

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ADVANCEPCS**

**I. PREAMBLE**

AdvancePCS hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, AdvancePCS is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

This CIA is entered into in connection with the Settlement Agreement, which sets forth certain allegations made by the United States against AdvancePCS. AdvancePCS does not admit to any of the allegations set forth in the Settlement Agreement and does not admit to fault or liability for claims asserted in the Civil Actions referenced in the Settlement Agreement or any other claims. The allegations made relate to certain “Covered Conduct” of AdvancePCS (as described in the Settlement Agreement) occurring between January 1, 1999 and January 27, 2004, prior to the date that AdvancePCS was acquired by CaremarkRx, Inc. (“Parent”). The United States in the Settlement Agreement does not assert allegations of violations of law against Parent or any other division, subsidiary, or affiliate of Parent other than AdvancePCS. Parent, in order to effectuate the settlement embodied in the Settlement Agreement, has voluntarily agreed to comply with the obligations applicable to its subsidiary, AdvancePCS, as set forth in this CIA.

Prior to the Effective Date of the CIA, AdvancePCS’ Parent had established a compliance program which included, among other things, the appointment of a Compliance Officer

(Chief Compliance Officer or CCO), 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 Federal health care program requirements, the establishment of written policies and procedures, screening measures for Ineligible Persons, regular training to all employees, including Covered Persons, concerning Parent's Code of Conduct, and various training and auditing programs.

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

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

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) AdvancePCS' final annual report; or (2) any additional materials submitted by AdvancePCS 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:
  - a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between AdvancePCS and any actual or potential source of health care business or referrals to AdvancePCS or any actual or potential recipient of health care business or referrals from AdvancePCS. 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 Federal health care program. Such Arrangements shall include: (1) every arrangement or transaction whereby compensation or remuneration is received by AdvancePCS

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; (2) every arrangement or transaction between AdvancePCS and a client where “client” shall mean any governmental entity, employer, insurer, union or other entity that contracts with AdvancePCS to provide or administer a pharmacy benefit for such plan and its members or participants (hereinafter referred to as “Client Plans”); and (3) every arrangement or transaction between AdvancePCS and a broker engaged by AdvancePCS to perform services on its behalf.

2. “Covered Persons” includes:
  - a. all officers, directors, and employees of AdvancePCS;
  - b. all contractors, subcontractors, agents, and other persons engaged by AdvancePCS to provide patient care items or services or perform billing or coding functions on behalf of AdvancePCS;
  - c. all contractors, subcontractors and agents engaged by AdvancePCS to perform functions related to the marketing of items or services reimbursable by Federal health care programs on behalf of AdvancePCS; and
  - d. all contractors, subcontractors and agents engaged by AdvancePCS to perform functions related to the negotiation, development, approval, management, review or implementation of AdvancePCS’ Arrangements on behalf of AdvancePCS.

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.

3. “Relevant Covered Persons” means a Covered Person employed or engaged by AdvancePCS who is involved with the negotiation, development, approval, management, review or implementation of AdvancePCS’ Arrangements identified in section C.1.a above on behalf of AdvancePCS.

#### **D. Applicability of CIA**

1. Parent voluntarily agrees that, except as stated in section III.E.2, Parent and its other divisions, subsidiaries, and affiliates shall be bound by the terms of this CIA to the same extent as AdvancePCS is bound.

2. For purposes of satisfying the obligations of Sections III.A. through D. herein, AdvancePCS may rely on Parent’s existing compliance program.

3. Parent agrees to continue the operation of its compliance program. Parent may modify its compliance measures as appropriate but shall, at a minimum, ensure that it complies with the compliance obligations of the CIA.

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

AdvancePCS shall maintain a Compliance Program that includes the following elements:

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

1. **Compliance Officer.** Within 90 days after the Effective Date, AdvancePCS 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 developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of AdvancePCS, shall make periodic (at least quarterly) reports regarding

compliance matters directly to the Board of Directors of AdvancePCS, and shall be authorized to report on such matters 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 monitoring the day-to-day compliance activities engaged in by AdvancePCS as well as for any reporting obligations created under this CIA.

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

2. **Compliance Committee.** Within 90 days after the Effective Date, AdvancePCS 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 trade, client and account services, human resources, audit, and operations). 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).

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

**B. Written Standards.**

1. **Code of Conduct.** Within 120 days after the Effective Date, AdvancePCS shall distribute its written Code of Conduct with an accompanying letter to all Covered Persons. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood and shall abide by the letter and the Code of Conduct. AdvancePCS shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct and/or the accompanying letter shall, at a minimum, set forth:

- a. AdvancePCS' commitment to full compliance with all Federal health care program requirements, including those requirements applicable to Arrangements;
- b. AdvancePCS' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with AdvancePCS' own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of AdvancePCS' Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by AdvancePCS suspected violations of any Federal health care program requirements or of AdvancePCS' own Policies and Procedures;
- d. the possible consequences to both AdvancePCS and Covered Persons of failure to comply with Federal health care program requirements and with AdvancePCS' 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 AdvancePCS' commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the Code of Conduct referenced in section III.B.1. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

AdvancePCS shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read,

understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. ***Policies and Procedures.*** Within 120 days after the Effective Date, AdvancePCS shall implement written Policies and Procedures regarding the operation of AdvancePCS' compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- c. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of Arrangements.

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 individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on the intranet or other internal website available to all Covered Persons. If AdvancePCS uses such an electronic method of distribution, it must notify the Covered Persons that the Policies and Procedures will be distributed in such a manner and it must track the distribution to ensure that all appropriate Covered Persons received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), AdvancePCS shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures

shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

**C. Training and Education.**

1. **General Training.** Within 120 days after the Effective Date, AdvancePCS shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain AdvancePCS’:

- a. CIA requirements; and
- b. AdvancePCS’ 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 or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. AdvancePCS’ policies, procedures, and other requirements relating to Arrangements, including but not limited to the 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 the CIA;
- c. the personal obligation of each individual involved in the development, approval, management, or review of AdvancePCS’



Arrangements to know the applicable legal requirements and the AdvancePCS' policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and

e. examples of violations of the Anti-Kickback Statute 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. An AdvancePCS 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.

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

4. ***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 shall be made available to OIG, upon request.

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

6. ***Update of Training.*** AdvancePCS shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the

Arrangements Review, Unallowable Cost Review, if applicable, and any other relevant information.

7. ***Computer-based Training.*** AdvancePCS may provide the training required under this CIA through appropriate computer-based training approaches. If AdvancePCS 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 and Stark Law.**

1. ***Arrangements Procedures.*** Within 120 days after the Effective Date, AdvancePCS shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law 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 Arrangements that shall contain the information specified in Appendix A (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable 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 Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed

Arrangements do not violate the Anti-Kickback Statute and Stark Law;

f. requiring the Compliance Officer to review the Arrangements Database, 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 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 Arrangements.*** Prior to entering into new Arrangements or any amendment to an existing 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, AdvancePCS shall comply with the following requirements (Arrangements Requirements):

a. ensure that each Arrangement is set forth in writing and signed by AdvancePCS and the other parties to the Arrangement;

b. include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with AdvancePCS' Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, AdvancePCS shall provide each party to the Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures or shall provide access to the Code and relevant policies via the Internet or intranet, as appropriate;

c. include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback

Statute and the Stark Law with respect to the performance of the Arrangement.

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

**E. Review Procedures.**

1. With respect to the Unallowable Cost Review, if applicable, and the scope of the annual review of sample Arrangements performed by the relevant Independent Review Organization (“IRO”) further described in section E.2 herein, the following terms shall apply:

a. ***Engagement of Independent Review Organization.*** Within 90 days after the Effective Date, AdvancePCS 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 AdvancePCS in assessing AdvancePCS’ compliance with the obligations pursuant to Section III.D of this Agreement (Arrangements Review), and (ii) a review to analyze whether AdvancePCS sought payment for certain unallowable costs (Unallowable Cost Review). The IRO engaged by AdvancePCS to perform the Unallowable Costs Review shall have expertise in the cost reporting requirements applicable to AdvancePCS and in the general requirements of the Federal health care program(s) from which AdvancePCS seeks reimbursement.

Each IRO shall assess, along with AdvancePCS, 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 Arrangements Review shall not be deemed to create an attorney-

client relationship between AdvancePCS and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix B to this Agreement, which is incorporated by reference.

b. ***Frequency of Arrangements Review.*** The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual 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 AdvancePCS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and AdvancePCS) related to the reviews.

e. ***Responsibilities and Liabilities.*** Nothing in this Section III.E affects AdvancePCS' responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. ***Arrangements Review.*** The IRO shall perform a review to assess whether AdvancePCS is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The Arrangements Review covers Arrangements involving AdvancePCS, not those exclusively involving its Parent or any other subsidiaries, divisions or affiliates of Parent. The Arrangements Review shall consist of the IRO randomly selecting a sample of 25 Arrangements involving AdvancePCS that were entered into or renewed during the Reporting Period. The IRO shall assess whether AdvancePCS has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether AdvancePCS has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment of the Arrangements sample shall include, but is not limited to (a) verifying that the

Arrangement is listed in the Arrangements Database; (b) verifying that the 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 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 Arrangements Database, 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 and Stark Law are discovered; and (h) verifying that the AdvancePCS has met the requirements of Section III.D.2. AdvancePCS agrees that it will not seek to transfer any Arrangement to its other corporate affiliates for purposes of avoiding or limiting the Arrangements Review. Clients of AdvancePCS, however, may seek to contract with another affiliate based on the pharmacy benefit management services selected by the client.

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

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

Prior to initiating a Validation Review, OIG shall notify AdvancePCS of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, AdvancePCS may request a meeting with OIG to: (a) discuss the results of any Arrangements Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or Unallowable Cost Review or to correct the inaccuracy of the Arrangements Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. AdvancePCS agrees to provide any

additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review or Unallowable Cost Review issues with AdvancePCS prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

7. ***Independence/Objectivity Certification.*** The IRO shall include in its report(s) to AdvancePCS 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 Arrangements Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

**F. Disclosure Program.**

Within 120 days after the Effective Date, AdvancePCS shall establish 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 AdvancePCS' policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. AdvancePCS shall 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).

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, 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, AdvancePCS 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 Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and

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

c. “Screened Persons”

Screened Persons shall include the following:

(i) current and prospective officers, directors and employees;

(ii) current and prospective contractors and agents engaged

by AdvancePCS and acting on behalf of AdvancePCS; and

(iii) current and prospective owners (other than shareholders who (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading) of AdvancePCS.

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

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

b. AdvancePCS shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

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

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

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

**H. Notification of Government Investigation or Legal Proceedings.**

Within 30 days after discovery, AdvancePCS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to senior management at AdvancePCS conducted or brought by a governmental entity or its agents involving an allegation that AdvancePCS has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. AdvancePCS 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 AdvancePCS has received in excess of the amount due and payable under any Federal health care program requirements.

b. **Reporting of Overpayments.** If, at any time, AdvancePCS identifies or learns of any Overpayment, AdvancePCS shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also,

within 30 days after identification of the Overpayment, AdvancePCS 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, AdvancePCS shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, 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 policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. ***Reportable Events.***

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

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

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

b. **Reporting of Reportable Events.** If AdvancePCS determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, AdvancePCS 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 payor's name, address, and contact person to whom the Overpayment was sent; and

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

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

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

iv. any further steps AdvancePCS 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, AdvancePCS 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 Federal health care programs, AdvancePCS 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, AdvancePCS 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 the applicable Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
6. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the 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 AdvancePCS and the IRO; and (d) the proposed start and completion dates of the services to be performed by the IRO hereunder;
12. a certification from the IRO regarding its professional independence and/or objectivity with respect to AdvancePCS;
13. a description of the process by which AdvancePCS fulfills the requirements of Section III.G regarding Ineligible Persons;
14. the name, title, and responsibilities of any 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 Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
15. a list of all of AdvancePCS' 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); and the name and address of each Medicare contractor to which AdvancePCS currently submits claims;

16. a description of AdvancePCS' 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.** AdvancePCS shall submit to OIG annually a report with respect to the status of, and findings regarding, AdvancePCS' 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 individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

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

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

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

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



5. a description of any changes to the Arrangements Database required by Section III.D.1.a;
6. a description of any changes to the internal review and approval process required by Section III.D.1.e;
7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;
8. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);
9. AdvancePCS' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;
10. a summary and description of any and all current and prior engagements and agreements between AdvancePCS and the IRO, if different from what was submitted as part of the Implementation Report;
11. a certification from the IRO regarding its professional independence and/or objectivity with respect to AdvancePCS;
12. 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;
13. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;
14. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care 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 or Stark law;

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

16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by AdvancePCS 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 Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

17. 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;

18. a description of all changes to the most recently provided list of AdvancePCS' 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 AdvancePCS currently submits claims; and

19. 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, AdvancePCS is in compliance with all of the requirements of this CIA;

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

3. to the best of his or her knowledge, AdvancePCS has fulfilled the requirements for New and Renewed 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. AdvancePCS has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

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

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

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

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General

Corporate Integrity Agreement  
AdvancePCS

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

AdvancePCS:

Diane B. Nobles  
EVP Compliance & Integrity  
2211 Sanders Rd.  
Northbrook, IL 60062  
Telephone: 847.559.4714  
Facsimile: 847.559.4953

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

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

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

authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AdvancePCS' employees may elect to be interviewed with or without a representative of AdvancePCS present.

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

AdvancePCS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law).

## **IX. DISCLOSURES**

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

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

AdvancePCS is expected to fully and timely comply with all of its CIA obligations.

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

**B.**

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 AdvancePCS 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 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 AdvancePCS 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 AdvancePCS 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 AdvancePCS fails to submit the annual Arrangements Review Report or Unallowable Cost Review in accordance with the requirements of Section III.E.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of AdvancePCS 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 AdvancePCS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to AdvancePCS, stating the specific grounds for its determination that AdvancePCS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps AdvancePCS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after AdvancePCS receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

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

**C. Payment of Stipulated Penalties.**

1. ***Demand Letter.*** Upon a finding that AdvancePCS has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify AdvancePCS of: (a) AdvancePCS' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of

the Stipulated Penalties (this notification is referred to as the “Demand Letter”).

2. ***Response to Demand Letter.*** Within 10 days after the receipt of the Demand Letter, AdvancePCS shall either: (a) cure the breach to OIG’s satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event AdvancePCS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AdvancePCS cures, to OIG’s satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.



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

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

**D. Exclusion for Material Breach of this CIA.**

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

- a. a failure by AdvancePCS 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 AdvancePCS constitutes an independent basis for AdvancePCS' exclusion from participation in the Federal health care programs. Upon a determination by OIG that AdvancePCS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify AdvancePCS of: (a) AdvancePCS' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to

Exclude”).

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

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

4. **Exclusion Letter.** If, at the conclusion of the 30-day period, AdvancePCS fails to satisfy the requirements of Section X.D.3, OIG may exclude AdvancePCS from participation in the Federal health care programs. OIG shall notify AdvancePCS in writing of its determination to exclude AdvancePCS (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 AdvancePCS’ 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, AdvancePCS may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### **E. Dispute Resolution**

1. **Review Rights.** Upon OIG’s delivery to AdvancePCS 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, AdvancePCS shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated

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

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

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

- a. whether AdvancePCS 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) AdvancePCS had begun to take action to cure the material breach within that period; (ii) AdvancePCS has pursued and is pursuing such action with due diligence; and (iii) AdvancePCS provided to OIG within that period a reasonable timetable for curing the material breach and

AdvancePCS has followed the timetable.

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

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

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, AdvancePCS and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of AdvancePCS;

B. This CIA shall become final and binding on the Effective Date of the Settlement Agreement;

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 AdvancePCS' obligations under the CIA in the event of AdvancePCS' cessation of participation in Federal health care programs. If AdvancePCS withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, AdvancePCS shall notify OIG at least 30 days in advance of AdvancePCS' intent to reapply to participate in any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned AdvancePCS signatory represents and warrants that he is authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA. The undersigned Parent signatory represents and warrants that he is authorized to execute this CIA on behalf of Parent and all of its subsidiaries, divisions, and affiliates. As set forth in section II.D.1, the Parent signature is for the purpose of acknowledging and agreeing that, except as stated in section III.E.2, Parent and its subsidiaries, divisions, and affiliates voluntarily agree to be bound by the terms of the CIA in the same manner as AdvancePCS.

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



LEWIS MORRIS  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services



DATE

ON BEHALF OF ADVANCEPCS



Howard A. McLure  
President and Chief Financial Officer

\_\_\_\_\_  
DATE

\_\_\_\_\_  
Sanford Teplitzky, Esquire  
Ober, Kaler, Grimes & Shriver, PC

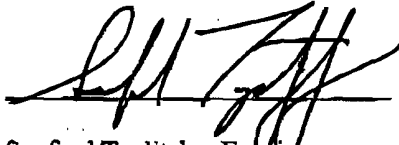
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ON BEHALF OF ADVANCEPCS

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Howard A. McLure  
President and Chief Financial Officer

DATE



Sanford Teplitzky, Esquire  
Ober, Kaler, Grimes & Shriver, PC

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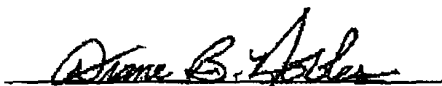
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DATE

Corporate Integrity Agreement  
AdvancePCS



ON BEHALF OF CAREMARK RX, INC.



Diane B. Nobles  
Executive Vice President  
Compliance & Integrity  
Caremark Rx, Inc.



DATE

## **APPENDIX A**

### **ARRANGEMENTS DATABASE**

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

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the 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 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 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.**

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

If AdvancePCS 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, AdvancePCS 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 AdvancePCS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, AdvancePCS 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 inquires 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 AdvancePCS.

E. IRO Removal/Termination.

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

Prior to requiring AdvancePCS to engage a new IRO, OIG shall notify AdvancePCS 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, AdvancePCS 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. AdvancePCS 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 AdvancePCS prior to requiring AdvancePCS to terminate the IRO. However, the final determination as to whether or not to require AdvancePCS 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:**

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