

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

**I. PREAMBLE**

CVS Caremark Corporation and its subsidiaries (collectively, CVS Caremark) 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).<sup>1</sup> CVS Caremark is an integrated pharmacy services health care provider and pharmacy benefits manager (PBM) engaged in certain business lines that do business with Federal health care programs. Except as otherwise noted herein, the terms of this CIA shall apply to CVS Caremark's PBM Operations, as defined in Section II.C.4, below.<sup>2</sup>

On November 22, 2013, the United States entered into a Settlement Agreement with CVS Caremark in which certain CVS Caremark entities, as specified in the Settlement Agreement, agreed to pay \$4.25 million, plus applicable interest, to the United States in exchange for a release from liability under the False Claims Act, and other civil and administrative authorities, for specified conduct detailed in Paragraph C of the Settlement Agreement (hereinafter referred to as the Covered Conduct). In the Settlement Agreement, the United States alleged that it had certain administrative claims against the CVS Caremark entities for the Covered Conduct, and OIG expressly reserved all rights to institute, direct, or maintain any administrative action seeking exclusion against the CVS Caremark entities, and/or their officers, directors, and employees, from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7(b) (permissive exclusion).

In consideration of the obligations of CVS Caremark set forth in the Settlement Agreement and this CIA, and conditioned upon the CVS Caremark entities' full payment of the Settlement Amount under Paragraph 1 of the Settlement Agreement, OIG agrees to

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<sup>1</sup> The provisions of this CIA do not supersede any applicable obligations or requirements under State law.

<sup>2</sup> This CIA does not replace or supersede the CIA entered into by CVS Caremark on March 14, 2008, as amended on April 14, 2011.

release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against CVS Caremark under 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 6 of the Settlement Agreement. OIG expressly reserves all rights to comply with any statutory obligations to exclude CVS Caremark, and/or its officers, directors, and employees, from Medicare, Medicaid, and all other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct.

CVS Caremark has a compliance program (Compliance Program) that includes, among other things, a Compliance Officer and a Compliance Committee responsible for compliance oversight. The Compliance Program also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations, and screening measures for Ineligible Persons. CVS Caremark shall continue the Compliance Program throughout the term of this CIA; shall expand the Compliance Program, as necessary, to cover any parts of the corporation not currently covered that conduct business with Federal health care programs; and shall do so in accordance with the terms of this CIA. CVS Caremark may modify the Compliance Program as appropriate, but, at a minimum, CVS Caremark shall ensure that the Compliance Program satisfies the obligations set forth herein during the term of this CIA.

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

A. Except as otherwise stated herein, the period of the compliance obligations assumed by CVS Caremark under this CIA shall be five years from the Effective Date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) CVS Caremark’s final annual report; or (2) any additional materials submitted by CVS Caremark 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 (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, and directors of CVS Caremark;

- b. all employees of CVS Caremark who are engaged in or have responsibilities relating to the PBM Operations (as defined in Section II.C.4, below);
- c. all contractors, subcontractors, agents, and other persons who perform any duties on behalf of CVS Caremark related to the Third-Party Liability Covered Functions (as defined in Section II.C.3, below); and
- d. for purposes of the requirements set forth in Section III.B.1 (Code of Conduct), Section III.C.1 (General Training), Section III.E (Disclosure Program), and Section III.F (Ineligible Persons), all employees, contractors, subcontractors, and agents of CVS Caremark who are engaged in or have job responsibilities relating to the sale of or billing for items or services payable by the Federal health care programs.

Notwithstanding the above, the term “Covered Persons” 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. “Third-Party Liability Claim” means a request for reimbursement of prescription drug benefits that has been submitted by or on behalf of a state Medicaid program, the U.S. Department of Veterans Affairs (VA), the U.S. Department of Defense (DOD), or the Indian Health Service (IHS) to CVS Caremark after those benefits were provided by one of those programs to a beneficiary of the program who may also have been eligible for prescription drug coverage through a PBM client health plan.

3. “Third-Party Liability Covered Functions” means, within the PBM Operations, the adjudication or processing of, or development of systems or policies related to, Third-Party Liability Claims.

4. “PBM Operations” means the operations conducted by CVS Caremark in its capacity as a PBM in the United States for health plan sponsors, including the processing of Third-Party Liability Claims and other prescription drug claims; implementation of client plan designs; administration of formularies; offering of retail pharmacy networks; and negotiation of discounts and rebates with drug manufacturers.

5. “Relevant Covered Persons” includes all Covered Persons who are engaged in Third-Party Liability Covered Functions (as defined in Section II.C.3, above).

### **III. CORPORATE INTEGRITY OBLIGATIONS**

CVS Caremark shall maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee**

1. *Compliance Officer.* Prior to the Effective Date, CVS Caremark appointed an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer is 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 continue to be a member of senior management of CVS Caremark, shall report directly to the Chief Executive Officer of CVS Caremark, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of CVS Caremark (or other authorized subcommittee), and shall be authorized to so report on such matters at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall continue to be responsible for monitoring the day-to-day compliance activities engaged in by CVS Caremark 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.

CVS Caremark agrees to maintain the position of Compliance Officer during the term of this CIA. CVS Caremark 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 such a change.

2. *Compliance Committee.* Prior to the Effective Date, CVS Caremark established a corporate compliance committee (Compliance Committee). The Compliance Committee shall continue to include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, human resources, audit, and operations). The Compliance Officer shall continue to chair the Compliance Committee and the Compliance Committee shall continue to support the Compliance Officer in fulfilling his/her responsibilities (e.g., assist in the analysis of the organization’s risk areas and oversee monitoring of internal and external compliance audits and investigations). The Compliance Committee shall meet at least quarterly.

CVS Caremark 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.

3. *Audit Committee or Other Authorized Subcommittee of the Board of Directors Compliance Obligations.* CVS Caremark's Board of Directors currently has, and shall maintain during the term of the CIA, an Audit Committee or other authorized subcommittee comprised of independent (*i.e.*, non-executive) directors of CVS Caremark (hereinafter Board Committee). The Board Committee is responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

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

- a. meeting at least quarterly to review and oversee CVS Caremark's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and
- b. for each Reporting Period of the CIA, adopting a resolution signed by each member of the Board Committee summarizing its review and oversight of CVS Caremark's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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

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

CVS Caremark shall report to OIG, in writing, any changes in the composition of

the Board Committee, or any actions or changes that would affect the Board 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.* Prior to the Effective Date, CVS Caremark developed, implemented, and distributed a written Code of Conduct to all Covered Persons. CVS Caremark 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 continue to set forth, at a minimum:

- a. CVS Caremark's commitment to full compliance with all Federal health care program requirements;
- b. CVS Caremark's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with CVS Caremark's own Policies and Procedures;
- c. the requirement that all of CVS Caremark's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by CVS Caremark, suspected violations of any Federal health care program requirements or of CVS Caremark's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and CVS Caremark's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Each Covered Person has certified, in writing or in electronic form, that he or she has received, read, understood, and shall abide by CVS Caremark'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.

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

2. *Policies and Procedures.* To the extent not already implemented, within 120 days after the Effective Date, CVS Caremark shall implement written Policies and Procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and CVS Caremark's compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1; and
- b. procedures to be used by the PBM Operations to ensure that the PBM Operations adjudicate or process Third-Party Liability Claims in accordance with the statutes, regulations, applicable case law, and written directives governing the various state Medicaid and other Federal health care programs that submit such claims to CVS Caremark.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed and/or made available (electronically, by publishing such Policies and Procedures on CVS Caremark's intranet or other internal website, or in hard copy form) to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), CVS Caremark shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed and/or made available (electronically, by publishing such Policies and Procedures on CVS Caremark's intranet or other internal website, or in hard copy form) to all Covered Persons whose job functions relate to those Policies and Procedures.

### C. Training and Education

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

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

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.

To the extent that General Training provided to Covered Persons during the three months immediately prior to the Effective Date satisfies the requirements set forth above, OIG shall credit the training towards the General Training requirements for the first Reporting Period. CVS Caremark may satisfy its remaining General Training obligations for those Covered Persons who received training as described above by notifying the Covered Persons of the fact that CVS Caremark has entered into a CIA and notifying them of CVS Caremark's requirements under the CIA.

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 regarding accurate handling of Third-Party Liability Covered Functions;
- b. the personal obligation of each individual involved in the Third-Party Liability Covered Functions to be appropriately familiar with applicable Federal health care program requirements relating to the payment of Third-Party Liability Claims;
- c. the legal sanctions for violations of Federal health care program requirements, including applicable legal sanctions and consequences of violations of the CIA;
- d. examples of proper and improper practices related to the processing of Third-Party Liability Claims; and
- e. policies and procedures for the reporting and repayment of Third-Party Liability Underpayments (as defined in Section III.H.3) to Federal health care programs.

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 addition to the General Training, in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, CVS Caremark shall provide at least one hour of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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

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

5. *Qualifications of Trainer.* Persons providing or preparing the training shall be knowledgeable about the subject area.

6. *Update of Training.* CVS Caremark shall review the training annually, and, where appropriate, update the training to reflect changes in applicable Federal health care program requirements; any material or recurring issues discovered during the Third-Party Liability Claims Review or PBM Platform Controls Assessment; and any other relevant information.

7. *Computer-based Training.* CVS Caremark may provide the training required under this CIA through appropriate computer-based training approaches. If CVS Caremark 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, CVS Caremark shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter Independent Review

Organization or IRO), to perform the reviews outlined in Appendix B (Third-Party Liability Claims Review) of this CIA. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

- b. *Frequency of Third-Party Liability Claims Review.* The Third-Party Liability Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO shall perform the components of each annual Third-Party Liability Claims Review described in Appendix B.
- c. *Retention of Records.* The IRO and CVS Caremark shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and CVS Caremark) related to the reviews.

2. *Third-Party Liability Claims Review.* The IRO shall review CVS Caremark's processing of Third-Party Liability Claims on each of its active PBM Operations platforms (Third-Party Liability Claims Review) and shall prepare a Third-Party Liability Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference. An active PBM Operations platform shall mean a claims adjudication platform that has been used to process at least 2% of the Third-Party Liability Claims received by CVS Caremark during the 12 months preceding the start of the Reporting Period.

3. *PBM Platform Controls Assessment.* CVS Caremark shall conduct an assessment of the Controls (as defined in Appendix C to this CIA) on each of its active PBM Operations platforms (PBM Platform Controls Assessment) and shall prepare a PBM Platform Controls Assessment Report, as outlined in Appendix C to this CIA, which is incorporated by reference. The PBM Platform Controls Assessment shall be performed periodically, but at least annually. CVS Caremark shall perform all components of each annual PBM Platform Controls Assessment.

4. *Validation Review.* In the event OIG has reason to believe that: (a) CVS Caremark's Third-Party Liability Claims Review or PBM Platform Controls Assessment fails to conform to the requirements of this CIA; or (b) the IRO's findings or Third-Party Liability Claims Review or PBM Platform Controls Assessment results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Third-Party Liability Claims Review or PBM Platform Controls Assessment complied with the requirements of the CIA and/or the IRO's findings or Third-Party Liability Claims Review or PBM Platform Controls Assessment results are inaccurate

(Validation Review). CVS Caremark shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of CVS Caremark's final Annual Report shall be initiated no later than one year after CVS Caremark's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify CVS Caremark 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, CVS Caremark may request a meeting with OIG to: (a) discuss the results of any Third-Party Liability Claims Review or PBM Platform Controls Assessment submissions or findings; (b) present any additional information to clarify the results of the Third-Party Liability Claims Review or PBM Platform Controls Assessment or to correct the inaccuracy of the Third-Party Liability Claims Review or PBM Platform Controls Assessment; and/or (c) propose alternatives to the proposed Validation Review. CVS Caremark agrees to provide any additional information as may be requested by OIG under this Section III.D.4 in an expedited manner. OIG will attempt in good faith to resolve any Third-Party Liability Claims Review or PBM Platform Controls Assessment issues with CVS Caremark 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.

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

#### E. Disclosure Program

Prior to the Effective Date, CVS Caremark established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CVS Caremark's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. CVS Caremark shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, through a posting on CVS Caremark's intranet or other internal website available to all Covered Persons, or by posting the information in prominent common areas).

The Disclosure Program shall continue to emphasize a nonretribution, nonretaliation policy, and shall continue to 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, CVS Caremark 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.

#### 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 System for Award Management (available through the Internet at <http://www.sam.gov>).

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

- a. CVS Caremark shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. CVS Caremark shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on a monthly basis thereafter.
- c. CVS Caremark shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If CVS Caremark has actual notice that a Covered Person has become an Ineligible Person, CVS Caremark shall remove such Covered Person from responsibility for, or involvement with, CVS Caremark'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 CVS Caremark 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, CVS Caremark 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, CVS Caremark shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to any member of senior management of CVS Caremark conducted or brought by a United States-based governmental entity or its agents involving an allegation that CVS Caremark 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. CVS Caremark 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. Overpayments and Third-Party Liability Underpayments

1. *Definition of PBM Overpayments.* For purposes of this CIA, a “PBM Overpayment” shall mean the amount of money the PBM Operations have received in excess of the amount due and payable under any Federal health care program requirements.

2. *Definition of Client Overpayments.* For purposes of this CIA, a “Client Overpayment” shall mean the amount of money a Client Health Plan has received in excess of the amount due and payable under any Federal health care program when such overpayment was likely caused by CVS Caremark’s PBM Operations. A “Client Health Plan” shall mean a health plan for which CVS Caremark provides PBM services through its PBM Operations.

3. *Definition of Third-Party Liability Underpayment.* For purposes of this CIA, a “Third-Party Liability Underpayment” shall mean, following submission by a Federal health care program (or its designee) of a Third-Party Liability Claim to CVS Caremark after the Effective Date, the amount that should have been, but was not, reimbursed to the Federal health care program for that claim on behalf of a PBM client due to a processing or other error occurring on a PBM Operations platform.

4. *Repayment of PBM Overpayments*

- a. If, at any time, CVS Caremark identifies or learns of any PBM Overpayment, CVS Caremark shall repay the PBM Overpayment to the appropriate payor within 60 days after identification of the PBM Overpayment and take remedial steps within 90 days after identification (or such additional

time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the PBM Overpayment from recurring. If not yet quantified, within 60 days after identification, CVS Caremark shall notify the payor of its efforts to quantify the PBM 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 PBM 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.

5. *Providing Information to Facilitate Client Overpayment Refunds.*

CVS Caremark agrees that for all potential Client Overpayments, CVS Caremark will take reasonable steps to ensure the applicable Client Health Plan has all PBM information needed for the Client Health Plan to determine whether there was a Client Overpayment. The responsibility to identify and repay any Client Overpayments to the affected Federal health care program shall be determined by applicable law.

6. *Processing and Reprocessing of Third-Party Liability Claims.*

When CVS Caremark receives a Third-Party Liability Claim after the Effective Date from a state Medicaid or other Federal health care program, CVS Caremark shall process the Third-Party Liability Claim no later than 150 days after receipt. If CVS Caremark learns information indicating that a Third-Party Liability Claim received after the Effective Date may have been improperly rejected or paid in an incorrect amount, CVS Caremark shall reprocess the applicable Third-Party Liability Claim no later than 150 days after receipt of such information.

I. Reportable Events

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

- a. a substantial PBM 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. a Third-Party Liability Claim adjudication platform issue of which CVS Caremark becomes aware that is recurring and that results in a substantial number of Third-Party Liability Claims incorrectly rejected or incorrectly processed after the Effective Date where the issue results in a substantial Third-Party Liability Underpayment to the Federal health care programs;
- d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- e. the filing of a bankruptcy petition by CVS Caremark.

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

2. *Reporting of Reportable Events.* If CVS Caremark determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, CVS Caremark 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 and c.* For Reportable Events under Section III.I.1.a and c, the report to OIG shall be made within 30 days of the identification of the PBM Overpayment or Third-Party Liability Underpayment, and shall include:

- a. a description of the steps taken by CVS Caremark to identify and quantify the PBM Overpayment or Third-Party Liability Underpayment;
- b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- c. if the Reportable Event involves a Third-Party Liability Claim adjudication platform issue, an identification of the platform involved, as well as a description of CVS Caremark's plan to identify the number of Third-Party Liability Claims incorrectly rejected, reprocess the incorrectly rejected Third-Party Liability Claims, and reimburse the affected Federal health care programs;

- d. a description of CVS Caremark's actions taken to correct the Reportable Event; and
- e. any further steps CVS Caremark plans to take to address the Reportable Event and prevent it from recurring.

Within 60 days of identification of the PBM Overpayment, CVS Caremark shall provide OIG with a copy of the notification and evidence of the repayment to the payor required in Section III.H.4.

4. *Reportable Events under Section III.I.1.b and d.* For Reportable Events under Section III.I.1.b and III.I.1.d, 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 CVS Caremark's actions taken to correct the Reportable Event;
- c. any further steps CVS Caremark plans to take to address the Reportable Event and prevent it from recurring;
- d. if the Reportable Event has resulted in a PBM Overpayment, a description of the steps taken by CVS Caremark to identify and quantify the PBM Overpayment; and
- e. if the Reportable Event may have resulted in Third-Party Liability Underpayments, a description of the steps CVS Caremark is taking to identify the number of Third-Party Liability Claims incorrectly rejected and reprocess those Third-Party Liability Claims so that the affected Federal health care program is properly paid.

CVS Caremark shall not be required to report as a Reportable Event a matter that is the subject of an ongoing investigation or legal proceeding conducted or brought by a United States-based governmental entity or its agents that CVS Caremark previously disclosed under Section III.G, above, or that was reported to OIG prior to the Effective Date.

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

J. Other Reports

CVS Caremark shall provide to OIG copies of Notices of Non-compliance, Warning Letters, and Notices of Immediate Imposition of Intermediate Sanctions issued by the Centers for Medicare and Medicaid Services (CMS) to CVS Caremark's Medicare Part D plan sponsors. CVS Caremark shall also provide any written issue reports submitted by CVS Caremark's Medicare Part D plan sponsors to CMS related to such Notices of Non-compliance, Warning Letters, and Notices of Immediate Imposition of Intermediate Sanctions. CVS Caremark shall provide the documents required under this Section J: (1) within 30 days of CVS Caremark's Medicare Part D plan sponsors receiving such documents from CMS, or (2) within 30 days of CVS Caremark's Medicare Part D plan sponsors submitting such documents to CMS.

**IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Sale of Business, Business Unit, or Location

In the event that, after the Effective Date, CVS Caremark proposes to sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, CVS Caremark shall notify OIG of the proposed sale of its business, business unit, or location no later than the date the sale is publicly announced. This notification shall include a description of the business, business unit, or location to be sold; a brief description of the terms of the sale; and the name and contact information of the prospective purchaser. To the extent the CIA is in effect and applicable to the business operations at issue, this CIA shall be binding on the purchaser of that business, business unit, or location, unless otherwise determined and agreed to in writing by OIG.

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

In the event that, after the Effective Date, CVS Caremark closes a business or business unit (1) related to the furnishing of items or services that may be reimbursed by Federal health care programs and (2) that is covered within the scope of this CIA, CVS Caremark shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of closure of the business or business unit.

In the event that CVS Caremark changes or closes a location (1) related to the furnishing of items or services that may be reimbursed by Federal health care programs and (2) that is covered within the scope of this CIA, CVS Caremark shall include in its Annual Report the information about each such location specified in Section V.B.

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

In the event that, after the Effective Date, CVS Caremark purchases or establishes a new business or business unit related to the furnishing of items or services that may be reimbursed by Federal health care programs, CVS Caremark shall notify OIG as soon as possible, but no later than within 30 days after the date of such purchase or the operation of the new business or business unit. This notification shall include the address of the new business or business unit; its phone number and fax number; the location's Medicare and state Medicaid program provider number and/or supplier number(s), if applicable; and the name and address of each Medicare and state Medicaid program contractor to which the newly acquired business at that time submits claims. Each new business or business unit then within the scope of the CIA and all Covered Persons at each such new business or business unit shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by OIG.

In the event that CVS Caremark purchases or establishes a new location related to the furnishing of items or services that may be reimbursed by Federal health care programs, CVS Caremark shall include in its Annual Report the information about each such new location specified in Section V.B.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, CVS Caremark 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.1, 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.2;
3. the names of the members of the full Board of Directors, as well as the Audit Committee (or other authorized subcommittee) members who are responsible for satisfying the compliance obligations described in Section III.A.3;
4. a copy of CVS Caremark's Code of Conduct required by Section III.B.1;

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 made available to OIG upon request);

6. a summary or copies of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);

7. the following information regarding the notification and each type of training required by Section III.C:

- a. a description of the notification procedures required under Section III.C.1, the number of individuals required to be notified, the percentage of individuals actually notified, and an explanation of any exceptions;
- b. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- c. the number of individuals required to be trained, the 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 made available to OIG upon request.

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

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

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

11. a list of all states in which the PBM Operations do business, the number of PBM Operations locations in each state, and any names other than CVS Caremark under which any of the PBM Operations locations are doing business;

12. a description of CVS Caremark'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

CVS Caremark shall submit to OIG annually a report with respect to the status of, and findings regarding, CVS Caremark'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.1 and III.A.2;

2. the Board resolution required by Section III.A.3;

3. a summary of any changes or amendments to CVS Caremark's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

4. 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 made available to OIG upon request);

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

6. 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 to support this information shall be made available to OIG upon request.

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

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

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

10. a certification from the IRO regarding its professional independence and objectivity with respect to CVS Caremark;

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

12. a report of the aggregate PBM Overpayments and Third-Party Liability Underpayments (as defined in Section III.H.1 and III.H.3, respectively) that have been returned to the Federal health care programs, as well as a summary of the instances when information was provided to a Client Health Plan to facilitate the Client Health Plan's determination of whether a Client Overpayment (as defined in Section III.H.2) existed. PBM Overpayment amounts shall be broken down into the following categories: Medicare Part D, Medicaid (reported separately by state, as applicable), and other Federal health care programs. Third-Party Liability Underpayments shall be broken down into the following categories: Medicaid (reported separately by state, as applicable), VA, DOD, and IHS;

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

14. any changes to the process by which CVS Caremark fulfills the requirements of Section III.F regarding Ineligible Persons;

15. 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;

16. a summary of the changes, closures, purchase, or establishment of new locations related to the furnishing of items or services that may be reimbursed by Federal health care programs, in accordance with Section IV.B and IV.C;

17. a description of all changes to the most recently provided list of information required by Section V.A.11; and

18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 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, CVS Caremark 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, CVS Caremark has not charged, directly or indirectly, the costs of implementing and remaining in compliance with the terms of this CIA to any contracts with the United States or any state Medicaid program, nor has CVS Caremark sought payment for such costs through any cost report, cost statement, information statement, or payment request submitted to the Federal health care programs by CVS Caremark or any of its subsidiaries or affiliates.

#### D. Designation of Information

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

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

OIG:

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

CVS Caremark:

John Buckley  
Chief Compliance Officer  
CVS Caremark Corporation  
One CVS Drive  
Woonsocket, RI 02895  
Telephone: 847.559.3800  
Facsimile: 480.862.8996

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, CVS Caremark 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 CVS Caremark's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of CVS Caremark's locations for the purpose of verifying and evaluating: (a) CVS Caremark's compliance with the terms of this CIA; and (b) CVS Caremark's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by CVS Caremark 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 CVS Caremark'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. CVS Caremark shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. CVS Caremark's employees may elect to be interviewed with or without a representative of CVS Caremark present.

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

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

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

CVS Caremark 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, CVS Caremark 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 CVS Caremark fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

- b. a Compliance Committee;
- c. the Board Committee compliance obligations;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of government investigations or legal proceedings;
- j. reporting of Reportable Events; and
- k. reporting under Section III.J.

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 CVS Caremark fails to engage and use an IRO, as required in Section III.D and Appendices A and B.

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 CVS Caremark 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 CVS Caremark fails to submit any Third-Party Liability Claims Review Report or PBM Platform Controls Assessment Report in accordance with the requirements of Section III.D and Appendices B and C.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of CVS Caremark as part of its Implementation Report, Annual Report,

additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

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

CVS Caremark 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 CVS Caremark 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 CVS Caremark receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that CVS Caremark 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 CVS Caremark of: (a) CVS Caremark'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, CVS Caremark 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 CVS

Caremark elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CVS Caremark 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 CVS Caremark 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 CVS Caremark to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D and Appendices A and B.

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, CVS Caremark fails to satisfy the requirements of Section X.D.3, OIG may exclude CVS Caremark from participation in the Federal health care programs. OIG shall notify CVS Caremark in writing of its determination to exclude CVS Caremark. (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 CVS Caremark's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, CVS Caremark 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 CVS Caremark 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, CVS Caremark 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 CVS Caremark was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. CVS Caremark 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 CVS Caremark to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless CVS Caremark 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 CVS Caremark 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) CVS Caremark had begun to take action to cure the material breach within that period; (ii) CVS Caremark has pursued and is pursuing such action with due diligence; and (iii) CVS Caremark provided to OIG within that period a reasonable timetable for curing the material breach and CVS Caremark 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 CVS Caremark, only after a DAB decision in favor of OIG. CVS Caremark's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude CVS Caremark 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 CVS Caremark 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. CVS Caremark 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 CVS Caremark, CVS Caremark 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**

CVS Caremark and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of CVS Caremark.

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 CVS Caremark's obligations under this CIA based on a certification by CVS Caremark 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 CVS Caremark is relieved of its CIA obligations, CVS Caremark will be required to notify OIG in writing at least 30 days in advance if CVS Caremark 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 CVS Caremark signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

**ON BEHALF OF CVS CAREMARK CORPORATION**

/John Buckley/

3/24/14

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JOHN BUCKLEY  
Chief Compliance Officer  
CVS Caremark Corporation

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DATE

/Peter J. Kocoras/

3/24/14

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PETER J. KOCORAS  
Winston & Strawn LLP  
Counsel for CVS Caremark Corporation

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DATE

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

/Robert K. DeConti/  
\_\_\_\_\_

3/25/14  
\_\_\_\_\_

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

DATE

/Tonya Keusseyan/  
\_\_\_\_\_

3/25/14  
\_\_\_\_\_

TONYA KEUSSEYAN  
Senior Counsel  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

DATE

/Kaitlyn L. Dunn/  
\_\_\_\_\_

3/25/2014  
\_\_\_\_\_

KAITLYN L. DUNN  
Associate Counsel  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

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

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

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Third-Party Liability Claims Review who have: (a) expertise in pharmacy benefit management claims processing; (b) expertise in the general requirements of the Federal health care program(s) from which CVS Caremark seeks reimbursement; and (c) substantive knowledge about the laws, rules, and regulations of the applicable state Medicaid and other Federal health care programs related to the processing of Third-Party Liability Claims as defined in Section II.C.2 of the CIA;

2. assign individuals to design and select the sample for the Third-Party Liability Claims Review who are knowledgeable about the appropriate statistical sampling techniques; and

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

C. IRO Responsibilities.

The IRO shall:

1. perform each Third-Party Liability Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicaid and other Federal health care program rules and reimbursement guidelines in making assessments in the Third-Party Liability Claims Review;

3. if in doubt of the application of a particular Medicaid or other Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., Medicaid agency);

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

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

D. IRO Independence and Objectivity.

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

E. IRO Removal/Termination.

1. *CVS Caremark and IRO.* If CVS Caremark terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, CVS Caremark 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. CVS Caremark must engage a new IRO in accordance with Section 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 Section B, is not independent and objective as set forth in Section D, or has failed to carry out its responsibilities as described in Section C, OIG may, at its sole discretion, require CVS Caremark to engage a new IRO in accordance with Section A of this Appendix. CVS Caremark must engage a new IRO within 60 days of termination of the IRO.

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

## APPENDIX B

### THIRD-PARTY LIABILITY CLAIMS REVIEW

A. Third-Party Liability Claims Review. CVS Caremark shall perform a Post-Processing Review of Third-Party Liability Claims annually to cover each of the five Reporting Periods. Additionally, the IRO will review a sample of Third-Party Liability Claims, as set forth in Section 3 below, for each Reporting Period.

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

- a. Quality Team: The Quality Team defined in Section A.2 of Appendix C to this CIA.
- b. Third-Party Liability Claim: A Third-Party Liability Claim as defined in Section II.C.2 of this CIA. Third-Party Liability Claims may be submitted via CVS Caremark's batch processing systems, manually, or as point-of-sale claims.
- c. PBM Platform: A pharmacy benefit management (PBM) claims adjudication platform that has been used to process at least 2% of the Third-Party Liability Claims received by CVS Caremark during the 12 months prior to the start of the applicable Reporting Period. The affected PBM Platforms subject to the Post-Processing Review will be determined at the beginning of each Reporting Period. As of the Effective Date, the PBM Platforms subject to this Post-Processing Review include RxClaim, RECAP, and Quantum Leap.
- d. Error Rate: The percentage of Third-Party Liability Claims randomly selected by the IRO for review that were improperly rejected (*i.e.*, no valid basis for rejecting the Third-Party Liability Claim) or paid in an incorrect amount. For purposes of determining an Error Rate, a Third-Party Liability Claim that contains an incorrect rejection reason or code, but that would have otherwise been appropriately rejected due to another reason that can be verified, does not constitute an "improperly rejected" Third-Party Liability Claim.
- e. Rejection Rate: The percentage of all Third-Party Liability Claims randomly selected by the IRO for review that contained an incorrect rejection reason or code, regardless of

whether the Third-Party Liability Claim would have otherwise been appropriately rejected due to another reason, or that were paid in an incorrect amount.

2. *Post-Processing Review.* The Quality Team shall select and review a statistically valid random sample of Third-Party Liability Claims received by CVS Caremark after the Effective Date for the purpose of identifying processing errors. As part of its reviews, the Quality Team will review in the aggregate at least 10,000 of the Third-Party Liability Claims processed during the applicable Reporting Period. Third-Party Liability Claims shall be selected for the Post-Processing Review in general proportion to the type of Third-Party Liability Claims processed (*e.g.*, batch claim, point-of-sale, manual) and the volume of Third-Party Liability Claims processed on each applicable PBM Platform. CVS Caremark shall use Third-Party Liability Claims processing data from the 12 months prior to the start of the applicable Reporting Period for purposes of determining the appropriate number of Third-Party Liability Claims to be sampled of each type on each PBM Platform.

a. Determination of Third-Party Liability Claims.

- i. For “paid” Third-Party Liability Claims, the Quality Team will determine whether the paid Third-Party Liability Claim was properly adjudicated, and if the payment to the applicable Federal health care program was correct.
- ii. For “rejected” Third-Party Liability Claims, the Quality Team will determine whether each Third-Party Liability Claim was properly rejected for a valid reason. If the Third-Party Liability Claim is determined to be improperly rejected (*i.e.*, the claim would not have been rejected for any reason that can be verified), then the cause of the improper rejection will be investigated. CVS Caremark shall also reprocess such Third-Party Liability Claims in accordance with Section A.6, below.

3. *IRO Review.* The IRO shall conduct a review of Third-Party Liability Claims covering each Reporting Period, as set forth below.

- a. The IRO will review a statistically valid random sample of at least 500 randomly selected Third-Party Liability Claims

from the sample of Third-Party Liability Claims reviewed by the Quality Team as part of the Post-Processing Review.

- b. As part of its review, the IRO shall determine the Error Rate applicable to the Third-Party Liability Claims reviewed. The Error Rate shall be used to determine whether a root cause analysis, as described below, will be performed.
- c. The IRO shall also determine the Rejection Rate applicable to the Third-Party Liability Claims reviewed. The Rejection Rate will be used solely for informational purposes to identify potential problems on the applicable PBM Platform and to consider related corrective actions.
- d. The IRO shall determine the Error Rate and Rejection Rate applicable to the Third-Party Liability Claims as originally processed, prior to any reprocessing done by the Quality Team pursuant to Section A.6, below.

4. *Root Cause Analysis.* If the Error Rate is 5% or greater, the Government Claims Team, as defined in Section A.1 of Appendix C to this CIA, in coordination with the IRO, shall conduct an analysis to determine the root cause of the Third-Party Liability Claims processing errors. The IRO will review the results of the root cause analysis and provide feedback and recommendations on the methodology used by the Government Claims Team. The root cause analysis is intended to assist with identification and remediation of systemic or other errors with the processing of Third-Party Liability Claims and to reduce the frequency of errors.

5. *Supporting Documentation.* The Quality Team shall maintain Supporting Documentation related to the review of Third-Party Liability Claims and its findings pursuant to the Post-Processing Reviews consistent with the document retention requirement in the CIA. The Quality Team shall provide the IRO with the Supporting Documentation related to the Third-Party Liability Claims subject to the IRO's review, as well as any additional documentation that the IRO may reasonably deem necessary to conduct its review pursuant to Section A.3, above.

6. *Reprocessing of Third-Party Liability Claims.*

- a. For each Third-Party Liability Claim that the Quality Team determines was improperly rejected pursuant to the Post-Processing Review, the Quality Team will ensure that the Third-Party Liability Claim is reprocessed no later than

150 days after such determination and that the applicable Federal health care program is appropriately reimbursed for the Third-Party Liability Claim.

- b. The Quality Team shall prepare and CVS Caremark shall provide to the OIG on an annual basis a report that identifies: (1) each Third-Party Liability Claim identified by the Quality Team pursuant to the Post-Processing Review as improperly rejected and reprocessed during the Reporting Period; and (2) the amount paid to each affected Federal health care program for each Third-Party Liability Claim that was reprocessed. This report will be provided along with CVS Caremark's Annual Report.

B. IRO Third-Party Liability Claims Review Report. The IRO Third-Party Liability Claims Review Report shall be submitted along with CVS Caremark's Annual Report for each Reporting Period.

1. *Contents of the IRO Report*. The IRO report shall include the following information:

- a. Credentials:
  - i. A description of the titles, credentials, training, and background of the Quality Team who conducted the Post-Processing Review, as well as the reporting structure of that team; and
  - ii. A description of the credentials of the IRO individuals who conducted the review.
- b. Methodology: The methodologies by which: (i) the Quality Team conducted its Post-Processing Review; and (ii) the IRO conducted its review pursuant to Section A.3, above.
- c. Supporting Documentation: An overview of the Supporting Documentation reviewed as part of the Quality Team's Post-Processing Review and the IRO's review pursuant to Section A.3, above.

- d. Summary of Findings:
- i. A description of the Quality Team’s findings during the Post-Processing Review regarding: (1) whether “paid” Third-Party Liability Claims were properly adjudicated, resulting in the correct payments to the applicable Federal health care programs; and (2) whether “rejected” Third-Party Liability claims were rejected for a valid reason.
  - ii. The IRO’s findings related to any deficiencies for processing Third-Party Liability Claims for each affected PBM Platform, including a narrative and quantitative summary of results and a description of any discrepancies between its conclusions about the Third-Party Liability Claims reviewed versus the Quality Team’s conclusions about those Third-Party Liability Claims.
- e. Recommendations: The IRO’s recommendations, if any, regarding CVS Caremark’s Third-Party Liability Claims processing and adjudication systems based on the findings of its review.
- f. Reprocessing Plan: A description of CVS Caremark’s plans to reprocess any improperly rejected Third-Party Liability Claims discovered during the Post-Processing Review, as well as the status of such reprocessing.
- g. Root Cause Analysis: For any root cause analysis, a description of the Government Claims Team’s methodology for that analysis; a description of the individuals within CVS Caremark who conducted that analysis; the findings of the root cause analysis and whether the root cause is a systemic or an isolated issue; any remediation recommendations or other corrective action plans; and management’s response to the root cause analysis.
- h. Certifications Regarding Decommissioned PBM Platforms: A certification indicating which PBM Platforms, if any, did not process any Third-Party Liability Claims or did not meet the 2% threshold to trigger a Post-Processing Review during

the applicable Reporting Period. This certification shall be executed by a management-level employee with appropriate operational knowledge.

## APPENDIX C

### PBM PLATFORM CONTROLS ASSESSMENT

#### A. PBM Platform Controls Assessment.

1. CVS Caremark has established and shall maintain an internal business team within its PBM business operations team (Government Claims Team) staffed by personnel knowledgeable about the processing of Third-Party Liability Claims. The Government Claims Team has developed or shall develop and implement appropriate internal controls specific to the processing of Third-Party Liability Claims on each applicable PBM Platform, as defined in Section A.1.c of Appendix B to this CIA.
2. As part of the Government Claims Team, CVS Caremark has established and shall maintain an internal business quality assurance team (Quality Team) staffed by personnel knowledgeable about the processing of Third-Party Liability Claims to conduct periodic and regular assessments of the processing of Third-Party Liability Claims on each applicable PBM Platform, including pre-processing and post-processing reviews as well as data analysis. The work of the Quality Team shall supplement CVS Caremark's internal controls specific to the processing of Third-Party Liability Claims as developed and implemented by the Government Claims Team.
3. Internal controls established or to be established within 120 days of the Effective Date by the Government Claims Team and Quality Team related to the processing of Third-Party Liability Claims, as set forth in Sections A.1 and A.2, above, shall be known as the "Controls." These Controls shall include:
  - a. mechanisms designed to properly process Third-Party Liability Claims consistent with applicable law;
  - b. mechanisms designed to prevent and detect systemic errors in the processing of Third-Party Liability Claims, including periodic internal review reports and trend analyses for batch-processed Third-Party Liability Claims;
  - c. policies and procedures to address the prompt investigation, evaluation, and remediation, as appropriate, of identified

systemic processing errors affecting Third-Party Liability Claims; and

- d. mechanisms designed to timely reprocess Third-Party Liability Claims that were submitted to CVS Caremark by Federal health care programs and that were improperly processed.
4. CVS Caremark, through its Compliance Department and Internal Audit Department, shall separately conduct an assessment of the Controls on each PBM Platform (PBM Platform Controls Assessment). The PBM Platform Controls Assessment will be performed for each applicable PBM Platform, as defined in Section A.1.c of Appendix B to this CIA.
5. Frequency of PBM Platform Controls Assessment. CVS Caremark will perform the PBM Platform Controls Assessment for each Reporting Period.
6. PBM Platform Controls Assessment. The PBM Platform Controls Assessment shall evaluate whether the Controls are operating as intended in managing significant risks, identify any deficiencies or areas for improvement in how the Controls are functioning, and propose constructive and timely strategies to address any problems identified. An assessment of whether the PBM Platforms are operated, overseen, and otherwise maintained by Relevant Covered Persons who have received appropriate and effective training that, at a minimum, includes the subject matters set forth in Section III.C.2 of CVS Caremark's CIA will be included as part of the PBM Platform Controls Assessment.
7. PBM Platform Migration. CVS Caremark has begun consolidating its various PBM Platforms to one destination platform consistent with its migration plan. The PBM Platform Controls Assessment shall determine for any current or newly planned PBM Platform migrations whether a migration plan related to the processing of Third-Party Liability Claims was developed in conformity with established written procedures. The PBM Platform Controls Assessment with regard to a PBM Platform migration shall also determine:
  - a. whether client acceptance testing was performed on various payment processing scenarios to ensure the successor PBM

Platform processes Third-Party Liability Claims for each client consistently with the source PBM Platform; and

- b. whether certification testing was performed in accordance with established CVS Caremark standards for such testing. Certification testing is intended to determine if Third-Party Liability Claims were processed consistently between platforms. Certification testing shall include an analysis of comparisons between the source PBM Platform and the target PBM Platform in the following scenarios:
  - i. Rejected / Rejected,
  - ii. Paid / Rejected,
  - iii. Rejected / Paid, and
  - iv. Paid / Paid.

The purpose of this analysis is to determine whether the same claims rejected for the same reason or paid in the same amount on each PBM Platform and, if not, why they did not.

B. PBM Platform Controls Assessment Report.

1. For each Reporting Period, CVS Caremark shall submit a written report to OIG (PBM Platform Controls Assessment Report) that sets forth, at a minimum:
  - a. a description of each of the Controls evaluated as part of the PBM Platform Controls Assessment;
  - b. a summary of CVS Caremark's activities in conducting the PBM Platform Controls Assessment;
  - c. any findings identifying instances where Controls are not operating as designed and any recommendations made as part of the PBM Platform Controls Assessment;
  - d. a description of any action plan correlated with the recommendations made as part of the PBM Platform Controls Assessment, as well as CVS Caremark's timeframe for implementing its action plan;

- e. a description of any PBM Platform migration plan that was established in accordance with Section A.7, above, as well as the results of the client acceptance testing and certification testing contemplated by Sections A.7.a and A.7.b; and
- f. a description of the credentials of the individuals who conducted the PBM Platform Controls Assessment.

2. CVS Caremark shall submit each PBM Platform Controls Assessment Report to OIG along with the corresponding Annual Report.