CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ELIZABETHTOWN HEMATOLOGY AND ONCOLOGY, PLC AND YUSUF K. DESHMUKH, M.D.

I. PREAMBLE

Elizabethtown Hematology and Oncology, PLC (EHO) and Yusuf K. Deshmukh, M.D. (individually "Provider," collectively, "Providers") 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, program requirements, 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, the Providers are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. This CIA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this CIA. 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, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Providers' final Annual Report; or (2) any additional materials submitted by Providers pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. all owners and employees of Providers, including but not limited to Dr. Deshmukh;

2. all employees of any entity in which Dr. Deshmukh or EHO has an ownership or control interest (as defined in 42 U.S.C. §1320a-3(a)(3)) at any time during the term of this CIA and any contractors,

subcontractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity (the employees of any third party billing company that submits claims to the Federal health care programs on behalf of such entities shall not be considered Covered Persons, provided that Providers and the third party billing company provide the certifications required by Section III.J).

III. CORPORATE INTEGRITY OBLIGATIONS

Providers shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer

Within 90 days after the Effective Date, Providers shall appoint a Covered Person to serve as their 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 report directly to the senior management of Providers, shall make periodic (at least quarterly) reports regarding compliance matters directly to the senior management of Providers, shall be authorized to report on such matters to the senior management at any time, and shall not be legal counsel to Providers. Written documentation of the Compliance Officer's reports to the senior management shall be made available to OIG upon request. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Providers as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Providers 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 five days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, Providers shall implement written Policies and Procedures regarding appropriate billing and medical documentation requirements for compliance with Federal health care programs, including, but not limited to, at a minimum:

1. ensuring proper and accurate submission of all claims to Federal health care programs;

2. the Federal health care program billing, coding and claim submission statutes, regulations, program requirements and directives relating to:

    a. medical necessity determinations;
    b. infusion therapy;
    c. evaluation and management coding; and
    d. timed coding.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Providers shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

C. Posting of Notice

Within 30 days after the Effective Date, Providers shall post in a prominent place accessible to all patients/customers and Covered Persons a notice that provides the name and phone number of the Compliance Officer, and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training

All Covered Persons shall receive at least three hours of training during the first Reporting Period, including at least one hour of training to be completed within 60 days after the Effective Date. Training may be completed in-person or online. These training requirements may be satisfied only by training courses that are submitted to OIG, prior to registration for the training course, for review and approval, and may include courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), or Providers' Medicare contractor, if they fulfill the requirements below.

At a minimum, required training sessions must include the following topics:

a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to the services furnished by Providers;

b. the role of individual medical necessity determinations in the decisions regarding intravenous infusions, including but not limited to chemotherapy administration;

c. the Federal health care program medical record documentation requirements relating to services furnished by Providers; and

d. the personal obligation of each individual involved in the medical record documentation and claims submission processes to ensure that medical records and claims are accurate.

The training must be appropriately tailored to the audience and their specific responsibilities.

Each individual who is required to attend training shall certify, in writing or in electronic form, 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.

E. Review Procedures

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Providers shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E.[1] The IRO must have the qualifications and must be able to meet the other requirements relating to the IRO outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. *Claims Review.* The IRO shall conduct a review of Providers' coding, billing, and claims submission to the Federal health care programs and the reimbursement received for each three-month period during the term of this CIA (Quarterly Claims Review or Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Infusion Therapy Review.* The IRO shall conduct a review of the medical necessity and appropriateness of infusion therapy treatments billed to the Federal health care programs and the associated reimbursement received for each three-month period during the term of this CIA (Quarterly Infusion Therapy Review or Infusion Therapy Review) and shall prepare a Quarterly Infusion Therapy Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Infusion Therapy Review requirement shall begin 30 days after the Effective Date. Each Quarterly Infusion Therapy Review Report

[1] In addition to any reviews performed of EHO's Federal health care program claims, Dr. Deshmukh must engage an IRO to perform the reviews described in this CIA of any claims he submits to Federal health care programs under his own provider identification number and of any claims submitted to Federal health care programs by any entity in which he has an ownership or control interest (other than in EHO).

shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

4. *Validation Review.* In the event OIG has reason to believe that: (a) any Claims Review or Infusion Therapy Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, Claims Review, or Infusion Therapy Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Infusion Therapy Review complied with the requirements of the CIA and/or the findings or Claims Review or Infusion Therapy Review results are inaccurate (Validation Review). Providers shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Providers' final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Providers in writing of its intent to conduct a Validation Review and the reasons OIG has determined a Validation Review is necessary. Providers shall have up to 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Claims Review or Infusion Therapy Review or to correct the inaccuracy of the Claims Review or Infusion Therapy Review and/or to propose alternatives to the proposed Validation Review. OIG will attempt in good faith to resolve any Claims Review or Infusion Therapy Review issues with Providers 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 and Objectivity Certification.* Prior to performing the first Quarterly Claims Review or Quarterly Infusion Therapy Review, and annually thereafter, the IRO shall provide to Providers a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

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) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, 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 (LEIE) (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (SAM) (available through the Internet at http://www.sam.gov)

2. *Screening Requirements*. Providers shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Providers shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Covered Persons to disclose whether they are Ineligible Persons.

b. Providers shall screen all current Covered Persons against the Exclusion Lists within 30 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

c. Providers shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

Providers shall maintain documentation demonstrating that Providers: (1) have checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) have required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the Providers' responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Providers understand that items or services furnished by excluded persons are not payable by Federal health care programs and that Providers may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Providers meet the requirements of Section III.F

3. *Removal Requirement.* If a Provider has actual notice that a Covered Person has become an Ineligible Person, the Provider shall remove such Covered Person from responsibility for, or involvement with, the Provider's 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 rendered, 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 a Provider 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, the Provider 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 the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, a Provider shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to the Provider conducted or brought by a governmental entity or its agents involving an allegation that Providers have committed a crime or have 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. The Provider 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 proceedings, if any.

H. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money a Provider has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Reporting of Overpayments*. If, at any time, a Provider identifies or learns of any Overpayment, the Provider(s) shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take steps to correct the problem and prevent the Overpayment from recurring within 90 days after identification (or such additional time as may be agreed to by the payor). If not yet quantified within 60 days after identification, the Provider(s) shall notify the payor at that time of its efforts to quantify the Overpayment amount and provide a schedule of when such work is expected to be completed. The Provider(s) should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

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

a. a substantial Overpayment;

b. 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;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by Providers.

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

2. *Reporting of Reportable Events.* If a Provider determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the Provider shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial Overpayment exists, and shall include:

a. a description of the steps taken by the Providers to identify and quantify the Overpayment;

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

c. a description of Providers' actions taken to correct the Reportable Event.

Within 60 days of identification of the Overpayment, Providers' shall send to OIG a copy of the notification and repayment (if quantified) to the payor required by Section III.I.2.

4. *Reportable Events under Section III.I.1.b and c.* For Reportable Events under Section III.I.1.b and III.I.1.c, the report to the OIG shall include

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

b. a description of the Providers' actions taken to correct the Reportable Event; and

c. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Providers to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Providers to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If a Provider identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then the Provider is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

J. Third Party Billing

If, prior to the Effective Date or at any time during the term of this CIA, Providers contract with a third party billing company to submit claims to the Federal health care programs on behalf of Providers, Providers must certify to OIG that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company.

Providers also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its

prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's System for Award Management; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in Providers' Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

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

B. Purchase or Establishment of New Location or Business. In the event that, after the Effective Date, a Provider purchases or establishes a new location or business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Providers shall notify OIG at least 30 days prior to such purchase or the operation of the new location or business. This notification shall include the address of the new location or business, phone number, fax number, Medicare and state Medicaid program provider identification number and/or supplier number, and the name and address of each Medicare and state Medicaid program contractor to which the Provider currently submits claims. Each new location or business and all Covered Persons at each new location or business shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

C. Sale of Location or Business. In the event that, after the Effective Date, a Provider proposes to sell any or all of its locations or businesses that are subject to this CIA, Providers shall notify OIG at least 30 days prior to the proposed sale. This notification shall include a description of the location or business 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 location or business, unless otherwise determined and agreed to in writing by OIG.

D. New Employment or Contractual Arrangement. At least 30 days prior to Dr. Deshmukh becoming an employee or contractor with another party related to the

furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Deshmukh shall notify OIG of his plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of Dr. Deshmukh's responsibilities with respect to such potential employer or contractor. In addition, prior to Dr. Deshmukh becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Deshmukh shall notify that party of this CIA. This notification shall include a copy of the CIA and a statement indicating the remaining term of the CIA. The CIA shall continue to apply to Dr. Deshmukh following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION, IRO REPORTS, AND ANNUAL REPORTS

A. Implementation Report. Within 90 days after the Effective Date, Providers shall submit a written report to OIG summarizing the status of their 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. a copy of the policies and procedures required by Section III.B.;

3. a copy of the notice Providers posted in their office(s) as required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

4. the following information regarding the training required by Section III.D: a copy of the training certifications for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program.

A copy of all training materials shall be made available to OIG upon request.

5. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Providers and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Providers;

6. a copy of the documentation demonstrating that Providers have screened all Covered Persons against the Exclusion Lists, as required by Section III.F within 30 days of the Effective Date;

7. a copy of any certifications from Providers and the third party billing company required by Section III.J (if applicable);

8. a list of all of Providers' 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 and state Medicaid program provider identification number(s), and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which Providers currently submits claims; and

9. certifications signed by Providers' Compliance Officer and owners that: (a) each has reviewed the CIA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Providers are in compliance with all of the requirements of this CIA; and (c) each has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. IRO Reports. Within 60 days following the end of each three-month period during the term of this CIA, the Providers shall provide to OIG a copy of the Quarterly Claims Review Report and Quarterly Infusion Therapy Review Report prepared by the IRO for each Quarterly Claims Review and Quarterly Infusion Therapy Review performed, along with the Providers' response and corrective action plan related to any recommendations made by the IRO in the report(s). Each Quarterly Claims Review Report and Quarterly Infusion Therapy Review Report shall include the information specified in Appendix B to this CIA.

C. Annual Reports. Providers shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Providers' compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

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

2. a description of any changes to the policies and procedures required by Section III.B.;

3. a description of any changes to the notice required by Section III.C, and the reason for such changes, along with a copy of the revised notice;

4. (in the first Annual Report) the following information regarding the training required by Section III.D: a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program;

A copy of all training materials shall be made 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;

6. Providers' response to the reports prepared pursuant to Section III.E, along with corrective action plan(s) related to any issues raised by the reports;

7. a summary and description of any and all current and prior engagements and agreements between Providers and the IRO(s) (if different from what was submitted as part of the Implementation Report);

8. a certification from the IRO(s) regarding its professional independence and objectivity with respect to Providers;

9. a copy of the documentation demonstrating that Providers screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.F;

10. 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;

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

12. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

13. a copy of any certifications from Providers and the third party billing company required by Section III.J (if applicable);

14. a description of all changes to the most recently provided list of Providers' locations (including addresses) as required by Section V.A.8; and

15. certifications signed by Providers' Compliance Officer and owners that: (a) each has reviewed the CIA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, the Provider is in compliance with all of the requirements of this CIA; and (c) each has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

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.

D. Designation of Information. Providers shall clearly identify any portions of their submissions that they believe 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. Providers 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, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Providers:

Yusuf K. Deshmukh M.D.
Elizabethtown Hematology/Oncology, PLC
1107 Woodland Drive , Suite 104
Elizabethtown, KY 42701-2789
Phone: (270) 769-6665

Unless otherwise specified, all notifications and reports required by this CIA shall 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, Providers 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 and/or request copies of Providers' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Providers' locations for the purpose of verifying and evaluating: (a) Providers' compliance with the terms of this CIA; and (b) Providers' compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Providers to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview Providers and any of Providers' Covered Persons 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. Providers shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Providers' Covered Persons may elect to be interviewed with or without a representative of Providers present.

VIII. DOCUMENT AND RECORD RETENTION

Providers shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and 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 Providers prior to any release by OIG of information submitted by Providers pursuant to their obligations under this CIA and identified upon submission by Providers as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Providers shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Providers are expected to fully and timely comply with all of their CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Providers and OIG hereby agree that failure to comply with certain obligations set forth in this CIA (unless a timely written request for an extension has been

submitted and approved in accordance with Section B below) 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 $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day a Provider fails to:

a. appoint a Compliance Officer as required by Section III.A;

b. implement the policies and procedures required by Section III.B;

c. establish and/or post a notice in accordance with the requirements of Section III.C;

d. complete the training required for Covered Persons and maintain training certifications, in accordance with the requirements of Section III.D;

e. engage and use an IRO in accordance with the requirements of Section III.E, Appendix A, and Appendix B;

f. screen Covered Persons in accordance with the requirements of Section III.F or require Covered Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;

g. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;

h. repay any Overpayments in accordance with Section III.H;

i. report a Reportable Event in accordance with Section III.I.; or

j. provide to OIG the certifications required by Section III.J relating to any third party biller engaged by Providers during the term of the CIA.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day a Provider fails to submit the Implementation Report, IRO Reports, or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of $1,000 for each day a Provider fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date a Provider fails to grant access.)

4. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of a Provider as part of its/his Implementation Report, IRO Reports, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this CIA.

5. A Stipulated Penalty of $1,000 for each day a Provider fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to the Provider stating the specific grounds for its determination that a Provider has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Provider shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date the Provider 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 1-4 of this Section.

B. Timely Written Requests for Extensions. Providers 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 a Provider 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 days after the Provider 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 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 a Provider 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 the Provider of: (a) the Provider's failure to comply; and (b) OIG's intent to exercise its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, the Provider shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for 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 the Provider elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the Provider 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 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 a Provider 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 a Provider to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;

b. repeated or flagrant violations 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, Appendix A, and Appendix B.

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

3. *Opportunity to Cure.* Providers 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. the Providers are 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) the Provider has begun to take action to cure the material breach; (ii) the Provider is pursuing such action with due diligence; and (iii) the Provider has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, the Provider fails to satisfy the requirements of Section X.D.3, OIG may exclude the Provider from participation in the Federal health care programs. OIG shall notify the Provider in writing of its determination to exclude the Provider. (This letter shall be

referred to 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 the Provider's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, the Provider 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 Providers 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, Providers 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 the 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether the Providers were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Providers shall have the burden of proving their 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 a Provider to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the Provider 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 Chapter 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 the Provider 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) the Provider had begun to take action to cure the material breach within that period; (ii) the Provider has pursued and is pursuing such action with due diligence; and (iii) the Provider provided to OIG within that period a reasonable timetable for curing the material breach and the Provider 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 Providers, only after a DAB decision in favor of OIG. Providers' election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Providers 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 Providers 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. Providers shall waive their 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 the Providers, the Providers shall be reinstated effective 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

Providers and OIG agree as follows:

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

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

C. OIG may agree to a suspension of a Provider's obligations under this CIA based on a certification by the Provider that it/he is no longer providing health care items or services that will be billed to any Federal health care programs and it/he does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If a Provider is relieved of its/his CIA obligations, the Provider shall be required to notify OIG in writing at least 30 days in advance if the Provider plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, the OIG shall evaluate whether the CIA will be reactivated or modified for that Provider.

D. All requirements and remedies set forth in this CIA are in addition to, and do not affect (1) Providers' responsibilities to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable program requirements.

E. The undersigned Provider signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are 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 ELIZABETHTOWN HEMATOLOGY AND ONCOLOGY, PLC

/Yusuf K. Deshmukh, M.D./

YUSUF K. DESHMUKH, M.D.

5/8/2014
DATE

/Marc S. Murphy/

MARC S. MURPHY
Stites & Harbison, PLLC
Counsel for Elizabethtown
Hematology and Oncology, PLC

5/13/14
DATE

ON BEHALF OF YUSUF K. DESHMUKH, M.D.

/Yusuf K. Deshmukh, M.D./

5/8/2014

YUSUF K. DESHMUKH, M.D. DATE

/Marc S. Murphy/

5/13/14

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

/Robert K. DeConti/

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ROBERT K. DECONTI
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DATE

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5/15/2014

SARAH K. KESSLER
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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.E of the CIA.

A. IRO Engagement

1. The Providers shall engage an IRO or IROs that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the reviews in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.5 of the CIA or any additional information submitted by the Providers in response to a request by OIG, whichever is later, OIG will notify the Providers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Providers may continue to engage the IRO.

2. If the Providers engage 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, the Providers shall submit the information identified in Section V.A.5 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by the Providers at the request of OIG, whichever is later, OIG will notify the Providers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Providers may continue to engage the IRO.

B. IRO Qualifications

The IRO(s) shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of the Federal health care program(s) from which the Providers seek reimbursement;

2. assign individuals to conduct the Infusion Therapy Reviews who are appropriately certified in the respective professional field/specialty, have expertise in infusion therapy and in the billing, coding, claims submission, and other Federal health care program reimbursement requirements for infusion therapy services;

3. assign individuals to design and select the Claims Review and Infusion Therapy Review samples who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review and Infusion Therapy Review who have a nationally recognized coding certification 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(s) shall:

1. perform each Claims and Infusion Therapy Review in accordance with the specific requirements of the CIA;

2. follow all applicable professional standards and Federal health care program rules and reimbursement guidelines in making assessments in the Claims and Infusion Therapy Reviews;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);

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 to the CIA.

D. IRO Independence and Objectivity

The IRO(s) must perform the Claims Reviews and Infusion Therapy Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *The Providers and IRO.* If the Providers terminate their IRO or if the IRO withdraws from the engagement during the term of the CIA, the Providers must submit a notice explaining their reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. The Providers must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and 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 the Providers to engage a new IRO in accordance with Paragraph A of this Appendix. The Providers must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring the Providers to engage a new IRO, OIG shall notify the Providers 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, the Providers may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with the Providers prior to requiring the Providers to terminate the IRO. However, the final determination as to whether or not to require the Providers to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS AND INFUSION THERAPY REVIEWS

A. Definitions. For the purposes of the Claims and Infusion Therapy Reviews, the following definitions shall be used:

1. *Overpayment*: The amount of money Providers have received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Sections C.3 and E.3 of this Appendix B.

2. *Paid Claim*: A claim submitted by Providers and for which Providers have received reimbursement from a Federal health care program.

3. *Claims Review Population*: The Claims Review Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

4. *Infusion Therapy Paid Claims:* All Paid Claims for infusion therapy (including, but not limited to, chemotherapy and biotherapy) performed by the Providers during the period covered by the Claims Review.

5. *Infusion Therapy Population:* For each Reporting Period, the Infusion Therapy Population shall be defined as all Paid Claims for Infusion Therapy Treatments performed by the Providers.

6. *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. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims or Infusion Therapy Paid Claims in the sample.

B. Claims Review.

1. *Quarterly Claims Sample.* Within 15 days following the end of each three-month period during the term of this CIA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of Providers during the preceding three-month period (Quarterly Claims Sample). The sample must be

selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/complCIAnce/rat-stats/index.asp. Providers shall provide the IRO with a list of all Providers' Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Claims Review Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Claims Review Population that will be subject to review by the IRO. The randomly selected 30 Paid Claims will be reviewed by the IRO based on the supporting documentation available at Providers' office or under Providers' control and applicable billing and coding regulations and guidance to determine whether each claim was correctly coded, submitted, and reimbursed. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

2. *Additional Steps if Error Rate is 5% or Greater.* If the Error Rate (as defined above) for any Quarterly Claims Review performed is 5% or greater, the IRO will estimate the actual Overpayment in the Claims Review Population for that three-month period by identifying the point estimate. To identify the point estimate, the IRO shall extrapolate the Error Rate as determined in the Quarterly Claims Sample to the Claims Review Population for the applicable Quarterly Claims Review. Providers shall be required to repay the point estimate of the extrapolated Overpayment in accordance with Section G, below. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Sample (and any related workpapers) to the appropriate Federal health care program payor for appropriate follow-up by that payor. The Quarterly Claims Review Report prepared by the IRO shall indicate the extrapolated Overpayment amount and the methodology used by the IRO to determine the extrapolated Overpayment amount.

C. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology.*

a. Claims Review Population. A description of the Claims Review Population subject to the Quarterly Claims Review.

b. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Quarterly 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 contractor manual or bulletins (including issue and date), other policies, regulations, or directives).

c. Review Protocol. A narrative description of how the Quarterly Claims Review was conducted and what was evaluated.

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of each Quarterly Claims Sample and Providers shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from Providers after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation.* A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings.*

a. Narrative Results.

i. For the first Quarterly Claims Review Report only, a description of Providers' billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing. Subsequent Quarterly Claims Review Reports should describe any significant changes to Providers' billing and coding system or, if no significant changes were made, state that the billing and coding systems remain the same as described in the prior Quarterly Claims Review Report.

ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Providers (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 Providers.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim:

Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure 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.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Providers' billing and coding system based on the findings of the Quarterly Claims Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

D. Infusion Therapy Review.

1. *Quarterly Infusion Therapy Sample.* Within 15 days following the end of each three-month period during the term of this CIA, the IRO shall randomly select a sample of 30 Infusion Therapy Paid Claims submitted by or on behalf of Providers during the preceding three-month period (Quarterly Infusion Therapy Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp. Providers shall provide the IRO with a list of all Providers' Infusion Therapy Paid Claims for the three-month period covered by the Quarterly Infusion Therapy Sample. The IRO should number each Infusion Therapy Paid Claim in the Infusion Therapy Population sequentially prior to generating the random numbers used to select the Quarterly Infusion Therapy Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Infusion Therapy Paid Claims in the Infusion Therapy Population that will be subject to review by the IRO. The randomly selected 30 Infusion Therapy Paid Claims will be reviewed by the IRO based on the supporting documentation available at Providers' office or under Providers' control and applicable billing and coding regulations and guidance and the established practice guidelines and generally accepted standards of medical practice, such as those set forth in the Chemotherapy Order Templates (NCCN Templates(r)) to help determine whether each procedure was medically necessary and appropriate. The

IRO shall prepare a written report of its findings from the Quarterly Infusion Therapy Sample, as described in Section E below (Quarterly Infusion Therapy Review Report). The Quarterly Infusion Therapy Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Infusion Therapy Review.

2. *Extrapolation.* If the Error Rate (as defined above) for any Quarterly Infusion Therapy Review performed is 5% or greater, the IRO will estimate the actual Overpayment in the Infusion Therapy Population for that three-month period by identifying the point estimate. To identify the point estimate, the IRO shall extrapolate the Error Rate as determined in the Quarterly Infusion Therapy Sample to the Infusion Therapy Population for the applicable Quarterly Infusion Therapy Review. Providers shall be required to repay the point estimate of the extrapolated Overpayment in accordance with Section G, below. OIG, in its sole discretion, may refer the findings of the Quarterly Infusion Therapy Sample (and any related workpapers) to the appropriate Federal health care program payor for appropriate follow-up by that payor. The Quarterly Infusion Therapy Review Report prepared by the IRO shall indicate the extrapolated Overpayment amount and the methodology used by the IRO to determine the extrapolated Overpayment amount.

3. *Systems Review.* If the Error Rate (as defined above) for any Quarterly Infusion Therapy Review performed is 5% or greater, the IRO shall also conduct an Infusion Therapy Systems Review. The Infusion Therapy Systems Review shall consist of the following:

a. a review of the Providers' policies, protocols, or procedures regarding determinations of the medical necessity and appropriateness of each individual's infusion therapy treatment, and billing and coding systems and processes relating to infusion therapy claims submitted to Federal health care programs (including, but not limited to, policies or protocols regarding determinations of medical necessity or appropriateness, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);

b. for each claim in the Quarterly Infusion Therapy Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and

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. Infusion Therapy Review Report. The IRO shall prepare an Infusion Therapy Review Report for each Quarterly Infusion Therapy Review performed (Quarterly Infusion Therapy Review Report). The following information shall be included in each Quarterly Infusion Therapy Review Report.

1. *Infusion Therapy Review Methodology.*

a. Infusion Therapy Review Population. A description of the Infusion Therapy Population subject to the Quarterly Infusion Therapy Review.

b. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Quarterly Infusion Therapy Review (e.g., medical records, physician orders, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare administrative contractor manual or bulletins (including issue and date), professional practice guidelines (e.g., ASCO-ONS Standards for Safe Chemotherapy Administration, or other policies, regulations, directives, or standards of medical practice).

c. Review Protocol. A narrative description of how the Quarterly Infusion Therapy Review was conducted and what was evaluated.

d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Infusion Therapy Paid Claims selected as part of each Quarterly Infusion Therapy Sample and Providers shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Infusion Therapy Sample. If the IRO accepts any supplemental documentation or materials from Providers after the IRO has completed its initial review of the Quarterly Infusion Therapy

Sample (Supplemental Materials), the IRO shall identify in the Quarterly Infusion Therapy Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Infusion Therapy Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation.* A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Infusion Therapy Sample.

3. *Infusion Therapy Review Findings.*

a. Narrative Results.

i. For the first Quarterly Infusion Therapy Review Report only, a description of Providers' medical necessity and/or infusion therapy policy and protocol, including the identification, by position description, of the personnel involved in drafting or editing the protocol. Subsequent Quarterly Infusion Therapy Review Reports should describe any significant changes to Providers' policy or protocols or, if no significant changes were made, state that the policy and protocol remains the same as described in the prior Quarterly Infusion Therapy Review Report.

ii. A narrative explanation of the results of the Quarterly Infusion Therapy Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Infusion Therapy Treatments were not medically necessary and appropriate (Claim Submitted) and therefore 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 Providers.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of Infusion Therapy Paid Claims included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Quarterly Infusion Therapy Sample results that includes the following information for each Paid Infusion Therapy Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, type of Infusion Therapy Treatment provided, whether the Infusion Therapy Treatment was medically necessary and appropriate, allowed amount reimbursed by payor, correct procedure 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.

c. Recommendations. The IRO's report shall include any recommendations for improvements to the Providers' protocols and practice based on the findings of the Infusion Therapy Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Infusion Therapy Review and (2) performed the Quarterly Infusion Therapy Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in the Providers' systems and processes for determining medical necessity and appropriateness of each individual's infusion therapy treatment; and

b. possible improvements to the systems and processes for determining medical necessity and appropriateness of infusion therapy treatments to address the specific problems or weaknesses that resulted in the identified Overpayments.

F. Other Requirements. The following requirements apply to any Quarterly Claims Review and Infusion Therapy Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation.* Any Paid Claim or Paid Infusion Therapy Claim for which Providers cannot produce documentation sufficient to support the Paid Claim or Paid Infusion Therapy Claim shall be considered an error and the total reimbursement received by Providers for such Paid Claim or Paid Infusion Therapy Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims or Paid Infusion Therapy Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn.* For the purposes of all samples discussed in this Appendix, the Paid Claims or Paid Infusion Therapy Claims selected in each first sample 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).

G. Repayment of Identified Overpayments. Providers shall repay within 60 days any Overpayment(s) identified in each Quarterly Infusion Therapy Sample or Quarterly Infusion Therapy Sample (including any extrapolated amounts identified in accordance with Sections B.2 and D.2 of this Appendix), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Providers shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.