

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LINCARE HOLDINGS INC. AND LINCARE INC.**

I. PREAMBLE

Lincare Holdings Inc. and Lincare Inc. (collectively "Lincare") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Lincare is entering into a Settlement Agreement with the OIG, and this CIA is incorporated by reference into the Settlement Agreement.

Before the effective date of this CIA (defined in Section II), Lincare initiated a voluntary compliance program, which includes a corporate compliance officer, a corporate compliance committee, a Code of Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, an ineligible persons screening program, and internal audit and review procedures. Lincare may modify its voluntary compliance measures as appropriate; however, Lincare agrees that it shall comply with the obligations enumerated in this CIA during the term of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Lincare under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after the OIG's receipt of: (1) Lincare's final Annual Report; or (2) any additional materials submitted by Lincare pursuant to the OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction entered into by Lincare that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Lincare and any actual or potential source of health care business or referrals of health care business to Lincare or any actual or potential recipient of health care business or referral from Lincare. The term "source" shall include any physician, contractor, vendor, or agent; and the term "health care business or referrals" shall be read to include referring, recommending, or arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature related to the provision of services to Lincare, including but not limited to, training, education, consulting, research, clinical studies, focus groups, and physician advisory boards.

b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.

2. "Covered Persons" includes:

a. all officers, directors, and employees of Lincare; and

b. all contractors, subcontractors, agents, and other persons who, on behalf of Lincare: (i) directly provide patient care items or services; (ii) perform billing or coding functions; and/or (iii) engage in sales and marketing.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons 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 the calendar year.

3. "Relevant Covered Persons" includes all Covered Persons who are involved in the:
 - a. preparation or submission of claims for reimbursement from any Federal health care program; and
 - b. preparation, handling, or submission of Certificates of Medical Necessity (CMNs), including but not limited to all Lincare sales representatives and all Lincare employees in the CMN Collection Center as described in Section III.F.
4. "Arrangements Covered Persons" includes all Covered Persons who are:
 - a. sales representatives, center, area, district and regional managers, compliance personnel, and accounts payable employees who are involved in handling or processing expense reports; and
 - b. officers of Lincare.

III. CORPORATE INTEGRITY OBLIGATIONS

Lincare shall establish, to the extent such elements do not already exist, and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Before the Effective Date of this CIA, Lincare appointed a Compliance Officer with responsibility for administering Lincare's Compliance Program. To the extent not already accomplished, within 120 days after the Effective Date, 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. To the extent not already accomplished, within 90 days after the Effective Date, the Compliance Officer shall be a member of senior management of Lincare, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Lincare, and shall be authorized to report on such matters to the Board of Directors at anytime. The Compliance Officer shall not be the General Counsel or Chief Financial Officer of Lincare nor shall the Compliance Officer be subordinate to the General Counsel or Chief Financial Officer of Lincare. The Compliance Officer shall be responsible for monitoring the day-to-day

compliance activities engaged in by Lincare as well as for any reporting obligations created under this CIA.

Lincare 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 affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Before the Effective Date of this CIA, Lincare appointed a Compliance Committee. To the extent not already accomplished, within 90 days after the Effective Date, Lincare shall establish a Compliance Committee that shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing/audit, marketing, human resources, and operations). The Compliance Officer shall chair the Compliance Committee, and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Lincare represented to the OIG that, before the Effective Date of this CIA, Lincare developed a Code of Conduct (known as the Corporate Health Care Law Compliance Program booklet or the Compliance Handbook or other relevant compliance policies and procedures herein referred to as "the Code of Conduct"). Lincare shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Lincare'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. Lincare's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Lincare's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individuals designated by Lincare, suspected violations of any Federal health care program requirements or of Lincare's own Policies and Procedures;
- d. the possible consequences to Lincare and Lincare's Covered Persons of failure to comply with all Federal health care program requirements and with Lincare's 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.G, and Lincare's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, Lincare shall distribute the Code of Conduct to each Covered Person and each Covered Person will certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Lincare's Code of Conduct. Lincare may distribute the Code of Conduct and the required certification to each Covered Person either electronically or in hard-copy form. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Lincare shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Lincare shall implement written Policies and Procedures regarding the operation of

Lincare's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the applicable Federal health care program requirements providing for the proper completion of CMNs;
- c. the applicable Federal health care program requirements governing coverage and reimbursement for oxygen including but not limited to the prohibition of performance or participation, by a Lincare employee, of the qualifying oximetry test for a Medicare beneficiary requiring home oxygen that will be supplied by Lincare;
- d. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures required under this Section, and this CIA;
- e. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- f. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Non-Contractual Arrangements Procedures and the Contractual Arrangements Procedures.

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

At least annually (and more frequently, if appropriate), Lincare shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall

be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Lincare shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain Lincare's:

- a. CIA requirements; and
- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues and Policies and Procedures regarding Contractual and Non-Contractual Arrangements).

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

2. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Contractual and Non-Contractual Arrangements that potentially implicate the Anti-Kickback Statute and the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. Lincare's policies, procedures, and other requirements relating to Non-Contractual Arrangements and Contractual Arrangements, including but not limited to the Non-Contractual Arrangements Procedures and Contractual Arrangements Procedures required by Section III.D of the CIA;
- c. the personal obligation of each individual involved in the development, approval, management, implementation, use, or review of Lincare's Non-Contractual Arrangements and Contractual

Arrangements to know the applicable legal requirements and Lincare's Policies and Procedures;

d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and

e. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. A Lincare employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least two hours of Arrangements Training annually.

3. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above and Arrangements Training, if applicable. This Specific Training shall include a discussion of the following items:

a. the Federal health care program requirements regarding the accurate coding and submission of claims;

b. the Federal health care program requirements regarding the accurate completion of CMNs;

c. the Federal health care program requirements governing coverage and reimbursement of oxygen, including but not limited to the prohibition of performance or participation by Lincare employees of the qualifying oximetry test for a Medicare beneficiary requiring home oxygen that will be supplied by Lincare;

d. policies, procedures, and other requirements applicable to the documentation of medical records;

- e. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- f. applicable reimbursement statutes, regulations, and program requirements and directives;
- g. the legal sanctions for violations of the Federal health care program requirements;
- h. examples of proper and improper claims submission practices; and
- i. examples of properly and improperly completed CMNs.

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

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training annually.

4. *Certification.* Each individual who is required to attend training pursuant to this Section III.C shall, upon completion of the training, certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to the OIG, upon request.

5. *Qualifications of Trainer.* Persons providing the training required by this Section III.C shall be knowledgeable about the subject area.

6. *Update of Training.* At least annually, Lincare shall review the training programs developed to satisfy the requirements of this Section III.C, and, where appropriate, update the training to reflect changes in Federal health care program

requirements, any issues discovered during internal audits, the Non-Contractual Arrangements Review, and any other relevant information.

7. *Training Methods.* Lincare may provide the training required under this CIA in-person, via telephone conference, through videotape, DVD, appropriate computer-based training approaches, or other comparable methods not involving in-person training. If Lincare chooses to provide the training required under this CIA through appropriate computer-based approaches, all applicable references to “hours” in this Section III.C. shall mean “normative hours,” meaning the number of hours usually required to complete the requirements of a training course through computer-based modules. (Normative hours may vary from the actual hours of training.) If Lincare chooses to provide training pursuant to any such method, they shall also make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Compliance with the Anti-Kickback Statute and the Stark Law.

1. *Non-Contractual Arrangements Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Lincare shall create procedures reasonably designed to ensure that each Non-Contractual Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Non-Contractual Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all Non-Contractual Arrangements to track all Non-Contractual Arrangements, in order to ensure that each Non-Contractual Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law; the Non-Contractual Arrangements Database shall contain the following information:

- (i) the name of the entity or individual receiving the remuneration (i.e., the Non-Contractual Arrangement);
- (ii) the type of Non-Contractual Arrangement (listing in the aggregate multiple distributions of the same type of Non-Contractual Arrangement to each entity or individual); and

(iii) the aggregate value of each type of Non-Contractual Arrangement given to each entity or individual during the Reporting Period;

b. tracking all Non-Contractual Arrangements in the Non-Contractual Arrangements Database;

c. establishing and implementing a written review and approval procedure for all Non-Contractual Arrangements, the purpose of which is to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute and/or the Stark Law; the procedure shall be subject to an annual legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

d. requiring the Compliance Officer to review the Non-Contractual Arrangements Database, internal review and approval procedure, and other Non-Contractual Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee on a quarterly basis; and

e. implementing corrective action when suspected violations of the Anti-Kickback Statute and/or the Stark Law are discovered, including disclosing Reportable Events pursuant to Section III.J (Reporting).

2. *Contractual Arrangements Procedures.* Before entering into new Contractual Arrangements or renewing existing Contractual Arrangements, Lincare shall comply with the following requirements (Contractual Arrangements Procedures):

a. ensure that each Contractual Arrangement is set forth in writing and signed by Lincare and the other parties to the Contractual Arrangement;

b. include in the written agreement a requirement that all individuals who meet the definition of Covered Persons, Relevant Covered Persons, and Arrangements Covered Persons shall comply with Lincare's Compliance Program, including the applicable training related to the Anti-Kickback Statute and the Stark Law. Additionally, Lincare shall provide each party to the Contractual Arrangement with a copy of the Code of Conduct and the Policies

and Procedures that relate to the Anti-Kickback Statute and the Stark Law;

c. include in the written agreement a certification by the parties to the Contractual Arrangement that the parties shall not violate the Anti-Kickback Statute and/or the Stark Law with respect to the performance of the Contractual Arrangement;

d. creating and maintaining a database of all Contractual Arrangements that shall contain the following information;

(i) the name of the entity or individual that is party to the Contractual Arrangement;

(ii) the type of Contractual Arrangement;

(iii) the amount of compensation to be paid pursuant to each Contractual Arrangement and the means by which the compensation is paid;

(iv) whether the compensation to be paid pursuant to the Contractual Arrangement is based on the volume or value of referrals to Lincare or a Lincare subsidiary; and

(v) whether the Contractual Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable;

e. tracking all Contractual Arrangements in the Contractual Arrangements Database;

f. establishing and implementing a written review and approval procedure for all Contractual Arrangements, the purpose of which is to ensure that all Contractual Arrangements do not violate the Anti-Kickback Statute and/or the Stark Law; the procedure shall be subject to an annual legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law; and

g. implementing corrective action when suspected violations of the Anti-Kickback Statute and/or the Stark Law are discovered,

including disclosing Reportable Events pursuant to Section III.J (Reporting).

3. *Records Retention and Access.* Lincare shall retain and make available to the OIG, upon request, the Contractual and Non-Contractual Arrangements Databases and all supporting documentation of the Contractual and Non-Contractual Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Contractual and Non-Contractual Arrangements.

4. *Sales Promotion Catalog.* Lincare provides to referral sources items from Lincare's Sales Promotion Catalog. Notwithstanding the definition of Non-Contractual Arrangement, the provision of Sales Promotion Catalog items to referral sources (such as physicians) shall not be considered a Non-Contractual Arrangement for purposes of Sections III.D.1.a and III.D.1.b. Lincare shall submit the Sales Promotion Catalog to the OIG with each Annual Report along with a description of any addition and/or change to the Sales Promotion Catalog that was made during the prior Reporting Period. Subject to review by the OIG, and in its sole discretion, the OIG shall determine whether any addition and/or change in the Sales Promotion Catalog items shall be Non-Contractual Arrangements for purpose of Sections III.D.1.a and III.D.1.b for the subsequent Reporting Period. Irrespective of the OIG's determination of whether the provision of items in the Sales Promotion Catalog to referral sources is considered a Non-Contractual Arrangement for purposes of Sections III.D.1.a and III.D.1.b, Lincare recognizes that the provision of anything of value to referral sources, depending on the specific facts and circumstances, may violate the Anti-Kickback Statute, the Stark Law, and/or other statutes, regulations, or guidelines applicable to such conduct.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Lincare shall engage an individual or entity (or entities), such as an auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist Lincare in assessing its compliance with the obligations pursuant to Sections III.D.1 of this Agreement (Non-Contractual Arrangements Review).

The IRO shall assess, along with Lincare, whether it can perform the IRO review in a professionally independent and/or objective fashion,

as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Non-Contractual Arrangements Review shall not be deemed to create an attorney-client relationship between Lincare and the IRO.

b. *Frequency of Non-Contractual Arrangements Review.* The Non-Contractual Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The first Reporting Period for purposes of the first Non-Contractual Arrangements Review shall begin 120 days after the Effective Date of this CIA and shall be for the remainder of the first Reporting Period. The IRO(s) shall perform all components of each annual Non-Contractual Arrangements Review.

c. *Retention of Records.* The IRO and Lincare 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 Lincare) related to the reviews.

d. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Lincare's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Non-Contractual Arrangements Review.* The IRO shall perform a review to assess whether Lincare is complying with the Non-Contractual Arrangements Procedures required by Section III.D.1 of this CIA. The IRO shall randomly select a sample of 100 Non-Contractual Arrangements that were entered into during the Reporting Period. The IRO shall assess whether Lincare has implemented the Non-Contractual Arrangements Procedures and, for each selected Non-Contractual Arrangement, the IRO shall assess whether Lincare has complied with the Non-Contractual Arrangements Procedures with respect to that Non-Contractual Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Non-Contractual Arrangement is listed in the Non-Contractual Arrangements Database; (b) verifying that the Non-Contractual Arrangement was subject to the internal review and approval procedure and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Non-Contractual Arrangement is properly tracked; (d) verifying that the Compliance

Officer is reviewing the Non-Contractual Arrangements Database, internal review and approval process, and other Non-Contractual Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; and (e) verifying that Lincare has implemented corrective action when potential violations of the Anti-Kickback Statute and/or the Stark Law are discovered.

3. *Non-Contractual Arrangements Review Report.* The IRO shall prepare a report based upon the Non-Contractual Arrangements Review performed (Non-Contractual Arrangements Review Report). The Non-Contractual Arrangements Review Report shall include the IRO's findings with respect to: (a) whether Lincare has generally implemented the Non-Contractual Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Lincare has complied with the Non-Contractual Arrangements Procedures with respect to each of the randomly selected Non-Contractual Arrangements reviewed by the IRO. In addition, the Non-Contractual Arrangements Review Report shall include observations, findings, and recommendations, if any, on possible improvements to Lincare's policies, procedures, and systems in place to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute and/or the Stark Law.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Lincare's Non-Contractual Arrangements Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Non-Contractual Arrangements Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Non-Contractual Arrangements Review complied with the requirements of this CIA and/or the findings or Non-Contractual Arrangements Review results are inaccurate (Validation Review). Lincare shall pay for the reasonable cost of any such review performed by the OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Lincare's final Annual Report must be initiated no later than one year after Lincare's final submission (as described in Section II) is received by the OIG.

Before initiating a Validation Review, the OIG shall notify Lincare 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, Lincare may request a meeting with the OIG to: (a) discuss the results of any Non-Contractual Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Non-Contractual Arrangements Review or to correct the inaccuracy of the Non-Contractual Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. Lincare 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 Non-Contractual Arrangements Review issues with Lincare before 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/Objectivity Certification.* The IRO shall include in its report(s) to Lincare a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Non-Contractual Arrangements Review and that the IRO has concluded that it is, in fact, independent and/or objective.

F. Procedures Related to Certificates of Medical Necessity.

1. *General Description.* Lincare has represented that it is revising its policies and procedures related to the collection of CMNs and that it will implement the new policies and procedures ("CMN Procedures") within 150 days after the Effective Date. Lincare makes the following representations about the CMN Procedures. Lincare is establishing a central CMN Collection Center. Pursuant to its CMN Procedures, Lincare personnel will complete Sections A and C of the CMN. Lincare personnel subsequently will deliver the CMN to the treating physician's office instructing them to appropriately complete Sections B and D of the CMN and to fax the CMN with the appropriately completed Sections B and D to Lincare's CMN Collection Center. CMNs will then be forwarded from the CMN Collection Center to the appropriate billing office to be processed for billing purposes. The CMN Collection Center will forward to the appropriate billing office only CMNs that were sent to the CMN Collection Center from treating physicians' offices who completed Sections B and D of the CMN.

2. *Validation Review.* Lincare shall conduct a monthly Validation Review of its CMN Procedures to ensure that they are operating as intended (CMN Validation Review). The CMN Validation Review shall consist of 10 randomly selected CMNs per month pursuant to which Lincare submitted a claim to a Federal health care program. Pursuant to the CMN Validation Review, Lincare shall ensure that all Federal health care program requirements pertaining to CMNs were followed. At a minimum, Lincare shall, for each CMN reviewed (1) verify that Lincare has an acceptable CMN in its files; (2) verify that the acceptable CMN matches exactly the electronic CMN submitted to the DMERC, if the CMN was submitted electronically; and (3) contact the treating physician's or health care professional's office to verify (a) that the signature is authentic; (b) that the physician or health care professional is in fact the treating physician or health care professional; (c) that Section B was completed exclusively by the treating physician's or health care professional's office; and (d) that the completed CMN was

faxed to the CMN Collection Center by the staff of the treating physician or health care professional. As part of the CMN Validation Review process, Lincare shall also verify, for CMNs pertaining to oxygen, that no Lincare employee performed and/or participated in the performance of the qualifying oximetry test.

G. Disclosure Program.

Lincare represented to the OIG that, before the Effective Date of this CIA, Lincare established a Disclosure Program. To the extent not already provided for in Lincare's current Disclosure Program, within 90 days after the Effective Date, Lincare shall establish and maintain a Disclosure Program that includes 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 Lincare'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. Lincare shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

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

H. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and
 - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).
- c. “Screened Persons” include all current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), all current and prospective officers, directors, employees, contractors, and agents of Lincare.

2. *Screening Requirements.* Lincare shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Lincare shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.
- b. Lincare shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis

thereafter. Lincare shall screen institutional shareholders if Lincare has notice that an institutional shareholder (1) has acquired an ownership interest of 5% or more as of the date of screening and (2) acquired that ownership interest through public trading.

c. Lincare shall implement a policy requiring all Screened Persons (except prospective and current owners who (1) have an ownership interest of 5% or more; and (2) acquired the ownership interest through public trading) to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Lincare to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Lincare has actual notice that a Screened Person has become an Ineligible Person, Lincare shall remove such person from responsibility for, or involvement with, Lincare's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or in 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 Lincare has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, Lincare shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

I. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by Lincare's Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Corporate Compliance Officer, or General Counsel, Lincare shall notify the OIG, in writing, of any ongoing investigation or legal proceeding known to Lincare, conducted or brought by a governmental entity or its agents involving an allegation that Lincare 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, if known. Lincare shall also provide written notice to the OIG within 30 days after the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the investigation or proceedings, if any.

J. Reporting.

1. *Overpayments.*

a. Definition of Overpayments. For purposes of this CIA, an "Overpayment" shall mean the amount of money Lincare 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, Lincare identifies or learns of any Overpayment, Lincare shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Lincare shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Lincare shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix A 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 Events.

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

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

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

b. Reporting of Reportable Events. If Lincare determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Lincare shall notify the OIG, in writing, within 30 days after 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 OIG shall be made at the same time as the notification to the payor required in Section III.J.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

iii. a description of Lincare's actions taken to correct the Reportable Event; and

iv. any further steps Lincare plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS

In the event that, after the Effective Date, Lincare sells, closes, purchases, or establishes a new business unit related to the delivery, sale, marketing, or furnishing of items or services that may be reimbursed by Federal health care programs, Lincare shall notify the OIG of this fact as soon as possible, but no later than within 60 days after the date of sale, closure, purchase, or establishment. This notification shall include the address of the new business unit, phone number, fax number, Medicare number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Lincare shall submit a written report to the OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

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

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. a copy of the applicable Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to the OIG, upon request);

6. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to the OIG, upon request.

7. a description of each of Lincare's Non-Contractual Arrangements Procedures required by Section III.D.1;

8. a description of each of Lincare's Contractual Arrangements Procedures required by Section III.D.2;

9. a description of the Disclosure Program required by Section III.G;

10. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Lincare and the IRO; and (d) the proposed start and completion dates of the Non-Contractual Arrangements Review;

11. a certification from the IRO regarding its professional independence and/or objectivity with respect to Lincare;

12. a certification that the CMN Procedures described in Section III.F are in place, including a statement of the percentage of CMNs collected through the CMN Procedures and the percentages of CMNs collected by other means, broken down by each method of collection; or copies of OIG correspondence demonstrating OIG's granting of any extension of time;

13. a description of the process by which Lincare fulfills the requirements of Section III.H regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.H; the actions taken in response to the screening and removal obligations set forth in Section III.H; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a list of all of Lincare's locations (including locations and mailing addresses); the corresponding name(s) under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare number(s), provider identification number(s), and/or supplier number(s);

16. a description of Lincare's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Lincare shall submit to the OIG annually a report with respect to the status of, and findings regarding, Lincare's compliance activities for each of the 5 Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a 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;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to the OIG, upon request);

4. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to the OIG, upon request.

5. a description of any changes to any of the Non-Contractual Arrangements Procedures required by Section III.D.1;
6. a description of any changes to any of the Contractual Arrangements Procedures required by Section III.D.2;
7. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);
8. Lincare's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;
9. a summary and description of any and all current and prior engagements and agreements between Lincare and the IRO, if different from what was submitted as part of the Implementation Report;
10. a certification from the IRO regarding its professional independence and/or objectivity with respect to Lincare;
11. a certification setting forth the number of Lincare's Contractual Arrangements, including an identification of new Contractual Arrangements Lincare entered into during the Reporting Period;
12. a summary of the CMN Validation Review, including the results of the review and any corrective actions taken in response to the review and a statement of the percentage of CMNs collected through the CMN Procedures set forth in Section III.F and the percentages of CMNs collected by other means, broken down by each method of collection;

13. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

14. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

15. a summary of the disclosures in the disclosure log required by Section III.G that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute and/or the Stark law;

16. any changes to the process by which Lincare fulfills the requirements of Section III.H regarding Ineligible Persons;

17. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.H; the actions taken by Lincare in response to the screening and removal obligations set forth in Section III.H; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

18. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. 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;

19. a list of all of Lincare's locations (including addresses) as required by Section V.A.15; the corresponding name(s) under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare number(s); provider identification number(s), and/or supplier number(s); and

20. the certifications 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 the OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Lincare is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, Lincare has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Non-Contractual Arrangements Procedures and Contractual Arrangements Procedures required in Sections III.D.1 and III.D.2, respectively;

3. to the best of his or her knowledge, Lincare has implemented and is maintaining the CMN Procedures set forth in Section III.F of the CIA; and

4. he or she has reviewed the applicable Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful.

D. Designation of Information. Lincare shall clearly identify any portions of their submissions that they believe 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. Lincare shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527

330 Independence Avenue, SW
Washington, D.C. 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Lincare:

Jenna Pederson
Corporate Compliance Officer
Lincare Inc.
19387 U.S. 19 North Highway
Clearwater, FL 33764
Telephone: (727) 530-7700 ext. 8273
Facsimile: (727) 532-9692

OR

Lisa Wegrzyn
General Counsel
Lincare Inc.
19387 U.S. 19 North Highway
Clearwater, FL 33764
Telephone: (727) 530-7700 ext. 8288
Facsimile: (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 the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Lincare's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Lincare's locations for the purpose of verifying and evaluating: (a) Lincare's compliance with the terms of this CIA; and (b) Lincare's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Lincare to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly

authorized representative(s) may interview any of Lincare'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 the OIG. Lincare's employees, contractors, or agents shall have the right to be represented by counsel, and any such employee, contractor, or agent may, at his, her, or its option, be accompanied by counsel for Lincare and/or their personal counsel at any interview by the OIG. Lincare shall assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Lincare's employees may elect to be interviewed with or without counsel and with or without a representative of Lincare present.

VIII. DOCUMENT AND RECORD RETENTION

Lincare 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 Lincare before any release by the OIG of information submitted by Lincare pursuant to their obligations under this CIA and identified upon submission by Lincare as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Lincare shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Lincare is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between Lincare and the OIG. Any breach by Lincare of the Settlement Agreement between Lincare and the OIG does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Lincare and the OIG hereby agree that failure to comply with certain obligations as 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 Lincare fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. the Non-Contractual Arrangements Procedures;
- g. the Contractual Arrangements Procedures;
- h. the CMN Procedures;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements; and
- k. Notification of Government investigations or legal proceedings.

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 Lincare fails to engage an IRO, as required in Section III.E.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lincare fails to submit the Implementation Report or the Annual Reports to the OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lincare fails to submit the annual Non-Contractual Arrangements Review Report in accordance with the requirements of Section III.E.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lincare fails to submit the summary of the annual CMN Validation Review, including a statement of the percentage of CMNs collected through the CMN Procedures set forth in Section III.F and the percentages of CMNs collected by other means, broken down by each method of collection, in accordance with the requirements of Section III.F.2.

6. A Stipulated Penalty of \$1,500 for each day Lincare fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Lincare fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Lincare as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$1,500 for each day after 150 days after the Effective Date of this CIA for which Lincare fails to have in place the CMN Procedures described in Section III.F.1 unless an extension to the deadline has been granted by the OIG.

9. A Stipulated Penalty of \$2,500 for each day Lincare fails to submit in its Annual Report the certification regarding the number of Lincare's Contractual Arrangements as required by Section V.B.11.

10. A Stipulated Penalty of \$1,000 for each day Lincare fails to comply fully and adequately with any obligation of this CIA. The OIG shall provide notice to Lincare, stating the specific grounds for its determination that Lincare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Lincare shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Lincare receives this notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Subsections 1-9 of this Section.

B. Timely Written Requests for Extensions. Lincare 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 the 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 Lincare fails to meet the

revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the 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 Lincare receives the 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 the 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 Lincare has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, the OIG shall notify Lincare of: (a) Lincare's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Lincare shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Lincare elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Lincare cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this 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 the 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 the OIG's decision that Lincare has materially breached this CIA, which decision shall be made at the 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 Lincare to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.J;
- 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 engage and use an IRO in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Lincare constitutes an independent basis for the exclusion of Lincare from participation in the Federal health care programs. Upon a determination by the OIG that Lincare has materially breached this CIA and that exclusion is the appropriate remedy, the OIG shall notify Lincare of: (a) Lincare's material breach; and (b) the 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.* Lincare shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. Lincare 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) Lincare has begun to take action to cure the material breach; (ii) Lincare is pursuing such action with due

diligence; and (iii) Lincare has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Lincare fails to satisfy the requirements of Section X.D.3, the OIG may exclude Lincare from participation in the Federal health care programs. The OIG shall notify Lincare in writing of its determination to exclude Lincare (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 Lincare's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Lincare may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Lincare 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, Lincare 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, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Lincare was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Lincare 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 the OIG with regard to a finding of a breach of this CIA and orders Lincare to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision

unless Lincare 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 the 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 Title 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 Lincare 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) Lincare has begun to take action to cure the material breach within that period; (ii) Lincare has pursued and is pursuing such action with due diligence; and (iii) Lincare provided to the OIG within that period a reasonable timetable for curing the material breach and Lincare has followed the timetable.

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

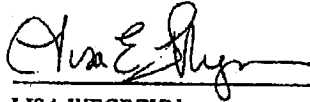
4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for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

- A. This CIA shall be binding on the successors, assigns, and transferees of Lincare;
- 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. The OIG may agree to a suspension of Lincare's obligations under the CIA in the event of Lincare's cessation of the delivery, sale, marketing, or furnishing of items or services reimbursed by any Federal health care programs. If such cessation occurs and Lincare is relieved of its CIA obligations by the OIG, Lincare shall notify the OIG at least 30 days in advance of the date on which Lincare intends to begin delivering, selling, marketing, or furnishing items or services reimbursed by any Federal health care programs. Upon receipt of such notification, the OIG shall evaluate whether the CIA should be reactivated or modified;
- E. Lincare may, in advance of a deadline imposed by this CIA, submit a timely written request to the OIG for an extension of time to perform any act or file any notification or report required by this CIA. The OIG, in its sole discretion, shall determine whether to grant such a request. Deadlines imposed by the CIA that occur on a holiday or weekend shall be due the next business day;
- F. The undersigned Lincare 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; and
- G. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

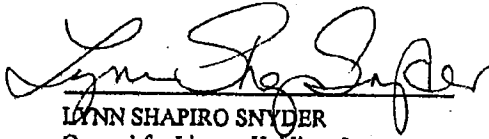
ON BEHALF OF LINCARE HOLDINGS INC. AND LINCARE INC.



LISA WEGRZYN
General Counsel
Lincare Holdings Inc. and Lincare Inc.

5-15-06

DATE



LYNN SHAPIRO SNYDER
Counsel for Lincare Holdings Inc.
and Lincare Inc.

5/15/06

DATE

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



GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
Office of Counsel to the Inspector General
U. S. Department of Health and Human Services

5/15/06

DATE

APPENDIX A

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

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

REFUND INFORMATION

For each Claim, provide the following:

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

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

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

Reason Codes:

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

**FIRST AMENDMENT TO THE
CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF THE INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LINCARE HOLDINGS INC. AND LINCARE INC.**

Lincare Holdings Inc. and Lincare Inc. (Lincare), hereby enter into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG) of the Department of Health and Human Services for the CIA that was executed by and between Lincare and OIG and that became effective May 15, 2006.

Lincare and OIG agree as follows:

1. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date).
2. All terms and conditions of the CIA shall be in effect, with the following modifications:

- a. *IRO Certificates of Medical Necessity (CMN) Review*. Section III.F of the CIA shall be amended to include the following provision:

3. *IRO CMN Review*. The IRO shall conduct quarterly reviews of Lincare's CMNs to ensure that the CMNs are in compliance with applicable Federal laws. Each quarter, the IRO shall randomly select (using RATS-STATS) and review 30 CMNs pursuant to which Lincare submitted claims to Federal health care programs. At a minimum, the IRO shall, for each CMN reviewed, (1) verify that Lincare has a valid CMN in its files; (2) verify that the valid CMN matches exactly the electronic CMN submitted to the DMERC or DME MAC, if the CMN was submitted electronically; and (3) contact the prescribing physician or health care professional to verify (a) that the signature on the CMN is authentic; (b) that the prescribing physician or health care professional did in fact determine that the DME prescribed was medically necessary; (c) that Section B was completed exclusively by the prescribing physician's or health care professional's office; and (d) that the completed CMN

was faxed to Lincare's CMN Collection Center by the staff of the prescribing physician or health care professional. As part of the CMN Review, the IRO shall also verify, for any randomly selected CMNs pertaining to oxygen, that no Lincare employee performed or participated in the performance of the qualifying oximetry test.

During each quarterly review, the IRO shall prepare a CMN Review Report based on its findings, including, but not limited to, whether any reviewed CMNs contained errors or were otherwise inappropriately altered by Lincare to support its submission of claims for reimbursement from a Federal health care program. Pursuant to Section V.B.12 of the CIA, the IRO's quarterly CMN Review Reports shall be submitted to the OIG as part of Lincare's Annual Reports for each Reporting Period.

- b. Annual Reporting. Section V.B.12 of the CIA shall be amended to include the following subsection:
 - a. A complete copy of the reports and findings prepared by the IRO pursuant to section III.F, as amended;
- c. Independent Review Organization. The CIA shall be amended to include the enclosed Appendix A.

ON BEHALF OF LINCARE



Lincare representative
Lisa Wearyzyn
GENERAL COUNSEL
Lincare Inc. + Lincare Holdings, Inc.

1/15/08

DATE

BARRY ALEXANDER
Counsel for Lincare

DATE

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

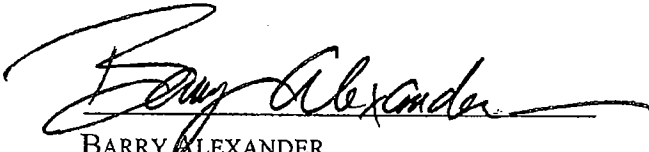
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

DATE

ON BEHALF OF LINCARE


Lincare representative

DATE


BARRY ALEXANDER
Counsel for Lincare

1/15/08
DATE

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



GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

1/17/08
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.F of the CIA.

A. IRO Engagement.

Pursuant to Section III.E, Lincare has already engaged an IRO for its Non-Contractual Arrangement Review.

Pursuant to Section III.F, Lincare must engage an IRO for its CMN Review. This IRO must possess the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Lincare if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lincare may continue to engage the IRO.

If Lincare engages a new IRO during the term of the CIA, Lincare must notify OIG in writing. This IRO shall also meet the requirements of this Appendix.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the CMN Review who have expertise in the applicable laws and regulations relating to CMNs and the submission of claims to Federal health care programs based on CMNs;
2. assign individuals to design and select the CMNs Review sample who are knowledgeable about the appropriate statistical sampling techniques;
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each CMN Review in accordance with the specific requirements of the CIA;

2. follow all applicable rules and reimbursement guidelines in making assessments in the CMN Review;

3. if in doubt of the application of a particular policy or regulation, request clarification from the appropriate authority;

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

D. IRO Independence and Objectivity.

The IRO must perform the CMN Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Lincare.

E. IRO Removal/Termination.

1. *Lincare.* If Lincare terminates its IRO during the course of the engagement, Lincare must submit a notice explaining its reasons to OIG no later than 30 days after termination. Lincare must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Lincare to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Lincare to engage a new IRO, OIG shall notify Lincare of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Lincare may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Lincare shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Lincare prior to requiring Lincare to terminate the IRO. However, the final determination as to whether or not to require Lincare to engage a new IRO shall be made at the sole discretion of OIG.