

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**OMNICARE, INC.**

**I. PREAMBLE**

Omnicare, Inc. (Omnicare) 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, Omnicare is entering into a Settlement Agreement with the United States.

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

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

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

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Omnicare's final annual report; or (2) any additional materials submitted by Omnicare pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:
  - a. all officers, directors, and employees of Omnicare; and
  - b. any contractors, subcontractors, and agents of Omnicare who are engaged to furnish pharmaceutical items or services to Federal health care program beneficiaries or to prepare or submit claims for pharmaceutical items or services to any Federal health care program.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year. Furthermore, this term only applies to those persons employed by Omnicare or a subsidiary, division, or affiliate of Omnicare that is involved in the furnishing of pharmaceutical items or services to Federal health care program beneficiaries or the preparing or submitting claims for pharmaceutical items or services to any Federal health care program.

2. "Relevant Covered Persons" includes:
  - a. all pharmacists; and
  - b. all corporate pharmacy staff, pharmacy technicians, and other Covered Persons employed or engaged by Omnicare who are involved in the development or implementation of therapeutic interchange programs.

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

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

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

1. *Compliance Officer.* Prior to the Effective Date of this CIA, Omnicare appointed an individual to serve as its Compliance Officer and shall maintain a

Compliance Officer for the term of this CIA. The Compliance Officer is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Omnicare, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of Omnicare, and shall be authorized to report on such matters to the Audit Committee of the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall continue to be responsible for monitoring the day-to-day compliance activities engaged in by Omnicare as well as for any reporting obligations created under this CIA.

Omnicare 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.* Prior to the Effective Date of this CIA, Omnicare appointed 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 billing, clinical, human resources, audit, and operations), and at least one member of the Board of Directors who is not an employee of Omnicare. The Compliance Officer shall continue to chair the Compliance Committee and the Committee shall continue to support the Compliance Officer in fulfilling his/her responsibilities (e.g., assist in the analysis of the organization's risk areas and oversee monitoring of internal and external audits and investigations).

Omnicare 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.* Prior to the Effective Date of this CIA, Omnicare developed, implemented, and distributed a written Code of Conduct to all Covered

Persons. Omnicare shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct, at a minimum, shall continue to set forth:

- a. Omnicare's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Omnicare's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Omnicare'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 Omnicare's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Omnicare suspected violations of any Federal health care program requirements or of Omnicare's own Policies and Procedures;
- d. the possible consequences to both Omnicare and Covered Persons of failure to comply with Federal health care program requirements and with Omnicare'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 Omnicare's 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 Omnicare's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Omnicare shall continue to periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 60 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.* To the extent not already implemented, within 120 days after the Effective Date, Omnicare shall implement written Policies and Procedures regarding the operation of Omnicare's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making therapeutic interchanges of drugs; and
- c. Omnicare's commitment to accuracy in all materials and information submitted to prescribers in relation to therapeutic interchange programs.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Omnicare's intranet or other internal website available to all Covered Persons. If Omnicare 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), Omnicare shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall

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

C. Training and Education.

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

- a. CIA requirements; and
- b. Omnicare'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 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

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

- a. the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug;
- b. the personal obligation of each individual involved in the claims submission process under Federal health care programs to ensure that such claims are accurate;
- c. applicable claims submission and reimbursement statutes, regulations, and program requirements and directives related to drug coverage under Federal health care programs;

- d. the importance of accuracy in all materials and information provided to prescribers in relation to therapeutic interchange programs;
- e. the record retention requirements of Federal health care programs;
- f. the legal sanctions for violations of the Federal health care program requirements; and
- g. examples of proper and improper implementation of therapeutic interchange programs and related claims submission practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An Omnicare employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to activities under therapeutic interchange programs and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least one hour of Specific Training annually.

3. *Certification.* Each individual who is required to 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.

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

5. *Update of Training.* Omnicare 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 IRO Therapeutic Interchange review, and any other relevant information.

6. *Computer-based Training.* Omnicare may provide the training required under this CIA through appropriate computer-based training approaches. If Omnicare 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 Requirements for Therapeutic Interchange Programs.

1. *Definitions.*

a. *Therapeutic Interchange.* For purposes of this CIA, the term “therapeutic interchange” shall refer to the substitution of a drug that has the same or similar therapeutic effects as the drug originally prescribed based on appropriate authorization of the prescriber. It does not refer to the substitution of a chemically identical generic drug in the same dosage and form as the branded drug originally prescribed, which generally does not require authorization of the prescriber under state law.

b. *Therapeutic Interchange Program.* For purposes of this CIA, the term “therapeutic interchange program” shall refer to a company-wide effort to implement a particular therapeutic interchange. A therapeutic interchange program is separate and apart from the individualized drug reviews, recommendations, and monthly drug regimen reviews required to be made by consultant pharmacists under the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), codified at 42 C.F.R. § 483.60(c).

2. *Therapeutic Interchange Program Procedures.* Within 120 days after the Effective Date of this CIA, Omnicare shall create procedures reasonably designed to ensure that all therapeutic interchange programs are developed and implemented by Omnicare consistent with the requirements of this CIA, Federal health care program requirements, and the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug. These procedures shall include the following:



- a. establishment of a centralized process for developing therapeutic interchange programs that will consider the relative therapeutic or pharmaceutical attributes of the drugs subject to the therapeutic interchange and, secondarily, the relative prices of the drugs subject to the therapeutic interchange;
- b. establishment of a centralized process for obtaining approval from senior management for therapeutic interchange programs before they are implemented;
- c. establishment of a centralized process for developing materials supporting therapeutic interchange programs which are accurate, not misleading, and include relevant information regarding the basis for the therapeutic interchange;
- d. procedures reasonably designed to ensure that communications from Relevant Covered Persons to prescribers related to therapeutic interchange programs are accurate, not misleading, and contain relevant information regarding the basis for the therapeutic interchange (*e.g.*, a brief summary of the process by which Omnicare develops therapeutic interchange programs and a brief summary of the relative therapeutic or pharmaceutical attributes and relative prices to payors of the drugs subject to the therapeutic interchange program); and
- e. procedures to ensure that all prescriber authorizations required under applicable state and federal laws have been obtained before a therapeutic interchange of a drug is made.

#### E. Review Procedures.

##### 1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Omnicare shall engage an entity (or

entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Omnicare in assessing and evaluating its development and implementation of therapeutic interchange programs and certain other obligations pursuant to this Agreement and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

Each IRO engaged by Omnicare shall have expertise in the billing, coding, reporting, and other requirements of the institutional pharmacy industry and in the general requirements of the Federal health care program(s) from which Omnicare seeks reimbursement. Each IRO shall assess, along with Omnicare, 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 IRO(s) review shall evaluate and analyze Omnicare’s development and implementation of therapeutic interchange programs (Therapeutic Interchange Review).

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

c. *Retention of Records.* The IRO and Omnicare shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Omnicare) related to the reviews.

2. Therapeutic Interchange Review. The IRO shall perform a review to assess whether Omnicare is complying with the requirements of this CIA in developing and implementing its therapeutic interchange programs. The IRO’s assessment shall include:

- a. verifying that Omnicare's process for developing its therapeutic interchange programs is consistent with the requirements of Section III.D;
- b. verifying that Omnicare's implementation of its therapeutic interchange programs is consistent with the requirements of Section III.D; and
- c. review of a random sample of one hundred fifty (150) therapeutic interchange transactions involving Federal health care program beneficiaries to determine whether each transaction is implemented consistent with Omnicare's therapeutic interchange programs, the requirements of this CIA, Federal health care program requirements related to making a therapeutic interchange, and the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug.

3. Therapeutic Interchange Review Report. The IRO shall prepare a report based upon the Therapeutic Interchange Review performed (Therapeutic Interchange Review Report). The Therapeutic Interchange Review Report shall include the IRO's findings with respect to (a) whether Omnicare has complied with the requirements of this CIA in the development and implementation of Omnicare's therapeutic interchange programs; (b) the IRO's observations, recommendations, and suggested improvements to the procedures used in the development and implementation of Omnicare's therapeutic interchange programs; and (c) specific findings as to whether the therapeutic interchanges reviewed by the IRO were consistent with Omnicare's therapeutic interchange programs, the requirements of this CIA, Federal health care program requirements related to making a therapeutic interchange, and the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug.

4. Validation Review. In the event OIG has reason to believe that: (a) Omnicare's Therapeutic Interchange Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Therapeutic Interchange Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the

Therapeutic Interchange Review complied with the requirements of this CIA and/or the findings or Therapeutic Interchange Review results are inaccurate (Validation Review). Omnicare 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 Omnicare's final Annual Report must be initiated no later than one year after Omnicare's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Omnicare 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, Omnicare may request a meeting with OIG to: (a) discuss the results of any Therapeutic Interchange Review submissions or findings; (b) present any additional information to clarify the results of the Therapeutic Interchange Review or to correct the inaccuracy of the Therapeutic Interchange Review; and/or (c) propose alternatives to the proposed Validation Review. Omnicare 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 Therapeutic Interchange Review issues with Omnicare prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. Independence/Objectivity Certification. The IRO shall include in its report(s) to Omnicare 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 Therapeutic Interchange Review and that it has concluded that it is, in fact, independent and/or objective.

F. Disclosure Program.

Prior to the Effective Date of this CIA, Omnicare established a Disclosure Program that included 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 Omnicare's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Omnicare 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).

The Disclosure Program shall continue to emphasize a nonretribution, nonretaliation policy, and shall continue to include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Omnicare 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" include prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of Omnicare.

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

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

c. Omnicare 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) Omnicare to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

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

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

4. *Pending Charges and Proposed Exclusions.* If Omnicare 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, Omnicare 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, Omnicare shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Omnicare conducted or brought by a governmental entity or its agents involving an allegation that Omnicare 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. Omnicare 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 Omnicare 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, Omnicare identifies or learns of any Overpayment, Omnicare 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, Omnicare 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, Omnicare 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 Omnicare determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Omnicare 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 Omnicare's actions taken to correct the Reportable Event; and
- iv. any further steps Omnicare 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, Omnicare 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, Omnicare shall notify OIG of this fact no less frequently than quarterly, or within 90 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, Omnicare 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 Omnicare's Code of Conduct required by Section III.B.1;

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

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

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

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

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

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

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

8. 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 Omnicare and the IRO; and (d) the proposed start and completion dates of the Therapeutic Interchange Review;

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

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

11. 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;

12. a list of all of Omnicare'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); a list of all states in which Omnicare does business relating to the Federal health care programs; and the name and address of each Medicare contractor to which Omnicare currently submits claims;

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

14. the certifications required by Section V.C.

B. Annual Reports. Omnicare shall submit to OIG annually a report with respect to the status of, and findings regarding, Omnicare'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 individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

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

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

9. 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;

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

11. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

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

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Omnicare 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;

14. 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;

15. a description of all changes to the most recently provided list of Omnicare's locations (including addresses) as required by Section V.A.11; 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); the list of all states in which Omnicare does business relating to the Federal health care programs; and the name and address of each Medicare contractor to which Omnicare currently submits claims; and

16. the certifications required by Section V.C.

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

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

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

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

3. Omnicare 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. Omnicare 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. Omnicare shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

**OIG:**

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

**Omnicare:**

Corporate Compliance Officer  
William Fitzpatrick, R. Ph.  
Omnicare, Inc.  
1600 Rivercenter II  
100 East Rivercenter Blvd.  
Covington, KY 41011  
Phone: 859-392-3334  
Fax: 859-392-3320

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. The OIG will endeavor to provide copies of notifications and reports to counsel for Omnicare, Sanford V. Teplitzky, Esq., Ober, Kaler, Grimes & Shriver, 120 E. Baltimore St., Baltimore, MD 21202 (Phone: 410-347-7364, Fax: 410-685-1120).

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

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

Omnicare 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 Omnicare prior to any release by OIG of information submitted by Omnicare pursuant to its obligations under this CIA and identified upon submission by Omnicare as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Omnicare shall have the rights set forth at 45 C.F.R. § 5.65(d).

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

Omnicare 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, Omnicare and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

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

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

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Omnicare 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 Omnicare fails to submit the annual Therapeutic Interchange Review Report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Omnicare 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 Omnicare fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Omnicare, stating the specific grounds for its determination that Omnicare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Omnicare shall take to comply with this CIA. (This Stipulated Penalty shall begin to accrue 10 days after Omnicare 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. Omnicare 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 Omnicare 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 Omnicare 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 Omnicare 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 Omnicare of: (a) Omnicare's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Omnicare 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 Omnicare elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Omnicare 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 Omnicare 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 Omnicare 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.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Omnicare constitutes an independent basis for Omnicare's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Omnicare has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Omnicare of: (a) Omnicare's 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.* Omnicare 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. Omnicare 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) Omnicare has begun to take action to cure the material breach; (ii) Omnicare is pursuing such action with due diligence; and (iii) Omnicare has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Omnicare fails to satisfy the requirements of Section X.D.3, OIG may exclude Omnicare from participation in the Federal health care programs. OIG shall notify Omnicare in writing of its determination to exclude Omnicare (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 Omnicare’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, Omnicare 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 Omnicare 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, Omnicare 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 Omnicare was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Omnicare 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 Omnicare to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Omnicare 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 Omnicare 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) Omnicare had begun to take action to cure the material breach within that period; (ii) Omnicare has pursued and is pursuing such action with due diligence; and (iii) Omnicare provided to OIG within that period a reasonable timetable for curing the material breach and Omnicare 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 Omnicare, only after a DAB decision in favor of OIG. Omnicare's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Omnicare 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 Omnicare 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. Omnicare 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 Omnicare, Omnicare 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, Omnicare and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Omnicare. If Omnicare sells a business unit or location, OIG may release the business unit or location from its obligations under the CIA provided that Omnicare has demonstrated to OIG's satisfaction that (1) such transaction constituted solely a disposition of assets of such business unit or location; (2) the buyer is an independent entity unrelated in any manner to Omnicare and has acquired the business unit or location at fair market value in an arms length transaction; (3) the Federal health care program provider numbers have not transferred to the successor entity; and (4) the business unit or location will not be operated in whole or in part by Omnicare. If a business unit or location is no longer to be considered subject to the CIA due to a sale, Omnicare shall require as a condition of the sale that the buyer represents and agrees that it has or shall implement and maintain with respect to its operation of the business unit or location an effective program to prevent and detect violations of the legal requirements applicable to the delivery of goods and services in connection with any health care benefits and that such a program will comply with the provisions of the U.S. Sentencing Guidelines relating to corporate compliance programs and will be mindful of any applicable guidance issued by OIG or other components of HHS; and that the buyer agrees that it will maintain such program for at least three years from the date of the sale or until the end of the term of this CIA, whichever period is longer.

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

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

D. OIG may agree to a suspension of Omnicare's obligations under this CIA in the event of Omnicare's cessation of participation in Federal health care programs. If Omnicare withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Omnicare shall notify OIG at least 30 days in advance of Omnicare's intent to reapply as a participating provider or supplier with any Federal

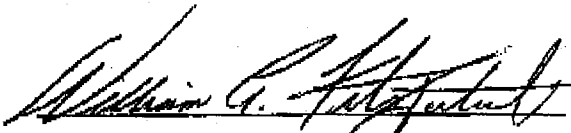
health care program. Upon receipt of such notification, OIG shall evaluate whether this CIA should be reactivated or modified.

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

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



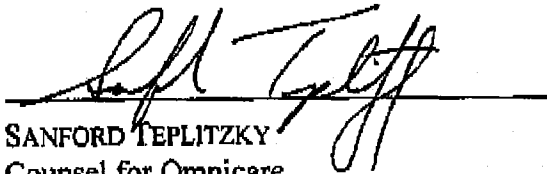
**ON BEHALF OF OMNICARE**



**WILLIAM A. FITZPATRICK**  
Corporate Compliance Officer  
Omnicare, Inc.

10/30/06

DATE



**SANFORD TEPLITZKY**  
Counsel for Omnicare

10/31/06

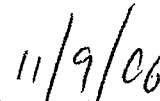
DATE

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



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



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DATE

## **APPENDIX A INDEPENDENT REVIEW ORGANIZATION**

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

### **A. IRO Engagement.**

Omnicare 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 Omnicare if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Omnicare may continue to engage the IRO.

If Omnicare 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, Omnicare 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 Omnicare if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Omnicare may continue to engage the IRO.

### **B. IRO Qualifications.**

The IRO shall:

1. assign individuals to conduct the Therapeutic Interchange Review who have expertise in (a) the billing, reporting, and other requirements of pharmaceutical reimbursement; (b) the general requirements of the Federal health care program(s) from which Omnicare seeks reimbursement; and (c) the laws applicable to therapeutic interchanges, including but not limited to applicable Medicare and Medicaid rules and regulations and state and local pharmacy laws;
2. assign individuals to design and select the Therapeutic Interchange 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 Therapeutic Interchange Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare and Medicaid rules and guidelines in the Therapeutic Interchange Review;
3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority;
4. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Therapeutic Interchange 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 Omnicare.

E. IRO Removal/Termination.

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

Prior to requiring Omnicare to engage a new IRO, OIG shall notify Omnicare 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, Omnicare 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.

Omnicare 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 Omnicare prior to requiring Omnicare to terminate the IRO. However, the final determination as to whether or not to require Omnicare to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B THERAPEUTIC INTERCHANGE REVIEW

### A. Therapeutic Interchange Review.

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

a. **Therapeutic Interchange Transaction:** a single transaction where one drug is substituted for another in the filling of a prescription pursuant to a therapeutic interchange program.

b. **Population:** The Population from which Therapeutic Interchange Transactions shall be drawn by the IRO for purposes of the Therapeutic Interchange Review shall include all Therapeutic Interchange Transactions for which Omnicare has received reimbursement from Medicare, Medicaid, or other Federal health care programs (i.e., Paid Claim) during the 12-month period covered by the applicable Therapeutic Interchange Review.

To be included in the Population, a Therapeutic Interchange Transaction must have resulted in at least one Paid Claim.

c. **Sample:** For each reporting period, the Sample shall include 150 Therapeutic Interchange Transactions for which Paid Claims were made during the applicable Reporting Period. The Therapeutic Interchange Transactions included in the Sample shall be drawn randomly.

d. **Replacement Sampling:** The first Therapeutic Interchange Transaction randomly drawn by the “Random Numbers” function of the statistical sampling software used by the IRO for each Federal health care program beneficiary for the Sample shall be included in the Sample. If the “Random Numbers” function of the statistical sampling software produces multiple Therapeutic Interchange Transactions for a single beneficiary, all Therapeutic Interchange Transactions for that beneficiary other than the first drawn shall be discarded, and replaced by Therapeutic Interchange Transactions chosen by additional random sampling until the Sample contains 150 Therapeutic Interchange Transactions from 150 different Federal health care program beneficiaries.

2. **Paid Claims without Supporting Documentation.** For the purpose of appraising Therapeutic Interchange Transactions included in the Therapeutic Interchange Review, any Paid Claim for which Omnicare cannot produce documentation sufficient to support the Paid Claim shall be considered an error. Replacement sampling for Paid Claims with missing documentation is not permitted.

B. Therapeutic Interchange Review Report. The following information shall be included in the Therapeutic Interchange Review Report for each sample.

1. Therapeutic Interchange Review Methodology.

- a. Therapeutic Interchange Review Population. A description of the Population subject to the Therapeutic Interchange Review.
- b. Therapeutic Interchange Review Objective. A clear statement of the objective intended to be achieved by the Therapeutic Interchange Review.
- c. Sampling Frame. A description of the sampling frame, which is the totality of Therapeutic Interchange Transactions from which the Sample has been selected.
- d. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Therapeutic Interchange Review.
- e. Review Protocol. A narrative description of how the Therapeutic Interchange Review was conducted and what was evaluated.

2. Statistical Sampling Documentation.

- a. The number of Therapeutic Interchange Transactions appraised in the sample.
- b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

3. Therapeutic Interchange Review Findings.

a. Narrative Results.

A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Therapeutic Interchange Review, including the results of the sample.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Omnicare were inconsistent with Omnicare's therapeutic interchange programs, the requirements of this CIA, Federal health care program requirements, and the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug.
- ii. A spreadsheet of the Therapeutic Interchange Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, and a description of any deviation. A deviation consists of a Therapeutic Interchange Transaction that was implemented in a manner inconsistent with Omnicare's Therapeutic Interchange Program Procedures.

4. Systems Review. Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated any inconsistencies with Omnicare's therapeutic interchange programs, the requirements of this CIA, Federal health care program requirements, and the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug.

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



## APPENDIX C

### 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> <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>	<p><u>MSP/Other Payer Involvement</u></p> <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>	<p><u>Miscellaneous</u></p> <p>13 - Insufficient Documentation                  14 - Patient Enrolled in an HMO                  15 - Services Not Rendered                  16 - Medical Necessity                  17 - Other (Please Specify)</p>
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**FIRST AMENDMENT TO THE  
CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF THE INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
OMNICARE, INC.**

Omnicare, Inc. (Omnicare), hereby enters into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG) of the Department of Health and Human Services to amend the CIA that was executed by and between Omnicare and OIG and that became effective November 9, 2006.

Omnicare and OIG agree as follows:

1. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date).
2. All terms and conditions of the CIA shall be in effect, with the following modifications:
  - a. Billing Covered Persons. Section II.C of the CIA shall be amended to include the following:
    3. "Billing Covered Persons" includes all Covered Persons who are involved in preparing or submitting claims for prescription medication to Federal health care programs for Federal health care program beneficiaries in hospice.
  - b. Policies and Procedures. Section III.B.2 of the CIA shall be amended to include the following subsections:
    - d. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements, including but not limited to claims to Federal health care programs for beneficiaries in hospice; and
    - e. procedures to be used by TCPI Acquisition Corp., d/b/a Specialized Pharmacy Services-West; Specialized Pharmacy Services, Inc.; Specialized Pharmacy Services North, Inc.; and,

excellRx, Inc., d/b/a Hospice Pharmacia (collectively, the “Michigan Pharmacies”), subsidiaries of Omnicare, to accurately determine whether a Federal health care program should be billed for hospice drugs. This Section III.B.2.e is applicable only to the Michigan Pharmacies, and shall be distributed only to Billing Covered Persons who may submit claims for the Michigan Pharmacies.

The Policies and Procedures required by this Amendment shall be implemented within 120 days of the Amendment Effective Date.

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

3. *Billing Training.* Within 120 days of the Amendment Effective Date each Billing Covered Person shall receive at least one hour of Billing Training. Billing Training shall include, at a minimum:

- a. Federal health care program billing requirements regarding the accurate preparation and submission of claims for prescription drugs provided to hospice patients;
- b. The personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- c. The legal sanctions for violations of Federal health care program requirements, including applicable legal sanctions and consequences of violations of the CIA;
- d. Examples of proper and improper claims submission practices; and
- e. Policies and procedures for the reporting and repayment of Overpayments to Federal health care programs and other payors.

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

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

4. Hospice Billing Review.

a. The IRO shall review whether the Michigan Pharmacies are in compliance with Federal health care program laws with respect to their preparation and submission of claims for prescription drugs for beneficiaries in hospice. Specifically, the IRO shall:

i. review whether the Michigan Pharmacies have developed effective policies and procedures to determine whether Medicaid should be billed for hospice drugs, including but not limited to a form to be received by the Michigan Pharmacies from the nursing home with respect to each drug for which a claim may be submitted to a Federal health care program designating whether the prescribed drug is therapeutic or palliative, and from which the Michigan Pharmacies can determine whether the drug is reimbursable by a Federal health care program (the "Hospice Drug Form");

ii. review whether the Michigan Pharmacies consistently and appropriately provide the Hospice Drug Form to nursing homes and encourage the use of the Hospice Drug Form by nursing homes; and

iii. randomly select and review 50 Paid Claims (the Discovery Sample) submitted by or on behalf of the Michigan Pharmacies, to determine whether such Paid Claims for prescription drugs were submitted in accordance with Federal health care program requirements, including but not limited to Michigan Medicaid rules governing reimbursement of therapeutic and palliative drugs.

The Paid Claims shall be reviewed based on the supporting documentation available at the locations of the Michigan Pharmacies or otherwise under Omnicare's control, including but not limited to copies of the Hospice Drug Form, and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

b. If the Error Rate (as defined in Attachment 1 to this Amendment) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Omnicare should, as appropriate, further analyze any errors identified in the Discovery Sample. Omnicare recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

c. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

i. *Full Sample.* If necessary, as determined by procedures set forth in Section III.E.4.a.iii, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Attachment 1. The Full Sample shall be designed to: (A) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (B) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at the Michigan Pharmacies' locations or under Omnicare's control, including but not limited to copies of the Hospice Drug Form, and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the

Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Omnicare may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (A) statistically appropriate and (B) Omnicare selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Omnicare to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, DME MAC, or DMERC), for appropriate follow-up by that payor.

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

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

The applicable definitions, procedures, and reporting requirements for the Hospice Billing Review are outlined in Attachment 1 to this Amendment, which is incorporated by reference.

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

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

1. a copy of all Policies and Procedures required by section 2.b of this Amendment;
2. the name and qualifications of the IRO(s), a summary/description of all engagements between Omnicare and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual Hospice Billing Review;
3. a copy of the IRO's engagement letter, including the length of the engagement;
4. a certification from the IRO regarding its professional independence and objectivity with respect to Omnicare;
5. the following information regarding the training required by section 2.c of this Amendment:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

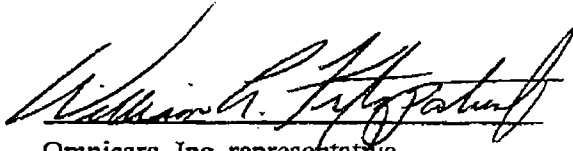
6. the certifications required by section V.C. of the CIA with respect to the requirements of this Amendment.
3. The Annual Reports required by section V.B of the CIA shall include the information relevant to Omnicare's compliance with the terms of this Amendment, as described in section V.B of the CIA.

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

5. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.



ON BEHALF OF OMNICARE, INC.

  
\_\_\_\_\_  
Omnicare, Inc. representative

10/25/07  
\_\_\_\_\_  
DATE

\_\_\_\_\_  
SANFORD TEPLITZKY  
Counsel for Omnicare

\_\_\_\_\_  
DATE

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

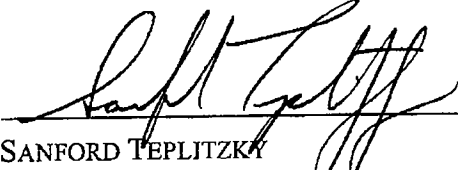
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GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

\_\_\_\_\_  
DATE

ON BEHALF OF OMNICARE, INC.

\_\_\_\_\_  
Omnicare, Inc. representative

\_\_\_\_\_  
DATE

  
\_\_\_\_\_  
SANFORD TEPLITZKY  
Counsel for Omnicare

\_\_\_\_\_  
10/25/07  
\_\_\_\_\_  
DATE

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

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

\_\_\_\_\_  
DATE

**ON BEHALF OF OMNICARE, INC.**

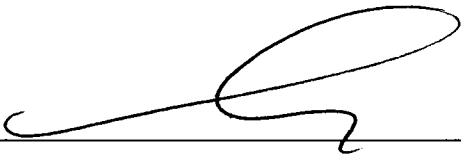
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Omnicare, Inc. representative

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DATE

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SANFORD TEPLITZKY  
Counsel for Omnicare

\_\_\_\_\_  
DATE

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

  
\_\_\_\_\_

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

10/26/07  
DATE

## **ATTACHMENT 1 HOSPICE BILLING REVIEW**

### A. Hospice Billing Review.

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

- a. Overpayment: The amount of money the Michigan Pharmacies have received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by the Michigan Pharmacies for drugs provided to patients in hospice and for which the Michigan Pharmacies have received reimbursement from the Medicaid program.
- d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of the Michigan Pharmacies and for which the Michigan Pharmacies have received reimbursement from Medicaid (i.e., Paid Claim) during the 12-month period covered by the first Hospice Billing Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which the Michigan Pharmacies have received reimbursement from Medicaid (i.e., Paid Claim) during the 12-month period covered by the Hospice Billing Review.

To be included in the Population, an Item must have resulted in at least one Paid Claim.

- e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

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

2. *Other Requirements.*

a. Paid Claims Without Supporting Documentation. For the purpose of appraising Items included in the Hospice Billing Review, any Paid Claim for which the Michigan Pharmacies cannot produce documentation within their control sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the Michigan Pharmacies for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

c. Use of First Samples Drawn. For the purposes of all the samples discussed in this Attachment, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the sample).

B. Hospice Billing Review Report. The following information shall be included in the Hospice Review Report for the sample.

1. *Hospice Billing Review Methodology.*

a. Sampling Unit. A description of the Item as that term is utilized for the Hospice Billing Review.

b. Hospice Billing Review Population. A description of the Population subject to the Hospice Billing Review.

c. Hospice Billing Review Objective. A clear statement of the objective intended to be achieved by the Hospice Billing Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Hospice Billing Review (*e.g.*, medical

records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Hospice Billing Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

- a. The number of Items appraised in the sample.
- b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

3. *Hospice Billing Review Findings.*

a. Narrative Results.

- i. A description of the Michigan Pharmacies’s billing and coding system(s) for hospice, including the identification, by position description, of the personnel involved in coding and billing for hospice.
- ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Hospice Billing Review.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by the Michigan Pharmacies (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to the Michigan Pharmacies.
- iii. Total dollar amount of all Overpayments in the sample.

