

**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);

- ii. prospective and current Covered Persons; and
- iii. prospective and current Covered Contractors.

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

- a. Medco shall screen or cause to be screened all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Screened Persons to disclose whether they are Ineligible Persons.
- b. Medco shall screen all Screened Persons against the Exclusion Lists within 90 days of the Effective Date and on an annual basis thereafter.
- c. Medco shall implement a policy requiring all Screened Persons to disclose immediately to Medco any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If Medco has actual notice that a Screened Person has become an Ineligible Person, Medco shall remove such person from responsibility for, or involvement with, Medco's business operations related to the Covered Federal Programs and shall remove such person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Covered Federal Programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Covered Federal Programs.

4. *Pending Charges and Proposed Exclusions or Debarments.* If Medco has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or 5 U.S.C. § 8902a or is

proposed for exclusion, suspension, or debarment during his or her employment or contract term, Medco shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Covered Federal Program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at Medco's corporate headquarters in New Jersey, Medco shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Medco conducted or brought by a governmental entity or its agents involving an allegation that Medco has committed a crime or has engaged in fraudulent activities in the United States (including the United States, the District of Columbia, and the territories and possessions of the United States). This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Medco shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reporting.

1. *Overpayments.*

- a. Definition of Overpayments. For purposes of this CIA, an "Overpayment" shall mean the amount of money Medco has received from a Covered Federal Program in excess of the amount due and payable under any Covered Federal Program requirements.
- b. Reporting of Overpayments. If, at any time, Medco identifies or learns of any Overpayment, Medco shall notify the payor (e.g., Medicare fiscal intermediary or carrier or FEHBP carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Medco shall

repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Medco shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payer's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to: (1) policies and procedures established by the payor; (2) regulations established pursuant to Medicare D; or (3) contracts between Medco and the payor should be handled in accordance with such policies, procedures, regulations, or contracts (as applicable).

2. *Reportable Events.*

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

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

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

b. Reporting of Reportable Events. If Medco determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Medco shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Medco shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payer's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to: (1) policies and procedures established by the payor; (2) regulations established pursuant to Medicare D; or (3) contracts between Medco and the payor should be handled in accordance with such policies, procedures, regulations, or contracts (as applicable).

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

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

b. Reporting of Reportable Events. If Medco determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Medco shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

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

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

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

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

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

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Medco changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Covered Federal Programs, Medco shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III. A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. a copy of Medco's Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
6. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

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

7. a description of the Focus Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a description of the Disclosure Program required by Section III.F;

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Medco and the IRO; and (d) the proposed start and completion dates of the Focus Arrangements Review and Unallowable Costs Review, if applicable;

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Medco;

13. a description of the process by which Medco fulfills the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any Screened Person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Covered Federal Programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. to the extent not already provided to OIG, a list of all of Medco's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s), if applicable; and the name and address of each Medicare contractor to which Medco currently submits claims;

16. to the extent not already provided to OIG, a description of Medco's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Medco shall submit to OIG annually a report with respect to the status of, and findings regarding, Medco's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

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

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

4. a summary of the steps taken to comply with the provisions of Section III.B.1 pertaining to Covered Contractors and the results of those steps, including identification of any instances in which Medco was unable to confirm that a Covered Contractor has a comparable compliance program

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

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

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

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

6. a description of any changes to the Focus Arrangements Database required by Section III.D.1.a;

7. a description of any changes to the internal review and approval process required by Section III.D.1.e;

8. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

9. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);

10. Medco's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

11. a summary and description of any and all current and prior engagements and agreements between Medco and the IRO, if different from what was submitted as part of the Implementation Report;

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Medco;

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

14. a report of the aggregate Overpayments, if any, that Medco has received and that have been returned to the Covered Federal Programs. Overpayment amounts shall be broken down into the following categories, as applicable to Medco: Medicare, Medicaid (report each applicable state separately, if applicable), FEHBP, and

other Covered Federal Programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

15. a summary of the Disclosures in the Disclosure log required by Section III.F that: (a) relate to Covered Federal Programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute, the Public Contract Anti- Kickback Act, or Stark law;

16. any changes to the process by which Medco fulfills the requirements of Section III.G regarding Ineligible Persons;

17. the name, title, and responsibilities of any Screened Person who is determined to be an Ineligible Person under Section III.G; the actions taken by Medco in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments from Covered Federal Programs received by Medco relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

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

19. a description of all changes to the most recently provided list of Medco's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Medco currently submits claims; and

20. the certifications required by Section V.C.

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

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

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Medco is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, Medco has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, and Stark Law, including the Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, Medco has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;

4. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

5. if applicable, Medco has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Covered Federal Program payers any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. Medco shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Medco shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

HHS-OIG:

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

OPM-OIG:

Debarring Official
Office of Inspector General
U.S. Office of Personnel Management
1900 E Street NW, Room 6400
Washington, DC 20415-1100
Telephone: (202) 606-1200
Facsimile: (202) 606-2153

Medco:

Dan Walden
Medco Health Solutions
100 Parsons Pond Drive mail stop B3-MS1
Franklin Lakes, NJ 07417
Telephone: (201) 269-5240
Facsimile: (201) 269-2910

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal

facsimile confirmation sheets do not constitute proof of receipt. In addition to sending notifications and correspondence to the Medco contact specified above, the OIG will endeavor to also provide copies of all notifications and correspondence to Medco's General Counsel at the address specified above.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Medco's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Medco's locations for the purpose of verifying and evaluating: (a) Medco's compliance with the terms of this CIA; and (b) Medco's compliance with the requirements of the Covered Federal Programs in which it participates. The documentation described above shall be made available by Medco to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction.

Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Medco's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Medco shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Medco's employees may elect to be interviewed with or without a representative of Medco present.

VIII. DOCUMENT AND RECORD RETENTION

Medco shall maintain for inspection all documents and records relating to reimbursement from the Covered Federal Programs, or to compliance with this CIA, for six years from the Effective Date (or longer if otherwise required by law).

IX. DISCLOSURES

A. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, HHS-OIG shall make a reasonable effort to notify Medco prior to any release by HHS-OIG of information submitted by Medco pursuant to its obligations under this CIA and identified upon submission by Medco as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Medco shall have the rights set forth at 45 C.F.R. § 5.65(d).

B. Consistent with OPM's FOIA procedures, set forth in 5 C.F.R. part 294, OPM-OIG shall make a reasonable effort to notify Medco prior to any release by OPM-OIG of information submitted by Medco pursuant to its obligations under this CIA and identified upon submission by Medco as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Medco shall have the rights set forth at 5 C.F.R. § 294.112.

X. BREACH AND DEFAULT PROVISIONS

Medco is expected to fully and timely comply with all of its CIA obligations. As between HHS-OIG and OPM-OIG, HHS-OIG will be responsible for determinations regarding Medco's compliance with the CIA obligations and determinations regarding whether to seek stipulated monetary penalties or exclusion for a breach of the CIA obligations. As set forth in Section X.F below, Medco agrees that a finding of material breach by HHS-OIG (or by an HHS ALJ or the HHS DAB if applicable) constitutes an independent basis for OPM to debar Medco from participation in the Federal Employee Health Benefits Program (FEHBP). The remedies available to HHS-OIG under this Section X do not preempt or limit any actions that OPM may take against Medco under applicable authorities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Medco and HHS-OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Medco fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee
- c. a written Code of Conduct;
- d. written Policies and Procedures;

- e. the training of Covered Persons;
- f. the Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements; and
- i. Notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Medco fails to engage an IRO, as required in Section III.E and Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Medco fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Medco fails to submit the annual Focus Arrangements Review Report and Unallowable Cost Review Report, if applicable, in accordance with the requirements of Section III.E.

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

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

7. A Stipulated Penalty of \$1,000 for each day Medco fails to comply fully and adequately with any obligation of this CIA. HHS-OIG shall provide notice to Medco, stating the specific grounds for its determination that Medco has failed to comply fully

and adequately with the CIA obligation(s) at issue and steps Medco shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Medco receives this notice from HHS-OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which HHS-OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Medco may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if HHS-OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Medco fails to meet the revised deadline set by HHS-OIG. Notwithstanding any other provision in this Section, if HHS-OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Medco receives HHS-OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by HHS-OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Medco has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, HHS-OIG shall notify Medco of: (a) Medco's failure to comply; and (b) HHS-OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such a Demand Letter shall specifically state the conduct that the HHS-OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Medco shall either: (a) cure the breach to HHS-OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute HHS-OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Medco elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Medco cures, to HHS-OIG's satisfaction, the alleged breach in dispute. Failure to

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

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

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

D. Exclusion for Material Breach of this CIA.

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Medco constitutes an independent basis for Medco's exclusion from participation in the Medicare, Medicaid, and other Federal health care programs. Upon a determination by HHS-OIG that Medco has materially breached this CIA and that exclusion is the appropriate remedy, HHS-OIG shall notify Medco in writing of: (a) Medco's material breach; and (b) HHS-OIG's intent to exercise its

contractual right to impose exclusion (this notification is hereinafter referred to as the “Notice of Material Breach and Intent to Exclude”).

3. *Opportunity to Cure.* Medco shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to HHS-OIG’s satisfaction that:

- a. Medco is in compliance with the obligations of the CIA cited by HHS-OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Medco has begun to take action to cure the material breach; (ii) Medco is pursuing such action with due diligence; and (iii) Medco has provided to HHS-OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Medco fails to satisfy the requirements of Section X.D.3, HHS-OIG may exclude Medco from participation in the Federal health care programs. HHS-OIG shall notify Medco in writing of its determination to exclude Medco (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Medco’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Medco may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights.* Upon HHS-OIG’s delivery to Medco of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Medco shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to

this CIA. Specifically, HHS-OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Medco was in full and timely compliance with the obligations of this CIA for which HHS-OIG demands payment; and (b) the period of noncompliance. Medco shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. HHS-OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with HHS-OIG with regard to a finding of a breach of this CIA and orders Medco to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Medco 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 HHS-OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Medco was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Medco had begun to take action to cure the material breach within that period; (ii) Medco has pursued and is pursuing such action with due diligence; and (iii) Medco provided to HHS-OIG within that period a reasonable

timetable for curing the material breach and Medco has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to HHS-OIG, or, if the ALJ rules for Medco, only after a DAB decision in favor of HHS-OIG. Medco's election of its contractual right to appeal to the DAB shall not abrogate HHS-OIG's authority to exclude Medco upon the issuance of an ALJ's decision in favor of HHS-OIG. If the ALJ sustains the determination of HHS-OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Medco may request review of the ALJ decision by the DAB. If the DAB finds in favor of HHS-OIG after an ALJ decision adverse to HHS-OIG, the exclusion shall take effect 20 days after the DAB decision. Medco shall waive its right to any notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Medco, Medco shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

F. Debarment for Material Breach of this CIA.

The parties agree that a material breach of this CIA by Medco constitutes an independent basis for Medco's debarment from participation in the FEHBP. Therefore, if HHS-OIG determines that Medco has materially breached this CIA and that exclusion is the appropriate remedy, and HHS-OIG excludes Medco under Section X.D.4, Medco agrees that OPM may debar it from participation in FEHBP. In such a case, OPM-OIG shall notify Medco in writing of its determination to debar Medco (this letter shall be referred to hereinafter as the "Debarment Letter".) The debarment shall go into effect 30 days after the date of Medco's receipt of the Debarment Letter.

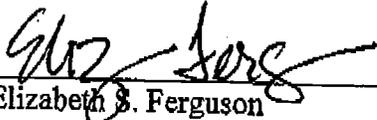
If Medco seeks a review of HHS-OIG's determination to exclude Medco for a material breach pursuant to Section X.E., and the ALJ or the DAB, as applicable, find in favor of HHS-OIG, Medco agrees that OPM may debar it from participation in FEHBP. In such a case, the debarment shall go into effect 20 days after the ALJ or DAB, as applicable, finds in favor of HHS-OIG.

XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This CIA shall be binding on the successors, assigns, and transferees of Medco;
- B. This CIA shall become final and binding on the Effective Date;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Medco's obligations under the CIA in the event of Medco's cessation of participation in Covered Federal Programs. If Medco withdraws from participation in Covered Federal Programs and is relieved of its CIA obligations by OIG, Medco shall notify OIG at least 30 days in advance of Medco's intent to reapply as a participating provider or supplier with any Covered Federal Program or to enter into a contract with any FEHBP carrier. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified;
- E. The undersigned Medco signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA; and
- F. This CIA may be executed in counterparts, each of which shall constitute an original and all of which taken together shall constitute one and the same agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this CIA.

ON BEHALF OF MEDCO HEALTH SOLUTIONS, INC.



Elizabeth S. Ferguson
Vice President, Litigation
and Government Programs

20 October 2006
DATE

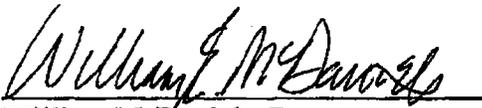
William McDaniels, Esq.
Counsel for Medco

DATE

ON BEHALF OF MEDCO HEALTH SOLUTIONS, INC.

Elizabeth S. Ferguson
Vice President, Litigation
and Government Programs

DATE



William McDaniels, Esq.
Counsel for Medco



DATE

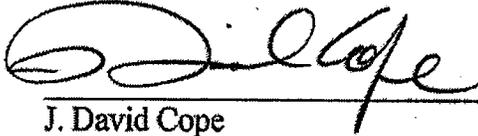
**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

10/23/06
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE OFFICE OF PERSONNEL MANAGEMENT



J. David Cope
Debarring Official
Office of Inspector General
U.S. Office of Personnel Management

10/20/2006
DATE

APPENDIX A

ARRANGEMENTS DATABASE

Medco shall create and maintain an Arrangements Database to track all new and existing Focus Arrangements in order to ensure that each Focus Arrangement does not violate the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, or the Stark Law. The Arrangements Database shall contain certain information to assist Medco in evaluating whether each Focus Arrangement violates the Anti-Kickback Statute, the Public Contract Anti-Kickback Act, or the Stark Law, including but not limited to the following:

1. Each party involved in the Focus Arrangement;
2. The type of Focus Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Focus Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Focus Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Focus Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Focus Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.D.2; and
8. Whether the Focus Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

APPENDIX B
INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

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

If Medco engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Medco shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO.

Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Medco if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Medco may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Arrangements Review and, if applicable, Unallowable Cost Review engagements who have expertise in the requirements of the reviews being performed and in the general requirements of the applicable Federal health care program(s);
2. assign individuals to design and select the Arrangements Review sample who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

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

D. IRO Independence/Objectivity.

The IRO must perform the Arrangements 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 engagements that may exist between the IRO and Medco.

E. IRO Removal/Termination.

1. *Provider.* If Medco terminates its IRO during the course of the engagement, Medco must submit a notice explaining its reasons to OIG no later than 30 days after termination. Medco must engage a new IRO in accordance with Paragraph A of this Appendix.
2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Medco to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Medco to engage a new IRO, OIG shall notify Medco of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Medco may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its

responsibilities and to present additional information regarding these matters. Medco shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Medco prior to requiring Medco to terminate the IRO. However, the final determination as to whether or not to require Medco to engage a new IRO shall be made at the sole discretion of OIG.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____ AMOUNT
 OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

<p><u>Billing/Clerical Error</u></p> 01 - Corrected Date of Service 02 - Duplicate 03 - Corrected CPT Code 04 - Not Our Patient(s) 05 - Modifier Added/Removed 06 - Billed in Error 07 - Corrected CPT Code	<p><u>MSP/Other Payer Involvement</u></p> 08 - MSP Group Health Plan Insurance 09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including Black Lung 12 - Veterans Administration	<p><u>Miscellaneous</u></p> 13 - Insufficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 - Other (Please Specify)
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