rotech shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Rotech to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Rotech 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 Rotech 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) Rotech had begun to take action to cure the material breach within that period;
 - (ii) Rotech has pursued and is pursuing such action with due diligence; and
 - (iii) Rotech provided to OIG within that period a reasonable timetable for curing the material breach and Rotech 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 the Rotech, only after a DAB decision in favor of OIG. Rotech's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Rotech upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Rotech 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. Rotech agrees to waive its/his/her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. 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, Rotech and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Rotech;
- 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 Rotech's obligations under the CIA in the event of Rotech's cessation of participation in Federal health care programs. If Rotech withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Rotech agrees to notify OIG 30 days in advance of Rotech's intent to reapply as a participating Rotech or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.
- E. The undersigned Rotech 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 ROTECH MEDICAL CORPORATION

Stephen D'Lineh	2/7/
Stephen D. Linehan	DATE
President and CEO	22
Rotech Medical Corporation	

Roger S. Goldman Latham & Watkins

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

APPENDIX A

A. Claims Review.

- 1. Facility Selection Methodology: Rotech assigns each of its storefront locations a unique identifier known as a "Lawson Unit." For each annual Claims Review, the Lawson Units shall be stratified for purposes of these Reviews. The basis for such strata determination shall be the sales recorded by such Lawson Units in the preceding calendar year. Based on such data any Lawson Units with annual revenue of \$9 million or greater shall be placed into a "special" strata. All remaining Lawson Units shall be equally divided (to the extent possible) into "small," "medium" and "large" strata based on sales revenue (i.e., the largest strata contains the top 3rd Lawson Units with the highest revenues; the medium strata the next 3rd in revenues; and the small strata the lowest 3rd in revenues).
 - a. The Claims Review shall annually be performed for each Lawson Unit within the special strata, however, if the special strata contains more than 5 Lawson Units, no more than 5 Lawson Units in the special strata will be randomly selected for review. After the 2d annual Claims Review, (i) Rotech may request that the OIG reevaluate the revenue threshold for determining the special strata or (ii) the OIG may reevaluate the revenue threshold for determining the special strata. The OIG will make the final decision on the revenue threshold for the special strata.
 - b. For each annual Claims Review, the remainder of the Lawson Units that do not meet the criteria for inclusion in the special strata, shall be divided into three equal strata based on the annual revenues of the Lawson Units. The Lawson Units shall be assigned to a strata at the end of each CIA reporting period. On an annual basis, Rotech or the IRO shall perform a Claims Review on a sample of Lawson Units using the following methodology: randomly select 20% of the Lawson Units in the large strata, 15% of Lawson Units in the medium strata, and 10% of the Lawson Units in the small strata for a Claims Review.
 - c. Rotech or the IRO shall select the Lawson Units for the Claims Review by using a random number generator. Every Lawson Unit in

each strata shall be included in the facility selection process for each annual Claims Review.

- 2. **Definitions**. For the purposes of the Claims Review, the following definitions shall be used:
 - a. <u>Overpayment:</u> The amount of money Rotech 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 Rotech and for which Rotech has received reimbursement from the Medicare program.
 - d. <u>Population</u>: All Items for which Rotech has submitted a code or line item and for which Rotech has received reimbursement from the Medicare program (<u>i.e.</u>, a Paid Claim) during the 12-month period covered by the Claims review, except in the first year of the CIA as explained below. To be included in the Population, an Item must have resulted in at least one Paid Claim.
 - e. <u>Treatment of Reviews in First Year</u>: Notwithstanding the other provisions of this Appendix, Rotech or the IRO may choose to conduct its Claims Review in the first year after the effective date of the CIA in the follow manner. The Claims Review shall cover Items related to the time period from the date of Rotech's Bankruptcy confirmation, to the date of the Claims Review (rather than always relating to the full preceding 12-month time period as is required in other years).
 - i. At least 25% of each Claims Review conducted shall cover the period from the date of Rotech's Bankruptcy confirmation to a date at least one year after the effective date of the CIA.
 - ii. At least 25% of each Claims Review conducted shall cover the period from the date of Rotech's Bankruptcy confirmation to a date at least 9 months after the effective date of the CIA.

- iii. The remaining Claims Review (that not described in i. and ii. above) shall include the period from the date of Rotech's Bankruptcy confirmation to a date at least 6 months after the effective date of the CIA.
- iv. If Rotech or the IRO chooses to conduct the first year reviews in accordance with this paragraph, the Lawson Units in the special strata shall be reviewed first followed by the Lawson Units in the large strata, the medium strata and finally the small strata.
- f. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. 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. If Rotech is permitted to perform the Claims Review internally with the IRO verification, the following payment errors should be included in calculating the error rate: (i) all payment errors identified by Rotech and not verified by the IRO; (ii) all payment errors identified by Rotech and verified by the IRO; and (iii) all payment errors identified by the IRO and not identified by Rotech.

3. 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 Rotech cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Rotech 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 each Claims Review Report for the Claims Review(s) performed:
 - 1. Claims Review Methodology

- a. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (<u>e.g.</u>, claim, line item, beneficiary, patient encounter, etc.).
- 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 specific documentation relied upon by Rotech or the IRO when performing the Claims Review (<u>e.g.</u>, 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. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated.
- g. Lawson Unit Data: The annual revenue for each Lawson Unit with the strata designations

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 Rotech or the IRO.

- c. A description or identification of the statistical sampling software package used to conduct the sampling.
- d. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.

3. Claims Review Results

a. Narrative Results.

- i. A description of Rotech's billing and coding system(s), including the identification, by position description, of the personnel involved in the coding and billing.
- ii. A narrative explanation of Rotech'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 (based on Rotech's internal Claims Review, if applicable) in which Rotech determined that the Paid Claims submitted by Rotech ("Claims 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 (based on Rotech's internal Claims Review, if applicable) in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Rotech.
- iii. Based on Rotech's or the IRO's Claims Review, total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- iv. Error Rate in the sample(s), as defined in section A.1.e of this Appendix.

- v. For each Discovery and Full Sample performed by Rotech: (1) the number of Items the IRO verified; (2) the number of instances in which the IRO disagreed with Rotech's payment determinations; and (3) the dollars associated with the difference between the IRO's and Rotech's payment determinations.
- vi. 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 Rotech's internal billing review) correct procedure code (as determined by the IRO verification), correct allowed amount (as determined by Rotech's internal billing review), correct allowed amount (as determined by the IRO verification), dollar difference between allowed amount reimbursed by payor and the correct allowed amount (as determined by Rotech's internal billing review); and dollar difference between allowed amount reimbursed by payor and the correct allowed amount (as determined by the IRO verification). (See Attachment 1 to this Appendix.)
- 4. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.
- 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 Unallowable Costs Review; (2) performed the Claims Review and Unallowable Costs Review; and (3) performed the verification review, if applicable.

Attachment 1

Claim Review Results

Dollar Difference between Amt Reimbursed and Correct Allowed Amt						The second secon	
Correct Allowed Amt Reimbursed (IRO determined)							
Correct Procedure Code (IRO determined)						3 -	
Allowed Amount Reimbursed					4.5		
Procedure Code Reimbursed							
Procedure Code Submitted							
Date of Service							
Bene HIC #							
Federal Health Care Program Billed							

Rotech CIA Attachment 1 Final.wpd

Rotech Corporate Integrity Agreement

OVERPAYMENT REFUND

	TO B	E COMPI	ETED B	Y MEI	DICARE	CONT	RACTOR	
Date:							LUTOTOR	
Contractor Depo Contractor	sit Control	#		Date	of Depo	sit:		
#		_						Phone
C o Address:	n	t	r	a	c		t	o r
Contractor Fax:								
Please complete containing the fo check is properly PROVIDER/PH	and forwa Ellowing info Frecorded a	rd to Med rmation, s nd applied	dicare Co hould acc l.	ontracto	r This	form	IAN/SUPI or a simile refund so th	ar document
ADDRESS								
PROVIDER/ NUMBER#_								
CONTACT # DATE	PERSOI	N: AN	TOUNT	OF C	HECK	<u> </u>		PHONE CHECK
DATE				-	· · · · · · · · · · · · · · · · · · ·	Ψ		_ CHECK
			-					
For each Claim	nnovido th	o followis	REFU	ND INF	<u>ORMAT</u>	<u>IOÑ</u>		
For each Claim Patient Na #	ame							HIC
# Medicare Cla \$	aim Num	ber			(Claim	Amount	Refunded
Reason Code for							below. Us	e one reaso
n per ciaim) Note: If Specifi	(Please list c Patient/Hi l Sampling, d	<u>all</u> claim i C/Claim i please ind	numbers . #/Claim 2	involved Amount hodolog	l. Attach data not	se para availah	te sheet, if le for all c	necessary)
For Institutiona	l Facilities	Only:						
Cost Report Yea								
(If multiple cost i	report years a	are involve	d, provid	e a breal	kdown by	amount	and corres	ponding cost
report year.)								
For OIG Repor Do you have a C			roomont	∴4L OIC	10	37		NT
	orporate in	CALITA WAI	eement w	Aut OIC	J.	Ye	<u> </u>	<u>No</u>
Reason Codes: Billing/Clerical Erro 01 - Corrected Date 02 - Duplicate HMO		08 - MS	her Payer I P Group Ho - MSP No I	ealth Plar	Insurance	Miscella 13 - Inst	ifficient Doc	umentation nt Enrolled in a
03 - Corrected CPT 04 - Not Our Patien 05 - Modifier Adde 06 - Billed in Error 07 - Corrected CPT	nt(s) d/Removed	11 - MS Bla	- MSP Lia P, Workers ack Lung erans Admi	Comp.(l	Including		15 - Servidical Necessi - Other (Ple	

DUE DILIGENCE QUESTIONNAIRE

Name/address of Company: Company Name: Company Address: Primary Contact: Telephone Number: Respondent: Corporate Counsel: Counsel Telephone # Compliance: A. General Operations. 1. What types of health care professionals does the Company employ? 2. Do all nurses, respiratory therapists, and other health care professionals employed or engaged by the Company hold all necessary licenses and meet Medicare qualifications? 3. Have any licenses of the Company or health care professionals that it has employed or engaged been revoked, suspended, restricted, or denied renewal, or have other disciplinary actions been taken against the Company or any of its current or former physicians or health care professionals by a state licensure authority? Does the Company obtain criminal and abuse background checks for personnel that it 4. hires or retains?

5.	Does the Company have any Union or Collective Bargaining agreements? If so, please provide name of Union(s), number of employees involved, and job titles of such.
6.	What types of health care services, supplies, and equipment does the Company provide?
7.	Does the Company provide its services and equipment directly or through arrangements with other providers?
8.	Where does the Company provide health care services and equipment (e.g., patients home, long-term care facilities, assisted living facilities)? What kinds of services and supplies are provided to facilities like nursing homes and assisted living facilities? Who does the Company bill for those Services?
9.	Is the Company licensed by the state? Has the Company complied with all conditions applicable to its licenses or certificates of need?
10.	How does the Company monitor compliance with its policies and procedures?
11.	How are certificates of medical necessity prepared and completed?

12.	How does the Company monitor inventories of supplies and equipment maintained at patients' homes?
13.	How much waste or loss of supplies or equipment occurs?
14.	Other than a patient, who may sign claim forms, assignment forms, or request for payment statements? Under what circumstances does someone other than a patient sign? Are those circumstances documented when someone other than a patient signs?
15.	When an existing customer leases or purchases a new item of durable medical equipment, do you obtain the customer's signature on a new request for payment statement or a new assignment form?
16.	Where is inventory stored? Who owns inventory prior to sale?
17.	Do you honor all warranties on the items and services the Company sells?
18.	Do you provide maintenance and repairs for all items rented to beneficiaries?

19.	Do you accept returns of substandard or unsuitable items?
20.	How do you handle complaints? Do you keep written records of complaints?
21.	How does the Company monitor rental to purchase conversions on durable medical equipment? Do you offer beneficiaries the option to purchase after they have been renting a certain length of time?
22.	How do you distinguish new and used equipment for Medicare billing purposes?
23.	What accreditations does the Company hold?
24.	Does any facility or physician give the Company access to patient medical records?

В.

25.	Has the Company moved its physical location at any time? If so, has a change of address form been completed and sent to National Supplier Clearinghouse (has Medicare been notified of the change of address)?
<u>Co</u>	ntracts and Other Compensation Arrangements.
1.	How is the Company compensated for its services and the items it sells? Medicare? Medicaid? Private insurance?
2.	Does the Company subcontract any services that it undertakes to provide to patients?
3.	How are such subcontractors compensated?
4.	What other services does the Company obtain from physicians or other health care providers or entities?
5.	How does the Company compensate the provider for those services?
6.	For each case, what was the basis upon which the parties determined the compensation for the services provided?

7.	Does the Company have any contract or compensation arrangement with any person (or family member of such person) or entity that is in a position to refer patients to the Company?
8.	Does the Company lease space, equipment, or other property to or from physicians or other health care providers?
9.	Does the Company permit physicians or other health care providers to use the Company's space, equipment, supplies, or other property without charge?
10.	Does the Company provide any goods or services to physicians or other health care providers (other than supplies provided to employed professionals for use in the ordinary course of their employment duties)?
11.	Does the Company participate in any group purchasing arrangement?
12.	Does the Company routinely provide goods or services at a discount?

Does the Company have any investment or other financial arrangement with any other 13. provider of health care items or services, including loans, guaranties, joint ventures, and other ownership or investment interests? Does the Company receive any free or discounted goods or services from any vendors 14. or other health care entities? Does the Company provide any free or discounted goods or services to vendors or 15. other health care entities? Patient Sources and Marketing Practices. 1. What are the Company's sources of referrals? Does the Company participate in any referral services or cross-referral arrangements? 2. Does the Company routinely waive copayments or deductibles for patients? 3. Are Medicare Part B deductibles and copayments waived only in situations involving 4. a patient's particular hardship? Are the hardship, efforts to collect from the patient, and reasons for any waiver always documented?

C.

APPENDIX C 5. Does the Company engage in any of the following practices: Advertisements that state or imply that Medicare payment is accepted as a. payment in full. Advertisements that promise discounts, gifts or free services, such as b. transportation, housekeeping, or grocery shopping/meals to Medicare beneficiaries or other potential patients to choose or switch to the Company? Collection of coinsurance and deductibles from a Medicare beneficiary only c. when the beneficiary has medical insurance? d. Charges to Medicare beneficiaries that are higher than those made to other persons for the same or similar services? Frequent use of financial hardship forms? e. f. Payment of a fee to a physician for each certificate of medical necessity or plan of care certified by the physician? Provision of free services or equipment, such as education and training, g. discharge dunning, home care coordinators, or home care liaisons to other health care providers?

h.

Acceptance of delivery of or solicitation of excessive volumes of medical supplies from vendors to be kept as inventory?

	i.	Permit vendors or other providers of health care services access to patient records?
	j.	Provision of free services or supplies to retirement homes, nursing homes, assisted living facilities, or other types of facilities?
	k.	Approach and market the Company's services and equipment directly to potential patients?
6.	arrang patient	he Company have any utilization management policy or any compensation ements with physicians or others in a position to treat, diagnose, or refer ts, that may create an incentive not to provide, or not to refer a patient to the any or elsewhere for the provision of, medically necessary health are items or es?

7. Does any health care professional or health care entity (or a family member of any health care professional who is in a position to refer patients to the Company) have an ownership or investment interest including debt or equity) in any part of the Company or in any joint venture with the Company? Does the Company ever treat Medicare or Medicaid patients any differently from other 8. patients or example, in the timing or scheduling of deliveries or the assignment of nurses or therapists)? Describe the activities of your marketing personnel and sales representatives. 9. Has the Company made any charitable donations or grants to any entities which are, 10. own, or control potential patient referral sources? Fraud and Abuse Investigations and Sanctions 1. Has the Company ever been served with a search warrant or a grand jury or administrative subpoena for documents or testimony?

D.

2.	Has any government official formally or informally investigated the Company or
	sought to interview any of the Company's personnel, or requested information or documents from the Company (other than requests in connection with routine
	licensure and certification processes)?
3.	During the past five years, has the Company been accused of patient neglect or abuse?
4.	Has any owner or employee of the Company ever been excluded from the Medicare or Medicaid program?
Third-Par	ty Billing and Reimbursement.
1	
1.	Does the Company have a program to assure the accuracy, including medical necessity, of Medicare, Medicaid and other third-party payer claims?
2.	What services does the Company provide that are reimbursed by Medicare (specifically including reimbursement under Medicare Part B)?
	(opening) merading remodiscincit under violated at D):
3.	Does the Company purchase items or services from any "related organization" for
	which the Company bills Medicare or Medicaid? ("Related" means the provider to a significant extent is associated or affiliated or has control of or is controlled by the organization furnishing the services, facilities or supplies).

E.

4.	Does the Company have written agreements with physicians and other health care providers concerning the assignment to the Company of such providers' Medicare Part B or other third-party payer fees and receivables?
5.	Does the Company handle Medicare or other third-party payer billing for items or services provided (either to the Company or others) by other providers or vendors?
б.	Does the Company have any pending Medicare or Medicaid appeals?
7.	Has any governmental agency ever challenged, or threatened to terminate or limit, the Company's right to participate in the Medicare or Medicaid program?
8.	Are there any pending Medicare or Medicaid disputes not identified in the responses to the foregoing questions?
9.	Has the Company ever received overpayments from Medicare, Medicaid or other third party payers, regardless of whether assessed on post-payment reviews?

10.	Does the Company have any programs to train employees concerning Medicare and Medicaid or other third-party billing policies, procedures, and regulations?
11.	Does the Company have an employee "hot line" or other in-house reporting
	mechanism in place through which employees can report suspect third party billing practices? If so, please explain
	-
CERTIFI	CATE
	hereby certify that the responses to the questions are true, correct, and complete to the best of my knowledge as of,
Date:	
Owner's	Name (Print)
Owner's	Signature