CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SORKIN'S RX LTD. t/a and/or D/B/A CAREMED PHARMACEUTICAL SERVICES

I. PREAMBLE

Sorkin's Rx Ltd. t/a and/or d/b/a CareMed Pharmaceutical Services (CareMed) 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 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). CareMed is a retail specialty pharmacy that does business with Federal health care programs.

On October 8, 2014, the United States entered into a Stipulation and Order of Settlement and Dismissal with CareMed in which CareMed agreed to pay to the United States $9,534,577.00 (U.S. Settlement Amount), plus applicable interest, in exchange for a release from liability under the False Claims Act, and other civil and administrative authorities, for specified conduct detailed in the Stipulation and Order of Settlement and Dismissal (hereinafter referred to as the Covered Conduct). In the Stipulation and Order of Settlement and Dismissal, the United States reserved certain administrative claims against CareMed, and reserved the right to institute, direct, or maintain any administrative action seeking exclusion from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against CareMed under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7(b) (permissive exclusion).

In consideration of the obligations of CareMed set forth in the Stipulation and Order of Settlement and Dismissal and this CIA, and conditioned upon CareMed's full payment of the U.S. Settlement Amount under Paragraph 3 of the Stipulation and Order of Settlement and Dismissal, OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against

CareMed under 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 5 of the Stipulation and Order of Settlement and Dismissal. OIG expressly reserves all rights to comply with any statutory obligations to exclude CareMed from Medicare, Medicaid, and all other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based on the Covered Conduct.

Prior to the execution of this CIA, CareMed established a Compliance Program. The Compliance Program includes Policies and Procedures, a Code of Ethics, and a Compliance Officer. CareMed and OIG agree that CareMed may utilize and adapt any component of the Compliance Program existing at the time of the execution of this CIA as necessary to comply with the integrity obligations created by this CIA. To the extent that CareMed's existing Compliance Program cannot be modified or maintained to meet the corporate integrity obligations created by this CIA, CareMed shall modify its Compliance Program or create a new compliance program, so that CareMed shall meet the corporate integrity obligations created by this CIA.

II. TERM AND SCOPE OF THE CIA

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

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

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

1. "Covered Persons" includes:

   a. all owners, officers, directors, and employees of CareMed; and

   b. all contractors, subcontractors, agents, and other persons who provide patient care items or services, or who perform billing or coding related functions on behalf of CareMed, including

intake and other personnel who gather, handle, store or transmit patient and insurance information. "Covered Persons" does not include vendors whose sole connection with CareMed is selling or otherwise providing medical supplies or equipment to CareMed and who do not bill the Federal health care programs for such medical supplies or equipment.

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 during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during a Reporting Period.

2. "Relevant Covered Persons" includes:

   a. all pharmacists;

   b. all pharmacy technicians or clinical care coordinators;

   c. all Covered Persons who solicit, obtain, receive, or fill orders from physicians or individuals for pharmacy items or supplies, durable medical equipment and/or supplies on behalf of CareMed;

   d. all Covered Persons who code or submit to Federal health care programs claims for pharmacy items or supplies, durable medical equipment and/or supplies on behalf of CareMed;

   e. all Covered Persons who are involved in the delivery of patient care items or services including, but not limited to infusion therapy, respiratory therapy, and health management;

   f. all Covered Persons who make or implement company policy and procedures for CareMed with regard to pharmacy supplies, durable medical equipment, supplies, and/or billing Federal health care programs; and

g. all Covered Persons whose job responsibilities relate to Restocking and Crediting Related Functions or Claims Related Functions or who directly supervise Covered Persons involved in those functions.

"Restocking Related Functions" include processing and restocking drugs not delivered to customers/patients or returned to CareMed from customers/patients, for which CareMed has received reimbursement from a Federal health care program.

"Claims Related Functions" include submission of claims to any Federal health care program. Claims Related Functions also include providing credit to Federal health care programs for returned and restocked drugs for which CareMed has received reimbursement from Federal health care programs.

III. CORPORATE INTEGRITY OBLIGATIONS

CareMed shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee

1. *Compliance Officer*. Within 90 days after the Effective Date, CareMed will appoint a Covered Person to serve as its new Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be a member of senior management of CareMed. The Compliance Officer shall report directly to the Board of Directors, including the Chief Executive Officer of CareMed, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for CareMed. The Compliance Officer shall be responsible for, without limitation:

a. 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;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of CareMed, and shall be authorized to report on such matters to

the Board of Directors at any other time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by CareMed as well as any reporting obligations created under this CIA.

Any job responsibilities of the Compliance Officer that do not involve compliance shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee*. Within 120 days after the Effective Date, CareMed shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer, and at least four other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, medical records, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of CareMed's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of CareMed (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program

requirements and the obligations of this CIA. The Board may include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee CareMed's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to the OIG in Annual Reports a description of the documents and other materials it reviewed, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of CareMed's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of CareMed's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, CareMed has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at CareMed.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain CareMed employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable CareMed department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer, Senior Vice President of Sales and Marketing, Director of Training, Intake Coordinator, Senior Clinical Registered Pharmacist, Claims Processing Manager, Coding and Billing Managers, and Director of the Call Center (Patient Referrals and Orders). For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to _____, an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ department with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and CareMed policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ department of CareMed is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, CareMed shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

1. *Code of Ethics*. CareMed has established a Code of Ethics. The Code of Ethics shall be augmented as necessary to reflect:

a. CareMed'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. CareMed's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with CareMed's own Policies and Procedures;

c. the requirement that all of CareMed's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individuals designated by CareMed, suspected violations of any Federal health care program requirements or of CareMed's own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and CareMed's commitment to no retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, CareMed shall distribute the Code of Ethics, as augmented, to all Covered Persons. CareMed shall make the promotion of, and adherence to, the Code of Ethics an element in evaluating the performance of all employees.

CareMed shall review the Code of Ethics at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Ethics shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures*. CareMed has developed written Policies and Procedures regarding CareMed's operations. Within 120 days after the Effective Date, CareMed shall review its written Policies and Procedures to ensure that the written Policies and Procedures are consistent with its compliance program and comply with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Ethics identified in Section III.B.1;

b. the proper procedures for gathering, handling, transmission, and storing of patient information in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA);

c. the proper procedures for processing prescription drug orders that require pre-dispensing authorization from health plans;

d. the proper and accurate documentation of medical and prescription records;

e. the proper and accurate dispensing of prescription drugs;

f. the requirements under Federal health care programs for filing claims for patient care items and services and pharmacy items and supplies;

g. the proper procedures for reversing claims that were processed for prescriptions that were filled (including automatic refills) but never delivered to or picked up by the beneficiaries or customers;

h. the proper procedures for reversing claims that were processed for prescriptions that were filled and delivered to or picked up by the beneficiaries or customers, but returned unused by the beneficiaries or customers; and

i. procedures for safeguarding against dispensing expired or adulterated prescription drugs (dispensing drugs that are expired, drugs whose strength differs from, or its purity or quality falls below, that which it purports or is represented to possess, or drugs that have not been stored or handled in accordance with manufacturer and U.S. Food and Drug Administration (FDA) requirements).

Throughout the term of this CIA, CareMed shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

Within 120 days after the Effective Date, CareMed shall distribute the Policies and Procedures to all Covered Persons. CareMed shall make available appropriate and knowledgeable persons to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), CareMed shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, CareMed shall provide to all affected Covered Persons a description of the revisions. CareMed shall distribute to all Covered Persons any revised or new Policies and Procedures.

C. Training and Education

1. *Training Plan.* Within 120 days after the Effective Date, CareMed shall develop a written plan (Training Plan) that outlines the steps CareMed will take to ensure that: (a) all Covered Persons receive adequate training regarding CareMed's CIA requirements and Compliance Program, including the Code of Ethics and (b) all Relevant Covered Persons receive adequate training regarding: (i) applicable state pharmacy requirements; (ii) the Federal health care program requirements regarding the accurate coding and submission of claims, including pharmacy billing and crediting requirements; (iii) the Federal health care program requirements regarding physician orders for pharmacy items and supplies and for dispensing of pharmacy items and supplies; (iv) policies, procedures, and other requirements applicable to the documentation of medical records and the processing of physician orders for prescription drugs that require prior authorization from health plans; (v) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (vi) applicable reimbursement statutes, regulations, and program requirements and directives; (vii) the legal sanctions for violations of the Federal health care program requirements; and (viii) examples of proper and improper claims submission practices.

The Training Plan shall include information regarding the training topics, the categories of Covered Persons and Relevant Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of CareMed's Training Plan, OIG will notify CareMed of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, CareMed may implement its Training Plan. CareMed shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training*. Within 120 days after the Effective Date, CareMed shall provide at least two hours of training to each member of the Board of Directors. This training shall address CareMed's CIA requirements and Compliance Program (including the Code of Ethics), the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

3. *Certification.* Each individual who is required to attend training shall 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.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training Plan.* CareMed shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information. Any updates to the Training Plan must be submitted to the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to CareMed's Training Plan, OIG will notify CareMed of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, CareMed may implement the revised Training Plan.

6. *Computer-based Training.* CareMed may provide the training required under this CIA through appropriate computer-based training approaches. If CareMed chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 120 days after the Effective Date, CareMed shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist CareMed in assessing and evaluating its Claims Related Functions and Restocking Related Functions, and certain other obligations pursuant to this CIA and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. *Claims and Restocking Reviews.* The IRO shall review CareMed's coding, billing, and claims submission to Federal health care programs and the reimbursement received (Claims Review), and CareMed's practices related to restocking of drugs whose prescriptions were filled (including automatic refills) but never delivered or for drugs that were delivered but returned unused (Restocking Review). The IRO shall prepare Claims Review and Restocking Review Reports, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review*. In the event OIG has reason to believe that: (a) the IRO's Claims Review, or the IRO's Restocking Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, Claims Review and/or Restocking Review results are inaccurate; OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review and/or Restocking Review complied with the requirements of the CIA and/or the findings of the Claims Review and/or Restocking Review results are inaccurate (Validation Review). CareMed shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any

Validation Review of Reports submitted as part of CareMed's final Annual Report shall be initiated no later than one year after CareMed's final submission (as described above in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify CareMed 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, CareMed may request a meeting with OIG to: (a) discuss the results of any Claims Review and/or Restocking Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review and/or Restocking Review or to correct the inaccuracy of the Claims Review and/or Restocking Review; and/or (c) propose alternatives to the proposed Validation Review. CareMed agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review and/or Restocking Review issues with CareMed 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.

4. *Independence and Objectivity Certification.* The IRO shall include in its reports to CareMed a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, CareMed shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Federal health care program beneficiaries. The risk assessment and internal review process should include: (1) a process for identifying and prioritizing risks, (2) developing remediation plans in response to those risks, including internal auditing and monitoring of the identified risk areas, and (3) tracking results to assess the effectiveness of the remediation plans. The risk assessment and internal review process should require compliance, legal, and department leaders, at least annually, to evaluate and identify risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries and develop and implement specific plans to address and mitigate the identified risks. The risk assessment and internal review work plans shall be developed annually. CareMed shall implement the risk assessment and internal review work plans and track the implementation of the work plans. CareMed shall

maintain the risk assessment and internal review process for the term of the CIA. Copies of any internal audit reports developed pursuant to the risk assessment and internal review process shall be made available to OIG upon request.

F. Disclosure Program

Within 120 days after the Effective Date, CareMed shall establish 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 CareMed'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. CareMed 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 no retribution, no retaliation 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, CareMed 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 and shall record each disclosure in the disclosure log within 48 hours of receipt of the disclosure, excepting weekends and holidays. The disclosure log shall include a 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.

G. 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 scope 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 (LEIE) (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (SAM) (available through the Internet at http://www.sam.gov).

2. *Screening Requirements.* CareMed shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements, which requirements may be met by engaging an outside entity to conduct the screening.

a. CareMed shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. CareMed shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

c. CareMed shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.F affects CareMed's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. CareMed understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that CareMed may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether CareMed meets the requirements of Section III.G.

3. *Removal Requirement*. If CareMed has actual notice that a Covered Person has become an Ineligible Person, CareMed shall remove such Covered Person from responsibility for, or involvement with, CareMed's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If CareMed has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, CareMed shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, CareMed shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to CareMed conducted or brought by a governmental entity or its agents involving an allegation that CareMed 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. CareMed shall also provide written notice to OIG

within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money CareMed has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* Within 120 days after the Effective Date, CareMed shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

a. If, at any time, CareMed identifies any Overpayment, CareMed shall repay the Overpayment to the appropriate payor (i.e., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 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. If not yet quantified, within 60 days after identification, CareMed 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.

b. 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.

J. Reportable Events

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

a. a substantial Overpayment;

b. 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;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by CareMed.

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

2. *Reporting of Reportable Events*. If CareMed determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, CareMed shall notify OIG, in writing, within 45 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a*. For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 45 days of the identification of the Overpayment, and shall include:

a. a complete description of all details relevant to the Reportable Event, including, at minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. the Federal health care programs affected by the Reportable Event;

c. a description of the steps taken by CareMed to identify and quantify the Overpayment; and

d. a description of CareMed's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, CareMed shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;

c. the Federal health care programs affected by the Reportable Event;

d. a description of CareMed's actions taken to correct the Reportable Event and prevent it from recurring; and

e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by CareMed to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion Lists screening that CareMed completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Reportable Event was discovered; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.J.1.d*. For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law*. Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by CareMed to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If CareMed identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then CareMed is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit or Location.

In the event that, after the Effective Date, CareMed proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, CareMed shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, business unit, or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit or Location

In the event that, after the Effective Date, CareMed changes locations or closes a business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, CareMed shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit or location.

C. Purchase or Establishment of New Business, Business Unit or Location

In the event that, after the Effective Date, CareMed purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, CareMed shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which CareMed currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit, or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, CareMed shall submit a written report to 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. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of CareMed's Code of Ethics required by Section III.B.1;

6. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);

7. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training; and when the training was provided);

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between CareMed and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to CareMed;

9. a description of the risk assessment and mitigation process required by Section III.E;

10. a description of the Disclosure Program required by Section III.F;

11. a certification that CareMed has conducted the screening required by Section III.G regarding Ineligible Persons, or a description of why CareMed cannot provide such a certification;

12. a copy of CareMed's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

13. a list of all of CareMed's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which CareMed currently submits claims;

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

15. the certifications required by Section V.C.

B. Annual Reports

CareMed shall submit to OIG annually a report with respect to the status of, and findings regarding, CareMed's compliance activities for each of the five 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; any change in the membership of the Compliance Committee described in Section III.A, any change in the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3, and any change in the group of Certifying Employees described in Section III.A.4;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.A.3, and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a copy of CareMed's written process for Certifying Employees to follow for purposes of completing the certification required by Section III.A.4;

5. a summary of any significant changes or amendments to the Code of Ethics or the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

6. a copy of CareMed's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which CareMed ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

8. CareMed's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

9. a summary and description of any and all current and prior engagements and agreements between CareMed 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 objectivity with respect to CareMed;

11. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;

12. a copy of CareMed's internal review work plans, and a list of all reviews completed during the Reporting Period pursuant to Section III.E;

13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

14. a certification that CareMed has completed the screening required by Section III.G regarding Ineligible Persons;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

17. 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;

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

19. a summary describing any audits conducted during the applicable Reporting Period by a Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and CareMed's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

20. a description of all changes to the most recently provided list of CareMed's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding

phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which CareMed currently submits claims; and

21. the certifications required by Section V.C.

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

C. Certifications

1. *Certifying Employees.* In each Annual Report, CareMed shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

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

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

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, CareMed has complied with its obligations under the Settlement Agreement: (a) 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; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

CareMed 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. CareMed shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

CareMed:

CareMed
Attention: Compliance Officer
1981 Marcus Ave
Suite 225
Lake Success, NY 11042

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. Upon request by OIG, CareMed may be required to provide OIG with an electronic copy of each

notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of CareMed's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of CareMed's locations for the purpose of verifying and evaluating: (a) CareMed's compliance with the terms of this CIA; and (b) CareMed's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by CareMed to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of CareMed's Covered Persons 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. CareMed shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. CareMed's Covered Persons may elect to be interviewed with or without a representative of CareMed present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify CareMed prior to any release by OIG of information submitted by CareMed pursuant to its obligations under this CIA and identified upon submission by CareMed as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, CareMed shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

CareMed 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, CareMed and 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 business day after the date the obligation became due) for each day CareMed fails to establish and implement any of the following obligations as described in Sections III and IV:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations;

d. the management certification obligations;

e. a written Code of Ethics;

f. written Policies and Procedures;

g. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Board Members;

h. a risk assessment and mitigation process as required in Section III.E;

i. a Disclosure Program;

j. Ineligible Persons screening and removal requirements;

k. notification of Government investigations or legal proceedings;

l. policies and procedures regarding the repayment of Overpayments;

m. the repayment of Overpayments as required by Section III.I;

n. reporting of Reportable Events; and

o. disclosure of changes to business units or locations.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the business day after the date the obligation became due) for each day CareMed fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the business day after the date the obligation became due) for each day CareMed fails to submit the Implementation Report or any Annual Reports to 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 business day after the date the obligation became due) for each day CareMed fails to submit any Claims Review Report or Restocking Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of $1,500 for each day CareMed fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date CareMed fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of CareMed as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day CareMed fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to CareMed stating the specific grounds for its determination that CareMed has failed to comply fully and adequately with the CIA obligation(s) at issue and steps CareMed shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after CareMed receives this notice from OIG of the failure to comply.) A Stipulated Penalty as

described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

CareMed 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 business day after CareMed 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 CareMed 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 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 CareMed 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 CareMed of: (a) CareMed's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, CareMed 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 CareMed elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CareMed 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

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 CareMed 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by CareMed to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;

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.D, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by CareMed constitutes an independent basis for CareMed's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that CareMed has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify CareMed of: (a) CareMed's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure*. CareMed shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30 day period, but that: (i) CareMed has begun to take action to cure the material breach; (ii) CareMed is pursuing such action with due diligence; and (iii) CareMed has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, CareMed fails to satisfy the requirements of Section X.D.3, OIG may exclude CareMed from participation in the Federal health care programs. OIG shall notify CareMed in writing of its determination to exclude CareMed. (This letter shall be referred to 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 CareMed's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, CareMed 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 OIG's delivery to CareMed 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, CareMed shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 CareMed was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. CareMed shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders CareMed to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless CareMed 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 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 whether CareMed was in material breach of this CIA and, if so, whether:

a. CareMed cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following CareMed's receipt of the Notice of Material Breach: (i) CareMed had begun to take action to cure the material breach; (ii) CareMed pursued such action with due diligence; and (iii) CareMed provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for CareMed, only after a DAB decision in favor of OIG. CareMed's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude CareMed upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that CareMed 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. CareMed 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 CareMed, CareMed 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

CareMed and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of CareMed's obligations under this CIA based on a certification by CareMed that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If CareMed is relieved of its CIA obligations, CareMed will be required to notify OIG in writing at least 30 days in advance if CareMed plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. The undersigned CareMed signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF CAREMED

/Nuaman Tyyeb/	11/24/2014
NUAMAN TYYEB President, Sorkin's RX Ltd. As the Executor of the Estate of Muhammad Tyyeb	DATE
/Joseph P. Goldberg/	11/24/14
JOSEPH P. GOLDBERG Counsel for CareMed	DATE
	DATE

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

/Robert K. DeConti/ 11/21/14

ROBERT K. DECONTI DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Henry E. Green/ 12/1/2014

HENRY E. GREEN DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. CareMed shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the reviews in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by CareMed in response to a request by OIG, whichever is later, OIG will notify CareMed if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CareMed may continue to engage the IRO.

2. If CareMed engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If CareMed engages a new IRO, CareMed shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by CareMed at the request of OIG, whichever is later, OIG will notify CareMed if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CareMed may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in applicable Federal health care program and state pharmacy requirements as they pertain to Claims Related Functions (including claims for drugs that require pre-dispensing authorization from health plans), and Restocking Related Functions. As such, the assigned individuals shall be knowledgeable about the general requirements of the Federal health care program(s) from which CareMed seeks reimbursement;

2. assign individuals to design and select the Claims Review and Restocking Review samples who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to the Restocking Review who have expertise in pharmacy crediting requirements;

4. assign individuals to the Claims Review who have expertise in pharmacy billing; and

5. 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 Claims Review and each Restocking Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program rules and reimbursement guidelines, as well as applicable state pharmacy requirements in making assessments in the Claims Review and Restocking Review;

3. if in doubt of the application of a particular Federal health care programs policy or regulation, or state pharmacy requirement, request clarification from the appropriate Federal health care program or state authority;

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

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review and the Restocking Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO*. If CareMed terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, CareMed must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. CareMed must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and 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 CareMed to engage a new IRO in accordance with Paragraph A of this Appendix. CareMed must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring CareMed to engage a new IRO, OIG shall notify CareMed 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, CareMed may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with CareMed prior to requiring CareMed to terminate the IRO. However, the final determination as to whether or not to require CareMed to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

I. General Description

The IRO shall perform reviews to assist CareMed in assessing and evaluating (1) CareMed's systems, processes, policies, procedures, and practices for CareMed's Claims Related Functions; and (2) CareMed's systems, processes, policies, procedures, and practices for CareMed's Restocking Related Functions.

II. IRO Reviews

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

a. Overpayment: The amount of money CareMed has received in excess of the amount due and payable under any Federal health care program, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

b. Paid Claim: A claim submitted by CareMed and for which CareMed has received reimbursement from a Federal health care program.

c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross

Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at CareMed's office or under CareMed's control, (including but not limited to, an electronic or hard copy of the prescription, proof of delivery of the prescription, and any documentation relating to prior authorizations required by the payor for the prescription), applicable billing regulations and guidance, and Part D plan payment provisions to determine whether the claim was correctly submitted and reimbursed. For each Paid Claim reviewed, the IRO should verify that CareMed maintained documentation of (1) the prescription or order for the drug, item, or supply dispensed; (2) the delivery of the drug, item, or supply; and (3) any required preauthorization.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, CareMed should, as appropriate, further analyze any errors identified in the Discovery Sample. CareMed recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample*. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at CareMed or under CareMed's control (including but not limited to, an electronic or hard copy of the prescription, proof of delivery of the prescription, and any documentation relating to prior authorizations required by the payor for the prescription), and applicable billing and coding regulations and guidance, and Part D plan payment provisions to determine whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim reviewed, the IRO should verify that CareMed maintained documentation of (1) the prescription or order for the drug, item, or supply dispensed; (2) the delivery of the drug, item, or supply; and (3) any required preauthorization. For purposes of calculating the

size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from CareMed to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *Systems Review*. If CareMed's Discovery Sample identifies an Error Rate of 5% or greater, CareMed's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

a. a review of CareMed's billing systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which CareMed prepares and submits claims for drugs that require pre-dispensing authorization from health plans, the process by which CareMed maintains documentation of prescriptions and orders and of the delivery of all drugs and supplies dispensed, safeguards to ensure proper claims submission and billing; and procedures to identify and correct inaccurate billing);

b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements*

a. Supplemental Materials. The IRO shall request all

documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and CareMed shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from CareMed after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which CareMed cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by CareMed for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* CareMed shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. CareMed shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*

a. Claims Review Population. A description of the Population subject to the Claims Review.

b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., physician orders (including drug prescriptions), certificates of medical necessity, requisition forms, health plan authorizations respecting drugs that require pre-dispensing authorization, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*

a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

a. Narrative Results

i. A description of CareMed's billing and coding system(s), including the identification, by position description, of the personnel involved in billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results

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

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

iii. Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).

iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.

v. Error Rate in the Discovery Sample and the Full Sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, national drug code (NDC) and amount dispensed, date of service, amount claimed, allowed amount reimbursed by payor, correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

c. Recommendations. The IRO's report shall include any recommendations for improvements to CareMed's billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings*. With respect to the Claims Systems Review, the IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in CareMed's billing systems and processes;

b. analysis of the reason for each error in the Claims Review Discovery Sample and the Claims Review Full Sample; and

c. possible improvements to CareMed's billing systems and processes to address the specific problems or weaknesses that resulted in the identified Claims Review Overpayments.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the

Claims Review and (2) performed the Claims Review.

C. Restocking Review. The IRO shall conduct unannounced Restocking Reviews twice for each Reporting Period of the CIA.

1. *Definitions*. For the purposes of the Restocking Review, the following definitions shall be used:

a. Restocking Review Overpayment. The amount of money that CareMed has failed to credit to a Federal payor for the original dispensing event after the drugs were not delivered or were returned, and then restocked.

b. Undelivered Drugs. Drugs dispensed by CareMed for which CareMed received reimbursement from Federal health care programs and that CareMed did not deliver to the Federal health beneficiary after the drugs were dispensed.

c. Returned Drugs. Drugs dispensed by CareMed for which CareMed received reimbursement from Federal health care programs and that CareMed picks up or receives from patients/beneficiaries and that are unused and still packaged.

d. Staged Drugs. Undelivered Drugs or Returned Drugs (that have not been unsealed or had their original dispensing labels removed) that have been staged for restocking.

e. Credited Drug. A Staged Drug that has been processed to provide credit to the Federal payor that was billed for the original dispensing event.

f. Restocking Review Population. The Restocking Review Population shall be defined as all Staged Drugs at the time of the IRO's review.

g. Credit Report. A report generated by CareMed from its billing system of Undelivered and Returned Drugs that have been Credited.

h. Restocking Review Error Rate. The Restocking Review Overpayment divided by the total payment received by CareMed for the Staged Drugs in the sample.

2. *Restocking Review Discovery Sample.* For each Restocking Review, the IRO shall randomly select and review a sample of 50 Staged Drugs (Restocking Review Discovery Sample) from the Restocking Review Population. The IRO shall request that CareMed generate a Credit Report covering a period to include all Staged Drugs in the Restocking Review Discovery Sample. The IRO shall review the quantity returned for each Staged Drug and calculate the appropriate credit amount for that Staged Drug and compare that credit amount to the credit amount reflected in the Credit Report, to determine if the appropriate amount was credited to the applicable Federal health care program for each Staged Drug. If the Restocking Review Error Rate (as defined above) for the Restocking Review Discovery Sample is less than 5%, no additional sampling is required, nor is the Restocking Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, CareMed should, as appropriate, further analyze any errors identified in the Restocking Review Discovery Sample. CareMed recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Items included, or errors identified, in the Restocking Review Discovery Sample or any other segment of the universe.)

3. *Restocking Review Full Sample*. If the Restocking Review Discovery Sample indicates that the Restocking Review Error Rate is 5% or greater, the IRO shall conduct the same review as in the Restocking Review Discovery Sample for the remaining Staged Drugs in the Restocking Review Population.

4. *Restocking Systems Review*. If the Restocking Review Discovery Sample identifies an Restocking Review Error Rate of 5% or greater, the IRO shall review the system(s) and process(es) for each Staged Drug in the Restocking Review Discovery Sample and Restocking Review Full Sample that resulted in a Restocking Review Overpayment and identify any problems or weaknesses that may have resulted in the identified Restocking Review Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) for Restocking Related Functions.

5. *Other Requirements*

a. Return and Credit Process. Returned Drugs that will be processed as a Credited Drugs shall remain as Staged Drugs for at least 48 hours before the label for the original dispensing event is removed.

b. Restocking Review Supporting Documentation. The IRO shall request all documentation and materials required for its review of the Staged Drugs selected as part of the Restocking Review Discovery Sample or Restocking Review Full Sample (if applicable), and CareMed shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Restocking Review Discovery Sample or Restocking Review Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from CareMed after the IRO has completed its initial review of the Restocking Review Discovery Sample or Restocking Review Full Sample (if applicable) (Restocking Review Supplemental Documentation), the IRO shall identify in the Restocking Review Report the Restocking Review Supplemental Documentation, the date the Restocking Review Supplemental Documentation was accepted, and the relative weight the IRO gave to the Restocking Review Supplemental Documentation in its review. In addition, the IRO shall include a narrative in the Restocking Review Report describing the process by which the Restocking Review Supplemental Documentation was accepted and the IRO's reasons for accepting the Restocking Review Supplemental Documentation.

c. Items without Restocking Review Supporting Documentation. Any Staged Drug for which CareMed cannot produce documentation sufficient to support that the Staged Drug was a Credited Return shall be considered an error and the amount that should have been credited for such Staged Drug shall be deemed a Restocking Review Overpayment. Replacement sampling for Staged Drugs with missing documentation is not permitted.

6. *Payment of Credit Amounts.* Within 30 days of its receipt of the IRO's Restocking Review Report, CareMed shall pay any amount(s) that have not been credited to the applicable Federal health care program for any Staged Drug. CareMed shall make available to OIG all documentation that reflects the payment(s) to the Federal health care program payor(s).

D. Restocking Review Report. The IRO shall prepare a Restocking Review Report as described in this Appendix for each Restocking Review performed. The following information shall be included in the Restocking Review Report for each Restocking Review Discovery Sample and Restocking Review Full Sample (if applicable).

1. *Restocking Review Methodology and Sampling Documentation*

a. Restocking Review Population. A description of the Restocking Review Population subject to the Restocking Review.

b. Review Protocol. A narrative description of how the Restocking Review was conducted and what was evaluated.

c. Restocking Review Supplemental Documentation. A description of any Restocking Review Supplemental Documentation as required by II.C.5.b., above.

d. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

2. *Restocking Review Findings*

a. Narrative Results

i. A description of CareMed's Restocking process(es), including the identification, by position description, of the personnel involved in providing credit for undelivered and Returned Drugs.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the review.

b. Quantitative Results

i. Total number and percentage of Staged Drugs for which the IRO determined that the credits provided by CareMed differed from what should have been the correct credit.

ii. The total dollar amount of aggregated Restocking Review Overpayments in the Restocking Review.

iii. The Restocking Review Overpayment divided by the total value of Staged Drugs that should have been credited in the Restocking Review.

iv. A spreadsheet of the review results that includes the following information for each Staged Drugs: Federal health care program billed, beneficiary, national drug code (NDC) and amount dispensed, date of service, amount returned, amount credited to a Federal payor by CareMed, the correct credit amount (as determined by the IRO), dollar difference between amount credited by CareMed and the correct allowed amount, and with respect to any errors, health insurance claim number.

c. Recommendations. The IRO's report shall include any recommendations for improvements to CareMed's Restocking Related Functions, system(s), and processes based on the findings of the review.

d. Credentials. The names and credentials of the individuals who performed the review.

E. Systems Review Findings. With respect to any Restocking Systems Review, the IRO shall prepare a Report that shall include the IRO's observations,

findings, and recommendations regarding:

a. the strengths and weaknesses in CareMed's Restocking Related Functions;

b. an analysis of the reason for each error in the Restocking Review Discovery Sample and Restocking Review Full Sample; and

c. possible improvements to CareMed's Restocking Related Functions to address the specific problems or weaknesses that resulted in the identified Restocking Review Overpayments.