

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
RHINE DRUG COMPANY AND ANDY CARTER CLEMENTS, JR.**

**I. PREAMBLE**

Rhine Drug Company and Andy Carter Clements, Jr. (collectively, Rhine Drug) hereby enter into this Integrity Agreement (IA) 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 IA, Rhine Drug is entering into a Settlement Agreement with the United States.

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

A. This IA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. 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) Rhine Drug's final annual report; or (2) any additional materials submitted by Rhine Drug pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. Andy Carter Clements, Jr. (Carter Clements), and all employees of Rhine Drug Company; and

2. all contractors, agents, and other persons who are involved in the dispensing of prescription drugs or who perform billing functions on behalf of Rhine Drug.

### **III. INTEGRITY OBLIGATIONS**

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

#### **A. Posting of Notice**

Within 60 days after the Effective Date, Rhine Drug shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

#### **B. Training and Education**

1. *Training.* All Covered Persons shall receive at least three hours of training during the first Reporting Period. Training may be completed in-person or online. These training requirements may be satisfied by training courses that are submitted to OIG, including any provided by the State Pharmacy Association or Medicare Part D plan prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

- a. the Federal health care program requirements, including billing, coding and claim submission statutes, regulations, and program requirements and the requirements relating to dispensing of and billing for prescription drugs by Rhine Drug;
- b. State Board of Pharmacy requirements relating to the dispensing of prescription drugs, including but not limited to prescription documentation requirements;
- c. Federal and state health care program requirements regarding the accurate submission of pharmacy claims, including requirements regarding prescription refills, billing, and crediting requirements; and

- d. the Federal health care program requirements and State requirements relating documentation of physician orders for prescription drugs and documentation that the prescription drugs were dispensed.

New Covered Persons shall receive at least three hours of training within 90 days after becoming a Covered Person.

The OIG may, in its discretion, require that Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second and third years of the IA. The OIG shall provide notice to Rhine Drug of such additional required training at least 180 days prior to the required completion date for such training.

2. *Training Records.* Rhine Drug shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

### C. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 60 days after the Effective Date, Rhine Drug shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.C. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Rhine Drug shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Rhine Drug ) related to the reviews.

2. *Claims Review.* The IRO shall conduct a review of Rhine Drug’s claims submitted to and reimbursed by the Medicare and Medicaid programs, to

determine whether the prescription drugs furnished by Rhine Drugs were dispensed according to a valid prescription, whether appropriate documentation of a valid prescription was maintained, and whether the claims were appropriately submitted and reimbursed for each three-month period during the term of this IA (Quarterly Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Independence and Objectivity Certification.* Prior to performing the first Quarterly Claims Review, and annually thereafter, the IRO shall provide to Rhine Drug a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.C and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this IA. The IRO's certification shall include a summary of all current and prior engagements between Rhine Drug and the IRO.

#### D. Ineligible Persons

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

- a. an "Ineligible Person" shall include an individual or entity who:
  - i. is currently excluded from participation in any Federal health care program; or
  - ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription

or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. Rhine Drug shall screen all prospective Covered Persons against the Exclusion List 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. Rhine Drug shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.
- c. Rhine Drug shall require all Covered Persons to disclose immediately if they become an Ineligible Person.

Rhine Drug shall maintain documentation (i.e., a print screen of the search results) in order to demonstrate that Rhine Drug: (1) has checked the Exclusion List and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

Nothing in this Section III.D affects Rhine Drug’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. Rhine Drug understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Rhine Drug may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Rhine Drug meets the requirements of Section III.D.

3. *Removal Requirement.* If Rhine Drug has actual notice that a Covered Person has become an Ineligible Person, Rhine Drug shall remove such Covered

Person from responsibility for, or involvement with, Rhine Drug's business operations related to the Federal health care program(s) from which such Covered Person has been excluded 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 any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Rhine Drug 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, Rhine Drug 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 or the accuracy of any claims submitted to any Federal health care program.

E. Notification of Government Investigation or Legal Proceeding

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

F. Overpayments

1. *Definition of Overpayments.* An "Overpayment" means any funds that Rhine Drug receives or retains under any Federal health care program to which Rhine Drug, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Repayment of Overpayments.* If, at any time, Rhine Drug identifies any Overpayment, Rhine Drug shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) in accordance with the requirements of the Centers for Medicare and Medicaid Services (CMS) overpayment statute and regulations, 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305, and any applicable CMS guidance. Rhine

Drug should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

G. Reportable Events

1. *Definition of Reportable Event.* For purposes of this IA, 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.D.1.a; or
- d. the filing of a bankruptcy petition by Rhine Drug.

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

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

3. *Reportable Events under Section III.G.1.a and III.G.1.b.* For Reportable Events under Section III.G.1.a and 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, if any;
- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by Rhine Drug to identify and quantify any Overpayments; and
- d. a description of Rhine Drug's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Rhine Drug shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.G.1.c.* For Reportable Events under Section III.G.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 Persons employment or contractual relationship;
- c. a description of the Exclusion List screening that Rhine Drug completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.G.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include

documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark law) should be submitted by Rhine Drug to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Rhine Drug identifies a probable violation of the Stark law and repays the applicable Overpayment directly to the CMS contractor, then Rhine Drug is not required by this Section III.F to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT**

##### **A. Sales or Purchase of a Location or Business**

In the event that, after the Effective Date, Rhine Drug Company or Carter Clements proposes to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, a sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or proposed purchase, Rhine Drug Company or Carter Clements wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, Rhine Drug Company or Carter Clements (as applicable) must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the location or business to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the proposed purchaser.

##### **B. New Employment or Contractual Arrangement**

At least 30 days prior to Carter Clements becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Carter Clements shall notify OIG of his plan to

become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of Carter Clements's responsibilities with respect to such potential employer or contractor. In addition, prior to Carter Clements becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Carter Clements shall notify that party of this IA. This notification shall include a copy of the IA and a statement indicating the remaining term of the IA. The IA shall continue to apply to Carter Clements following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

## **V. IMPLEMENTATION REPORT, IRO REPORTS AND ANNUAL REPORTS**

### **A. Implementation Report**

Within 90 days after the Effective Date, Rhine Drug shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. a copy of the notice required by Section III.A, a description of where the notice is posted, and the date the notice was posted;
2. the following information regarding the IRO: (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 IA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Rhine Drug;
3. a copy of the search result print screens demonstrating that Rhine Drug has screened all Covered Persons against the Exclusion List, as required by section III.D, within 30 days of the Effective Date;
4. a list of all of Rhine Drug's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s), and/or supplier number(s); and
5. a certification by Carter Clements that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a

copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Rhine Drug is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. IRO Reports

Within 60 days following the end of each three-month period during the term of this IA, Rhine Drug shall provide to OIG a copy of the Quarterly Claims Review Report prepared by the IRO for each Quarterly Claims Review performed, along with Rhine Drug's response and corrective action plan related to any recommendations made by the IRO in the Quarterly Claims Review Report. Each Quarterly Claims Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports

Rhine Drug shall submit to OIG a report on its compliance with the IA requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall, at a minimum, include:

1. (in the first Annual Report) the following information regarding the training required by Section III.B during the first reporting period (and any additional hours of training required for the second and third reporting periods): a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program. A copy of all training materials shall be made available to OIG upon request;
2. a certification from the IRO regarding its professional independence and objectivity with respect to Rhine Drug Company and Carter Clements;
3. a copy of the search result print screens demonstrating that Rhine Drug screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.D;
4. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.E. 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;

5. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

6. a summary of Reportable Events (as defined in Section III.G) identified during the Reporting Period;

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

8. a description of all changes to the most recently provided list of Rhine Drug's locations (including addresses) as required by Section V.A.4; and

9. a certification signed by Carter Clements that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, Rhine Drug is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

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.

#### D. Designation of Information

Rhine Drug 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. Rhine Drug 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 IA shall be submitted to the following entities:

### OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, DC 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

### Carter Clements and Rhine Drug Company:

Andy Carter Clements, Jr.  
119 First Street  
Rhine, GA 31077  
Phone: (229) 385-5351  
Fax: (229) 385-6807

Unless otherwise specified, all notifications and reports required by this IA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Rhine Drug may be required to provide OIG with an electronic copy of each notification or report required by this IA, 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 conduct interviews, examine or request copies of Rhine Drug's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Rhine Drug's locations for the purpose of

verifying and evaluating: (a) Rhine Drug's compliance with the terms of this IA and (b) Rhine Drug's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Rhine Drug 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 Rhine Drug and any of Rhine Drug's employees or contractors 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. Rhine Drug shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Rhine Drug's employees and contractors may elect to be interviewed with or without a representative of Rhine Drug present.

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

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

## **X. BREACH AND DEFAULT PROVISIONS**

Rhine Drug is expected to fully and timely comply with all of its IA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Rhine Drug and OIG hereby agree that failure to comply with certain obligations set forth in this IA 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Rhine Drug fails to:

- a. post a notice in accordance with the requirements of Section III.A;
- b. complete the training required for Covered Persons and maintain training records, in accordance with the requirements of Section III.B;
- c. screen Covered Persons in accordance with the requirements of Section III.D; require Covered Persons to disclose if they are excluded in accordance with the requirements of Section III.D; or maintain copies of print screens from search results to demonstrate the required screening has been performed in accordance with the requirements of Section III.D;
- d. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.E;
- e. repay any Overpayments as required by Section III.F and Appendix B; or
- f. report a Reportable Event in accordance with Section III.G.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Rhine Drug fails to engage and use an IRO, as required by Section III.C, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Rhine Drug fails to submit a complete Implementation Report, Annual Report, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Rhine Drug fails to submit any Quarterly Claims Review Report in accordance with the requirements of Section III.C and Appendix B or fails to repay any Overpayment identified by the IRO, as required by Appendix B.

5. A Stipulated Penalty of \$1,000 for each day Rhine Drug fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Rhine Drug fails to grant access.)

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

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

Rhine Drug 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 IA. 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 Rhine Drug 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 Rhine Drug 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 Rhine Drug 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 Rhine Drug of: (a) Rhine Drug'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, Rhine Drug 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 Rhine Drug elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Rhine Drug 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 IA 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 Rhine Drug has materially breached this IA, 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 IA

1. *Definition of Material Breach.* A material breach of this IA means:
  - a. a failure by Rhine Drug to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.G;
  - b. repeated violations or a flagrant violation of any of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;
  - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
  - d. a failure to engage and use an IRO in accordance with Section III.C, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by Rhine Drug constitutes an independent basis for Rhine Drug'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 three years per material breach. Upon a determination by OIG that Rhine Drug has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify Rhine Drug of: (a) Rhine Drug'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.* Rhine Drug 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) Rhine Drug has begun to take action to cure the material breach; (ii) Rhine Drug is pursuing such action with due diligence; and (iii) Rhine Drug has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Rhine Drug fails to satisfy the requirements of Section X.D.3, OIG may exclude Rhine Drug from participation in the Federal health care programs. OIG shall notify Rhine Drug in writing of its determination to exclude Rhine Drug. (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 Rhine Drug's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Rhine Drug 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 Rhine Drug of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, Rhine Drug 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 IA. 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 IA shall be: (a) whether Rhine Drug was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Rhine Drug 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 IA and orders Rhine Drug to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Rhine Drug 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 IA shall be whether Rhine Drug was in material breach of this IA and, if so, whether:

- a. Rhine Drug 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 Rhine Drug's receipt of the Notice of Material Breach: (i) Rhine Drug had begun to take action to cure the material breach; (ii) Rhine Drug pursued such action with due diligence; and (iii) Rhine Drug 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 Rhine Drug, only after a DAB decision in favor of OIG. Rhine Drug's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Rhine Drug 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 Rhine Drug 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. Rhine Drug shall waive their 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 Rhine Drug, Rhine Drug 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Rhine Drug and OIG agree as follows:

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

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

C. OIG may agree to a suspension of Rhine Drug Company's or Carter Clement's obligations under this IA based on a certification by Rhine Drug Company or Carter Clements (as applicable) that it or he is no longer providing health care items or services that will be billed to any Federal health care program and it or he 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 Carter Clements or Rhine Drug Company is relieved of its or his IA obligations, Carter Clements or Rhine Drug Company (as applicable) shall be required to notify OIG in writing at least 30 days in advance if Carter Clements or Rhine Drug Company 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 IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to and do not affect: (1) Rhine Drug's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Rhine Drug signatories represent and warrant that he is authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

F. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this IA.

**ON BEHALF OF RHINE DRUG**

/Carter Clements/

Carter Clements  
Rhine Drug Company

DATE

5/10/17

/Steve Sadow/

Steve Sadow  
Counsel for Rhine Drug Company

DATE

5/10/17

**ON BEHALF OF ANDY CARTER CLEMENTS, JR.**

/Andy Carter Clements/

~~Andy Carter Clements, Jr.~~

DATE

5/10/17

/Steve Sadow/

Steve Sadow  
Counsel for Andy Carter Clements, Jr.

DATE

5/10/17

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

/Lisa M. Re/

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LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

6/02/17  
DATE

/Christina K. McGarvey/

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CHRISTINA K. MCGARVEY  
Senior Counsel

6/2/17  
DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. Rhine Drug 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.2 of the IA or any additional information submitted by Rhine Drug in response to a request by OIG, whichever is later, OIG will notify Rhine Drug if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Rhine Drug may continue to engage the IRO.

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

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Quarterly Claims Review who have expertise in the Medicare Part D, state Medicaid program, and state Board of Pharmacy requirements applicable to the dispensing of and billing for prescription drugs;

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

3. have sufficient staff and resources to conduct the reviews required by the IA on a timely basis.

#### C. IRO Responsibilities

The IRO shall:

1. perform each Quarterly Claims Review in accordance with the specific requirements of the IA;
2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines, as well as applicable State Board of Pharmacy requirements, in making assessments in the Claims Review;
3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation;
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 IA.

D. IRO Independence and Objectivity

The IRO must perform each Quarterly Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Rhine Drug and IRO.* If Rhine Drug terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, Rhine Drug must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG no later than 30 days after termination or withdrawal. Rhine Drug 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 shall notify Rhine Drug in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Rhine Drug shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Rhine Drug regarding its IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Rhine Drug in writing that Rhine Drug shall be required to engage a new IRO in accordance with Paragraph A of this Appendix.

Rhine Drug must engage a new IRO within 60 days of receipt of OIG's written notice. The final determination as to whether or not to require Rhine Drug to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### CLAIMS REVIEW

A. Quarterly Claims Review. The IRO shall conduct a review of Rhine Drug's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether the prescription drugs furnished by Rhine Drugs were dispensed according to a valid prescription, whether Rhine Drug has documentation of the prescription for each drug dispensed (including any refills of such drug), and whether the claims were correctly billed and reimbursed, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed. The first three-month period shall begin 30 days following the Effective Date of this IA.

1. *Definitions*. For the purposes of this Appendix B, the following definitions shall be used:

- a. Overpayment: The amount of money Rhine Drug has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. Paid Claim: A prescription drug claim submitted by Rhine Drug and for which Rhine Drug has received reimbursement from the Medicare program or a state Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims during the three-month period covered by the Quarterly Claims Review.

2. *Quarterly Claims Sample*.

- a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of Rhine Drug during the preceding three-month period (Quarterly Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at <https://oig.hhs.gov/compliance/rat-stats/index.asp>.

- b. Rhine Drug shall provide the IRO with a list of all Rhine Drug's Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO.
- c. The randomly selected 30 Paid Claims shall be reviewed by the IRO based on the supporting documentation available at Rhine Drug's office or under Rhine Drug's control and applicable Medicare and state Medicaid program requirements and applicable State Board of Pharmacy requirements to determine whether each prescription drug furnished by Rhine Drug was dispensed according to a valid prescription, whether documentation of the prescription (including any prescription refills) is maintained, and whether the claim was correctly submitted and reimbursed. For each Paid Claim reviewed, the IRO should verify that Rhine Drug maintained documentation of: (1) the prescription or order for the drug dispensed; (2) the delivery of the drug; and (3) any required steps to initiate a prescription refill.
- d. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Repayment of Identified Overpayments.* Rhine Drug shall repay within 60 days any Overpayments identified by the IRO in the Quarterly Claims Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305 (and any applicable CMS guidance) (the "CMS overpayment rule"). If Rhine Drug determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Rhine Drug shall repay that amount at the mean point estimate as calculated by the IRO. Rhine Drug shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Review Sample (and any related work papers) received from Rhine Drug to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by that payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.

- a. Claims Review Population. A description of the Population subject to the Quarterly Claims Review.
- b. Source of Data. A description of (1) the process used to identify claims in the Population, and (2) the specific documentation relied upon by the IRO when performing the Quarterly Claims Review (e.g., physician orders (including drug prescriptions), State pharmacy law or regulation regarding the dispensing of prescription drugs, any applicable local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare contractor manual or bulletins (including issue and date), other policies, regulations, or directives).
- c. Review Protocol. A narrative description of how the Quarterly Claims Review was conducted and what was evaluated.
- d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in each Quarterly Claims Sample and Rhine Drug shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from Rhine Drug after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly 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 Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation*. A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings.*

a. Narrative Results.

- i. For the first Quarterly Claims Review Report only, a description of (a) Rhine Drug's billing system, including the identification, by position description, of the personnel involved in billing, and (b) a description of the controls in place to ensure that all prescription drugs billed to Medicare or a state Medicaid program are dispensed and billed in accordance with a valid prescription and that Rhine Drug maintains documentation of such prescription. Subsequent Quarterly Claims Review Reports should describe any significant changes to items (a) or (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Claims Review Report.
- ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Rhine Drug (Submitted Claim) differed from what should have been the correct claim (Correct Claim) and in which such difference resulted in an Overpayment to Rhine Drug.
- ii. Total number and percentage of instances in which the IRO determined that Rhine Drug did not maintain adequate documentation of a prescription drug (or refill) for which a Paid Claim was submitted and in which such documentation errors resulted in an Overpayment to Rhine Drug.
- iii. Total dollar amount of all Overpayments in the Quarterly Claims Review Sample.
- iv. Total dollar amount of Paid Claims included in the Quarterly Claims Review Sample.
- v. Error Rate in the Quarterly Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in

the Quarterly Claims Review Sample by the total dollar amount associated with the Paid Claims in the Quarterly Claims Review Sample.

- vi. An estimate of the actual Overpayment in the Population at the mean point estimate.
  - vii. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, national drug code submitted, quantity prescribed, quantity dispensed, quantity billed, amount reimbursed by the payor, correct amount reimbursed (as determined by the IRO), and any dollar difference between the amount reimbursed by payor and the correct amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Rhine Drug's billing system or to Rhine Drug's controls for ensuring that all prescription drugs billed to Medicare or a state Medicaid program are dispensed and billed in accordance with a valid prescription and that Rhine Drug maintains documentation of such prescription, based on the findings of the Quarterly Claims Review.
- d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Other Requirements. The following requirements apply to any Quarterly Claims Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation.* Any Paid Claim for which Rhine Drug cannot produce documentation shall be considered an error and the total reimbursement received by Rhine Drug for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn.* For the purposes of all samples 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 sample).