

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
NOEL R. BOTSCH, R.PH AND PHARMACY I.V. ASSOCIATES OF DEXTER,  
INC. D/B/A O.P.T.I.O.N. CARE PHARMACY, NOW D/B/A SPECIAL DESIGN  
HEALTH CARE**

**I. PREAMBLE**

Noel R. Botsch, R.Ph. (“Botsch”) and Pharmacy I.V. Associates of Dexter, Inc. d/b/a O.P.T.I.O.N. Care Pharmacy, now d/b/a Special Design Health Care (“Pharmacy I.V. Associates”) hereby enter 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). This Agreement applies to Pharmacy I.V. Associates and any entity that Pharmacy I.V. Associates owns or in which Pharmacy I.V. Associates has a control interest, as defined in 42 U.S.C. § 1320a-7(a)(3), and any such entity’s Covered Persons as defined in Section II.C. Contemporaneously with this CIA, Pharmacy I.V. Associates is entering into a Settlement Agreement with the United States.

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

A. The period of the compliance obligations assumed by Pharmacy I.V. Associates under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Pharmacy I.V. Associates' final annual report; or (2) any additional materials submitted by Pharmacy I.V. Associates 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 owners, officers, directors, and employees of Pharmacy I.V. Associates; and
- b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Pharmacy I.V. Associates, excluding vendors whose sole connection with Pharmacy I.V. Associates is selling or otherwise providing medical supplies or equipment or pharmacy items and supplies to Pharmacy I.V. Associates and who do not bill the Federal health care programs for such medical supplies or equipment or pharmacy items and supplies.

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.

2. "Relevant Covered Persons" includes:

- a. all Covered Persons who solicit, obtain, receive, fill, or otherwise handle orders from physicians or individuals for pharmacy supplies, durable medical equipment and/or supplies on behalf Pharmacy I.V. Associates;

- b. all Covered Persons who code or submit to Medicaid claims for pharmacy supplies, durable medical equipment and/or supplies on behalf Pharmacy I.V. Associates;
- c. all Covered Persons who are involved in the delivery of patient care items or services including, but not limited to infusion therapy, respiratory therapy, and health management; and
- d. all Covered Persons who make or implement company policy and procedures for Pharmacy I.V. Associates with regard to pharmacy supplies, durable medical equipment, supplies, and/or Medicaid billing.

D. Botsch agrees to devote his best efforts to ensuring that Pharmacy I.V. Associates discharges its corporate integrity and related obligations under Sections III–XI as long as he is an officer, director, or sole shareholder of that corporation.

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

Pharmacy I.V. Associates shall establish and maintain a Compliance Program that includes the following elements:

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

1. *Compliance Officer.* Within 90 days after the Effective Date, Pharmacy I.V. Associates shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Pharmacy I.V. Associates, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Pharmacy I.V. Associates, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel

or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Pharmacy I.V. Associates as well as for any reporting obligations created under this CIA.

Pharmacy I.V. Associates shall report to OIG in writing within 15 days 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.

2. *Compliance Committee.* Within 90 days after the Effective Date, Pharmacy I.V. Associates shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., managers with authority over various core functions such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Pharmacy I.V. Associates shall report to OIG in writing within 15 days 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.

B. Written Standards.

1. *Code of Conduct.* Pharmacy I.V. Associates has developed a written Code of Conduct. Within 60 days after the Effective Date, Pharmacy I.V. Associates shall review its written Code of Conduct and ensure that the Code of Conduct sets forth:

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

Within 90 days after the Effective Date, Pharmacy I.V. Associates shall implement and distribute the written Code of Conduct to all Covered Persons. Pharmacy I.V. Associates shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Pharmacy I.V. Associates' Code of Conduct. New Covered Persons shall receive the Code of Conduct

and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures.* Pharmacy I.V. Associates has developed written Policies and Procedures regarding Pharmacy I.V. Associates' operations. Within 60 days after the Effective Date, Pharmacy I.V. Associates shall review its written Policies and Procedures to ensure that the written Policies and Procedures are consistent with its compliance program and comply 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 the Federal health care programs for filing claims for patient care services, pharmacy items and supplies, and durable medical equipment and/or supplies.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be implemented and distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, Pharmacy I.V. Associates shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Pharmacy I.V. Associates’:

- a. CIA requirements; and
- b. Pharmacy I.V. Associates’ Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 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 Federal health care program requirements regarding physician orders for pharmacy items and supplies, dispensing of pharmacy items and supplies, and regarding durable medical equipment and supplies;
- b. the Federal health care program requirements regarding accurate coding and submission of claims;
- c. policies, procedures, and other requirements applicable to the documentation of medical records;

- d. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- e. applicable reimbursement statutes, regulations, and program requirements and directives;
- f. the legal sanctions for violations of the Federal health care program requirements; and
- g. examples of proper and improper claims submission practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. A Pharmacy I.V. Associates employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services 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 in each subsequent Reporting Period.

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.* Pharmacy I.V. Associates shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information.

6. *Computer-based Training.* Pharmacy I.V. Associates may provide the training required under this CIA through appropriate computer-based training approaches. If Pharmacy I.V. Associates choose 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. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Pharmacy I.V. Associates 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 Pharmacy I.V. Associates in assessing and evaluating its billing and coding practices and certain other obligations pursuant to this CIA and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

The IRO shall have expertise in the billing, coding, reporting and other requirements for submission of claims to Medicaid, and other Federal health care programs for pharmaceutical items and services and durable medical equipment and supplies. The IRO shall assess, along with Pharmacy I.V. Associates, 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 Pharmacy I.V. Associates's coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review).

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

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

2. *Claims Review.* The Claims Review shall include a Discovery Sample of 50 Paid Claims and, if the Error Rate for the Discovery Sample is 5% or greater, a Full Sample and Systems Review. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B.

4. *Repayment of Identified Overpayments.* In accordance with Section III.H.1, Pharmacy I.V. Associates 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. Pharmacy I.V. Associates shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Pharmacy I.V. Associates a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Within 90 days after the Effective Date, Pharmacy I.V. Associates shall establish and implement a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person, any identified issues or questions associated with Pharmacy I.V. Associates' 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. Pharmacy I.V. Associates shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Pharmacy I.V. Associates 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.

F. 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 scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
  
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Pharmacy I.V. Associates shall ensure that no prospective and current Covered Persons are Ineligible Persons, as defined in Section III.F.1 above, by implementing the following screening requirements.

- a. Pharmacy I.V. Associates shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall

require such Covered Persons to disclose whether they are Ineligible Persons.

b. Pharmacy I.V. Associates shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Pharmacy I.V. Associates shall implement a policy requiring all Covered 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) Pharmacy I.V. Associates to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Pharmacy I.V. Associates understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Pharmacy I.V. Associates may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Pharmacy I.V. Associates meets the requirements of Section III.F.

3. *Removal Requirement.* If Pharmacy I.V. Associates has actual notice that a Covered Person has become an Ineligible Person, Pharmacy I.V. Associates shall remove such Covered Person from responsibility for, or involvement with, Pharmacy I.V. Associates' business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Pharmacy I.V. Associates has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for

exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, Pharmacy I.V. Associates shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Pharmacy I.V. Associates shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Pharmacy I.V. Associates conducted or brought by a governmental entity or its agents involving an allegation that Pharmacy I.V. Associates 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. Pharmacy I.V. Associates 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.

H. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Pharmacy I.V. Associates 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, Pharmacy I.V. Associates identifies or learns of any Overpayment, Pharmacy I.V. Associates 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, Pharmacy I.V. Associates 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, Pharmacy I.V. Associates 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;
- 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; or
- iii. the filing of a bankruptcy petition by Pharmacy I.V. Associates.

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

b. *Reporting of Reportable Events.* If Pharmacy I.V. Associates determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Pharmacy I.V. Associates 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.H.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 Pharmacy I.V. Associates' actions taken to correct the Reportable Event; and

iv. any further steps Pharmacy I.V. Associates plans to take to address the Reportable Event and prevent it from recurring.

v. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of

the filing and a description of any Federal health care program authorities implicated.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Pharmacy I.V. Associates changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Pharmacy I.V. Associates shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Pharmacy I.V. Associates 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, Pharmacy I.V. Associates shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number and/or supplier number, and the name and address of the contractor that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Pharmacy I.V. Associates proposes to sell any or all of its business units or locations that are subject to this CIA, Pharmacy I.V. Associates shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the Effective Date, Pharmacy I.V. Associates 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 Pharmacy I.V. Associates' 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.E;

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Pharmacy I.V. Associates and the IRO;

9. a certification from the IRO regarding its professional independence and objectivity with respect to Pharmacy I.V. Associates;

10. a description of the process by which Pharmacy I.V. Associates fulfills the requirements of Section III.F regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; 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 Pharmacy I.V. Associates'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 and/or supplier number(s); and the name and address of each Medicare contractor to which Pharmacy I.V. Associates currently submits claims;

13. a description of Pharmacy I.V. Associates' 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. Pharmacy I.V. Associates shall submit to OIG annually a report with respect to the status of, and findings regarding, Pharmacy I.V. Associates' compliance activities for each of the 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);
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; and
  - 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.D, along with a copy of the IRO's engagement letter (if applicable);
6. Pharmacy I.V. Associates' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. a summary and description of any and all current and prior engagements and agreements between Pharmacy I.V. Associates 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 objectivity with respect to Pharmacy I.V. Associates;

9. a summary of Reportable Events (as defined in Section III.H) 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: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

12. any changes to the process by which Pharmacy I.V. Associates fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Pharmacy I.V. Associates in response to the screening and removal obligations set forth in Section III.F; 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;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. 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 Pharmacy I.V. Associates' locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s) and/or supplier number(s); and the name and address of each Medicare contractor to which Pharmacy I.V. Associates 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, Pharmacy I.V. Associates 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. to the best of his or her knowledge, Pharmacy I.V. Associates has complied with its obligations under the Settlement Agreement that Pharmacy I.V. Associates will 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.

D. Designation of Information. Pharmacy I.V. Associates 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. Pharmacy I.V. Associates 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

Pharmacy I.V. Associates:

Brian Bradshaw, R.Ph.  
61 Doctor's Park  
Cape Girardeau, MO 63701  
Telephone: (573) 339-1999  
Facsimile: (573) 335-7233

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. Upon request by OIG, Pharmacy I.V. Associates may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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

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

Pharmacy I.V. Associates 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) from the Effective Date.

## **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 Pharmacy I.V. Associates prior to any release by OIG

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

**X. BREACH AND DEFAULT PROVISIONS**

Pharmacy I.V. Associates is expected to comply fully and timely with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Pharmacy I.V. Associates 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 Pharmacy I.V. Associates 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 and Relevant 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 Pharmacy I.V. Associates fails to engage an IRO, as required in Section III.D 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 Pharmacy I.V. Associates fails to submit the Implementation Report or any 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 Pharmacy I.V. Associates fails to submit any Claims Review Report or Unallowable Cost Review Report in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Pharmacy I.V. Associates 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 Pharmacy I.V. Associates fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Pharmacy I.V. Associates stating the specific grounds for its determination that Pharmacy I.V. Associates has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Pharmacy I.V. Associates shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Pharmacy I.V. Associates 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. Pharmacy I.V. Associates 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 Pharmacy I.V. Associates 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 Pharmacy I.V. Associates 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 Pharmacy I.V. Associates 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 Pharmacy I.V. Associates of: (a) Pharmacy I.V. Associates' 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, Pharmacy I.V. Associates 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 Pharmacy I.V. Associates elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Pharmacy I.V. Associates 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 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

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 Pharmacy I.V. Associates 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 Pharmacy I.V. Associates to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Pharmacy I.V. Associates constitutes an independent basis for Pharmacy I.V. Associates' exclusion from participation in the Federal health care programs. Upon a determination by OIG that Pharmacy I.V. Associates has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall

notify Pharmacy I.V. Associates of: (a) Pharmacy I.V. Associates' 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.* Pharmacy I.V. Associates' 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. Pharmacy I.V. Associates 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) Pharmacy I.V. Associates has begun to take action to cure the material breach; (ii) Pharmacy I.V. Associates is pursuing such action with due diligence; and (iii) Pharmacy I.V. Associates has provided to OIG a reasonable timetable for curing the material breach.

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

Pharmacy I.V. Associates and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Pharmacy I.V. Associates unless otherwise agreed to in writing by OIG prior to the sale, assignment or transfer.

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

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

D. OIG may agree to a suspension of Pharmacy I.V. Associates's obligations under the CIA in the event of Pharmacy I.V. Associates' cessation of participation in Federal health care programs. If Pharmacy I.V. Associates ceases participating in Federal health care programs and is relieved of its CIA obligations by OIG, Pharmacy I.V. Associates shall notify OIG at least 30 days in advance of Pharmacy I.V. Associates' intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Pharmacy I.V. Associates 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 constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**On Behalf of Noel R. Botsch, R.Ph.**

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Noel R. Botsch

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DATE

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Harvey M. Tettlebaum  
Robert L. Hess II  
Husch Blackwell Sanders LLP  
Counsel for Noel R. Botsch

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DATE

**Pharmacy I.V. Associates of Dexter, Inc. d/b/a O.P.T.I.O.N. Care Pharmacy, now  
d/b/a Special Design Health Care**

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Pharmacy I.V. Associates of Dexter, Inc.  
d/b/a O.P.T.I.O.N. Care Pharmacy,  
now d/b/a Special Design Health Care

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DATE

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Harvey M. Tettlebaum  
Robert L. Hess II  
Husch Blackwell Sanders LLP  
Counsel for Pharmacy I.V. Associates of Dexter, Inc.

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DATE

**On Behalf of the Office of Inspector General of the  
Department of Health and Human Services**

/Gregory E. Demske/

8/11/09

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

\_\_\_\_\_  
DATE

I.V. Associates shall notify OIG at least 30 days in advance of Pharmacy I.V. Associates' intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Pharmacy I.V. Associates 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 constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**On Behalf of Noel R. Botsch, R.Ph.**

/Noel R. Botsch/

Noel R. Botsch

7/27/09

DATE

/Harvey M. Tettlebaum/

Harvey M. ~~Tettlebaum~~  
Robert L. Hess II  
Husch Blackwell Sanders LLP  
Counsel for Noel R. Botsch

7/31/09

DATE

**Pharmacy I.V. Associates of Dexter, Inc. d/b/a O.P.T.I.O.N. Care Pharmacy, now  
d/b/a Special Design Health Care**

/Noel R. Botsch/

7/27/09

Pharmacy I.V. Associates of Dexter, Inc.  
d/b/a O.P.T.I.O.N. Care Pharmacy,  
now d/b/a Special Design Health Care

DATE

/Harvey M. Tettlebaum/

7/31/09

Harvey M. Tettlebaum  
Robert L. Hess II  
Husch Blackwell Sanders LLP  
Counsel for Pharmacy I.V. Associates of Dexter, Inc.

DATE

**On Behalf of the Office of Inspector General of the  
Department of Health and Human Services**

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

\_\_\_\_\_  
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.

Pharmacy I.V. Associates 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 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 Pharmacy I.V. Associates if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pharmacy I.V. Associates may continue to engage the IRO.

If Pharmacy I.V. Associates 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, Pharmacy I.V. Associates shall submit the information identified in Section V.A.8 of the CIA 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 Pharmacy I.V. Associates if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pharmacy I.V. Associates may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review engagement who have expertise in the billing, coding, and the requirements for submission of claims to Medicaid, and other Federal health care program(s) from which Pharmacy I.V. Associates seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification (e.g., CCA, CCS, CCS-P, CPC, RRA, etc.) and who have maintained this certification (e.g., completed applicable continuing education requirements); and

4. 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 Claim Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicaid policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Claims Review in a professionally independent and 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 Pharmacy I.V.

Associates.

E. IRO Removal/Termination.

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

Prior to requiring Pharmacy I.V. Associates to engage a new IRO, OIG shall notify Pharmacy I.V. Associates 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, Pharmacy I.V. Associates 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. Pharmacy I.V. Associates 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 Pharmacy I.V. Associates prior to requiring Pharmacy I.V. Associates to terminate the IRO. However, the final determination as to whether or not to require Pharmacy I.V. Associates to engage a new IRO shall be made at the sole discretion of OIG.

**APPENDIX B**  
**CLAIMS REVIEW**

A. Claims Review.

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

a. Overpayment: The amount of money Pharmacy I.V. Associates has 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 Pharmacy I.V. Associates and for which Pharmacy I.V. Associates has 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 Pharmacy I.V. Associates and for which Pharmacy I.V. Associates has received reimbursement from Medicaid (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which Pharmacy I.V. Associates has received reimbursement from Medicaid (i.e., Paid Claim) during the 12-month period covered by the Claims 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. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of Pharmacy I.V. Associates (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Pharmacy I.V. Associates' office or under Pharmacy I.V. Associates' control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) 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, Pharmacy I.V. Associates should, as appropriate, further analyze any errors identified in the Discovery Sample. Pharmacy I.V. Associates 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.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) 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 (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Pharmacy I.V. Associates or under

Pharmacy I.V. Associates' control and applicable billing and coding regulations and guidance to determine whether the claim 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, Pharmacy I.V. Associates 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: (1) statistically appropriate and (2) Pharmacy I.V. Associates 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 Pharmacy I.V. Associates to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

4. *Systems Review.* If Pharmacy I.V. Associates' Discovery Sample identifies an Error Rate of 5% or greater, Pharmacy I.V. Associates' IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full 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.

5. *Other Requirements.*

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Pharmacy I.V. Associates cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Pharmacy I.V. Associates 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 samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, 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 Discovery Sample or Full Sample).

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*.

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

b. Claims Review Population. A description of the Population subject to the Claims Review.

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

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full 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 Claims 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 Claims Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full 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.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of Pharmacy I.V. Associates’ billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Pharmacy I.V. Associates (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 Pharmacy I.V. Associates.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.
- vi. A spreadsheet of the Claims 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, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

4. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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