

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND**

**WOODHAVEN PHARMACY SERVICES, LLC D/B/A REMEDI SENIORCARE**

**I. PREAMBLE**

Woodhaven Pharmacy Services, LLC d/b/a Remedi Seniorcare (Woodhaven) 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). Contemporaneously with this CIA, Woodhaven is entering into a Settlement Agreement with the United States.

**II. TERM AND SCOPE OF THE CIA**

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

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Woodhaven's final annual report; or (2) any additional materials submitted by Woodhaven 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 who are natural persons (except for owners who own less than 5 percent of Woodhaven and who are former employees of Woodhaven);

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- b. all officers, directors, and employees of Woodhaven; and
- c. all contractors, subcontractors, agents, and other persons who provide patient care items or services, who provide pharmaceutical services, or who perform billing functions on behalf of Woodhaven, excluding
  - (i) vendors who provide information technology services to Woodhaven and who do not bill the Federal healthcare programs for such services;
  - (ii) vendors who provide debt collection services to Woodhaven and who do not bill the Federal healthcare programs for such services; and
  - (iii) vendors whose sole connection with Woodhaven is selling or otherwise providing medical supplies or equipment to Woodhaven 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 per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Restocking Related Functions" include processing and restocking drugs returned to Woodhaven from nursing facilities, including skilled nursing facilities (SNF), for which Woodhaven has received reimbursement from a Federal health care program.

3. "Claims Related Functions" includes submission of claims to any Federal health care program. Claims Related Functions also includes providing credit for returned and restocked drugs to Federal health care programs.

4. "Relevant Covered Persons" includes 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.

### III. CORPORATE INTEGRITY OBLIGATIONS

Woodhaven shall establish and maintain a Compliance Program that includes the following elements:

#### A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 120 days after the Effective Date, Woodhaven shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Woodhaven, shall report directly to the Chief Executive Officer of Woodhaven, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Woodhaven, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Woodhaven as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Woodhaven shall report to OIG, in writing, any change in the identity 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 days after the change.

2. *Compliance Committee.* Within 120 days after the Effective Date, Woodhaven shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant

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departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Woodhaven's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Woodhaven 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 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Within 120 days after the Effective Date, Woodhaven shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Woodhaven shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Woodhaven'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. Woodhaven's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and Maryland State Board of Pharmacy Requirements and with Woodhaven's own Policies and Procedures;
- c. the requirement that all of Woodhaven's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Woodhaven, suspected violations of any Federal health care program requirements, Maryland State Board of Pharmacy Requirements, or any of Woodhaven's own Policies and Procedures; and

- d. the right of all individuals to use the Disclosure Program described in Section III.E, and Woodhaven's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

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

2. *Policies and Procedures.* Within 120 days after the Effective Date, Woodhaven shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA, and Woodhaven's compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. Woodhaven's policy that it shall maintain any Returned Drugs that will be processed for credit to Federal payors as Staged Drugs, as defined in Appendix B, for a minimum of 48 hours before the label from the original dispensing event is removed;
- b. the proper procedures for restocking and crediting returns for pharmaceutical products returned to Woodhaven for which Woodhaven has received reimbursement from a Federal health care program;
- c. the proper procedures for accurate preparation and submission of claims in accordance with Federal health care program requirements;

- d. the proper procedures for repaying overpayments to Federal health care programs; and
- e. the proper procedures for handling and dispensing pharmaceuticals, consistent with Maryland State Board of Pharmacy requirements and any other Federal or state law governing the operations of pharmacies.

Within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Woodhaven shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

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

- a. CIA requirements; and
- b. Compliance Program, including the Code of Conduct.

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

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

- a. the Federal health care program requirements and state requirements regarding restocking, crediting, and refunding overpayments in connection with returns for pharmaceuticals for which Woodhaven has received reimbursement from a Federal health care program;
- b. the Federal health care program requirements regarding the accurate submission of claims;
- c. Federal health care program requirements regarding refunding overpayments;
- d. the personal obligation of each individual involved in Restocking and Crediting Related Functions to ensure that such credits are accurate;
- e. the legal sanctions for violations of the Federal health care program requirements; and
- f. examples of proper and improper restocking and crediting practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least one hour of Specific Training in each subsequent Reporting Period.

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

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

5. *Update of Training.* Woodhaven shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or Independent Review Organization reviews, and any other relevant information.

6. *Computer-based Training.* Woodhaven may provide the training required under this CIA through appropriate computer-based training approaches. If Woodhaven 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, Woodhaven 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 Woodhaven in assessing and evaluating its Restocking Related Functions and Claims 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.

The IRO shall have expertise in applicable Federal health care program requirements and state pharmacy requirements as appropriate for the IRO review. The IRO shall assess, along with Woodhaven, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO shall conduct reviews that assess Woodhaven's systems, processes, policies, procedures, and practices related to Restocking

Related Functions and Claims Related Functions (collectively, "IRO Review").

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Review shall consist of a Restocking Review and a Claims Review and cover each of the five Reporting Periods.

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

2. *IRO Review Reports.* The IRO shall prepare a report (or reports) based upon each Review Performed (IRO Review Report). Information to be included in the IRO Review Reports is described in Appendix B.

3. *Repayment of Identified Overpayments.* Woodhaven shall repay within 30 days any Overpayment(s) identified. Woodhaven shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

a. This obligation to repay any Overpayments includes any Claims Review Overpayments identified in the Claims Review Discovery Sample or the Claims Review Full Sample (if applicable), regardless of the Claims Review Error Rate, to the appropriate payor and in accordance with payor refund policies; and

b. This obligation to repay any Overpayments includes any Restocking Review Overpayments identified in the Restocking Review Discovery Sample or the Restocking Review Full Sample (if applicable), regardless of the Restocking Review Error Rate, to the appropriate payor and in accordance with payor refund policies.

4. *Unallowable Cost Review.* If applicable, the IRO shall conduct a review of Woodhaven's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Woodhaven has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to

identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable costs analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Woodhaven or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

6. *Unallowable Cost Review Report.* If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether Woodhaven has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

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

Prior to initiating a Validation Review, OIG shall notify Woodhaven 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, Woodhaven may request a meeting with OIG to: (a) discuss any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Woodhaven agrees to provide any additional information as may be requested by OIG under this Section III.D.7 in an expedited manner. OIG will attempt in good faith to

resolve any IRO Review issues with Woodhaven 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.

8. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Woodhaven a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review, Restocking Review, and Unallowable Cost Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Within 120 days after the Effective Date, Woodhaven 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 Woodhaven's policies, conduct, practices, or procedures with respect to Federal health care program requirements or Maryland State Board of Pharmacy Requirements believed by the individual to be a potential violation of criminal, civil, or administrative law. Woodhaven shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Woodhaven shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. 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 (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Woodhaven shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Woodhaven shall screen all prospective and current 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. Woodhaven shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Woodhaven 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 this Section affects Woodhaven's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Woodhaven understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Woodhaven may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Woodhaven meets the requirements of Section III.F.

3. *Removal Requirement.* If Woodhaven has actual notice that a Covered Person has become an Ineligible Person, Woodhaven shall remove such Covered Person from responsibility for, or involvement with, Woodhaven'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 Woodhaven 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, Woodhaven 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.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Repayment of Overpayments.

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

2. *Repayment of Overpayments.*

a. If, at any time, Woodhaven identifies any Overpayment, Woodhaven shall repay the Overpayment to the appropriate payor within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 30 days after identification, Woodhaven 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.

## I. 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.F.1.a; or
- d. the filing of a bankruptcy petition by Woodhaven.

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

2. *Reporting of Reportable Events.* If Woodhaven determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Woodhaven shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made at the same time as the repayment to the payor required in Section III.H, and shall include:

- a. a copy of the notification and repayment to the payor required in Section III.H.2;
- b. a description of the steps taken by Woodhaven to identify and quantify the Overpayment;

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

d. a description of Woodhaven's actions taken to correct the Reportable Event; and

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

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

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

b. a description of Woodhaven's actions taken to correct the Reportable Event;

c. any further steps Woodhaven plans to take to address the Reportable Event and prevent it from recurring; and

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

5. *Reportable Events under Section III.L.1.d.* For Reportable Events under Section III.L.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.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Woodhaven changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Woodhaven 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 location.

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

C. Sale of Unit or Location. In the event that, after the Effective Date, Woodhaven proposes to sell any or all of its business units or locations that are subject to this CIA, Woodhaven shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the 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 such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

#### V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Woodhaven 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. a copy of Woodhaven's Code of Conduct required by Section III.B.1;

4. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to OIG upon request);

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

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

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the Disclosure Program required by Section III.E;

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; and (d) a summary and description of any and all current and prior engagements and agreements between Woodhaven and the IRO;

9. a certification from the IRO regarding its professional independence and objectivity with respect to Woodhaven;

10. a description of the process by which Woodhaven fulfills the requirements of Section III.F regarding Ineligible Persons;

11. a list of all of Woodhaven'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 state Medicaid program

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provider number and/or supplier number(s); Medicare National Provider Identifier number; and the name and address of each Medicare and state Medicaid program contractor to which Woodhaven currently submits claims;

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

13. the certifications required by Section V.C.

B. Annual Reports. Woodhaven shall submit to OIG annually a report with respect to the status of, and findings regarding, Woodhaven'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 and any change in the membership of the Compliance Committee described in Section III.A;

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

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

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

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually

completed the initial and annual training, and an explanation of any exceptions.

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

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

6. Woodhaven'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;

7. a summary and description of any and all current and prior engagements and agreements between Woodhaven and the IRO, (if different from what was submitted as part of the Implementation Report);

8. a certification from the IRO regarding its professional independence and objectivity with respect to Woodhaven;

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

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare Part D, 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;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

12. any changes to the process by which Woodhaven fulfills the requirements of Section III.F regarding Ineligible Persons;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a

description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a description of all changes to the most recently provided list of all of Woodhaven'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 state Medicaid program provider number and/or supplier number(s); Medicare National Provider Identifier number, and the name and address of each Medicare and state Medicaid program contractor to which Woodhaven currently submits claims; and

15. 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. The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

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

2. 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; and

3. to the best of his or her knowledge, Woodhaven 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. Woodhaven 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

Woodhaven CIA

under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Woodhaven 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

Woodhaven: Michael Bronfein  
Chief Executive Officer  
Remedi SeniorCare  
6225 Smith Avenue  
Marbury Building, Suite 202  
Baltimore, Maryland 21209  
Telephone: 443.730.8957  
Facsimile: 410.484.6021

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, Woodhaven 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 or request copies of Woodhaven's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Woodhaven's locations for the purpose of verifying and evaluating: (a) Woodhaven's compliance with the terms of this CIA; and (b) Woodhaven's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Woodhaven to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Woodhaven's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Woodhaven shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Woodhaven's employees may elect to be interviewed with or without a representative of Woodhaven present.

## **VIII. DOCUMENT AND RECORD RETENTION**

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

**X. BREACH AND DEFAULT PROVISIONS**

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

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons and Relevant Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings;  
and
- i. reporting of Reportable Events.

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

Woodhaven CIA

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Woodhaven 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 day after the date the obligation became due) for each day Woodhaven fails to submit the IRO Review Reports in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Woodhaven 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 Woodhaven fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Woodhaven stating the specific grounds for its determination that Woodhaven has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Woodhaven shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Woodhaven 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. Woodhaven may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Woodhaven 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 Woodhaven receives OIG's written denial of such request or the

Woodhaven CIA

original due date, whichever is later. A “timely written request” is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Woodhaven 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 Woodhaven of: (a) Woodhaven’s failure to comply; and (b) OIG’s exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the “Demand Letter”).

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Woodhaven 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 Woodhaven elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Woodhaven 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 Woodhaven has materially breached this CIA, which decision shall be made at OIG’s discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Woodhaven to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.D and Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Woodhaven constitutes an independent basis for Woodhaven's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Woodhaven has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Woodhaven of: (a) Woodhaven's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

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

- a. Woodhaven is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Woodhaven has begun to take action to cure the material breach; (ii) Woodhaven is pursuing such action with due diligence; and (iii) Woodhaven has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Woodhaven fails to satisfy the requirements of Section X.D.3, OIG may exclude Woodhaven from participation in the Federal health care programs. OIG shall notify Woodhaven in writing of its determination to exclude Woodhaven (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Woodhaven's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Woodhaven 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 Woodhaven 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, Woodhaven 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.

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 Woodhaven was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Woodhaven 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 Woodhaven to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a

decision unless Woodhaven 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:

- a. whether Woodhaven was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Woodhaven had begun to take action to cure the material breach within that period; (ii) Woodhaven has pursued and is pursuing such action with due diligence; and (iii) Woodhaven provided to OIG within that period a reasonable timetable for curing the material breach and Woodhaven has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Woodhaven, only after a DAB decision in favor of OIG. Woodhaven's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Woodhaven 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 Woodhaven 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. Woodhaven 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 Woodhaven, Woodhaven 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**

Woodhaven and OIG agree as follows:

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

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

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

D. OIG may agree to a suspension of Woodhaven's obligations under this CIA based on a certification by Woodhaven 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 Woodhaven is relieved of its CIA obligations, Woodhaven will be required to notify OIG in writing at least 30 days in advance if Woodhaven 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.

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

G. 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.

Woodhaven CIA

ON BEHALF OF WOODHAVEN

/Michael Bronfein/

11/22/10

~~MICHAEL BRONFEIN~~  
Chief Executive Officer  
Woodhaven Pharmacy Services, LLC

DATE

/Stephen J. Immelt/

11/22/10

STEPHEN J. IMMELT  
Hogan Lovells

DATE

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

/Gregory E. Demske/

---

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

11/23/10  
\_\_\_\_\_  
DATE

## 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. Woodhaven 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 review 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.8 and Section V.A.9 of the CIA or any additional information submitted by Woodhaven in response to a request by the OIG, whichever is later, OIG will notify Woodhaven if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Woodhaven may continue to engage the IRO.

2. If Woodhaven engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Woodhaven shall submit the information identified in Section V.A.8 and 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 Woodhaven at the request of OIG, whichever is later, OIG will notify Woodhaven if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Woodhaven 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 requirements and state pharmacy requirements relating to Restocking Related Functions and Claims Related Functions. As such, the assigned individuals shall be knowledgeable about the general requirements of the Federal health care program(s) from which Woodhaven seeks reimbursement;

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

3. assign an individual(s) to the Restocking Review who has expertise in pharmacy crediting requirements;

4. assign an individual(s) to the Claims Review who has 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 IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program requirements, request clarification from the appropriate authority (e.g., the Centers for Medicare and Medicaid Services or state Medicaid agency);

4. respond to all OIG inquiries 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 IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Woodhaven.

E. IRO Removal/Termination.

1. *Provider and IRO.* If Woodhaven terminates its IRO or if the IRO withdraws from during the term of the CIA, Woodhaven 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. Woodhaven must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Woodhaven to engage a new IRO in accordance with Paragraph A of this Appendix. Woodhaven must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier

Prior to requiring Woodhaven to engage a new IRO, OIG shall notify Woodhaven 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, Woodhaven 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 Woodhaven prior to requiring Woodhaven to terminate the IRO. However, the final determination as to whether or not to require Woodhaven to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### I. General Description

As specified more fully below, Woodhaven shall retain an Independent Review Organization (IRO) to perform reviews to assist Woodhaven in assessing and evaluating its systems, processes, policies, procedures, and practices for Woodhaven's Restocking Related Functions and Claims Related Functions (IRO Review). Woodhaven may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

### II. IRO Reviews

#### A. Claims Review.

1. *Frequency.* The IRO shall conduct a Claims Review for each Reporting Period of the CIA.

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

- a. Claims Review Overpayment: The amount of money Woodhaven has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Paid Claim: A claim submitted by Woodhaven and for which Woodhaven has received reimbursement from a Federal health care program.
- c. Claims Review Population: The Claims Review Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- d. Claims Review Error Rate: The Claims Review Error Rate shall be the percentage of net Claims Review Overpayments identified in the sample. The net Claims Review Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Claims Review Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Claims Review Overpayment calculation. Rather, only underpayments identified as part of the Claims Review Discovery Sample

shall be included as part of the net Claims Review Overpayment calculation.)

The Claims Review Error Rate is calculated by dividing the net Claims Review Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

3. *Claims Review Discovery Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims (Claims Review Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Woodhaven's office or under Woodhaven's control and applicable billing regulations and guidance and Part D plan contract payment provisions to determine whether the claim was correctly submitted and reimbursed.

If the Claims Review Error Rate (as defined above) for the Claims Review Discovery Sample is less than 5%, no additional sampling is required, nor is the Claims Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Woodhaven should, as appropriate, further analyze any errors identified in the Claims Review Discovery Sample. Woodhaven 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 Claims Review Discovery Sample or any other segment of the universe.)

4. *Claims Review Full Sample.* If the Claims Review Discovery Sample indicates that the Claims Review Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Claims Review Full Sample) using commonly accepted sampling methods. The Claims Review Full Sample shall be designed to: (1) estimate the actual Claims Review Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Claims Review Full Sample shall be reviewed based on the supporting documentation available at Woodhaven's office or under Woodhaven's control and applicable billing regulations and guidance and Part D plan contract payment provisions to determine whether the claim was correctly submitted and reimbursed. For purposes of calculating the size of the Claims Review Full Sample, the Claims Review Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Claims Review Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Claims Review Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Claims Review Full Sample Paid Claims using the seed number generated by the Claims Review Discovery Sample. OIG, in its sole

discretion, may refer the findings of the Claims Review Full Sample (and any related workpapers) received from Woodhaven to the appropriate Federal health care program payor, including the Medicare contractor (e.g., the relevant Medicare Part D plan) or single state Medicaid agency, for appropriate follow-up by that payor.

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

- a. a review of Woodhaven'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 claims are submitted to Federal payors, safeguards to ensure proper billing, and procedures to identify and correct inaccurate billing;
- b. for each claim in the Claims Review Discovery Sample and Claims Review Full Sample that resulted in a Claims Review 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 Claims Review Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

6. *Other Requirements.*

- a. Claims Review Supporting Documentation. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Claims Review Discovery Sample or Claims Review Full Sample (if applicable), and Woodhaven shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Claims Review Discovery Sample or Claims Review Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Woodhaven after the IRO has completed its initial review of the Claims Review Discovery Sample or Claims Review Full Sample (if applicable) (Claims Review Supplemental Documentation), the IRO shall identify in the Claims Review Report the Claims Review Supplemental Documentation, the

date the Claims Review Supplemental Documentation was accepted, and the relative weight the IRO gave to the Claims Review Supplemental Documentation in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Claims Review Supplemental Documentation was accepted and the IRO's reasons for accepting the Claims Review Supplemental Documentation.

- b. Paid Claims without Claims Review Supporting Documentation. Any Paid Claim for which Woodhaven cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Woodhaven for such Paid Claim shall be deemed a Claims Review Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of all samples (Claims Review Discovery Sample(s) and Claims Review 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 Claims Review Discovery Sample or Claims Review Full Sample).

## B. Restocking Review

- 1. *Frequency of Review.* The IRO shall conduct unannounced Restocking Reviews twice for each Reporting Period of the CIA.
- 2. *Definitions*
  - a. Restocking Review Overpayment. The amount of money that Woodhaven has failed to credit to a Federal payor for the original dispensing event after the drugs were returned and restocked.
  - b. Returned Drugs. Drugs dispensed by Woodhaven for which Woodhaven received reimbursement from Federal health care programs and that Woodhaven picks up from nursing facilities and that are unused and still packaged.

- c. Staged Returns. Returned Drugs that have been staged for restocking and that have not had their original dispensing labels removed.
- d. Credited Return. A Staged Return that has been processed to provide credit to the Federal payor that was billed for the original dispensing event.
- e. Restocking Review Population. The Restocking Review Population shall be defined as all Staged Returns at the time of the IRO's unannounced visit.
- f. Item. A prescription drug dispensing event for which Woodhaven received payment from a Federal health care program.
- g. Credit Report. A report generated by Woodhaven from its billing system of Returned Drugs that have been Credited.
- h. Restocking Review Error Rate. The Restocking Review Overpayment divided by the total value of Items Credited in the Sample.

3. *Restocking Review Discovery Sample*. The IRO shall randomly select and review a sample of 50 Items (Restocking Review Discovery Sample) from all Staged Returns at the time of the IRO's unannounced visit. The IRO shall request that Woodhaven generate a Credit Report covering a time period to include all Items in the Restocking Review Discovery Sample. 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, Woodhaven should, as appropriate, further analyze any errors identified in the Restocking Review Discovery Sample. Woodhaven 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 Discovery Sample or any other segment of the universe.)

4. *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 Items in the Restocking Review Population.

5. *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 Item 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.

6. *Other Requirements*

- a. Return and Credit Process. Returned Drugs that will be processed as a Credited Return shall remain as a Staged Return 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 Items selected as part of the Restocking Review Discovery Sample or Restocking Review Full Sample (if applicable), and Woodhaven 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 Woodhaven 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 Item for which Woodhaven cannot produce documentation sufficient to support that the Item was

a Credited Return shall be considered an error and the amount that should have been credited for such Item shall be deemed a Restocking Review Overpayment. Replacement sampling for Items with missing documentation is not permitted.

### III. IRO Reports

A. 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 Claims Review Discovery Sample and Claims Review Full Sample (if applicable).

#### 1. *Claims Review Methodology*

- a. Claims Review Population. A description of the Claims Review 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., medical records, physician prescriptions, applicable prior authorization, local medical review policies (including title and policy number), CMS regulations, CMS guidance (including citation and date), Medicaid manual (including citation and issue date), Part D plan contract or subcontract paragraph, and other policies, regulations, or directives.
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Claims Review Supplemental Documentation. A description of any Claims Review Supplemental Documentation as required by II.A.6.a, above.

#### 2. *Claims Review 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 Claims Review Full Sample, if applicable.
  - c. A description or identification of the statistical sampling software package used to select the sample and determine the Claims Review Full Sample size, if applicable.
3. *Claims Review Findings.*
- a. Claims Review Narrative Results.
    - i. A description of Woodhaven's billing 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 Claims Review Discovery Sample, and the results of the Claims Review 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 Woodhaven (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 Claims Review Overpayment to Woodhaven.
    - iii. Total dollar amount of all Claims Review Overpayments in the Claims Review sample.
    - iv. Total dollar amount of Paid Claims included in the sample and the net Claims Review Overpayment associated with the Claims Review sample.

- v. Claims Review Error Rate in the 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.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Woodhaven's billing system(s) based on the findings of the Claims Review

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.

B. 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.B.6.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 Woodhaven's Restocking process(es), including the identification, by position description, of the personnel involved in providing credit for 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 Items for which the IRO determined that the credits provided by Woodhaven differed from what should have been the correct credit.
- ii. The total dollar amount of aggregated Restocking Review Overpayments in the Restocking Review sample.
- iii. The Restocking Review Overpayment divided by the total value of Items that should have been credited in the Restocking Review sample.
- vi. A spreadsheet of the review results that includes the following information for each credit: 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 Woodhaven, the correct credit amount (as determined by the IRO), dollar difference between amount credited by Woodhaven 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 Woodhaven'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.
- C. Systems Review Report. The IRO shall prepare a Report based on any Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:
1. With respect to any Claims Systems Review,
    - a. the strengths and weaknesses in Woodhaven's billing systems and processes;
    - b. an analysis of the reason for each error in the Claims Review Discovery Sample and the Claims Review Full Sample; and
    - c. possible improvements to Woodhaven's billing systems and processes to address the specific problems or weaknesses that resulted in the identified Claims Review Overpayments.
  2. With respect to any Restocking Systems Review,
    - a. the strengths and weaknesses in Woodhaven'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 Woodhaven's Restocking Related Functions to address the specific problems or weaknesses that resulted in the identified Restocking Review Overpayments.