

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ALPHA RESPIRATORY INC.

I. PREAMBLE

Alpha Respiratory Inc. (“Alpha Respiratory”) 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 promote compliance by the Covered Centers (as defined in Section III below) and the Covered Centers’ employees and any of the Covered Centers’ third parties, including contractors and agents (whether individuals or entities) who are (1) engaged to bill/submit reimbursement claims at or for the Covered Centers; (2) responsible for the provision, marketing or documentation of items or services at or for the Covered Centers, which are reimbursable by Federal health care programs; (3) or directly responsible for the preparation of claims, reports or other requests for reimbursement for such items or services provided by the Covered Centers (“Covered Persons”) with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal health care program requirements”). Employees who are Covered Persons shall be referred to as “Covered Employees.”

The term Covered Person shall not include any contractor who might otherwise satisfy the definition of a Covered Person, if the contractor’s agreement with Alpha Respiratory predates the Effective Date of the CIA. However, with respect to such contractors Alpha Respiratory shall take the steps set forth in section III. I. below.

The term Covered Person shall not include any part-time or per diem employees, agents or contractors who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during any 12 month period.

Contemporaneously with this CIA, Lincare Holdings Inc. and Lincare Inc., parent corporations of Alpha Respiratory (collectively known as “Lincare”) are entering into a

Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Alpha Respiratory under this CIA shall be 5 years from the Effective Date of this CIA (unless otherwise specified). The “Effective Date” of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from the later of OIG’s receipt of: (1) Alpha Respiratory’s final annual report; or (2) any additional materials required hereunder or submitted by Alpha Respiratory pursuant to the OIG’s reasonable request, which request must be made within 180 days of the OIG’s receipt of Alpha Respiratory’s final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

This CIA shall apply to, except as otherwise noted herein, only the following business and/or billing center(s) owned and operated by Alpha Respiratory: the Chico Center (supplier number 0294030029), the Redding Center (supplier number 0294030027), and the Designated Regional Billing and Collection Office responsible for billing Federal health care program claims for the Chico Center and the Redding Center (the “Covered Centers”).

Alpha Respiratory shall, within 15 days of the Effective Date of this CIA, apply for a Medicare supplier number (which may be the same supplier number billed prior to the date hereof by Lincare if the National Supplier Clearinghouse (“NSC”) authorizes the transfer thereof to Alpha Respiratory or may be a new supplier number if such is required by the NSC) for each of the foregoing centers and provide same to the OIG in its Implementation Report, or if not then transferred or issued, as the case may be, within 10 days thereafter.

Alpha Respiratory represents that upon the Effective Date of this CIA, it shall adopt as its corporate compliance program (“Program”) the corporate-wide compliance program maintained and operated by its parent corporation, Lincare Inc. (“Lincare Program”). Pursuant to and for the duration of this CIA, Alpha Respiratory shall

maintain and operate such Program so that it adheres to or includes the following obligations or elements.

A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall engage the Lincare Program Compliance Officer to serve as its Compliance Officer, consistent with the following requirements. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Alpha Respiratory, shall make periodic (at every Alpha Respiratory Board of Director's meeting or quarterly, whichever occurs less frequently) reports regarding compliance matters of the Covered Centers directly to the Board of Directors of Alpha Respiratory, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities of the Covered Centers engaged in by Alpha Respiratory as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management of Alpha Respiratory or of Lincare if Alpha Respiratory obtains such support functions from Lincare necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas at the Covered Centers and shall oversee monitoring of internal and external audits and investigations at the Covered Centers).

Alpha Respiratory shall report to the OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would

substantially affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall distribute to its employees the Lincare Program's "Corporate Health Care Law Compliance Program" booklet (hereinafter "Compliance Handbook"), which for purposes of this CIA shall be deemed to serve as the Code of Conduct. For the duration of this CIA, Alpha Respiratory shall maintain the Compliance Handbook or similar document delineating Alpha Respiratory's compliance principles. Alpha Respiratory shall make the promotion of, and adherence to, the Compliance Handbook an element in evaluating the performance of all Covered Employees. The Compliance Handbook shall, at a minimum, set forth:

- a. Alpha Respiratory's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Alpha Respiratory's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Alpha Respiratory's own Policies and Procedures as implemented pursuant to section III.B.2 (including the requirements of this CIA);
- c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer or other individual designated by Alpha Respiratory suspected violations of any Federal health care program requirements or of Alpha Respiratory's own Policies and Procedures;
- d. the possible consequences to both Alpha Respiratory and Covered Persons of failure to comply with Federal health care program requirements and with Alpha Respiratory's own Policies and Procedures and the failure to report such non-compliance; and

- e. the right of all individuals to use the Disclosure Program described in section III.E, and Alpha Respiratory's commitment to maintain confidentiality, as may be required, and non-retaliation with respect to such disclosures.

To the extent not already accomplished, within 120 days of the Effective Date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Alpha Respiratory's Compliance Handbook. New Covered Persons shall receive the Compliance Handbook and shall complete the required certification within one month after becoming a Covered Person or within 120 days of the Effective Date of the CIA, whichever is later.

Alpha Respiratory shall periodically, but not more often than annually unless Alpha Respiratory deems necessary, review the Compliance Handbook and make any necessary revisions based on such a review. Any substantial revisions to the Compliance Handbook shall be distributed to Covered Persons within 45 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revisions to the Compliance Handbook within 30 days of the distribution of such revisions.

2. Policies and Procedures. For the duration of this CIA, Alpha Respiratory shall maintain Lincare's written Policies and Procedures regarding the operation of the Lincare Program and its compliance with Federal health care program requirements as adopted and applied to Alpha Respiratory. Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall review the existing Policies and Procedures and amend them, if necessary, to ensure that they at a minimum address the specific risk areas associated with the provision and reimbursement of home oxygen therapy and durable medical equipment and supplies under the Federal health care programs, as identified below.

- a. Coverage rules and criteria;
- b. Medical necessity requirements;
- c. Certificates of Medical Necessity ("CMNs");
- d. Physician's orders;
- e. Qualification of patients for oxygen therapy;
- f. Billing;
- g. Selection of HCPCS codes;
- h. Capped rentals;

- i. Collection of Medicare co-pay and deductibles; and
- j. Kickbacks and Self-Referrals.

To the extent that Alpha Respiratory substantially revises its existing Policies and Procedures to address the risk areas identified above, within 120 days of the Effective Date of the CIA, the relevant portions of the revised Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures. Knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if Alpha Respiratory deems necessary), Alpha Respiratory shall assess and update as necessary the Policies and Procedures. Within 45 days of the Effective Date of any substantial revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall provide at least 1 hour of general training to Covered Persons. This training, at a minimum, shall explain Alpha Respiratory's:

- a. CIA requirements; and
- b. The Lincare Program (including the Compliance Handbook and the Policies and Procedures as they pertain to general compliance issues) as adopted and applied to Alpha Respiratory.

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 1 hour of general training annually.

2. *Specific Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is directly involved in the delivery of patient care items or services and/or directly involved in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant

Covered Persons”) shall receive at least 3 hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

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

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

New Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the Effective Date of this CIA, whichever is later. An Alpha Respiratory employee or a Lincare employee engaged by Alpha Respiratory for such purpose, 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 his/her applicable training.

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

3. *Certification.* Each Covered Person who is required to attend training shall certify, in writing, that he or she has received the required training. The certification

shall specify the type of training received and the date received. 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. Engagement Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform certain engagements to assist Alpha Respiratory in assessing and evaluating its billing and coding practices and systems at or for the Covered Centers. From time to time, and during the term of this CIA, Alpha Respiratory shall have the right, in its sole discretion, to select new or alternate IROs. Each IRO retained by Alpha Respiratory shall have expertise in the billing, coding, reporting and other requirements of home oxygen therapy and durable medical equipment and supplies and in the general requirements of the Federal health care program(s) from which Alpha Respiratory seeks reimbursement. Each IRO shall assess, along with Alpha Respiratory, 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. The IRO(s) shall address and analyze Alpha Respiratory’s billing and coding at or for the Covered Centers to the Federal health care programs (“Claims Engagement”).

b. Frequency of Claims Engagement. The Claims Engagement shall be performed annually and shall cover each Reporting Period (as defined in Section V.B). The IRO(s) shall perform all components of each annual Claims Engagement.

c. Retention of Records. The IRO(s) and Alpha Respiratory shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those

exchanged between the IRO and Alpha Respiratory related to the engagements).

2. *Claims Engagement.* The Claims Engagement shall include a Discovery Sample and, if necessary as set forth below, a Full Sample and Systems Engagement. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Alpha Respiratory at or for the Covered Centers. The Paid Claims shall be reviewed based on the supporting documentation available at Alpha Respiratory or under Alpha Respiratory's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

b. 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 Engagement required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Alpha Respiratory should, as appropriate, further analyze any errors identified in the Discovery Sample. Alpha Respiratory recognizes that the OIG or other HHS component, in its discretion and as authorized by law, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Engagement, as described below.

c. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.b, 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 estimate the actual Overpayment in the population with a 90%

confidence level and with a maximum relative precision of 25% of the point estimate. The Paid Claims shall be reviewed based on supporting documentation available at Alpha Respiratory or under Alpha Respiratory'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, Alpha Respiratory 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 Alpha Respiratory to the appropriate Medicare Program contractor (e.g., carrier or DMERC), for appropriate follow-up.

d. Systems Engagement. If Alpha Respiratory's Discovery Sample identifies an Error Rate of 5% or greater, Alpha Respiratory's IRO shall also conduct a Systems Engagement using agreed-upon procedures. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) which generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments.

e. Repayment of Identified Overpayments. In accordance with section III.H. of the CIA, Alpha Respiratory agrees to repay within thirty (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. Alpha Respiratory agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment to the payor and the associated documentation.

3. *Claims Engagement Report*. The IRO shall prepare a report based upon the Claims Engagement performed (the "Claims Engagement Report"). The Claims Engagement Report shall include:

- a. a description of Alpha Respiratory's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;
- b. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Engagement, 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 [Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included.];
- c. if applicable, the IRO's findings and recommendations concerning the Systems Engagement (if any). Alpha Respiratory may prepare a response to the IRO's findings and recommendations concerning the Systems Engagement (if any) that Alpha Respiratory intends to implement and those recommendations that Alpha Respiratory intends to reject, along with the reasons therefore. Nothing in this CIA shall obligate Alpha Respiratory to implement, in whole or in part, any of the recommendations set forth in the Systems Engagement Report and such action shall not be construed as non-compliance with this CIA.

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

Prior to initiating a Validation Review, the OIG shall notify Alpha Respiratory 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, Alpha Respiratory may request a meeting with the OIG to discuss the results of any engagement submission or findings; present any additional or relevant information to clarify the results of the engagement or to correct the inaccuracy, if any, in the Claims Engagement; and/or propose alternatives to the proposed Validation Review. Pursuant to Section VII hereof, Alpha Respiratory agrees to provide any additional information as may be reasonably requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Engagement issues with Alpha Respiratory prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

5. *Independence Certification.* Within 120 days from the Effective Date of this CIA, and within 120 days of Alpha Respiratory's selection of any alternate IRO, each IRO shall provide to Alpha Respiratory a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements as applied to each IRO and that it has concluded that it is, in fact, independent. The initial certification shall be included in Alpha Respiratory's Implementation Report submission. Annual independence certifications shall be included in each Annual Report. Alpha Respiratory shall in good faith attempt to obtain such independence certification from each IRO it engages. However, the failure to obtain an independence certification from the IRO shall not constitute a breach of this CIA (whether a material breach or otherwise) and shall not constitute a basis upon which the OIG may impose Stipulated Penalties or seek exclusion pursuant to this CIA.

E. Disclosure Program.

Within 120 days of this CIA, Alpha Respiratory shall adopt, and thereafter maintain and operate for the duration of this CIA, the Lincare Program "Reporting System" (hereinafter referred to as the "Disclosure Program"), and to the extent necessary, shall amend the Disclosure Program within 120 days after the Effective Date of this CIA, to ensure that it 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 Alpha Respiratory's policies, conduct, practices, or procedures at the Covered Centers with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. Alpha Respiratory shall publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas at the Covered Centers).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous and confidential communications. Upon receipt of a disclosure related to a Covered Center, 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 related to a Covered Center to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure related to a Covered Center that is sufficiently specific so that it reasonably: (1) permits a determination as to the propriety of the alleged practice; and (2) provides an opportunity for taking corrective action, Alpha Respiratory 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) relating to a Covered Center, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log relating to the Covered Centers shall be available to OIG, upon request; provided however, that such disclosure shall be subject to any conflicting confidentiality obligations imposed by law.

F. Ineligible Persons.

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 that falls within

the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* Alpha Respiratory shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Alpha Respiratory shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring such applicants to disclose whether they are Ineligible Persons; and (b) querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this section affects the responsibility of (or liability for) Alpha Respiratory to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 120 days of the Effective Date of this CIA, Alpha Respiratory shall review its list of current Covered Persons against the Exclusion Lists. Thereafter, Alpha Respiratory shall review its list of current Covered Persons against the Exclusion Lists annually. In addition, Alpha Respiratory shall require Covered Persons to disclose immediately any debarment, exclusion, or other event that makes the Covered Person an Ineligible Person.

If Alpha Respiratory has actual notice that a Covered Person has become an Ineligible Person, Alpha Respiratory shall remove such person from responsibility for, or involvement with, Alpha Respiratory'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 Alpha Respiratory has actual notice that a Covered Person 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 term, Alpha Respiratory shall take all actions that Alpha Respiratory deems necessary, including termination of such Covered Person, 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.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Overpayments*

a. *Definition of Overpayments.* For purposes of this CIA, the term “Overpayment” shall mean the amount of money Alpha Respiratory has received on behalf of or for a Covered Center’s supplier number in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, Alpha Respiratory identifies or learns of any Overpayments, Alpha Respiratory shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of such Overpayment and take remedial steps within 60 days of identification (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 such Overpayment, Alpha Respiratory shall repay the Overpayment to the relevant payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days of identification, Alpha Respiratory shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is

expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Reportable Event.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

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

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If Alpha Respiratory determines through any means that there is a Reportable Event, Alpha Respiratory shall notify OIG, in writing, within 30 days of making the determination that the Reportable Event exists. The report to the OIG shall include the following information:

- (i) If the Reportable Event 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 or will be sent; and

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

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

(iii) a description of Alpha Respiratory's actions taken to correct the Reportable Event; and

(iv) any further steps Alpha Respiratory plans to take to address the Reportable Event and prevent it from recurring.

I. Application of CIA Obligations to Non-Covered Person Contractors.

Alpha Respiratory shall take the following steps with respect to a contractor described in the Preamble to this CIA, who does not meet the definition of Covered Person: (1) provide the contractor with a copy of its Code of Conduct and relevant Policies and Procedures; (2) attempt in good faith to amend or modify the existing contract such that the contractor shall conform to all applicable provisions of this CIA; or if agreement cannot be reached with respect to all applicable CIA terms, then as many applicable terms as possible shall be included in the amended or modified contract.

IV. CHANGES IN COVERED CENTERS' LOCATIONS AND/OR OPERATIONS

In the event that, after the Effective Date of this CIA, Alpha Respiratory changes its Covered Centers' locations; or sells, closes, or makes any other organizational changes to its Covered Centers with respect to how they operate or are organized as business units within Alpha Respiratory; or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Alpha Respiratory shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of such event. In the event of any change other than sale or closure, the notification shall include the location of the new or reorganized operation(s), phone and fax numbers, their Federal health care program supplier identification number(s), and the contractor (including name and address) that issued each supplier identification number. All person's who meet the definition of Covered Persons at such

new locations shall be subject to the applicable requirements in the CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number, and position description of the Compliance Officer required by section III.A, and a summary of other non-compliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. a copy of Alpha Respiratory's Code of Conduct required by section III.B.1;
4. a copy of all Policies and Procedures required by section III.B.2;
5. a copy of all 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;
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 Relevant 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.E;
8. the identity of the IRO(s), a summary/description of all engagements between Alpha Respiratory and the IRO, including, but not limited to, any ongoing outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the the first annual Claims Engagement;
9. a certification from each IRO regarding its professional independence from Alpha Respiratory;
10. a summary of personnel actions (other than hiring) taken pursuant to section III.F.; and
11. the certification required by section V.C.

B. Annual Reports. Alpha Respiratory shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Alpha Respiratory's compliance activities at the Covered Centers or as otherwise required by this CIA 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, or substantial change in the position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;
2. a certification by the Compliance Officer that:

- a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1; and
- b. 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.

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 new compliance-related Policies and Procedures implemented during the Reporting Period;
4. a copy of all 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;
5. a complete copy, each prepared in accordance with the requirements set forth in this CIA, of the Claims Engagement Report, the Systems Engagement Report, if applicable, and a copy of each IRO's Engagement letter;
6. Alpha Respiratory's response and corrective action plan(s), if any, related to any issues concerning the Covered Centers raised by the IRO(s) as a result of the Claims Engagement and, if applicable, the Systems Engagement;
7. a revised summary/description of all engagements between Alpha Respiratory and the IRO, including, but not limited to, any then ongoing outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO(s) regarding its professional independence from Alpha Respiratory;
9. a summary of Reportable Events (as defined in III.H) at the Covered Centers identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
10. a report of the aggregate Overpayments to the Covered Centers' supplier numbers that have been returned to the Federal health care programs and that have been identified as a result of the compliance program or CIA. For purposes of this CIA, all Overpayment amounts will be classified as "outpatient Medicare". Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;
11. a summary of the disclosures in the disclosure log related to Covered Centers required by section III.E 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 Alpha Respiratory as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the 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.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
14. a description of any changes in the Covered Centers' locations, mailing addresses, or names under which the Covered Centers' do business, their phone and fax numbers, their Federal health care program supplier identification number(s), and the contractor (including name and address) that issued each supplier 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. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Alpha Respiratory 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. Designation of Information: Alpha Respiratory 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. Alpha Respiratory 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

Alpha Respiratory:

Alpha Respiratory CIA

Corporate Compliance Officer
Alpha Respiratory Inc.
19387 U.S. 19 North
Clearwater, FL 33764
Phone: 727-530-7700
Fax: 727-532-4091

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 Alpha Respiratory's books, records, and other documents and supporting materials relating to the Covered Centers and/or conduct on-site reviews of the Covered Centers or Alpha Respiratory corporate headquarters with respect to the Covered Centers for the purpose of verifying and evaluating: (a) Alpha Respiratory's compliance with the terms of this CIA; and (b) the Covered Centers' compliance with the requirements of the Federal health care programs in which they participate. Documentation reasonably requested by OIG described above shall be made available by Alpha Respiratory 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 Alpha Respiratory'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 with prior notice to Alpha Respiratory in accordance with section VI of this CIA. Alpha Respiratory agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Alpha Respiratory's employees may elect to be interviewed with or without a representative of Alpha Respiratory present.

Notwithstanding the foregoing, the OIG's rights to examine or request copies of Alpha Respiratory's books, records, and other documentation and supporting materials or to conduct on-site reviews described above shall be subject to any applicable privileges, including but not limited to the attorney-client, work product doctrine, or other applicable

privileges. Notwithstanding that fact, the existence of any such privilege does not affect Alpha Respiratory's obligation to otherwise comply with the provisions of this CIA.

VIII. DOCUMENT AND RECORD RETENTION

Alpha Respiratory shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs for the Covered Centers, 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 Alpha Respiratory prior to any release by OIG of information submitted by Alpha Respiratory pursuant to its obligations under this CIA and identified upon submission by Alpha Respiratory as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Alpha Respiratory shall have the rights set forth at 45 C.F.R. § 5.65(d). Alpha Respiratory 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

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Alpha Respiratory 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 Alpha Respiratory fails to have in place any of the following obligations described in section III:

- a. a Compliance Officer;

- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.

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

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Alpha Respiratory knowingly employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Alpha Respiratory'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 Alpha Respiratory can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day Alpha Respiratory 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 Alpha Respiratory fails to grant access.)

6. A Stipulated Penalty of \$1,000 for each day Alpha Respiratory fails to comply fully and adequately with any obligation of this CIA. In its notice to Alpha

Respiratory, OIG shall state the specific grounds for its determination that Alpha Respiratory has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Alpha Respiratory must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the Alpha Respiratory receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.

With respect to the Stipulated Penalty provision in this Section X.A.6 only, the OIG shall not seek a Stipulated Penalty if Alpha Respiratory demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that (i) Alpha Respiratory has begun to take action to cure the failure to comply; (ii) Alpha Respiratory is pursuing such action with due diligence; and (iii) Alpha Respiratory has provided to OIG a reasonable timetable for the curing the failure to comply.

B. Timely Written Requests for Extensions. Alpha Respiratory 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 Alpha Respiratory 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 Alpha Respiratory 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 Alpha Respiratory has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties should be imposed, OIG shall notify Alpha Respiratory of: (a) Alpha Respiratory's failure to comply together with a basis for such finding; 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, Alpha Respiratory 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 Alpha Respiratory elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Alpha Respiratory cures, to OIG's satisfaction, the alleged breach in dispute. If the decision of the ALJ is in Alpha Respiratory's favor, no Stipulated Penalties shall be due, except as authorized by the ALJ. 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 Alpha Respiratory 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 Alpha Respiratory to report a Reportable Event, take corrective action and make 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.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Alpha Respiratory constitutes an independent basis for Alpha Respiratory's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Alpha Respiratory has materially breached this CIA and that exclusion should be imposed, OIG shall notify Alpha Respiratory of: (a) Alpha Respiratory'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.* Alpha Respiratory 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. Alpha Respiratory 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) Alpha Respiratory has begun to take action to cure the material breach; (ii) Alpha Respiratory is pursuing such action with due diligence; and (iii) Alpha Respiratory has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period or such longer period of time set forth in the timetable provided by Alpha Respiratory pursuant to section X.D.3.c.(iii), Alpha Respiratory fails to satisfy the requirements of section X.D.3, OIG may exclude Alpha Respiratory from participation in the Federal health care programs. OIG will notify Alpha Respiratory in writing of its determination to exclude Alpha Respiratory (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, Alpha Respiratory wishes to apply for reinstatement, Alpha Respiratory must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Alpha Respiratory 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, Alpha Respiratory 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 Alpha Respiratory was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Alpha Respiratory shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to stipulated penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Alpha Respiratory to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Alpha Respiratory 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 Alpha Respiratory 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) Alpha Respiratory had begun to take action to cure the material breach within that period;

(ii) Alpha Respiratory has pursued and is pursuing such action with due diligence; and

(iii) Alpha Respiratory provided to OIG within that period a reasonable timetable for curing the material breach and Alpha Respiratory 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 Alpha Respiratory, only after a DAB decision in favor of OIG. Alpha Respiratory's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Alpha Respiratory 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 Alpha Respiratory 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. Alpha Respiratory agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB and a copy of such decision is provided to Alpha Respiratory. If the DAB finds in favor of Alpha Respiratory, Alpha Respiratory will be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This CIA shall be binding on the successors, assigns, and transferees of Alpha Respiratory;

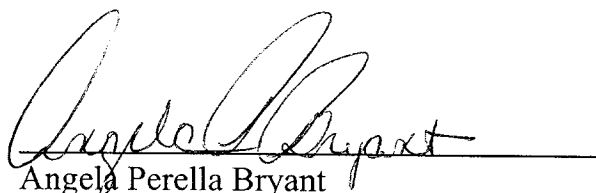
B. This CIA shall become final and binding on the Effective Date;

C. Any modifications to this CIA shall be made only with the prior written consent of all the parties to this CIA;

D. OIG may agree to a suspension of Alpha Respiratory's obligations under the CIA in the event of Alpha Respiratory's cessation of participation in Federal health care programs. If Alpha Respiratory withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Alpha Respiratory agrees to notify OIG 30 days in advance of Alpha Respiratory's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

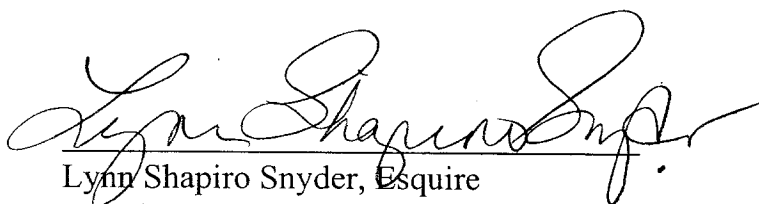
E. The undersigned Alpha Respiratory signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF ALPHA RESPIRATORY INC.



Angela Perella Bryant
General Counsel
Alpha Respiratory Inc.

12/14/01
DATE

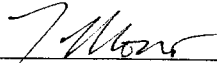


Lynn Shapiro Snyder, Esquire
Epstein Becker & Green, P.C.

12/13/01
DATE



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



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

12/14/01
DATE

Alpha Respiratory CIA Final.wpd

APPENDIX A

A. Claims Engagement

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

a. Overpayment: As defined in section III.H.1.a of the CIA, the amount of money Alpha Respiratory has received in excess of the amount due and payable under any Federal health care program requirements for the Covered Centers' supplier numbers.

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

c. Paid Claim: A code or line item submitted by a Covered Center during the Reporting Period and for which the Covered Center has received reimbursement from the Medicare program by the 30th day after the last day of said Reporting Period.

d. Population: All Items for which the Covered Centers have submitted a code or line item and for which the Covered Centers have received reimbursement from the Medicare program (i.e., a Paid Claim) during the Reporting Period covered by the Claims Engagement. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

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

b. Use of First Samples Drawn. For the purposes of all samples (Discovery

b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

c. A description or identification of the statistical sampling software package used to conduct the sampling.

3. Claims Engagement Results. For the Discovery Sample and Full Sample (if any), the following information should be included in the Claims Engagement Report:

a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Alpha Respiratory (“Claims Submitted”) differed from what should have been the correct claim (“Correct Claim”), regardless of the effect on the payment.

b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Alpha Respiratory.

c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

d. Error Rate in the sample.

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

4. Systems Engagement. Observations and recommendations on possible improvements to the system(s) and process(es) which 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 methodology utilized for the Claims Engagement; and (2) performed the Claims Engagement.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

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

REFUND INFORMATION

For each Claim, provide the following:

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

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

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

Reason Codes:

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