CORPORATE INTEGRITY AGREEMENT

BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CVS CORPORATION

I. PREAMBLE

CVS Corporation, solely for itself and its retail pharmacy subsidiaries CVS Pharmacy, Inc. and ProCare Pharmacy, Inc. (hereinafter, collectively, "CVS"), hereby agrees to enter into this Corporate Integrity Agreement (hereinafter, "CIA") with the Office of Inspector General (hereinafter, the "OIG") of the United States Department of Health and Human Services (hereinafter, "HHS"). CVS also agrees to implement all reasonable and necessary policies, procedures, and practices to promote compliance by its corporate officers and directors, and by its pharmacists, pharmacy technicians and other persons employed or engaged by CVS to provide pharmacy services or prepare and/or submit claims for pharmacy services to any Federal health care programs (as such term is defined below) (hereinafter, "pharmacy/billing employees") with the terms of this CIA and the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter, collectively referred to as the "Federal health care programs"). CVS's compliance with the terms and conditions in this CIA shall constitute an element of CVS's present responsibility with regard to participation in the Federal health care programs.

Contemporaneously with this CIA, CVS is entering into a settlement agreement with the United States for conduct relating to partial-fills (as hereinafter defined in Section III.C). In addition, CVS will soon be entering a settlement agreement with the United States for possible conduct by Revco Drug Stores, Inc. (hereinafter, "Revco"), which merged with CVS in 1997, relating to canceled prescriptions and this CIA is incorporated into those settlement agreements by

¹ During the course of this CIA, CVS may purchase or otherwise acquire new business lines or entities engaged in the pharmacy business that may, from time to time, dispense partial-fill prescriptions that are reimbursed by Federal health care programs (as defined in this CIA). CVS is committed to ensuring that any such new business entities comply with the applicable requirements of this CIA and the Federal health care programs from which they are reimbursed.

reference. In addition, CVS has or will soon enter individual settlement agreements with certain States relating to the partial filling of prescriptions and this CIA is also incorporated into those settlement agreements by reference.

Prior to the execution of this CIA, the OIG acknowledges that CVS has undertaken audit and compliance endeavors and has in place a compliance program which provides for an Internal Audit Department (hereinafter, the "IAD"), an Audit Committee, a corporate compliance officer, a corporate compliance committee, a corporate code of conduct entitled *Roles not Rules*, training and education initiatives, a confidential hotline and other policies, programs, and procedures that, as represented by CVS, are aimed in part at promoting compliance with the requirements of the Federal health care programs as they relate to the submission of pharmacy claims by CVS.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by CVS under this CIA shall be four (4) years from the Effective Date (as defined below) of this CIA (unless otherwise specified herein). The effective date of the CIA will be the date of the final signature on this CIA (hereinafter, the "Effective Date"). Sections IV, VII, VIII, IX, and X shall remain in effect until CVS submits all information required by the OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

Prior to the Effective Date, CVS has established a compliance program consisting of the following audit and compliance procedures (hereinafter, collectively the "Compliance Program"). CVS agrees to continue the operation of its Compliance Program for the term of this CIA in accordance with the provisions set forth below. CVS may modify the Compliance Program as appropriate, but, at a minimum, CVS shall ensure that it complies with the integrity obligations enumerated in this Section III of the CIA.

A. <u>Compliance Committee and Compliance Officer</u>. Prior to the Effective Date, CVS has established a compliance committee, the Ethics and Business Conduct Committee (hereinafter, the "EBCC") and appointed an individual to serve as its Corporate Compliance Officer (hereinafter, the "CCO"). The EBCC is responsible for developing and implementing the Compliance Program and policies, procedures, and practices designed to promote compliance with the requirements set forth in this CIA, and with the requirements of the Federal health care programs. The CCO is and shall continue to be a member of senior management of CVS and shall make quarterly reports on

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compliance matters to the EBCC. The EBCC shall make regular reports regarding compliance to the Audit Committee, and the Chairman of the Audit Committee shall report regularly to the Board of Directors of CVS Corporation (hereinafter, the "CVS Board") regarding compliance matters. Additionally, the CCO is authorized to report directly to the CVS Board at any time.

The CCO (or designee) shall be responsible for overseeing the compliance activities in which CVS engages, as well as for any reporting obligations created, under this CIA. CVS agrees to maintain the position of CCO during the term of this CIA. In the event a new CCO is appointed during the term of this CIA, CVS shall notify the OIG, in writing, within fifteen (15) days of such change.

For at least the term of this CIA, CVS shall continue to maintain its compliance committee, the EBCC. At a minimum, the EBCC shall continue to include persons in the following positions, or comparable corporate officers or titles:

- (1) the Vice President, General Counsel, and CCO;
- (2) Senior Vice President of Administration and Chief Legal Officer;
- (3) Senior Vice President of Human Resources;
- (4) Vice President Store Operations; and
- (5) Director of Internal Audit.

The CCO shall continue to chair the EBCC, and the EBCC shall continue to support the CCO in fulfilling his responsibilities. The EBCC shall make at least annual reports to the CVS Board.

B. <u>Code of Conduct</u>. Within one hundred twenty (120) days after the Effective Date of this CIA, to the extent not already accomplished, CVS shall develop and implement its code of conduct statement and policy (hereinafter, the "Code of Conduct"). Like the current *Roles Not Rules*, the Code of Conduct shall provide that all CVS employees, including CVS's pharmacy/billing employees, shall comply with the Code of Conduct. Within one hundred twenty (120) days after the Effective Date of the CIA, to the extent CVS has not already done so, the Code of Conduct shall be made available to all CVS employees who are pharmacy/billing employees and placed in prominent locations accessible to such employees. With respect to any contractors that are pharmacy/billing employees and have been engaged by CVS to prepare and/or submit, or assist in the preparation and/or submission of, claims for pharmacy services to any Federal health care programs in CVS facilities or on CVS premises, CVS shall inform such contractors of CVS's obligations under this

CIA applicable to such contractors' provision of services to CVS and that such contractors must abide by such obligations, as well as any applicable provisions of law, as a condition of providing services to CVS. Each such contractor will certify, in writing or electronically, that such contractor understands such obligations and will abide by them in providing services to CVS.

At a minimum, the Code of Conduct shall set forth CVS's commitment to compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate billings consistent with the Federal health care program requirements. It shall set forth CVS's requirement that all pharmacy/billing employees shall be expected to comply with all Federal health care program requirements and with CVS's own policies and procedures. It will also set forth the possible consequences to both CVS and any CVS employees who are pharmacy/billing employees of a failure to comply with all Federal health care program requirements; the requirement that all CVS employees report suspected violations of these requirements or of CVS's own policies and procedures; and the right of all CVS employees to use the Confidential Disclosure Program required in Section III.F below.

Within one hundred fifty (150) days of the Effective Date of this CIA, each of CVS's employees who are pharmacy/billing employees shall certify, in writing or electronically (either via CVS's interactive voice response system or other electronic means), that he or she has received and read the Code of Conduct, understands it, and will abide by it. New CVS employees who become pharmacy/billing employees shall receive the Code of Conduct and complete the required certifications within four (4) weeks after the commencement of their employment or within one hundred fifty (150) days of the Effective Date of this CIA, whichever is later. Compliance staff or supervisors should be available to explain any provision of the Code of Conduct if necessary.

CVS will annually review the Code of Conduct and will revise it as necessary. To the extent CVS makes any substantial changes to the minimum requirements of the Code of Conduct set forth above, a revised Code of Conduct shall be distributed and made available to CVS employees who are pharmacy/billing employees and such employees shall certify, in writing or electronically (either via CVS's interactive voice response system or other electronic means), within one hundred fifty (150) days of distribution to such employees of such revisions that they have received, read, understood, and will abide by the revised Code of Conduct. All certifications required pursuant to this Section III.B shall be maintained by CVS and shall be made available to the OIG upon a request

by the OIG made in writing as outlined in Section VI below and sent to the individuals named in Section VI below.

C. <u>Policies and Procedures</u>. To the extent not already accomplished, within one hundred twenty (120) days of the Effective Date of this CIA, CVS shall develop and initiate implementation of written policies and procedures. At a minimum, these policies and procedures should address CVS's corporate integrity program, CVS's compliance generally with applicable Federal health care program requirements, CVS's IAD, and CVS's Third Party Billing Department (hereinafter, collectively "Policies and Procedures").

In addition to other requirements as determined by the EBCC, the Policies and Procedures shall specifically address the manner in which CVS shall submit claims to the Federal health care programs for prescriptions that were only partially filled, <u>i.e.</u>, where CVS is unable to fill the entire prescribed amount of medication to the program beneficiary or recipient due to inadequate inventory at such time (hereinafter, "partial-fill"). With regard to partial-fill situations, the Policies and Procedures shall continue to provide the following:

- (1) the pharmacist will dispense a partial quantity (suggested 72-hour supply) of the prescription to the program beneficiary or recipient;
- (2) at such time, no bill shall be submitted to the Federal health care program and no co-payment shall be collected from the program beneficiary or recipient;
- (3) once the partial-fill has been completely filled in accordance with the prescription, and whether or not the program beneficiary or recipient has returned to pick up the prescription, CVS will bill the Federal health care programs and when the program beneficiary or recipient returns to collect the remainder of the prescription, CVS will collect the applicable co-payment from the program beneficiary or recipient in accordance with CVS's Policies and Procedures; and
- (4) if the program beneficiary or recipient fails to return to collect the remainder of the prescription, the pharmacist shall cancel the prescription and return the unused medication to stock according to CVS's return to stock policy (hereinafter, "RTS Policy"). CVS then, in accordance with the CVS Reconciliation Process (as hereinafter defined), will reconcile with the applicable Federal health care program for any payment made to CVS by such Federal health care program for the undelivered prescription.

In addition, the Policies and Procedures shall continue to provide for the following with respect to the RTS Policy:

- (1) upon cancellation of a medication for failure of the program beneficiary or recipient to return to collect the remainder of the prescription, the pharmacist notes on the prescription that the balance has not been filled and returns the unused medication to stock and reconciles the previous automated billing by deleting the prescription from its in-store claims processing system;
- (2) the pharmacist must then reverse the transaction by overriding the price of the original partial-fill quantity to zero, input an override code to document the partial-fill, and reconcile with the applicable Federal health care program for any payment made to CVS by such Federal health care program;
- (3) if the program beneficiary or recipient later returns and requests the balance of the prescription, the pharmacist must edit the prescription to the full quantity (by crossing out the "return to stock" or "RTS" note on the back of the prescription and indicating that the balance has been filled), the remainder of the prescription will be dispensed and the Federal health care program will be billed and the co-payment will be collected in accordance with CVS's Policies and Procedures;
- (4) if a program beneficiary or recipient cancels a prescription for any reason after the prescription has been filled, but before the program beneficiary or recipient picks it up, the pharmacist must follow the preceding RTS procedure, including proper reconciliation with any applicable Federal health care program; and
- (5) the pharmacist must perform, at a minimum, a RTS process every month; during this RTS process, any prescriptions that are not picked up by the program beneficiary or recipient after twenty eight (28) days from the dispense date, unless the program beneficiary or recipient specifically requests the pharmacist to hold the medication for a longer period of time, must be returned to stock in accordance with the RTS Policy, and the reconciliation process contained in the RTS Policy (hereinafter, the "CVS Reconciliation Process") must be followed.

If CVS has mailed any medication to a Federal health care program beneficiary that is returned to CVS and not ultimately delivered to the beneficiary, CVS shall follow the preceding RTS

procedure, including proper reconciliation with any applicable Federal health care program.

CVS shall only collect a single dispensing fee from the Federal health care programs for any partial-fill prescription. Also, in a partial-fill situation, CVS will not collect any additional copayment amounts from program beneficiaries or recipients that exceed the total co-payment amount applicable to the prescription at issue.

In addition, the Policies and Procedures shall require CVS to accurately inform the program beneficiary or recipient of the amount of the prescribed medication that is available for dispensing. If a partial-fill is provided by CVS to a program beneficiary or recipient, CVS shall 1) provide accurate information to such person as to the reason for furnishing a partial-fill and 2) affirmatively inform such person that he or she was furnished with a partial-fill.

The Policies and Procedures shall also include methods for employees to make complaints and notifications about compliance issues to CVS's management through the Confidential Disclosure Program required in Section III.F below. CVS shall review and update the Policies and Procedures whenever appropriate. An index of the applicable Policies and Procedures will be provided to the OIG in the Implementation Report (as hereinafter defined in Section V.A). The Policies and Procedures will be made available by CVS to the OIG upon a request by the OIG made in writing as outlined in Section VI below and sent to the individuals named in Section VI below.

To the extent not already accomplished, within one hundred twenty (120) days of the Effective Date of this CIA, these Policies and Procedures shall be made available to all pharmacy/billing employees who provide services in CVS facilities or on CVS premises. In addition, pharmacy/billing employees who provide services in CVS facilities or on CVS premises shall receive training about these Policies and Procedures in accordance with the provisions of Section III.D below. Members of the EBCC, Store Managers, Team Leaders, Technician Trainers, Regional Healthcare Managers and District Managers, as appropriate, shall be available to explain any and all Policies and Procedures if necessary.

D. <u>Training and Education Initiatives</u>. CVS shall continue its training and educational initiatives. To the extent not already accomplished, within one hundred fifty (150) days of the Effective Date of this CIA, CVS shall provide appropriate training to each of its pharmacy/billing employees who provide services in CVS facilities or on CVS premises, which training shall in written or electronic summary form:

- (1) explain the requirements of this CIA;
- (2) explain CVS's Code of Conduct;
- (3) explain CVS's Compliance Program, including, but not limited to, the Policies and Procedures as they pertain to the submission of accurate claims for partial-fills as appropriate for the type of employee;
- (4) explain reimbursement rules and statutes under the Federal health care programs;
- (5) explain the personal obligation of each pharmacy/billing employee who provides services in CVS facilities or on CVS premises to ensure that billings are accurate;
- (6) explain the legal sanctions for improper billings under the Federal health care programs;
- (7) provide examples of proper and improper billing practices under the Federal health care programs; and
- (8) explain to pharmacy/billing employees who provide services in CVS facilities or on CVS premises how potential violations of CVS's Policies and Procedures should be handled and that any failure to comply may result in disciplinary action, up to and including termination of employment. Persons providing the training must have the requisite expertise and qualifications to conduct the required training.

Any new pharmacy/billing employees who provide services in CVS facilities or on CVS premises shall receive the training described above within one hundred fifty (150) days of the commencement of their employment or within one hundred fifty (150) days after the Effective Date of this CIA, whichever is later. A pharmacy/billing employee who has completed the training shall review such new pharmacy/billing employee's work, to the extent the work relates to the preparation or submission of claims for reimbursement from any Federal health care program, until such time as such new pharmacy/billing employee completes the training.

The applicable Store Manager, Team Leader, Regional Healthcare Manager, District Manager or Technician Trainer shall certify, in writing or electronically, that the applicable pharmacy/billing employee has received the required training. The certification shall specify the date of the training. CVS shall maintain the certifications and these shall be made available to the OIG upon a request by the OIG made in writing as outlined in Section VI below and sent to the

individuals named in Section VI below.

E. Audits and Disclosures.

Internal Audits of CVS's Billing and Compliance Practices. Prior to the (1) Effective Date, CVS has developed an internal audit workplan (hereinafter, the "IA Workplan"), as stipulated in Attachment A attached hereto and incorporated herein by reference, which may change from time to time as provided below. The IAD will use this IA Workplan on an annual basis to assist CVS management in assessing the adequacy of CVS's billing and compliance practices pursuant to this CIA. To the extent not already accomplished, within one hundred twenty (120) days of the Effective Date of this CIA, CVS shall engage an independent review organization (hereinafter, "IRO"), such as an accounting firm or consulting firm, to conduct agreed upon procedures (hereinafter, the "Agreed Upon Procedures"), as stipulated in Attachment B attached hereto and incorporated herein by reference, which may change from time to time as provided below, and to report, in accordance with the standards of the American Institute of Certified Public Accountants, regarding its findings pursuant to the Agreed Upon Procedures to assist CVS management in evaluating the effectiveness of its Compliance Program consistent with the requirements of this CIA. Each IRO shall assess, along with CVS, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. Within one hundred twenty (120) days of the Effective Date of this CIA, the IRO shall provide to CVS a certification or sworn affidavit that it has evaluated its professional independence with regard to the Agreed Upon Procedures and that it has concluded that it is, in fact, independent. Such certification shall be included in CVS's Implementation Report submission. The reviews conducted pursuant to the IA Workplan and the Agreed Upon Procedures shall be an annual requirement and each shall cover successive twelve (12) month periods based on successive anniversary dates of the Effective Date of this CIA, with the results of the full and final 12-month review reported with the Annual Report (as defined in Section V.B below). Both the IAD and the IRO must have expertise in billing, claims submission, reporting and other requirements of the Federal health care programs from which CVS seeks reimbursement.

The IA Workplan and corresponding Agreed Upon Procedures may change from time

to time. If changes are made to the compliance or sampling audit portions of those documents (as defined below), CVS shall provide a copy of any revised IA Workplan and Agreed Upon Procedures to the OIG prior to the time they are implemented and the OIG shall have the opportunity to comment on the new workplans. Any comments or recommendations made by the OIG after reviewing any revised IA Workplan or Agreed Upon Procedures will not preclude the OIG from making further comments or recommendations after reviewing the reports issued by the IAD or the IRO. Provided, however, that during the term of this CIA, the sampling audits (as defined below) will include a review of compliance with the partial-fill and RTS issues. Once the IA Workplan has been developed each year by the IAD, the IAD will deliver the IA Workplan to the IRO. In addition, the IAD will share with the IRO any and all of the IAD's annual audit results under the IA Workplan.

The IAD will conduct two separate reviews in accordance with the IA Workplan. The first review (i.e., Sampling Audits) will allow CVS to verify the adequacy of procedures for CVS's claims submissions to the Federal health care programs. The second review (i.e., Compliance Audits) will allow CVS to verify compliance with this CIA. The IRO will perform the Agreed Upon Procedures to determine IAD's compliance with the IA Workplan as a means of monitoring CVS's compliance with the terms of this CIA.

In the event the OIG has reason to believe that: (a) CVS's Sampling or Compliance Audits fail to conform to the requirements of this CIA or the findings or results of the audits are inaccurate or (b) the IRO's performance of the Agreed Upon Procedures fails to conform to the requirements of this CIA, the OIG may, at its sole discretion, conduct its own review to determine whether the Sampling and Compliance Audits and the IRO's performance of the Agreed Upon Procedures comply with the requirements of the CIA and/or the findings or results are inaccurate. CVS agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in Section II) is received by the OIG.

Prior to initiating such a review, the OIG shall notify CVS of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, CVS may request a meeting with the OIG to discuss the results

of any Sampling or Compliance Audit or Agreed Upon Procedures; present any additional or relevant information to clarify the results of the Sampling or Compliance Audits or the Agreed Upon Procedures or to correct the identified inaccuracies; and/or propose alternatives to the OIG's proposed review. CVS agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Sampling or Compliance Audit and/or Agreed Upon Procedure issues with CVS prior to conducting its own review. However, the final determination as to whether or not to proceed with such a review shall be made at the sole discretion of the OIG.

The IRO and CVS shall retain and make available to the OIG, upon a request made in writing as outlined in Section VI below and sent to the individuals named in Section VI below, all work papers and supporting documentation, correspondence, and draft reports (those exchanged between the IRO and CVS) related to the Agreed Upon Procedures performed by the IRO.

- (2) Disclosure of Overpayments and Material Deficiencies.
- a. <u>Definition of Overpayments</u>. For purposes of this CIA, an "overpayment" shall mean the amount of money CVS has received in excess of the amount due and payable to CVS under identifiable Federal health care program requirements. CVS may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."
- b. <u>Reporting of Overpayments</u>. If, after following the CVS Reconciliation Process or through any other means, CVS identifies or learns of an overpayment, CVS shall repay (by remitting payment in the amount of the overpayment to the payor) the overpayment to the applicable payor (e.g., the Medicaid carrier or contractor) in accordance with the payor's policies. CVS shall repay (by remitting payment in the amount of the overpayment to the payor) the overpayment within forty (40) days of CVS identifying or learning of such overpayment, unless otherwise instructed by the payor. Further, CVS shall take any appropriate remedial steps within sixty (60) days of identification (or such additional time as may be agreed to by the payor) of an overpayment to correct any underlying

problem which has resulted in an overpayment, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the payor should be done in accordance with the payor's policies.

c. <u>Material Deficiencies</u>.

(i) Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves: 1) a substantial overpayment, or 2) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

- (ii) Reporting of Material Deficiencies. If CVS determines that a Material Deficiency has occurred, CVS shall notify the OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:
 - (1) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.E(2)(b), and shall include all of the information reported to the payor, as well as: (A) the payor's name, address, and contact person to whom the overpayment was sent; and (B) if applicable, the date of the check and identification number (or electronic transaction number) on which the overpayment was remitted to the applicable payor;
 - (2) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - (3) a description of CVS's actions taken to correct the Material Deficiency; and
 - (4) any further steps CVS plans to take to address the

Program, which consists of the CVS Ethics Line, to enable its employees to disclose, among other things, any issues or questions relating to the Federal health care programs or CVS's practices or procedures in connection with the Federal health care programs that the individual alleges to be improper. This disclosure shall be made to the CCO or some other person who is not in the reporting individual's chain of command. CVS shall continue to publicize the existence of this Confidential Disclosure Program to its employees.

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the CCO (or designee) shall gather information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The CCO (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 such a disclosure and ensure that proper follow-up is conducted.

The CCO (or designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received through the use of the Confidential Disclosure Program, the status of the respective investigations, and any corrective action taken in response to such investigation. The confidential disclosure log shall be available to the OIG for examination upon request, but only as to those log entries that relate to allegations received relating to the Federal health care programs or CVS's practices or procedures in connection with Federal health care programs (hereinafter, collectively, "Federal health care program allegations") or any alleged patient harm or abuse resulting from CVS's pharmacy practices (hereinafter, "patient harm allegations"). At such time as CVS makes the confidential disclosure log available for review by the OIG as specified above, it will also report to the OIG the following information (but only as it relates to those log entries other than those for Federal health care program allegations or patient harm

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allegations): the total number of disclosures received and included in the confidential disclosure log for such period, the general categories into which the disclosures fell (including, at a minimum, the following categories: personnel, loss prevention, controlled substance issues), the number of disclosures in each category, and a general description of how CVS followed up on the disclosures in each category. CVS is not required to provide log entries other than those for Federal health care program allegations or patient harm allegations when making the confidential disclosure log available to the OIG. When CVS provides access to the confidential disclosure log to the OIG as specified in this Section F, it shall provide the log to the OIG upon request as soon as is practicable, but no later than ten (10) business days from the date of the OIG request.

G. <u>Ineligible Persons</u>.

- (1) Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible.
- contractors any Ineligible Person in situations where those Ineligible Persons will be engaged in the delivery of prescription services or the preparation or submission of claims for payment for those services. To prevent hiring or contracting with any such Ineligible Person, CVS shall screen all prospective pharmacy/billing employees prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

CVS may perform its review of the Exclusion Lists with its own resources by performing individual searches. CVS may also choose to contract with a third party company for review of the Exclusion Lists. Either method chosen by CVS is acceptable and will satisfy its screening requirements under this CIA.

- Date of this CIA, CVS will review its list of current pharmacy/billing employees to ensure that none of them is an Ineligible Person. CVS may satisfy this obligation by comparing its list of pharmacy/billing employees against the Exclusion Lists. Thereafter, CVS will review its pharmacy/billing employee list once annually. If CVS has notice (through the use of the Exclusion Lists or other means) that a pharmacy/billing employee has become an Ineligible Person, CVS will remove such person from responsibility for, or involvement with, CVS business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, 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 into the Federal health care programs.
- (4) Pending Charges and Proposed Exclusions. If and when CVS has notice that a pharmacy/billing employee is indicted, charged by criminal information, or arrested by warrant for a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with CVS, CVS shall take all appropriate actions to ensure that the responsibilities of that employee or contractor shall not adversely affect the quality of care rendered to any beneficiary or patient or the accuracy of any claims submitted to any Federal health care program.
- M. Notification of Government Investigations/Proceedings. If CVS learns it is the subject of any ongoing government investigation or legal proceeding 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, CVS shall notify the OIG of this fact within forty-five (45) days of learning of it. (However, CVS shall not be required to report any information related to such investigation or proceeding if disclosure of that information to the OIG by CVS would violate any applicable order by a competent court or any subpoena or other legal requirement that prevents such disclosure.) The notification shall describe the allegation, identify the investigating or prosecuting agency, and describe the status of such investigation or legal proceeding. CVS shall also notify the OIG in writing within thirty (30) days of the resolution of the matter, and shall provide the OIG with

a description of the findings and/or results of the proceedings to the extent permitted by applicable law.

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, CVS agrees to grant certain inspection, audit and review rights to the OIG. The 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 onsite reviews for the purpose of verifying and evaluating: (i) CVS's compliance with the terms of this CIA; and (ii) CVS's compliance with the requirements of the Federal health care programs in which it participates. Upon the OIG's request, CVS will make available the documentation described above at all reasonable times during reasonable business hours for inspection, audit, review, or reproduction by the OIG or its duly authorized representative(s) or agent(s). Furthermore, for purposes of this provision, upon the OIG's request, the OIG or its duly authorized representative(s) or agent(s) may interview any of CVS's employees who consent to be interviewed at their place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG and CVS agrees to assist the OIG in contacting and arranging interviews with such employees upon the OIG's request. CVS employees may elect to be interviewed with or without a representative of CVS present.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within one hundred eighty (180) days after the Effective Date of this CIA, CVS shall submit a written report to the OIG summarizing the status of implementation of the requirements of this CIA (hereinafter, the "Implementation Report"). This Implementation Report shall include:

- (1) the name, address, phone number and position description of the CCO and the members of the EBCC required in Section III.A;
 - (2) a copy of the Code of Conduct required in Section III.B;
 - (3) an index of the Policies and Procedures required by Section III.C;
- (4) a description of the training initiatives undertaken pursuant to Section III.D and a copy of any training materials specifically generated to comply with CVS's training obligations under Section III.D(1) through (8);

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- (5) a certification by the CCO that:
- a. the Policies and Procedures required by Section III.C have been developed, are being implemented, and have been made available to the appropriate pharmacy/billing employees in accordance with Section III.C;
- b. all pharmacy/billing employees have completed the certifications required by Section III.B; and
- c. all appropriate pharmacy/billing employees have completed the training and the applicable Store Managers, Team Leaders, Regional Healthcare Managers, District Managers or Technician Trainers have executed the certification with regard thereto, each in accordance with and to the extent required by Section III.D;
- (6) the identity of the IRO and the proposed start and completion dates of the first reviews to be undertaken pursuant to Section III.E;
- (7) a summary/description of all current engagements between CVS and the IRO; a summary/description of all engagements between CVS and the IRO relating to the work of or issues examined by the IRO in connection with the Agreed Upon Procedures, and a certification from the IRO regarding its professional independence from CVS;
- (8) a description of the Confidential Disclosure Program implemented pursuant to Section III.F; and
- (9) a summary of personnel or contract actions (other than hiring) taken with regard to Ineligible Persons pursuant to Section III.G.

If any of the above-referenced materials were previously provided to the OIG, and the materials have not changed since the time they were supplied, the Implementation Report may so indicate and the materials need not be supplied again.

B. Annual Report.

Thereafter, CVS shall submit to the OIG an annual report within the timeframes specified below (hereinafter, an "Annual Report" or the "Annual Reports"), with respect to the status and findings of CVS's compliance activities for each subsequent one-year period beginning on the Effective Date. (The one-year period covered by each Annual Report shall be called the "Reporting Period.")

CVS Corporate Integrity Agreement

The Annual Reports shall include:

- (1) any change in the identity or position description of the CCO and EBCC described in Section III.A;
 - (2) a certification by the CCO that:
 - a. the Code of Conduct was distributed to all CVS employees who are pharmacy/billing employees, and, if any substantial changes were made to the Code of Conduct (as explained in Section III.B), CVS distributed such changes to its employees who are pharmacy/billing employees in accordance with the requirements of Section III.B as they relate to certification of any substantial changes to the Code of Conduct; and that such employees completed a certification as to substantial changes to the Code of Conduct required in Section III.B; and
 - b. all appropriate pharmacy/billing employees have completed the training in accordance with Section III.D and the applicable Store Managers, Team Leaders, Regional Healthcare Managers, District Managers or Technician Trainers have executed the certification with regard thereto, each in accordance with and to the extent required in Section III.D;
- (3) notification of any changes or amendments to the Policies and Procedures as they relate to the issue of the partial-fills and RTS Policy and the reason for any such change;
- (4) a complete copy of the final reports from the IAD and the IRO based on their reviews conducted pursuant to the IA Workplan and the Agreed Upon Procedures for the applicable 12-month period and any corrective action CVS plans to undertake or has undertaken in response to these reports;
- (5) a revised summary/description of all engagements between CVS and the IRO as described in Section V.A(7), if different from what was submitted as part of the Implementation Report;
- (6) a summary of any Material Deficiency discovered and reported throughout the course of the previous 12 months pursuant to Section III.E(2)(c)(ii) and the status of any corrective or preventative actions undertaken by CVS;
- (7) a report of the aggregate overpayments that have been returned to the Federal health care programs during the Reporting Period. These overpayment amounts should be

broken down into the following categories (to the extent CVS can identify the applicable payor): Medicare, Medicaid (report each applicable state separately) and other Federal health care programs, as applicable;

- (8) a summary of the disclosures received through the Confidential Disclosure Program that relate to Federal health care program allegations or patient harm allegations (as defined in Section III.F above);
- (9) a description of any personnel or contract action (other than hiring) taken by CVS as a result of the obligations set forth in Section III.G and the name, title, and responsibility of any person that falls within the ambit of Section III.G(4) and the actions taken in response to the obligations set forth in that Section;
- (10) pursuant to and in accordance with the requirements of Section III.H, a statement regarding any ongoing government investigation or legal proceeding with the government. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding, or requests for information; and
- (11) a description of the training required by Section III.D conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, percentage of attendance, a schedule of when the training sessions were held, and a copy of any training materials specifically generated to comply with CVS's training obligations under Section III.D(1) through (8)(to the extent not already provided).

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

C. Certifications.

The Implementation Report and Annual Reports shall include a certification by the CCO verifying that (1) except as otherwise described, CVS is in compliance with all of the requirements of this CIA, to the best of his or her knowledge, and (2) the CCO has reviewed the Implementation Report or Annual Report, as the case may be, has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise agreed by the OIG and CVS in writing subsequent to the Effective Date of this CIA, all notifications and reports required under the terms of this CIA shall be in writing and delivered to the following entities:

If to the OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General Office of Inspector General U.S. Department of Health and Human Services 330 Independence Avenue, SW Cohen Building, Room 5527 Washington, DC 20201 Phone 202.619.2078 Fax 202.205.0604

If to CVS:

CVS Corporation
One CVS Drive
Woonsocket, RI 02895
Attn: Zenon P. Lankowsky, Esq.
Vice President & General Counsel and Corporate Compliance Officer
Phone 401.765.1500, ext. 3550
Fax 401.765.7887

and (without duplication) to

CVS Corporation
One CVS Drive
Woonsocket, RI 02895
Attn: Corporate Compliance Officer
Phone 401.765.1500

and to

Charles H. Roistacher Powell, Goldstein, Frazer & Murphy LLP 1001 Pennsylvania Avenue, N.W. Suite 600 South Washington, D.C. 20004-2505 Phone 202.624-7218 Fax 202.624.7222 and to

Sara Kay Wheeler Powell, Goldstein, Frazer & Murphy LLP 191 Peachtree Street, N.E. 16th Floor Atlanta, Georgia 30303-1740 Phone 404.572.6905 Fax 404.572.6999

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified or registered mail and return receipt requested, overnight mail or delivery service, 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. DOCUMENT AND RECORD RETENTION

CVS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and relating to compliance with this CIA. CVS shall maintain these records for a period of one (1) year longer than the term of this CIA (or longer if otherwise required by law).

VIII. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify CVS prior to any release by the 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. Further, information provided under this CIA will be subject to all other applicable exemptions from public access contained in the applicable provisions of Subpart F of Part 5 of 45 C.F.R. With respect to such releases, CVS shall have the rights set forth at 45 C.F.R. Section 5.65(d). CVS shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as a waiver by CVS of CVS's attorney-client, work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect

CVS Corporate Integrity Agreement

CVS's obligation to comply with the provisions of this CIA.

IX. BREACH AND DEFAULT PROVISIONS

CVS shall be expected to fully and timely comply with all of the obligations to which it agrees in this CIA. Such compliance shall be expected throughout the compliance period required by this CIA.

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

As a contractual remedy, CVS and the OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter, the "Stipulated Penalties") in accordance with the following provisions:

- (1) A Stipulated Penalty of \$5,000 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS fails to have in place any of the following during the entire period beginning one hundred fifty (150) days after the Effective Date of this CIA and concluding at the end of the term of this CIA as provided in Section II above:
 - a. a compliance officer (the CCO);
 - b. a compliance committee (the EBCC);
 - c. a written Code of Conduct;
 - d. written Policies and Procedures;
 - e. training initiatives; and
 - f. a Confidential Disclosure Program.
- (2) A Stipulated Penalty of \$5,000 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS fails to meet any of the deadlines for submission of the Implementation Report and any Annual Report to the OIG.
- (3) A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day CVS employs or contracts, to CVS's knowledge, with an Ineligible Person and that person has responsibility for, or involvement with, CVS's business operations related to the Federal health care programs or is in a position for which the person's salary or the items or services rendered, 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 (the Stipulated Penalty described in this paragraph shall not apply for any

time period during which CVS can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry as described in Sections III.G(2) and (3) as to the status of the person).

- (4) A Stipulated Penalty of \$3,000 (which shall begin to accrue on the date CVS fails to grant reasonable access) for each day CVS fails to grant reasonable access to the information or documentation necessary to exercise the OIG's inspection, audit and review rights in accordance with Section IV of this CIA.
- (5) 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 retain an IRO, as required in Section III.E.
- (6) A Stipulated Penalty of \$1,000 for each day CVS fails to comply fully and adequately with any obligation of this CIA not already covered by Sections IX.A(1)-(5) above. In its notice to CVS, OIG shall state 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 must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue ten (10) days after the date that the OIG provides notice to CVS of CVS's failure to comply.)

B. Payment of Stipulated Penalties.

Obligations described in Section IX.A and determining that Stipulated Penalties are appropriate, the OIG shall notify CVS in accordance with Section VI of: (i) CVS's failure to comply and state the specific grounds for its determination that CVS has failed to comply with this CIA; and (ii) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within ten (10) days of CVS's receipt of the Demand Letter, CVS shall either: (i) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (ii) request a hearing before an HHS administrative law judge (hereinafter, "ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section IX.D.

In the event CVS elects to request an ALJ hearing, the Stipulated Penalties shall

continue to accrue until CVS cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allotted time period shall be considered a Material Breach of this CIA and shall be grounds for the OIG to impose the Material Breach penalty (as defined below).

- (2) Timely Written Requests for Extensions. CVS may submit a timely written request for an extension of time to perform any act or file a notification or report required by this CIA. Notwithstanding any other provision in this Section IX, if the OIG grants the timely written request an extension, Stipulated Penalties for failure to fulfill an obligation under this CIA shall not begin to accrue until one (1) day after CVS fails to meet the revised deadline granted by the extension. Notwithstanding any other provision in this Section IX, if the 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 two (2) business days after CVS receives the OIG's written denial of such a request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by the OIG at least five (5) 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.
- (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 the OIG at the address set forth in Section VI.
- (4) Independence from Material Breach Determination. Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that CVS has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in Section IX.C below.

C. Monetary Penalties for Material Breach of this CIA.

- (1) Material Breach Defined. A Material Breach of this CIA means:
- a. a failure by CVS to report a Material Deficiency, take corrective action, and pay all appropriate refunds, required by Section III.E(2)(c)(ii);
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in Section IX.A;

- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section IX.B above; or
- d. a failure to retain and use the IRO for review purposes in accordance with Section III.E.
- (2) Notice of Material Breach and Intent to Collect Material Breach Penalty. The parties agree that a Material Breach of this CIA by CVS constitutes grounds for the OIG to impose an enhanced stipulated penalty that is separate and apart from the Stipulated Penalties described above. This monetary penalty (hereinafter, the "Material Breach Penalty") shall be \$20,000 per day. Upon a determination by the OIG that CVS has materially breached this CIA and that a Material Breach Penalty should be imposed, the OIG shall notify CVS in accordance with Section VI of: (i) CVS's Material Breach and state the specific grounds for its determination that CVS has materially breached this CIA; and (ii) the OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach Letter").
- (3) Opportunity to Cure. CVS shall have thirty (30) days from the date of its receipt of the Notice of Material Breach Letter to demonstrate to the OIG's satisfaction that:
 - a. CVS is in full compliance with this CIA;
 - b. the alleged Material Breach has been cured; or
 - c. the alleged Material Breach cannot be cured within the thirty (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 the OIG a reasonable timetable for curing the Material Breach.
- (4) Penalty Letter. If at the conclusion of the thirty (30) day period, subject to any extension granted pursuant to Section IX.B(2), CVS fails to satisfy the requirements of Section IX.C(3), the OIG may impose the Material Breach Penalty on CVS and such Material Breach Penalty will begin to accrue on that day. The OIG will notify CVS in writing of its determination to impose the Material Breach Penalty (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within ten (10) days of its receipt of the Material Breach Penalty Letter, CVS shall either: (i) cure the Material Breach to the OIG's satisfaction and pay the applicable Material Breach Penalty; or (ii) request a

hearing before an ALJ to dispute the OIG's determination of Material Breach, pursuant to the agreed upon provisions set forth below in Section IX.D below. If CVS elects to request an ALJ hearing, the Material Breach Penalties shall continue to accrue until CVS cures, to OIG's satisfaction, the alleged Material Breach in dispute.

D. <u>Dispute Resolution</u>.

- (1) Review Rights. Upon the OIG's delivery to CVS of a Demand Letter or of a Material Breach Penalty Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligation of 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. § 1005 as if they applied to the Stipulated Penalties or Material Breach Penalties sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or Material Breach Penalties shall be subject to review by an ALJ and/or the Departmental Appeals Board (hereinafter, the "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 or Material Breach Penalties shall be made within ten (10) days of CVS's receipt of the Demand Letter and the request for a hearing involving a Material Breach shall be made within twenty-five (25) days of CVS's receipt of the Material Breach Penalty Letter.
- (2) Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (i) whether CVS was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (ii) 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. If the ALJ finds for the OIG with regard to whether there was a breach of this CIA and orders CVS to pay Stipulated Penalties, such Stipulated Penalties shall be due and payable twenty (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 twenty (20) days after the DAB issues its decision.

- (3) Material Breach Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for imposition of the Material Breach Penalty shall be:
 - a. whether CVS was in Material Breach of this CIA;
 - b. whether such breach was continuing on the date of the Material Breach Penalty Letter; and
 - c. whether the alleged Material Breach could not be cured within the thirty (30) day period, but (a) CVS timely began to take action the cure the Material Breach; (b) CVS pursued or is pursuing such action with due diligence; and (c) CVS has provided to the OIG a reasonable timetable for curing the Material Breach.

If CVS invokes the Dispute Resolution Procedures in this Section, the Material Breach Penalty shall be imposed only after an ALJ decision that is favorable to the OIG. If the ALJ sustains the determination of the OIG and determines that the imposition of the Material Breach Penalty is authorized, payment of the Material Breach Penalty will be required twenty (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 Material Breach Penalty shall become due and payable twenty (20) days after the DAB issues its decision.

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreements pursuant to which this CIA is entered, and into which this CIA is incorporated, CVS and the OIG agree as follows:

- (1) this CIA shall be binding on the successors, assigns, and transferees of CVS;
- (2) this CIA shall become final and binding on the Effective Date;
- (3) any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
- (4) 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.

ON BEHALF OF CVS CORPORATION

DATE

O717/01

ZENON P. LANKOWSKY, Esq.
Vice President & General Counsel, Corporate
Secretary and Corporate Compliance Officer
CVS Corporation

7 | 03 | 04

CHARLES H. ROISTACHER, Esq.
SARA KAY WHEELER, Esq.
CHARLENE L. McGINTY, Esq.
SUMMER H. MARTIN, Esq.
Attorneys for CVS Corporation
Powell, Goldstein, Frazer & Murphy LLP

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

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

Attachment "A"

CVS CORPORATION Internal Audit Workplan

I. Objective

To provide analysis that will enable CVS Corporation (hereinafter, "CVS") and the Office of Inspector General (hereinafter, "OIG") to determine whether CVS is in compliance with its Corporate Integrity Agreement (hereinafter, "CIA") and to determine whether CVS has taken the appropriate steps to comply with Medicare, Medicaid and other Federal health care programs.

II. Scope

- A. Compliance Audits -- Annually, IAD will perform procedures to verify compliance with certain specifics of the CIA, as more fully discussed in Section III below.
- B. Sampling Audits -- Monthly, IAD will randomly select statistically valid samples that will allow CVS to verify the adequacy of procedures for Partial Fills, Return to Stock and Dispensed as Written (hereinafter, "DAW") Code 1 for Federal health care program prescriptions. Following notification to and agreement by the OIG, sample sizes may be modified based on the results of the previous audit. IAD will review and file Workpapers and audit reports (either in electronic form or written form), as more fully discussed in Section IV below.

III. Compliance Audits

- A. Corporate Compliance Officer (hereinafter, "CCO") -- To verify that the CCO is functioning in a manner consistent with the terms of the CIA and meeting reporting obligations:
 - 1. Review Ethics and Business Conduct Committee agenda and minutes for the review period.
 - 2. Interview select individuals.
 - 3. Document observations and exceptions on workpapers.
- B. Ethics and Business Conduct Committee (hereinafter, "EBCC") -- To verify that the EBCC is functioning in a manner consistent with the terms of the CIA and meeting reporting obligations:
 - 1. Review EBCC agenda and minutes for the review period.
 - 2. Review Audit Committee agenda and minutes for the review period.

- 3. Review EBCC membership list for the review period.
- 4. Document observations and exceptions on workpapers.
- C. Code of Conduct -- To verify that the CVS Code of Conduct is functioning in a manner consistent with the terms of the CIA:
 - 1. Review the Code of Conduct to verify that it sets forth the minimum requirements delineated in the CIA.
 - 2. Review the CVS Code of Conduct Corporate Exceptions Report to verify that CVS employees who are pharmacy/billing employees (as such term is defined in the CIA) are completing the required Code of Conduct certifications in accordance with the CIA.
 - a) Select a sample of pharmacy/billing employees to review.
 - b) For individuals selected, verify certification or recertification documentation is proper.
 - 3. Review vendor correspondence to verify that any contractors who are pharmacy/billing employees and have been engaged by CVS to prepare and/or submit, or assist in the preparation and/or submission of, claims for pharmacy services to any Federal health care programs in CVS facilities or on CVS premises, are informed of CVS's obligations under the CIA applicable to such contractors' provision of services to CVS and that such contractors must abide by such obligations, as well as any applicable provisions of law, as a condition of providing services to CVS.
 - 4. Review vendor certifications to verify that any contractors who are pharmacy/billing employees and have been engaged by CVS to prepare and/or submit, or assist in the preparation and/or submission of, claims for pharmacy services to any Federal health care programs in CVS facilities or on CVS premises are completing the required certifications in accordance with the CIA.
 - 5. Document observations and exceptions on workpapers.
- D. Policies and Procedures -- To verify that CVS Policies and Procedures are functioning in a manner consistent with the terms of the CIA and Federal health care program requirements:
 - 1. Review selected policies and procedures to verify that they address the categories delineated in the CIA.

- 2. Review billing policies and procedures to verify that they address the manner in which CVS shall submit claims to Federal health care programs for partial-fill prescriptions and the CVS return to stock policy, as required in the CIA.
- 3. Review the record retention policy to verify that it complies with the requirements of the CIA.
- 4. Review the overpayment policy to verify that it complies with the requirements of the CIA.
- 5. Document observations and exceptions on workpapers.
- E. Training Initiatives -- To verify that CVS CIA training initiatives are functioning in a manner consistent with the terms of the CIA:
 - 1. Review the relevant training materials, policies, and other compilations required by the CIA to verify that such material includes the content required in the CIA.
 - 2. Review the CVS Training Certification Exceptions Report to verify that pharmacy/billing employees who provide services in CVS facilities or on CVS premises are completing the required certifications in accordance with the CIA.
 - a) Select a sample of employees to review.
 - b) For individuals selected, verify certification documentation is proper.
 - 3. Review CVS policies and procedures to verify that CVS policy requires the work of new pharmacy/billing employees, to the extent that such work relates to the preparation or submission of claims for reimbursement from any Federal health care program, is reviewed by pharmacy/billing employees who have received training until the new pharmacy/billing employee completes the training required by the CIA.
 - 4. Document observations and exceptions on workpapers.
- F. Audit Procedures -- To verify that CVS audit procedures are functioning in a manner consistent with the terms of the CIA:
 - 1. Review the reconciliation process to verify that identified overpayments to Federal health care programs are repaid in accordance with the CIA.
 - 2. Review any notifications made to the OIG concerning Material Deficiencies (as such term is defined in the CIA) to verify that such notifications are completed as required in the CIA.
 - 3. Document observations and exceptions on workpapers.

- G. Confidential Disclosure Program -- To verify that the Confidential Disclosure Program (The CVS Ethics Line) is functioning in a manner consistent with the terms of the CIA:
 - 1. Review the Confidential Disclosure Program to verify that the policy is current and meets the requirements of the CIA.
 - 2. Review materials distributed and made available to CVS employees to verify that CVS maintains procedures to notify employees of the existence of the Confidential Disclosure Program.
 - 3. Review the Confidential Disclosure Program log to verify that:
 - a) log entries are kept, including log entries related to Federal health care program allegations and patient harm allegations;
 - b) the nature of the call is documented completely and classified properly;
 - c) follow-up is completed; and
 - d) remedial action is taken as outlined in the CIA.
 - 4. Document observations and exceptions on workpapers.
- H. Ineligible Persons -- To verify that the ineligible persons screening, review, and removal procedures are functioning in a manner consistent with the terms of the CIA:
 - 1. Review all applicable excluded individuals' documentation to verify that pharmacy/billing employees are checked against the General Service Administration and HHS/OIG lists of excluded individuals and entities and that any ineligible persons (as such term is defined in the CIA) are removed from any position or responsibilities, as required in the CIA.
 - 2. Review application for pharmacy/billing employees to verify that it requires applicants to disclose whether they are ineligible persons.
 - 3. Review any actions pursued by CVS when CVS has notice that a pharmacy/billing employee is indicted, charged by criminal information, or arrested by warrant for a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with CVS, to verify that CVS has taken all appropriate actions as required in the CIA.
 - 4. Document observations and exceptions on workpapers.

- I. Notification of Government Investigations/Proceedings -- To verify that reporting obligations are met in a manner consistent with the terms of the CIA:
 - 1. Review any notifications to the OIG concerning any ongoing government investigation or legal proceeding 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 to verify that such notifications are completed as required in the CIA.
 - 2. Verify through appropriate methods that all notifications required to have been made to the OIG in accordance with Section III.H of the CIA were, in fact, made.
 - 3. Document observations and exceptions on workpapers.

IV. Sampling Audits

- A. Partial Fills -- In this sample, CVS will determine: "How many Federal health care program Partial Fill prescription deviations will there be in the population of Federal health care program prescriptions and what is the dollar value of those deviations?" For purposes of this Partial Fill sample, a deviation consists of a Federal health care program Partial Fill prescription transaction where CVS billed the Federal health care program in a manner inconsistent with CVS policy. In this audit procedure, IAD will use a statistically valid random sampling technique. This audit procedure will be performed at CVS headquarters with no store pharmacy involvement provided that all relevant and appropriate information and documentation required for the audit is available at the CVS headquarters.
 - 1. Monthly, capture Federal health care program Partial Fill prescription history, from the data warehouse, from the point the prescriptions are filled as cash to when they are reimbursed by a Federal health care program using the following steps.
 - a) Identify prescription numbers that change from cash to a Federal health care program condor code.
 - b) Compare the dispensed quantity from the cash transaction to the quantity dispensed from the Federal health care program transaction.
 - c) If the dispensed quantity of the cash transaction is less than the dispensed quantity of the Federal healthcare program transaction, consider the prescription a Federal health care program Partial Fill prescription.
 - 2. Monthly, randomly select a sample of 250 Federal health care program Partial Fill prescriptions from the prescriptions identified in Step 1 above. This sample

shall be selected through the use of RAT-STATS "Random Numbers" function.

- a) Capture the billing history from the data warehouse.
- b) Verify that CVS has not billed in a manner inconsistent with CVS policy.
- c) Document observations and deviations on Workpapers.
- 3. Monthly, quantify the dollar value of deviations. Probable dollar exposure will be computed by multiplying the average dollar error per sample unit by the number of sample units in the total population.
- B. Return to Stock -- In this sample, CVS will determine: "How many Federal health care program cancellation prescription reimbursement deviations will there be in the population of Federal health care program prescriptions and what is the dollar value of those deviations?" For purposes of this Return to Stock sample, a deviation consists of a Federal health care program cancellation prescription where CVS failed to reconcile with a Federal health care program according to the CVS Reconciliation Process. In this audit procedure, IAD will use a statistically valid random sampling technique. This audit procedure will be performed at CVS headquarters with no store pharmacy involvement provided that all relevant and appropriate information and documentation required for the audit is available at the CVS headquarters.
 - 1. Monthly, identify Federal health care program cancellation prescriptions, which include return to stock prescriptions, from the data warehouse. Filter out instances where the co-pay is equal to or greater than the billed amount (in these cases no money was billed to the Federal health care program).
 - 2. Monthly, randomly select a sample of 30 Federal health care program cancellation prescriptions from the prescriptions identified in Step 1 above. This sample shall be selected through the use of RAT-STATS "Random Numbers" function.
 - a) Capture the billing history from the data warehouse.
 - b) Verify that the cancellation prescription was reconciled according to the CVS Reconciliation Process.
 - c) Document observations and deviations on Workpapers.
 - 3. Monthly, quantify the dollar value of deviations. Probable dollar exposure will be computed by multiplying the average dollar error per sample unit by the number of sample units in the total population.

- C. Dispensed as Written (DAW) Code 1 (brand) -- In this sample, CVS will determine: "How many DAW Code 1 (brand) Federal health care program prescription deviations will there be in the population of Federal health care program prescriptions and what is the dollar value of those deviations?" In this audit procedure, IAD will use a statistically valid random sampling technique. This audit procedure will be performed at CVS headquarters with follow-up at the applicable store pharmacy.
 - 1. Monthly, extract DAW 1 Federal health care program prescriptions from the data warehouse.
 - 2. Monthly, randomly select a sample of 30 DAW 1 Federal health care program prescriptions from the prescriptions identified in Step 1 above. This sample shall be selected through use of RAT-STATS "Random Numbers" function.
 - a) Identify each DAW 1 Federal health care program prescription where a generic is available.
 - b) If a generic is available, call the applicable store pharmacy and ask the pharmacist to fax a hard copy of the prescription to IAD.
 - c) Verify that the brand has been dispensed in compliance with regulations.
 - d) Document observations and deviations on Workpapers.
 - 3. Monthly, quantify the dollar value of deviations. Probable dollar exposure will be computed by multiplying the average dollar error per sample unit by the number of sample units in the total population.

Attachment "B"

CVS Corporation Agreed Upon Procedures Year 1

I. Objective

To define procedures that will be followed by an Independent Review Organization (hereinafter, "IRO") that contracts with CVS to conduct agreed upon procedures to provide analysis and report findings to assist CVS Corporation (hereinafter, "CVS") management and the Office of Inspector General (hereinafter, "OIG") in evaluating whether CVS: 1) is in compliance with the terms of the CIA and 2) has taken appropriate steps to ensure that its claims submissions to Federal health care programs comply with applicable requirements.

II. Scope

- A. Compliance Audits Review Annually, the IRO will perform procedures to verify the compliance of CVS's Internal Audit Department (hereinafter, "IAD") with the Compliance Audits, as set forth in the IA Workplan (as such term is defined in the CIA), and to monitor the effectiveness of CVS's Compliance Program consistent with the requirements of the CIA, as more fully discussed in Section III below.
- B. Sampling Audits Review Annually, the IRO will perform procedures to verify IAD's compliance with the Sampling Audits, as set forth in the IA Workplan, and to monitor CVS's claims submissions to Federal health care programs, as more fully discussed in Section IV below.

III. Compliance Audits Review

- A. Verify that IAD is performing annual Compliance Audits to monitor CVS's compliance with the terms of the CIA using the following steps:
 - 1. Obtain the IA Workplan and IAD's annual Compliance Audits workpapers and reports.
 - 2. Verify that IA Workplan procedures for Compliance Audits address all sections of the CIA.
 - 3. Verify that IAD's Compliance Audits workpapers document procedures performed and findings regarding CVS's compliance with the terms of the CIA.
 - 4. Document observations and exceptions on workpapers.

- B. Monitor CVS's Compliance Program for compliance with requirements of the CIA using the following steps:
 - 1. Compliance Officer ("CCO")
 - a) To verify that the CCO maintains the position, chairs the Ethics and Business Conduct Committee ("EBCC"), and that the required roles and responsibilities of the CCO are being met pursuant to CIA requirements:
 - i) Review EBCC agenda and minutes.
 - ii) Review the IAD Compliance Audits workpapers.
 - iii) Interview the CCO.
 - b) Review EBCC minutes for the review period and verify that the CCO is, at least quarterly, reporting on compliance matters to the EBCC as required in the CIA.
 - c) Verify, if applicable, notification to OIG naming any newly appointed CCO.
 - d) Document observations and exceptions on workpapers.
 - 2. Ethics and Business Conduct Committee
 - a) Review minutes of the most recent EBCC meeting to verify that departments were represented as required under the CIA, that CCO was in attendance or meeting documentation was maintained for review by the CCO, and that issues discussed were documented for follow-up.
 - b) Review IAD Compliance Audits workpapers to verify that compliance reporting requirements are being met as required in the CIA.
 - c) Review current EBCC membership list to verify that the current membership at a minimum includes the persons in the positions stated in the CIA or comparable officers or titles pursuant to CIA requirements.
 - d) Document observations and exceptions on workpapers.

3. Code of Conduct

- a) Verify that Code of Conduct was developed and implemented within 120 days of the Effective Date of the CIA.
- b) Verify that the Code of Conduct at least sets forth the minimum requirements delineated in the CIA.
- c) To verify that CVS employees who are pharmacy/billing employees (as such term in defined in the CIA) are completing the required Code of Conduct certifications in accordance with the CIA:
 - i) Review IAD Compliance Audits workpapers.
 - ii) Review CVS Code of Conduct Corporate Exception Report.
- d) If applicable, to verify that CVS employees who are pharmacy/billing employees are completing the required Code of Conduct certifications in accordance with the CIA if any substantial changes were made to the Code of Conduct within the review period:
 - i) Review IAD Compliance Audits workpapers
 - ii) Review CVS Code of Conduct Corporate Exception Report
- e) Document observations and exceptions on workpapers.

4. Policies and Procedures

- a) To verify that the policies and procedures listed in the Implementation Report, at a minimum, address the manner in which CVS shall submit claims to Federal health care programs for prescriptions that were only partially filled (as defined in the CIA) and CVS's return to stock policy, pursuant to CIA requirements:
 - i) Review the index of the applicable Policies and Procedures provided to the OIG as part of the Implementation Report required pursuant to the CIA.
 - ii) Review IAD Compliance Audits workpapers.
- b) Document observations and exceptions on workpapers.

5. Training Initiatives

a) Obtain relevant training materials, policies, and other compilations

required by the CIA and verify that such materials exist and include the content as required in the CIA.

- b) To verify that training was provided in accordance with the requirements of the CIA and that the required certifications for pharmacy/billing employees who provide services in CVS facilities or on CVS premises were completed in accordance with the CIA:
 - i) Review IAD Compliance Audits Workpapers.
 - ii) Review CVS Training Certification Exceptions Report.
- c) Document observations and exceptions on workpapers.

6. Audits and Disclosures

- a) See Section IV below for Sampling Audit Reviews
- b) Review IAD Compliance Audit workpapers to verify that any Material Deficiencies (as such term is defined in the CIA and as determined by CVS) are reported to the OIG as required by the CIA.
- c) Document observations and exceptions on workpapers.

7. Confidential Disclosure Program

- a) Verify that the Confidential Disclosure Program (as set forth and defined in the CIA) includes procedures for non-retribution, non-retaliation, and reporting mechanisms for anonymous, confidential communication.
- b) Verify that the hotline number is operational.
- c) Review IAD Compliance Audits workpapers to verify that CVS maintains procedures to notify employees of the existence of the Confidential Disclosure Program:
- d) Review IAD Compliance Audits workpapers to verify that disclosures were followed up on in accordance with the requirements of the CIA.
- e) Document observations and exceptions on workpapers.

8. Ineligible Persons

a) Review IAD Compliance Audits workpapers to verify the existence

- of policies and procedures to fulfill the CIA screening requirements for prospective pharmacy/billing employees.
- b) Review IAD Compliance Audits workpapers to verify that pharmacy/billing employees were screened in accordance with the requirements of the CIA.
- c) Review IAD Compliance Audits workpapers to verify that any cases where CVS had notice that a pharmacy/billing employee has become an Ineligible Person (as such term is defined in the CIA), CVS acted in accordance with the requirements of the CIA.
- d) Document observations and exceptions on workpapers.
- 9. Notification of Government Investigations/Proceedings
 - a) Review IAD Compliance Audits workpapers to verify that any ongoing government investigation or legal proceeding, as described in the CIA, is reported to the OIG as required in the CIA.
 - b) Document observations and exceptions on workpapers.

10. Implementation Report

Review the Implementation Report to verify that the report was submitted within 180 days after the Effective Date of the CIA and includes the content required in the CIA.

C. Prepare an annual report summarizing all findings and provide a copy of the annual report to CVS.

IV. Sampling Audits Review

- A. Verify that IAD is performing annual Sampling Audits to monitor the adequacy of procedures for claims submissions to Federal health care programs using the following steps:
 - 1. Obtain the IA Workplan and IAD's annual Sampling Audits workpapers and reports.
 - 2. Verify that IA Workplan procedures for Sampling Audits address CVS's claims submissions to Federal health care programs to determine compliance with applicable CVS policy, including a review of partial fills, return to stock, and dispense as written ("DAW") Code 1.

- 3. Verify IAD's Sampling Audits workpapers document procedures performed and findings regarding CVS's compliance with applicable CVS policy for Federal health care program prescription claim submissions.
- 4. Document observations and exceptions on workpapers.
- E. Verify IAD's Sampling Audits workpapers document procedures performed and findings regarding CVS's claims submissions to Federal health care programs using the following steps:

1. Partial Fills

- a) On a quarterly basis, obtain a summary report of the monthly audits done for that quarter and verify that the required monthly audits are being completed as stated in the CIA.
- b) Annually verify the validity of the statistical sample used to select Federal health care program Partial Fill prescriptions.
- c) Annually, verify that the work performed is documented in the workpapers.
- d) Annually, verify the calculation of the average dollar error per sample unit and the dollar value of deviations.
- e) Document observations and exceptions on workpapers.

6. Return to Stock

- a) On a quarterly basis, obtain a summary report of the monthly audits done for that quarter and verify that the required monthly audits are being completed as stated in the CIA.
- b) Annually, verify the validity of the statistical sample used to select Federal health care program cancellation prescriptions.
- c) Annually, verify that the work performed is documented in the workpapers.
- d) Annually, verify the calculation of the average dollar error per sample unit and the dollar value of deviations.
- e) Document observations and exceptions on workpapers.
- 6. Dispense As Written Code 1 (brand)

- a) On a quarterly basis, obtain a summary report of the monthly audits done for that quarter and verify that the required monthly audits are being completed as stated in the CIA.
- b) Annually, verify the validity of the statistical sample used to select DAW Code 1 (brand) Federal health care program prescriptions.
- c) Annually, verify that the work performed is documented in the workpapers.
- d) Annually, verify the calculation of the average dollar error per sample unit and the dollar value of deviations.
- e) Document observations and exceptions on workpapers.
- C. Prepare an annual report summarizing all findings and provide a copy of the annual report to CVS.