

**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 (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). The terms of this CIA shall be applicable to CVS Caremark's retail pharmacy subsidiary, CVS Pharmacy, Inc., and any division of any of CVS's subsidiaries or affiliates that conduct mail order pharmacy operations (collectively, "CVS"). Contemporaneously with this CIA, CVS Caremark is entering into a Settlement Agreement with the United States.

Prior to the execution of this CIA, CVS established a voluntary corporate compliance program. CVS agrees to operate its compliance program in a manner that meets the requirements of this CIA during the term of this CIA. CVS may modify the compliance program as appropriate, but at a minimum, CVS shall ensure that the compliance program meets the requirements of this CIA.

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

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

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) CVS's final annual report; or (2) any additional materials submitted by CVS 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 officers and directors of CVS; and
  - b. all employees, contractors, subcontractors, and agents of CVS or a subsidiary, division, or affiliate of CVS who are engaged to furnish pharmaceutical items or services to Federal health care program beneficiaries or to prepare or submit claims for pharmaceutical items or services to any Federal health care program.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes: all officers, directors, and other Covered Persons who are involved in corporate-level purchasing, pricing, or dispensing decisions that affect reimbursement from Federal health care programs.
3. "Therapeutic Interchange Program" refers to a company-wide effort or practice to implement the substitution of a drug that has the same or similar therapeutic effects as the drug originally prescribed based on appropriate authorization of the prescriber. It does not refer to the substitution of a chemically identical generic drug in the same dosage and form as the branded drug originally prescribed that does not require authorization of the prescriber under state law.

### III. CORPORATE INTEGRITY OBLIGATIONS

CVS has established and shall maintain a Compliance Program that includes the following elements:

#### A. Compliance Officer and Committee.

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

CVS agrees to maintain the position of Compliance Officer during the term of this CIA. CVS shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days of such a change.

2. *Compliance Committee.* Prior to the Effective Date of this CIA, CVS established a corporate compliance committee (Compliance Committee). The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall continue to chair the Compliance Committee and the 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 audits and investigations). The Compliance Committee shall make at least annual reports to Board of Directors of CVS.

CVS 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 of the Board of Directors.* CVS's Board of Directors currently has, and shall maintain during the term of the CIA, an Audit Committee comprised of independent directors of CVS (hereinafter "Board Committee"). The Board Committee is responsible for review and oversight of matters related to compliance with the requirements of Federal health care programs and the obligations of this CIA. The Board Committee shall, at a minimum, meet at least quarterly and shall review and oversee CVS's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee. CVS 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 of this CIA, CVS developed, implemented, and distributed a written Code of Conduct to all Covered Persons. CVS 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, at a minimum, shall continue to set forth:

- a. CVS's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. CVS's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with CVS's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

- c. the requirement that all of CVS's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by CVS suspected violations of any Federal health care program requirements or of CVS's own Policies and Procedures;
- d. the possible consequences to both CVS and Covered Persons of failure to comply with Federal health care program requirements and with CVS's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and CVS'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 electronically, that he or she has received, read, understood, and shall abide by CVS'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 shall continue to periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. To the extent CVS makes any material changes to the Code of Conduct, a revised Code of Conduct shall be distributed and made available to Covered Persons within 60 days after such changes are made and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

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

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the proper and accurate preparation and submission of claims to Federal health care programs;
- c. the reimbursement requirements of the Federal health care programs, including the Maximum Allowable Cost (MAC) programs maintained by states in which CVS does business, and the Federal Upper Limit (FUL) program maintained by CMS;
- d. the proper maintenance of prescription records;
- e. the proper and accurate dispensing of prescription drugs, including federal and state law requirements relating to prior authorization; and
- f. the establishment of a centralized process for developing Therapeutic Interchange Programs that (i) considers the potential impact of the Therapeutic Interchange Program to Federal health care programs, and (ii) includes the documentation of relevant information regarding the basis for the Therapeutic Interchange Program.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on CVS's intranet or other internal website available to all Covered Persons. If CVS uses such an electronic method of distribution, it must notify the Covered Persons that the Policies and Procedures will be distributed in such a manner and it must track the distribution to ensure that all appropriate Covered Persons received the 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 shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall

be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 150 days after the Effective Date, CVS shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain CVS's:

- a. CIA requirements; and
- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 150 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 annually.

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

- a. the applicable statutes, regulations, requirements, and directives of the Federal health care programs relating to reimbursement, including MAC programs maintained by the states and the FUL program maintained by CMS;
- b. drug substitution practices and examples of proper and improper drug substitution practices as they relate to Federal health care programs; and
- c. the legal sanctions for violations of the Federal health care program requirements.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons. After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least one hour of Specific Training annually.

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

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

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

6. *Computer-based Training.* CVS may provide the training required under this CIA through appropriate computer-based training approaches. If CVS 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 shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the review described in Section III.D.2, below (Government Reimbursement Review). Each IRO shall assess, along with CVS, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the

engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

b. *Frequency of Government Reimbursement Review.* The Government Reimbursement Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual IRO Review.

c. *Retention of Records.* The IRO and CVS 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) related to the reviews.

2. *Government Reimbursement Review.* For each Reporting Period, the IRO shall perform a review as follows:

a. *Selection of State.* Within 90 days of the end of each Reporting Period, the IRO shall provide OIG with its recommendation for one state to be reviewed. The state recommended by the IRO shall be a state that maintained a MAC program and in which CVS did business during the Reporting Period. Within 30 days after OIG receives the IRO's recommendation, OIG shall notify the IRO if its recommendation is acceptable. If OIG determines that the IRO's recommendation is acceptable, the state recommended by the IRO shall be reviewed. Absent notification from OIG that the IRO's selection is unacceptable, the IRO shall review the state it recommended. The state selected pursuant to this process for each Reporting Period shall be referred to herein as the "Selected State."

b. *Selection of Drugs.* At least 90 days before the end of each Reporting Period, the IRO shall provide OIG with its recommendation for three Drug Entities to be reviewed in accordance with this Section III.D. For purposes of this CIA, the term "Drug Entity" shall mean a molecular compound of which one or more forms or strengths are approved for prescription use by the U.S. Food and Drug Administration, and for which at least one available form or strength is included in the MAC program for the Selected State or the FUL program. In choosing the three Drug Entities, the IRO shall consider any drugs for which CVS has made significant corporate-level purchasing,

stocking, or dispensing decisions (including the implementation of any Therapeutic Interchange Program(s)) during the current or previous Reporting Period. Within 30 days after OIG receives the IRO's recommendation, OIG shall notify the IRO if its recommendation is acceptable. If OIG determines that the IRO's recommendations are acceptable, the drugs recommended by the IRO shall be reviewed in accordance with this Section III.D. Absent notification from OIG that the IRO's recommendations are unacceptable, the IRO shall review the recommended drugs. Each drug selected pursuant to this process for each Reporting Period shall be referred to herein as a "Selected Drug."

c. *Review.* The IRO shall analyze CVS's reimbursement from the Selected State's Medicaid Program for each available strength and form of each Selected Drug during the Reporting Period. The IRO shall review information under CVS's control, including but not limited to claims submission and reimbursement data, dispensing policies, drug substitution programs, Therapeutic Interchange Programs, claims submission policies, as well as the FUL program and the Selected State's Medicaid policies and procedures (including the MAC program). The IRO shall specifically determine whether CVS implemented any Therapeutic Interchange Program for the purpose of (i) avoiding the Selected State's MAC program or the FUL maintained by CMS, (ii) circumventing the Selected State's Medicaid reimbursement or drug dispensing rules, or (iii) otherwise violating any requirements of the Selected State's Medicaid Program. If the IRO so determines, the IRO shall perform a root cause analysis to determine how the Therapeutic Interchange Program occurred based on information available to CVS, interviews with relevant personnel, CVS policies and procedures, supporting documentation regarding relevant prescriptions, and purchasing records. The IRO shall recommend corrective action in order to prevent further Therapeutic Interchange Programs based on avoiding the MAC or FUL programs, improperly increasing aggregate reimbursement from the Medicaid Program, or otherwise violating any requirements of the Selected State's Medicaid Program.

3. *Government Reimbursement Review Report.* The IRO shall prepare a report based upon each Government Reimbursement Review performed (Government Reimbursement Review Report). Information to be included in the Government Reimbursement Review Report is described in Appendix B.

4. *Validation Review.* In the event OIG has reason to believe that: (a) CVS's Government Reimbursement Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Government Reimbursement Review results are

inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Government Reimbursement Review complied with the requirements of this CIA and/or the findings or Government Reimbursement Review results are inaccurate (Validation Review). CVS 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's final Annual Report must be initiated no later than one year after CVS's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify CVS 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 may request a meeting with OIG to: (a) discuss the results of any Government Reimbursement Review submissions or findings; (b) present any additional information to clarify the results of the Government Reimbursement Review or to correct the inaccuracy of the Government Reimbursement Review; and/or (c) propose alternatives to the proposed Validation Review. CVS agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Government Reimbursement Review issues with CVS 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/Objectivity Certification.* The IRO shall include in its report(s) to CVS a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Government reimbursement Review and that it has concluded that it is, in fact, independent and objective.

#### E. Disclosure Program.

Prior to the Effective Date of this CIA, CVS 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'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 shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, posting on CVS'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 shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

#### F. Ineligible Persons.

##### 1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include any 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 ambit 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://oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

c. "Screened Persons" shall include prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of CVS.

2. *Screening Requirements.* CVS shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. CVS shall screen all Screened Persons against the Exclusion Lists prior to hiring them or engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. CVS shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

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

Nothing in this Section affects the responsibility of (or liability for) CVS to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If CVS has actual notice that a Screened Person has become an Ineligible Person, CVS shall remove such person from responsibility for, or involvement with, CVS's business operations related to the Federal health care

programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

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

G. Notification of Government Investigation or Legal Proceedings.

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

1. *Overpayments.*

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

b. Reporting of Overpayments. If, at any time, CVS identifies or learns of any Overpayment, CVS shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after

identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, CVS shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, CVS shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

## *2. Reportable Events.*

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

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

b. Reporting of Reportable Events. If CVS 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 shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

iii. a description of CVS's actions taken to correct the Reportable Event; and

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

#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date, CVS changes the location of its corporate headquarters or sells or purchases a business location related to the furnishing of items or services that may be reimbursed by Federal health care programs, CVS shall notify OIG of this fact within 60 days after the date of change of location, sale, or purchase. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each newly established and purchased business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, CVS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee or the Board Committee required by Section III.A;

3. a copy of CVS's Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

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

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

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

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

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

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

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between CVS and the IRO;

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

10. the proposed start and completion dates of the Government Reimbursement Review;

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

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

13. a list of all states in which CVS does business, and the number of CVS's locations in each state; any names other than CVS under which any of CVS's locations are doing business; and the name and address of each Medicare contractor to which CVS currently submits claims;

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

15. the certifications required by Section V.C.

B. Annual Reports. CVS shall submit to OIG annually a report with respect to the status of, and findings regarding, CVS'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 or the Board Committee described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy) and copies of any compliance-related Policies and Procedures;
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
6. CVS's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
7. summary and description of any and all current and prior engagements and agreements between CVS and the IRO, if different from what was submitted as part of the Implementation Report;

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

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

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories, if applicable: Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

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

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by CVS in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

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

15. a description of all changes to the most recently provided list of information required by Section V.A.13; a list of all states in which CVS does business, and the number of CVS's locations in each state; any names other than CVS under which any of CVS's locations are doing business; and the name and address of each Medicare contractor to which CVS currently submits claims; and

16. the certifications required by Section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, CVS 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 has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

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

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

OIG:

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

CVS:

Diane Nobles  
Compliance Officer  
CVS Caremark Corporation  
2211 Sanders Road  
10<sup>th</sup> Floor  
Northbrook, IL 60062  
Telephone: 847-559-4714  
Facsimile: 847-559-4953

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

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

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

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

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

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

a. a Compliance Officer;

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

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 fails to engage an IRO, as required in Section III.D and Appendix A.

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 fails to submit the Implementation Report or the 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 fails to submit the annual Government Reimbursement Review Report in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of CVS as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day CVS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to CVS, stating the specific grounds for its determination that CVS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps CVS shall take to comply with this CIA. (This Stipulated Penalty shall begin to accrue ten (10) days after CVS 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 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 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 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 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 of: (a) CVS's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within ten days after the receipt of the Demand Letter, CVS 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 elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CVS cures, to OIG's

satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that CVS has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by CVS constitutes an independent basis for CVS's exclusion from participation in the Federal health care programs. Upon a determination by OIG that CVS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify CVS of: (a) CVS's material breach and OIG's specific grounds

for its determination that CVS has materially breached this CIA; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* CVS 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 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 has begun to take action to cure the material breach; (ii) CVS is pursuing such action with due diligence; and (iii) CVS 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 fails to satisfy the requirements of Section X.D.3, OIG may exclude CVS from participation in the Federal health care programs. OIG shall notify CVS in writing of its determination to exclude CVS (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of CVS's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, CVS 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 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 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 was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. CVS 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 to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless CVS 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 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 had begun to take action to cure the material breach within that period; (ii) CVS has pursued and is pursuing such action with due diligence; and (iii) CVS

provided to OIG within that period a reasonable timetable for curing the material breach and CVS 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, only after a DAB decision in favor of OIG. CVS's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude CVS 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 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 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, CVS 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**

Consistent with the provisions in the Settlement Agreements pursuant to which this CIA is entered, CVS and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of CVS. If CVS sells a business unit or location, OIG may release the business unit or location from its obligations under the CIA provided that CVS has demonstrated to OIG's satisfaction that (1) such transaction constituted solely a disposition of assets of such business unit or location; (2) the buyer is an independent entity unrelated in any manner to CVS and has acquired the business unit or location at fair market value in an arms length transaction; (3) the Federal health care program provider numbers have not transferred to the successor entity; and (4) the business unit or location will not be operated in whole or in part by CVS. If a business unit or location is no longer to be considered subject to the CIA due to a sale, CVS shall require as a condition of the sale that the buyer represents and agrees that it has or shall implement and maintain with respect to its operation of the

business unit or location an effective program to prevent and detect violations of the legal requirements applicable to the delivery of goods and services in connection with any health care benefits and that such a program will comply with the provisions of the U.S. Sentencing Guidelines relating to corporate compliance programs and will be mindful of any applicable guidance issued by OIG or other components of HHS; and that the buyer agrees that it will maintain such program for at least three years from the date of the sale or until the end of the term of this CIA, whichever period is longer.

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

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. OIG may agree to a suspension of CVS's obligations under this CIA in the event of CVS's cessation of participation in Federal health care programs. If CVS withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, CVS shall notify OIG at least 30 days in advance of CVS's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether this CIA should be reactivated or modified.

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

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

ON BEHALF OF CVS CAREMARK CORPORATION

/C V S Caremark Corporation/

CVS Caremark Corporation

12/9/07  
DATE

/Counsel for C V S Caremark Corporation/

Counsel for CVS Caremark Corporation

12/10/07  
DATE

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

/Gregory E. Demske/

3/14/08

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

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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.

CVS shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify CVS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CVS may continue to engage the IRO.

If CVS 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 shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify CVS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CVS may continue to engage the IRO.

### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Government Reimbursement Review who have expertise in (a) the billing, reporting, and other requirements of pharmaceutical reimbursement; (b) the general requirements of the Federal health care program(s) from which CVS seeks reimbursement; and (c) the laws applicable to therapeutic interchanges, including but not limited to applicable Medicare and Medicaid rules and regulations and state and local pharmacy laws;
2. assign individuals to design and select the Government Reimbursement Review sample who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

### C. IRO Responsibilities.

The IRO shall:

1. perform each Government Reimbursement Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare and Medicaid rules and guidelines in the Government Reimbursement Review;
3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority;
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Government Reimbursement Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and CVS.

E. IRO Removal/Termination.

1. *Provider.* If CVS terminates its IRO during the course of the engagement, CVS must submit a notice explaining its reasons to OIG no later than 30 days after termination. CVS must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require CVS to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring CVS to engage a new IRO, OIG shall notify CVS 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 may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. CVS shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with CVS prior to requiring CVS to terminate the IRO. However, the final determination as to whether or not to require CVS to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B GOVERNMENT REIMBURSEMENT REVIEW REPORT

The following information shall be included in each Government Reimbursement Review Report.

### 1. *Government Reimbursement Review Methodology.*

- a. Government Reimbursement Review Objective. A clear statement of the objective intended to be achieved by the Government Reimbursement Review.
- b. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Government Reimbursement Review.
- c. Review Protocol. A narrative description of how the Government Reimbursement Review was conducted and what was evaluated.

### 2. *Government Reimbursement Review Findings.*

#### a. Narrative Results.

- i. A narrative explanation of the IRO's findings and supporting rationale (including patterns noted, etc.) regarding the Government Reimbursement Review.
- ii. If applicable, a narrative description of the results of the IRO's root cause analysis of any discrepancies, including any reimbursement for strengths or forms of the Selected Drugs not listed on the MAC list for the Selected State or the FUL list.
- iii. If applicable, a narrative description of the IRO's conclusion as to whether any discrepancies resulted from a likely violation of state or Federal laws or regulations.

#### b. Quantitative Results.

- i. Total dollar amount of all payments to CVS for each Selected Drug by the Selected State.
- ii. Total dollar value of any discrepancy with respect to each Selected Drug, and the percentage of total payments for each Selected Drug the Discrepancy represents.

3. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated any discrepancies.

4. *Credentials.* The names and credentials of the individuals who: (1) designed the review methodology utilized for the Government Reimbursement Review; and (2) performed the Government Reimbursement Review.

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

CVS Caremark Corporation (CVS Caremark) hereby enters into this First Amendment (Amendment) to the Corporate Integrity Agreement with the Office of Inspector General (OIG) of the Department of Health and Human Services to amend the Corporate Integrity Agreement that was executed by and between CVS Caremark and OIG and that became effective March 14, 2008 (CIA).

CVS Caremark and OIG agree as follows:

1. The period of compliance obligations assumed by CVS Caremark under this Amendment shall be three years from the Effective Date of this Amendment, unless otherwise specified. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date). Each one-year period following the Effective Date shall be referred to as an “Amendment Reporting Period.”
2. Commencing on the Amendment Effective Date, all terms and conditions of the CIA shall remain in effect for three years from the Amendment Effective Date, with the following modifications, which shall be applicable to CVS Caremark’s retail pharmacy subsidiary, CVS Pharmacy, Inc., and any of CVS Pharmacy, Inc.’s subsidiaries or affiliates that conduct retail pharmacy operations (collectively referred to as “CVS”):
  - a. Billing Covered Persons. Section II.C shall be amended to include the following subsection:
    4. “Billing Covered Persons” includes all Covered Persons whose professional responsibilities include the preparation or submission or the development of systems and/or policy related to the preparation or submission of pharmacy claims for health care items or services to the Medicaid programs in Alabama, Indiana, California, Florida, Massachusetts, Minnesota, Michigan, Nevada, New Hampshire, or Rhode Island.
  - b. Policies and Procedures. Section III.B.2 of the CIA shall be amended to include the following subsections:

g. procedures to be used by CVS to ensure that CVS bills the Medicaid programs in Alabama, Indiana, California, Florida, Massachusetts, Minnesota, Michigan, Nevada, New Hampshire, and Rhode Island in accordance with state Medicaid laws regarding the amount of Medicaid's secondary liability, when a Medicaid beneficiary for whom CVS bills Medicaid for a health care item or service also holds insurance coverage from a primary third party insurance plan (excluding Medicare) (hereinafter a "Primary Third Party Insurance Plan").

The Policies and Procedures required by this Amendment shall be implemented within 150 days of the Amendment Effective Date.

- c. *Training and Education.* Subsections 3, 4, 5, and 6 of Section III.C of the CIA shall be renumbered as subsections 4, 5, 6, and 7 of Section III.C of the CIA. Section III.C shall be amended to include the following new subsection 3.

3. *Billing Training.* Within 150 days of the Amendment Effective Date, each Billing Covered Person shall receive at least one hour of Billing Training. Billing Training shall include, at a minimum, as appropriate to job function:

- a. the proper procedures for the accurate preparation and submission of pharmacy claims in accordance with Federal health care program requirements in Alabama, Indiana, California, Florida, Massachusetts, Minnesota, Michigan, Nevada, New Hampshire, and Rhode Island, including but not limited to claims to Federal health care programs as secondary payors;
- b. the proper procedures for billing Medicaid in Alabama, Indiana, California, Florida, Massachusetts, Minnesota, Michigan, Nevada, New Hampshire, and Rhode Island in accordance with applicable state Medicaid laws governing prescription drug reimbursement for Medicaid beneficiaries who may also hold insurance coverage from a Primary Third Party Insurance Plan;
- c. the personal obligation of each individual involved in the claims submission process to ensure that such pharmacy claims are accurate;

- d. the legal sanctions for violations of Federal health care program requirements, including applicable legal sanctions and consequences of violations of the CIA;
- e. examples of proper and improper pharmacy claims submission practices; and
- f. policies and procedures for the reporting and repayment of Overpayments to Federal health care programs and other payors.

After receiving the initial Billing Training described above, each Billing Covered Person shall receive at least one hour of Billing Training in each subsequent Amendment Reporting Period.

To the extent that a Billing Covered Person receives training on the topics described in subsections (c), (d), (e) or (f), above, during the course of either General Training or Specific Training for any Amendment Reporting Period, those subsections shall be deemed to be complied with for such Billing Covered Person for the Amendment Reporting Period in which the General or Specific Training was given.

- d. *IRO Review.* Subsections 4 and 5 of Section III.D of the CIA shall be renumbered as subsections 7 and 8 of Section III.D of the CIA. Section III.D of the CIA shall be amended to include the following new subsections 4, 5, and 6.

4. Medicaid Billing Review. For each Amendment Reporting Period, the IRO shall review whether CVS is in compliance with Medicaid laws, rules, and regulations in Alabama, Indiana, California, Florida, Massachusetts, Minnesota, Michigan, Nevada, New Hampshire, and Rhode Island with respect to CVS's preparation and submission of pharmacy claims for prescription drugs for beneficiaries who also hold insurance coverage from a Primary Third Party Insurance Plan (Medicaid Billing Review). The Medicaid Billing Review shall include a Discovery Sample of 25 Paid Claims in each of these states to determine if CVS has billed Medicaid in accordance with each state's applicable laws, rules and regulations specifically governing coordination of benefits/third party liability (TPL) claims for beneficiaries who also hold insurance coverage from a Primary Third Party Insurance Plan. If the Error Rate for any Discovery Sample is 5% or greater, the IRO shall perform a Full Sample and Systems Review in that state. The applicable definitions, procedures, and reporting requirements are outlined in Attachment 1 to this CIA Amendment, which is incorporated by reference.

5. Medicaid Billing Review Report. The IRO shall prepare a report based upon the Medicaid Billing Review performed (Medicaid Billing Review Report). Information to be included in the Medicaid Billing Review Report is described in Attachment 1 to this CIA Amendment.

6. Repayment of Identified Overpayments. In accordance with Section III.H.1 of the CIA, CVS shall repay within 30 days any Overpayment(s) identified in any of the Discovery Samples or the Full Samples (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. CVS shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

e. *Amendment Implementation Report*. Within 150 days after the Amendment Effective Date, CVS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Amendment (Amendment Implementation Report). The Amendment Implementation Report shall, at a minimum, include:

1. a copy of all Policies and Procedures required by section 2.b of this Amendment;
2. the name and qualifications of the IRO(s) that will be conducting the Medicaid Billing Review and a summary and description of any and all current and prior engagements between CVS and that IRO;
3. a copy of the engagement letter with the IRO that will be conducting the Medicaid Billing Review;
4. a certification from the IRO that will be conducting the Medicaid Billing Review regarding its professional independence and objectivity with respect to CVS;
5. the following information regarding the training required by section 2.c of this Amendment:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.



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

6. the certifications required by section V.C of the CIA with respect to the requirements of this Amendment.
3. The Annual Reports required by section V.B of the CIA shall include any information relevant to CVS's compliance with the terms of this Amendment, as described in section V.B of the CIA.
4. CVS shall not be required to perform the Government Reimbursement Review described in section III.D of the CIA during the third Amendment Reporting Period.
5. The undersigned CVS signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing this Amendment in his official capacity and that he is authorized to execute this Amendment.
6. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.
7. This Amendment and the CIA that became effective March 14, 2008, constitute the complete agreement between the Parties. This agreement may not be amended, except by written consent of the Parties.

**ON BEHALF OF CVS CAREMARK CORPORATION**

\_\_\_\_\_  
CVS Caremark Corporation Representative

\_\_\_\_\_  
/Catherine M. O'Neil/

\_\_\_\_\_  
Counsel for CVS Caremark Corporation

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DATE

\_\_\_\_\_  
4/11/2011

\_\_\_\_\_  
DATE

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

\_\_\_\_\_  
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

\_\_\_\_\_  
DATE



CIA Amendment  
Attachment 1  
Medicaid Billing Review

A. Medicaid Billing Review.

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

- a. Overpayment: The amount of money CVS has received in excess of the amount due and payable under the applicable state Medicaid requirements specifically governing coordination of benefits/TPL claims.
- b. Paid Claim: A code or line item submitted by CVS to a Medicaid program and for which CVS has received reimbursement, including any applicable dispensing fee, from the Medicaid program for a health care item dispensed to a Medicaid beneficiary who also holds insurance coverage from a Primary Third Party Insurance Plan.
- c. Population: The Population shall be defined as all Paid Claims during each Amendment Reporting Period.
- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

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

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 25 Paid Claims in each of the following states: Alabama, Indiana, California, Florida, Massachusetts, Minnesota, Michigan, Nevada, New Hampshire, and Rhode Island (each set of 25 Paid Claims referred to as a “Discovery Sample”). The Paid Claims shall be reviewed based on the supporting documentation available at CVS’s pharmacies or corporate offices or otherwise under CVS’s control, and applicable billing and coding laws, rules and regulations to determine whether the claims were correctly coded, submitted, and reimbursed.

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

OIG or another HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims, included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If any Discovery Sample for a particular state indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims for the particular state (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designated to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at CVS's pharmacies or corporate offices or otherwise under CVS's control, and applicable billing and coding regulations and guidance to determine whether the claims were correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the relevant Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from CVS to the appropriate Medicaid program.

4. *Systems Review.* If any Discovery Sample for a particular state identifies an Error Rate of 5% or greater, CVS's IRO shall conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements.*

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

- b. Paid Claims without Supporting Documentation. Any Paid Claim for which CVS cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by CVS for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Amendment, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

B. Medicaid Billing Review Report. The following information shall be included in the Medicaid Billing Review Report for each Discovery Sample and Full Sample (if applicable) performed.

1. *Medicaid Billing Review Methodology*.

- a. Medicaid Billing Review Population. A description of the Population subject to the Medicaid Billing Review.
- b. Medicaid Billing Review Objective. A clear statement of the objective intended to be achieved by the Medicaid Billing Review.
- c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Medicaid Billing Review.
- d. Review Protocol. A narrative description of how the Medicaid Billing Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*.

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
- c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Medicaid Billing Review Findings.*

a. Narrative Results.

- i. A description of CVS's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, pattern noted, etc.) regarding the Medicaid Billing Review, including the results of the Discovery Samples, and the results of the Full Sample (if any).

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by CVS (Claim Submitted) differed from what should have been the correct claims (Correct Claim), regardless of the effect of on the payment.
  - ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to CVS.
  - iii. Total dollar amount of all Overpayments in the sample.
  - iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.
  - v. Error Rate in the sample.
  - vi. A spreadsheet of the Medicaid Billing Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, primary payor, primary payor's adjudicated reimbursement amount response, Medicaid adjudicated reimbursement amount response, amount billed to Medicaid (as determined by the IRO), correct allowed amount (as determined by the IRO), and dollar difference between amount reimbursed by Medicaid and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to CVS's billing and coding system based on the findings of the Medicaid Billing Review.

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

- a. the strengths and weaknesses in CVS's billing systems and processes;
- b. the strengths and weaknesses in CVS's coding systems and processes; and
- c. possible improvements to CVS's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Medicaid Billing Review; and (2) performed the Medicaid Billing Review.