

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE
OFFICE OF INSPECTOR GENERAL OF THE
OFFICE OF PERSONNEL MANAGEMENT
AND
MEDCO HEALTH SOLUTIONS, INC.**

I. PREAMBLE

Medco Health Solutions, Inc. (Medco) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General of the United States Department of Health and Human Services (HHS-OIG) and the Office of Inspector General of the United States Office of Personnel Management (OPM-OIG) (collectively referred to as "OIG") to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), and the Federal Employees Health Benefits Program (FEHBP) administered under the Federal Employees Health Benefits Act, 5 U.S.C. § 8901-8914 (all of which are collectively referred to as "Covered Federal Programs").

Contemporaneously with this CIA, Medco is entering into three Settlement Agreements with the United States (collectively the "Settlement Agreements.") Medco represents that prior to the Effective Date of the CIA (as defined in Section II. A below), Medco had established a voluntary compliance program (the "Voluntary Compliance Program") which included, among other things, the appointment of a Compliance Officer, the appointment of a Compliance Committee, the development and dissemination of a Code of Conduct, the establishment of a toll-free number for employees to report potential violations of Covered Federal Program requirements, the establishment of written policies and procedures, screening measures for Ineligible Persons (as defined in Section III.G.1.a below), regular training to all employees, including Covered Persons, concerning Medco's Code of Conduct, regular training to all employees, including Covered Persons (as defined in Section II.C.3 below, and various training and auditing programs.

Medco represents that its Voluntary Compliance Program is aimed at Medco's goal of promoting high ethical standards in the conduct of Medco's business practices. Medco agrees to continue the operation of its Voluntary Compliance Program in accordance with the terms set forth below during the term of this CIA. Medco may modify its Voluntary Compliance Program as appropriate (subject to the terms of this CIA), but shall ensure that during the term of this CIA it complies with the obligations of Medco set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Medco under this CIA shall be 5 years from the Effective Date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (the "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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Medco's final Annual Report; or (2) any additional materials submitted by Medco pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Arrangements" shall mean every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Medco and any actual or potential source of health care business or referrals to Medco or any actual or potential source of health care business or referrals from Medco. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Covered Federal Program.

2. "Focus Arrangements" means all Arrangements:
 - a. Under which compensation or remuneration is received by Medco from or on behalf of a pharmaceutical manufacturer, including but not limited to, rebates, regardless of how categorized, market share incentives, commissions, fees under products and services agreements, fees received for sales of utilization data and administrative or management fees but specifically does not include purchase discounts based upon invoiced purchase terms;
 - b. That are between Medco and a client where "client" shall mean any governmental entity, employer, insurer, union or other entity that contracts with Medco to provide or administer a pharmacy benefit for such plan and its members or participants (hereinafter referred to as "Client Plans"); or
 - c. That are between Medco and a broker or other agent engaged by Medco to perform services on its behalf.
3. "Covered Persons" includes:
 - a. all officers, directors, and employees of Medco;
 - b. all agents engaged by Medco to perform functions related to: (1) the marketing of items or services reimbursable by Covered Federal Programs on behalf of Medco; or (2) the negotiation, development, approval, management, review or implementation of Medco's Arrangements on behalf of Medco; and
 - c. all contractors or other persons engaged by Medco to provide pharmacy patient services, where pharmacy patient services is defined as having direct patient contact or processing of a prescription from receipt to shipping.

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.

4. “Covered Contractors” includes all contractors, who are not otherwise Covered Persons, engaged by Medco to perform functions related to the negotiation, development, approval, management, review or implementation of Medco’s Arrangements on behalf of Medco.
5. “Relevant Covered Persons” means a Covered Person employed or engaged by Medco who is involved with the negotiation, development, approval, management, review or implementation of Medco’s Arrangements identified in Section II.C above on behalf of Medco.

III. CORPORATE INTEGRITY OBLIGATIONS

Medco shall maintain a compliance program (the “Compliance Program”) that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* To the extent not already accomplished, within 90 days after the Effective Date, Medco shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for overseeing a staff that develop and implement policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Covered Federal Program requirements. The Compliance Officer shall be a member of senior management of Medco, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of Medco and shall be authorized to report on such matters directly to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for managing a compliance department that shall monitor the day-to-day compliance activities engaged in by Medco as well as for any reporting obligations created under this CIA.

Medco shall report to HHS-OIG, in writing, any changes in the identity of or any material changes in the 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 after such a change.

2. *Compliance Committee.* To the extent not already accomplished, within 90 days after the Effective Date, Medco shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as client and account services, human resources, audit and operations, and legal). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Medco shall report to HHS-OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, within 120 days after the Effective Date, Medco shall distribute a written Code of Conduct to all Covered Persons. Medco shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. Distribution may include publishing the Code of Conduct on Medco's intranet or other internal web site available to all of its employees and Covered Persons. If Medco uses such an electronic distribution method, it must notify the individuals of the distribution of the Code of Conduct in that manner and it must monitor the distribution to ensure that all appropriate individuals receive the revised Code of Conduct. The Code of Conduct shall, at a minimum, set forth:

- a. Medco's commitment to full compliance with all Covered Federal Program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

- b. Medco's requirement that all of its Covered Persons shall be expected to comply with all applicable Covered Federal Program requirements and with Medco'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 Medco's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Medco, suspected violations of any Covered Federal Program requirements or of Medco's own Policies and Procedures;
- d. the possible consequences to both Medco and Covered Persons of failure to comply with Covered Federal Program requirements and with Medco'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 Medco's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to disclosures made under the Disclosure Program.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Medco'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 90 days after the Effective Date, whichever is later.

Medco shall make available to each Covered Contractor, either through a contract attachment, posting on its web site or by other reasonable means, a copy of Medco's Code of Conduct, and shall confirm that the Covered Contractor has its own comparable compliance program. Medco shall request that the Covered Contractor make available a copy of the Medco Code of Conduct to its employees and/or agents who it believes are reasonably expected to provide Covered Contractor services to Medco for more than 160 hours each calendar year.

Medco shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any materially revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. In the case of a material change to the Code of Conduct, 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 materially revised Code of Conduct.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Medco shall implement written policies and procedures regarding the operation of Medco's compliance program and its compliance with Covered Federal Program requirements (collectively "Policies and Procedures"). 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. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute); 42 U.S.C. § 1395nn (Stark Law); 41 U.S.C. § 51 *et seq.* (Public Contract Anti-Kickback Act); 31 U.S.C. §§ 3729-3733 (False Claims Act), 18 U.S.C. § 666 (Theft or Bribery Concerning Programs Receiving Federal Funds); and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Covered Federal Program business in violation of any of these statutes;
- c. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law), including but not limited to the Focus Arrangements Database (as defined in section III.D.1.a below), the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals;

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered

Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Distribution may include publishing the Policies and Procedures on Medco's intranet or other internal web site available to all of its employees and Covered Persons. If Medco uses such an electronic distribution method, it must notify the individuals of the distribution of the Policies and Procedures in that manner and it must monitor the distribution to ensure that all appropriate individuals receive the revised Policies and Procedures.

At least annually (and more frequently, if appropriate), Medco shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures at issue.

C. Training and Education.

Medco represents that prior to the Effective Date, Medco had established compliance training programs for its Covered Persons and agrees that it shall continue to conduct appropriate training programs that meet the requirements of this CIA.

Medco represents that it provides training on a regular basis concerning a variety of topics to its employees. The training required by this CIA need not be separate and distinct from the regular training provided by Medco, but instead may be integrated fully into such regular training provided, however, that the training satisfies the requirements set forth in this CIA. The Compliance Officer shall be responsible for determining how many of the hours of regular training shall be credited toward the General and Arrangements Training requirements set forth in this Section III.C.

To the extent that Medco has provided training that satisfies the General or Arrangements Training requirements set forth below within one hundred eighty (180) days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying Medco's training obligations for the first Reporting Period of the CIA. For purpose of the General Training requirements, if Medco provided General Training that satisfies the requirements set forth in Section III.C. 1 below to Covered Person within 180 days prior to the Effective Date, Medco may satisfy its remaining General Training

obligation for the first Reporting Period by notifying those Covered Persons of the fact that Medco entered a CIA and notifying them in detail of Medco's requirements and obligations under the CIA.

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

- a. CIA requirements; and
- b. Medco's 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 90 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. *Arrangements Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute, the Stark Law, or the Public Contract Anti-Kickback Act, as well as the regulations and other guidance documents related to these statutes;
- b. Medco's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Focus Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of this CIA;
- c. the personal obligation of each Relevant Covered Person to know the applicable legal requirements and Medco's Policies and Procedures;

- d. the legal sanctions under the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and the Stark Law; and
- e. examples of violations of the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and the Stark Law.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. (To the extent a Relevant Covered Person is on a leave of absence when the training is provided, such Relevant Covered Person shall receive the Arrangements Training within 30 days after the conclusion of the leave of absence.) A Medco employee who has completed the Arrangements Training shall review a new Relevant Covered Person's work until such time as the new Relevant Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Relevant Covered Person shall receive at least two hours of Arrangements Training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These certifications 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.* Medco shall annually review the training, and, where appropriate, update the training to reflect changes in Covered Federal Program requirements, any issues discovered during internal audits or the Focus Arrangements Review, Unallowable Cost Review if applicable, and any other relevant information.

6. *Computer-based Training.* Medco may provide the training required under this CIA through appropriate computer-based training approaches. In that event, all applicable references to "hours" in this Section shall mean "normative hours" as that term is used in the computer-based training industry. If Medco 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. Compliance with the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law.

1. *Arrangements Procedures.* Within 90 days after the Effective Date, Medco shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute, the Stark Law, and/or the Public Contract Anti-Kickback Act, or the regulations, directives, and guidance related to these statutes (“Arrangements Procedures”). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Focus Arrangements that shall contain the information specified in Appendix A (“Focus Arrangements Database”);
- b. tracking remuneration to and from all parties to each Focus Arrangement;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangements are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process, where applicable, for all Arrangements, including but not limited to a legal review of Focus Arrangements by counsel with expertise in the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law, and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-

Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law;

- f. requiring the Compliance Officer to review the Focus Arrangements Database, the internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and
- g. implementing effective responses when suspected violations of the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Focus Arrangements.* Prior to entering into new Focus Arrangements or any amendment to an existing Focus Arrangement in which new terms and conditions (other than pricing terms and renewal dates) are negotiated and documented, in addition to complying with the Arrangements Procedures set forth above, Medco shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by Medco and the other parties to the Focus Arrangement;
- b. Include in the written agreement a requirement that all individuals employed or engaged by the other parties and who meet the definition of Covered Persons shall comply with Medco's Compliance Program, including the training related to the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and the Stark Law. Additionally, Medco shall provide each party to the Focus Arrangement with access to its Code of Conduct and Policies and Procedures related to the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and the Stark Law; and
- c. Include in the written agreement a statement by the parties to the Focus Arrangement that the parties shall not violate the Anti-

Kickback Statute, the Public Contract Anti-Kickback Act, and the Stark Law with respect to the performance of the Focus Arrangement.

3. *Records Retention and Access.* Medco shall retain and make available to OIG, upon request, the Focus Arrangements Database, all supporting documentation of the Focus Arrangements subject to this Section III.D and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures.

1. *General Description:*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Medco shall engage an individual or entity (or entities), such as an accounting, auditing, law or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the following reviews: (i) a review to assist Medco in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Focus Arrangements Review), and (ii) if applicable, a review to analyze whether Medco sought payment for certain unallowable costs (Unallowable Cost Review). The IRO engaged by Medco to perform the Unallowable Costs Review shall have expertise in the cost reporting requirements applicable to Medco and in the general requirements of the Covered Federal Program(s) from which Medco seeks reimbursement.

Each IRO shall assess, along with Medco, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Focus Arrangements Review shall not be deemed to create an attorney-client relationship between Medco and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix B to this CIA, which is incorporated by reference.

- b. *Frequency of Focus Arrangements Review.* The Focus Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Focus Arrangements Review.
- c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.
- d. *Retention of Records.* The IRO and Medco shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Medco) related to the Focus Arrangement Reviews and Unallowable Cost Reviews (if applicable) for a period of six years after the Effective Date.
- e. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Medco's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Covered Federal Program, including, but not limited to, the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and/or the Stark Law.

2. *Focus Arrangements Review.* The IRO shall perform a review to assess whether Medco is complying with the Arrangements Procedures and Focus Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The Focus Arrangements Review shall consist of the IRO randomly selecting a sample of 25 Focus Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Medco has implemented the Arrangements Procedures and, for each selected Focus Arrangement, the IRO shall assess whether Medco has complied with the Arrangements Procedures and Focus Arrangements Requirements specifically with respect to that Focus Arrangement.

The IRO's assessment of the Focus Arrangements sample shall include, but is not limited to (a) verifying that the Focus Arrangement is listed in the Focus Arrangements Database; (b) verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately

documented; (c) verifying that the remuneration related to the Focus Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (f) verifying that the Compliance Officer is reviewing the Focus Arrangements Database, the internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law are discovered; and (h) verifying that Medco has met the requirements of Section III.D.2.

3. *Focus Arrangements Review Report.* The IRO shall prepare a report based upon the Focus Arrangements Review performed (“Focus Arrangements Review Report”). The Focus Arrangements Review Report shall include the IRO’s findings with respect to (a) whether Medco has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Medco has complied with the Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Focus Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to Medco’s policies, procedures, and systems in place to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law.

4. *Unallowable Cost Review.* If applicable, the IRO shall conduct a review of Medco’s compliance with the unallowable cost provisions of the Settlement Agreements. The IRO shall determine whether Medco has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreements) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Medco or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or

financial statements from the year in which the Settlement Agreement were executed, as well as from previous years.

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

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

Prior to initiating a Validation Review, HHS-OIG shall notify Medco of its intent to do so and provide a written explanation of why HHS-OIG believes such a review is necessary. To resolve any concerns raised by HHS-OIG, Medco may request a meeting with HHS-OIG to: (a) discuss the results of any Focus Arrangements Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Focus Arrangements Review or Unallowable Cost Review or to correct the inaccuracy of the Focus Arrangements Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Medco agrees to provide any additional information as may be requested by HHS-OIG under this Section in an expedited manner. HHS-OIG will attempt in good faith to resolve any Focus Arrangements Review or Unallowable Cost Review issues with Medco 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 HHS-OIG.

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

F. Disclosure Program.

Medco represents that it has established and shall continue to maintain 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 Medco's policies, conduct, practices, or procedures with respect to a Covered Federal Program believed by the individual to be a potential violation of criminal, civil, or administrative law. Medco shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas, including on Medco's intranet or internal website available to all employees).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure associated with Medco's policies, conduct, practices or procedures with respect to any Covered Federal Program (each 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, Medco 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.

G. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Covered Federal 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://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).
- c. “Screened Persons” include:
 - i. prospective and current owners (other than shareholders who: (A) have an ownership interest of less than 5%; and (B) acquired the ownership interest through public trading);

