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

I. PREAMBLE

Curative Health Services, Inc. ("Curative") 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 officers, directors, and employees of its Specialty Healthcare Services unit who have responsibility for or involvement with Curative's provision of management services relating to wound care, with the applicable legal requirements contained in 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, Curative is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, Curative established a Corporate Compliance Program (the "Compliance Program"). This Compliance Program provides for policies and procedures and, as represented by Curative in this CIA, is aimed at ensuring that Curative's operations comply with the legal requirements contained in all applicable statutes, regulations and directives of the Federal health care programs. Therefore, pursuant to this CIA, Curative hereby agrees to operate its Compliance Program for the term of this CIA. The Compliance Program may be modified by Curative as appropriate but, at a minimum, shall comply with the integrity obligations enumerated in this CIA.

II. TERM OF THE CIA AND DEFINITIONS

A. *Term*. The period of the compliance obligations assumed by Curative under this CIA shall be five (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 (OIG Inspection, Audit and Review Rights), VIII (Document and Record Retention), IX (Disclosures), X (Breach and Default Provisions), and XI (Effective and Binding Agreement) shall expire no later than 120 days from the OIG's receipt of: (1) Curative's final annual report; or (2) any additional materials submitted by Curative pursuant to OIG's request, whichever is later.

B. *Definition of Covered Person*. This CIA pertains to Curative's business of providing management services relating to the provision of care for patients with chronic, non-healing wounds. For the purposes of this CIA, a "Covered Person" means any officer, director, employee or contractor of Curative's Specialty Healthcare Services unit who has responsibility for or involvement with Curative's provision of management services relating to wound care, and any corporate officer or employee with supervisory responsibility over Curative's Specialty Healthcare Services unit.

III. CORPORATE INTEGRITY OBLIGATIONS

Curative hereby agrees to maintain its Compliance Program during the term of this CIA that, at a minimum, shall continue to include the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer*. Curative represents to OIG that, pursuant to its Compliance Program, it has created a Compliance Officer position and appointed an individual to serve in that capacity. 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 Curative, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Curative (or a designated committee of the Board of Directors), 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 engaged in by Curative as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Curative represents to OIG that, pursuant to its Compliance Program, it has created a Compliance Committee to monitor the implementation of the Compliance Program and to provide advice and recommendations to Curative's Compliance Officer and Board of Directors on compliance issues, policies and procedures, and changes to the Compliance Program. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA. 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).

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

B. Written Standards.

1. *Code of Business Practices.* Curative represents to OIG that is has established a written Code of Business Practices which is applicable to its Specialty Healthcare Services unit. To the extent Curative has not already done so, the Code of Business Practices shall be distributed to all Covered Persons within ninety (90) days of the Effective Date of this CIA. Curative shall make the promotion of, and adherence to, the Code of Business Practices an element in evaluating the performance of all employees. The Code of Business Practices shall, at a minimum, set forth:

a. Curative's commitment to full compliance with all Federal health care program requirements;

b. Curative's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Curative's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

c. the requirement that all of Curative's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Curative suspected violations of any

Federal health care program requirements or of Curative's own Policies and Procedures;

d. the possible consequences to both Curative and Covered Persons of failure to comply with Federal health care program requirements and with Curative'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 Curative's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

Within one-hundred twenty (120) days of the Effective Date of the CIA, Curative shall require each Covered Person to certify, in writing or electronically, that he or she has received, read, understood, and will abide by Curative's Code of Business Practices. New Covered Persons shall receive the Code of Business Practices and shall complete the required certification within ninety (90) days after becoming a Covered Person or within one-hundred twenty (120) days of the Effective Date of the CIA, whichever is later.

Curative shall periodically review the Code of Business Practices to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Business Practices shall be distributed within 30 days of finalizing such changes. Curative shall require Covered Persons to certify, in writing or electronically, that they have received, read, understood and will abide by the revised Code of Business Practices within thirty (30) days of the distribution of such revisions.

2. *Policies and Procedures.* To the extent they do not already exist or are not already incorporated into the Code of Business Practices, within one-hundred twenty (120) days of the Effective Date of this CIA, Curative shall implement written Policies and Procedures regarding the operation of Curative'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 Business Practices identified in section III.B.1;

b. Curative's compliance with all laws, regulations and rules pertaining to the provision of guidance, assistance or advice

regarding the preparation or submission of claims for reimbursement from any Federal health care program including, but not necessarily limited to, issues pertaining to marketing and advertising costs; and

c. procedures requiring legal review of all contracts and agreements that are entered into with entities pursuant to which Curative will operate such entities' wound care centers.

To the extent Curative has not already done so, within one-hundred twenty (120) days of the Effective Date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Curative shall assess and update as necessary the Policies and Procedures. Within sixty (60) days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons.

C. Training and Education.

1. *General Training.* Within one-hundred twenty (120) days of the Effective Date of this CIA, Curative shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain Curative's:

a. CIA requirements; and

b. Curative's Compliance Program (including the Code of Business Practices and the Policies and Procedures as they pertain to general compliance issues).

Such General Training can be conducted in-person or electronically through Curative's web-based Compliance Program. New Covered Persons shall receive the General Training described above within sixty (60) days after becoming a Covered Person or within one-hundred twenty (120) days after the Effective Date of the CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training.* Within one-hundred twenty (120) days of the Effective Date of this CIA, each Covered Person who has responsibility for or

involvement with the provision of guidance, assistance or advice regarding 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 three (3) hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. applicable reimbursement statutes, regulations, and requirements and written directives of the Medicare and Medicaid programs;

b. the legal sanctions that may be imposed for the provision of improper reimbursement advice;

c. the legal sanctions that may be imposed for seeking reimbursement for non-reimbursable marketing and advertising activities;

d. examples of the provision of proper and improper reimbursement advice; and

e. examples of reimbursable and non-reimbursable marketing and advertising activities.

Persons providing the Specific Training must be knowledgeable about the subject areas.

Relevant Covered Persons shall receive this training within ninety 90 days of the beginning of their employment or becoming Relevant Covered Persons or within one-hundred twenty (120) days of the Effective Date of the CIA, whichever is later. A Curative employee who has completed the Specific Training shall review a new Relevant Covered Person's work 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 three (3) hours of Specific Training annually.

3. *Certification.* Curative shall require each Covered Person who is required to attend training to certify, in writing or electronically, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the

certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Credit for Prior Training.* For the purposes of this Section III.C, Curative shall receive credit for any General Training or Specific Training provided to Covered Persons and/or Relevant Covered Persons since September 1, 2001.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within one-hundred twenty (120) days of the effective date of this CIA, Curative shall retain an entity (or entities), such as a consulting or law firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Curative in assessing and evaluating its compliance obligations pursuant to this CIA and the Settlement Agreement and to assess Curative's adherence to its obligations under this CIA ("CIA Review"). Each IRO retained by Curative shall have expertise in the areas of Federal health care laws, regulations, guidelines and requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care programs. Each IRO shall assess, along with Curative, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO review shall also address and analyze guidance, assistance and advice regarding the preparation and submission of claims for reimbursement from any Federal health care program ("Reimbursement Advice") furnished by Curative's Reimbursement Department ("Reimbursement Department Review").

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

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

d. Retention of Records. The IRO(s) and Curative shall retain and make available to the OIG, upon reasonable advance request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO(s) and Curative related to the reviews).

2. *Reimbursement Department Review.* Each annual Reimbursement Department Review shall be conducted in accordance with the following procedures. First, the IRO(s) shall randomly select and review a sample of 50 items of Reimbursement Advice furnished by Curative's Reimbursement Department. The Reimbursement Advice shall be reviewed based on the supporting documentation available at Curative or under Curative's control to determine whether such Reimbursement Advice was consistent with the applicable billing and coding regulations and guidance. The IRO will determine pursuant to its review whether Curative has provided Reimbursement Advice that is consistent with the applicable billing and coding regulations and guidance. For each item of Reimbursement Advice that the IRO has found inconsistent with the applicable billing and coding regulations and guidance, the IRO shall provide Curative with written notice of such findings, and Curative shall furnish to the recipient of the Reimbursement Advice a new item of Reimbursement Advice consistent with the applicable billing and coding regulations and guidance.

3. *Reimbursement Department Review Report.* The IRO shall prepare a report based upon the Reimbursement Department Review performed (the "Reimbursement Department Review Report").

4. *CIA Review.* Pursuant to the CIA Review, the IRO(s) shall make findings regarding Curative's adherence to the obligations set forth in the CIA.

5. *CIA Review Report.* The IRO(s) shall prepare a report based upon the CIA Review performed (the "CIA Review Report").

6. *Validation Review.* In the event OIG has reason to believe that: (a) Curative's Reimbursement Department Review or CIA Review fails to conform to the requirements of this CIA; or (b) the IRO's findings are inaccurate, OIG may, at its sole

discretion, conduct its own review to determine whether the Reimbursement Department Review or CIA Review complied with the requirements of the CIA and/or the findings results are inaccurate ("Validation Review"). Curative agrees to pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated before one year after Curative's final submission (as described in section II) is received by OIG.

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

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

E. Disclosure Program.

Curative represents to OIG that it has established 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 Curative'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. Curative 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 continue to emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous

communications for which appropriate confidentiality will be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall use his or her best efforts to 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, Curative shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

1. *Definition.* For the 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.* Curative shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Curative shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://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) Curative to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within one-hundred twenty (120) days of the Effective Date of this CIA, Curative shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Curative shall review its list of current employees and contractors against the Exclusion Lists annually. In addition, Curative shall require employees and contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If Curative has actual notice that an employee or contractor has become an Ineligible Person, Curative shall remove such person from responsibility for, or involvement with, Curative'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 Curative has actual notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract term, Curative shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted by any other entity to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within thirty (30) days of discovery, Curative shall notify OIG, in writing, of any ongoing investigation known to Curative or legal proceeding conducted or brought by a governmental entity or its agents which Curative knows or has reason to know involves an allegation that Curative 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. Curative shall also provide written notice to OIG within thirty (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 the purposes of this CIA, and if applicable, an "overpayment" shall mean the amount of money Curative 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, Curative identifies or learns of any overpayments, Curative shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of 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 the overpayment, Curative shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, Curative 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 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. *Material Deficiencies.*

a. *Definition of Material Deficiency.* For the purposes of this CIA, a "Material Deficiency" means anything that involves:

(i) a substantial overpayment;

(ii) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any

Federal health care program for which penalties or exclusion may be authorized.

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

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

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

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

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

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

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

(iv) any further steps Curative plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this CIA, Curative's Specialty Healthcare Services unit changes locations or sells, closes, purchases or establishes new business units related to the provision of services, Curative shall notify OIG of this fact as soon as

possible, but no later than within thirty (30) days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), its phone number, fax number, and Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. ANNUAL REPORTS

A. Annual Reports. Curative shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Curative's compliance activities for each of the five one-year periods beginning on the Effective Date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. a copy of Curative's Code of Business Practices required by section III.B.1;

2. any change in the identity or position description of the Compliance Officer and any change in the composition of the Compliance Committee described in section III.A;

3. a certification by the Compliance Officer that, to the best of his knowledge:

   a. all Covered Persons have completed any Code of Business Practices certifications required by section III.B.1;

   b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

   c. the Polices and Procedures required by section III.B have been implemented and distributed to all appropriate Covered Persons; and

   d. if applicable, Curative has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement

Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

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

4. copies of any compliance-related Policies and Procedures and a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes;

5. a copy of all training materials used for the training required by section III.C, 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;

6. a complete copy of all reports prepared pursuant to the IRO's engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

7. Curative's response and corrective action plan(s) related to any issues raised by the IRO(s);

8. the identity of the IRO(s), a summary/description of all engagements between Curative and the IRO(s), including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;

9. a certification from the IRO regarding its professional independence from Curative;

10. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

11. where applicable, a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, 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;

12. a summary of the disclosures in the disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

13. a description of any personnel actions (other than hiring) taken by Curative 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;

14. 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;

15. a list of all of Curative's Specialty Healthcare Services unit locations (including mailing addresses), the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) (if applicable), and the contractor name and address that issued each provider identification number (if applicable) for Curative's operations at such location. For subsequent Reporting Periods, Curative need only supply any changes to this list; and

16. the certification required by section V.C.

The first Annual Report shall be received by OIG no later than ninety (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 Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Curative 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, Disclosures and Privileges: Curative 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. Curative shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA. Nothing set forth in this CIA or in communications or reports made pursuant to this CIA shall constitute a waiver of the attorney-client, work product or other applicable privileges.

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

Curative:

Thomas Axmacher
Corporate Compliance Officer
Curative Health Services, Inc.
150 Motor Parkway
Hauppauge, New York 11788-5145
Phone 631-232-7000
Fax 631-232-9322

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, subject to any applicable privileges, OIG or its duly authorized representative(s) may examine or request copies of Curative's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Curative's Specialty Healthcare Services unit locations, for the purpose of verifying and evaluating: (a) Curative's compliance with the terms of this CIA; and (b) where applicable, Curative's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Curative to OIG or its duly authorized representative(s) at all reasonable times, upon reasonable advance notice, for inspection, audit or reproduction. Furthermore, for purposes of this provision and upon reasonable advance notice to Curative, OIG or its duly authorized representative(s) may interview any of Curative's Specialty Healthcare Services unit 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. Curative agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's reasonable advance request. Curative's employees may elect to be interviewed with or without a representative of Curative present.

VIII. DOCUMENT AND RECORD RETENTION

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

Curative 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, Curative 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 Curative fails to have in place any of the obligations described in section III during the term of this CIA:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Business Practices;

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 Curative fails to retain an IRO, as required in section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Curative fails to meet any of the deadlines for the submission of 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 Curative employs or contracts with an Ineligible

Person and that person: (i) has responsibility for, or involvement with, Curative'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 Curative 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 Curative 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 Curative fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Curative fails to comply fully and adequately with any obligation of this CIA. In its notice to Curative, OIG shall state the specific grounds for its determination that Curative has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Curative must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the Curative 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. OIG shall not seek such a Stipulated Penalty if Curative shows that (i) Curative has begun to take action to cure the breach; (ii) Curative is pursuing such action with due diligence; and (iii) Curative has provided to OIG a reasonable timetable for curing the breach.

B. Timely Written Requests for Extensions. Curative 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 Curative 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 Curative 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 Curative has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Curative of: (a) Curative's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Curative 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 Curative elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Curative cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Curative 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 Curative to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in section III.H;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

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

4. *Exclusion Letter*. If at the conclusion of the 30-day period, Curative fails to satisfy the requirements of section X.D.3, OIG may exclude Curative's Specialty Healthcare Services unit from participation in the Federal health care programs. OIG will notify Curative in writing of its determination to exclude Curative (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, Curative wishes to

apply for reinstatement, Curative 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 Curative 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, Curative 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 Curative was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Curative 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 Curative to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Curative 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 Curative 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) Curative had begun to take action to cure the material breach within that period;

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

(iii) Curative provided to OIG within that period a reasonable timetable for curing the material breach and Curative 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 Curative, only after a DAB decision in favor of OIG. Curative's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Curative 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 Curative 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. Curative 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. If the DAB finds in favor of Curative, Curative will 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, Curative and OIG agree as follows:

A. This CIA shall be binding on all successors, assigns, and transferees of Curative who have responsibility for or involvement with the provision of management services relating to wound care;

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. Where applicable, OIG may agree to a suspension of Curative's obligations under the CIA in the event of Curative's cessation of participation in Federal health care programs. If Curative withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Curative agrees to notify OIG 30 days in advance of Curative'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 Curative 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 CURATIVE HEALTH SERVICES, INC.

GARY BLACKFORD
Chief Executive Officer
Curative Health Services, Inc.

DATE

MICHAEL K. FEE
Counsel for Curative Health Services, Inc.
Ropes & Gray

12/28/01
DATE

ON BEHALF OF CURATIVE HEALTH SERVICES, INC.

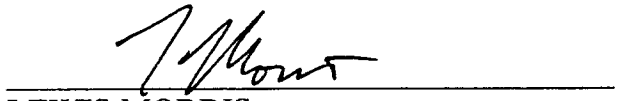
GARY BLACKFORD
Chief Executive Officer
Curative Health Services, Inc.

DATE

MICHAEL K. FEE
Counsel for Curative Health Services, Inc.
Ropes & Gray

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

12/28/07
DATE

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/SUPPLIERNAME_____
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 reaso
n 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
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____