

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES;
COMPASSIONATE CARE HOSPICE GROUP, LTD.;
AND COMPASSIONATE CARE HOSPICE OF NEW YORK, LLC**

I. PREAMBLE

Compassionate Care Hospice Group, Ltd. (CCH Group) and Compassionate Care Hospice of New York, LLC (CCH of New York) 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). CCH Group owns, operates, and provides management services to hospices in several states (the “CCH Hospices”). CCH Group and the CCH Hospices are collectively referred to herein as “CCH.” Contemporaneously with this CIA, CCH Group and CCH of New York are 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 CCH under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes 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 after OIG’s receipt of: (1) CCH’s final annual report; or (2) any additional materials submitted by CCH 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 CCH; 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 CCH, excluding vendors whose sole connection with CCH is selling or otherwise providing medical supplies or equipment to CCH and who do not bill the Federal health care programs for such medical supplies or equipment.

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 during a Reporting Period, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

2. “Billing, Coding, and Reimbursement Covered Persons” includes all Covered Persons involved, whether directly or in a supervisory role, in the coding, preparation, or submission of claims for reimbursement from any Federal health care program on behalf of CCH of New York.

3. “Clinical Services Covered Persons” includes all Covered Persons who are involved, whether directly or in a supervisory role, in: (a) the delivery of patient care items or services on behalf of CCH of New York or (b) quality assurance or the monitoring of clinical quality on behalf of CCH of New York.

4. “Relevant Covered Persons” means all Billing, Coding, and Reimbursement Covered Persons and Clinical Services Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

CCH 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, CCH shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be a member of senior management of CCH, shall report directly to the Chief Executive Officer of CCH, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or

supervising legal counsel functions for CCH. The Compliance Officer shall be responsible for, without limitation:

- a. 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;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Governing Authority of CCH, and shall be authorized to report on such matters to the Governing Authority at any time. Written documentation of the Compliance Officer's reports to the Governing Authority shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by CCH as well as fulfilling any reporting obligations created under this CIA. As part of his or her monitoring function, the Compliance Officer shall make visits to each CCH branch office at least once annually and more frequently, as appropriate.

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.

CCH 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.

2. *Compliance Committee.* Within 90 days after the Effective Date, CCH shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer, the Chief Quality Officer, and other members of senior management necessary to meet the requirements of this CIA (*e.g.*, senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). 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 CCH's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least

quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Chief Quality Officer.* Within 120 days after the Effective Date, CCH shall appoint a Covered Person to serve as its Chief Quality Officer and shall maintain a Chief Quality Officer for the term of the CIA. The Chief Quality Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with professionally recognized standards of care. The Chief Quality Officer shall be a member of senior management of CCH, shall report directly to the Compliance Officer of CCH, shall make periodic (at least quarterly) reports regarding quality assurance matters directly to the Governing Authority, and shall be authorized to report on such matters to the Governing Authority at any time. The Chief Quality Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Chief Quality Officer shall be responsible for monitoring the day-to-day quality of care and patient safety activities engaged in by CCH. Any non-quality assurance job responsibilities of the Chief Quality Officer shall be limited and must not interfere with the Chief Quality Officer's ability to perform the activities outlined in this CIA. The Chief Quality Officer shall have sufficient quality assurance experience to perform the responsibilities described in this Section III.A.3.

CCH shall report to OIG, in writing, any change in the identity of the Chief Quality Officer, or any actions or changes that would affect the Chief Quality Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

4. *Governing Authority Compliance Obligations.* The Governing Authority of CCH shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

The Governing Authority shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee CCH's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

- b. considering the results of the Compliance Program Reviews, as required by Section III.A.5.a.v;
- c. submitting to the OIG in each Annual Report a description of the documents and other materials it reviewed, as well as any additional steps taken, such as engagement of the Compliance Expert required by Section III.A.5 or other third party resources, in its oversight of the Compliance Program and in support of making the resolution below during each Reporting Period; and
- d. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Governing Authority summarizing its review and oversight of CCH's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Governing Authority has made a reasonable inquiry into the operations of CCH's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Governing Authority has concluded that, to the best of its knowledge, CCH has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Governing Authority is unable to provide such a conclusion in the resolution, the Governing Authority shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at CCH.

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

5. *Governing Authority Compliance Expert.* Within 120 days after the Effective Date, the Governing Authority shall retain an expert in corporate governance and compliance (Compliance Expert) to assist the Governing Authority in fulfilling the responsibilities described in Section III.A.4 of this CIA.

- a. Compliance Expert Obligations. At a minimum, the Compliance Expert shall:
 - i. meet with the Governing Authority quarterly to assist each Governing Authority member in meeting his or her obligation to review and oversee matters related to CCH's compliance with Federal health care program requirements and the obligations of this CIA;
 - ii. be kept apprised of any direct reports that the Compliance Officer otherwise makes to the Governing Authority;
 - iii. assist the Governing Authority in reviewing and assessing CCH's Compliance Program;
 - iv. offer recommendations periodically, as appropriate, to improve the effectiveness of CCH's Compliance Program; and
 - v. for the first, third, and fifth Reporting Periods, conduct a comprehensive review of the effectiveness of CCH's Compliance Program and prepare a report describing the results of such review (Compliance Program Review Report). A copy of the Compliance Program Review Report shall be provided to OIG along with the Annual Report for the applicable Reporting Period.

- b. Engagement of Compliance Expert. As part of CCH's Implementation Report, CCH shall provide the following information to OIG:
 - i. the identity, address, and phone number of the Compliance Expert;
 - ii. a copy of the engagement letter between the Governing Authority and the Compliance Expert;
 - iii. information demonstrating that the Compliance Expert has the background and qualifications necessary to

assist the Governing Authority in fulfilling the responsibilities described in Section III.A.4 of this CIA; and

- iv. a certification from the Compliance Expert that neither he or she nor his or her firm has a relationship to CCH or its officers, directors, or employees that would cause a reasonable person to question the Compliance Expert's impartiality.

Within 30 days of receiving the above information, or any additional information submitted by CCH in response to a request by OIG, whichever is later, OIG will notify CCH if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Governing Authority may continue to engage the Compliance Expert.

If a new Compliance Expert is engaged, CCH shall submit the above information to OIG within 30 days of engagement of the Compliance Expert. Within 30 days after receiving this information, or any additional information submitted by CCH at the request of OIG, whichever is later, OIG will notify CCH if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Governing Authority may continue to engage the Compliance Expert.

6. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain employees of CCH (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable CCH Group or CCH of New York department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the individuals who serve in the following capacities for CCH Group or CCH of New York: the Chief Executive Officer; Chief Financial Officer; Chief Operating Officer; Chief Quality Officer; any other Covered Person who is an officer or director; and any Program Director, Clinical Director, or Medical Director. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and CCH policies, and I have taken steps to promote such

compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of CCH Group [or CCH of New York] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, CCH Group and CCH of New York shall develop and implement a written process for their respective Certifying Employees to follow for the purpose of completing the certification required by this section (*e.g.*, reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

1. *Code of Conduct.* CCH has developed, implemented, and distributed a written Code of Conduct to all Covered Persons. Within 90 days after the Effective Date, CCH shall review and modify its Code of Conduct as necessary to conform to the requirements of this CIA and shall distribute any revised Code of Conduct to all Covered Persons. CCH shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. CCH’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. CCH’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with CCH’s Policies and Procedures;
- c. the requirement that all of CCH’s Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by CCH, suspected

violations of any Federal health care program requirements or of CCH's Policies and Procedures; and

- d. the right of all individuals to use the Disclosure Program described in Section III.F, and CCH's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

CCH shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures.* Within 90 days after the Effective Date, CCH shall develop and implement written Policies and Procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and compliance with Federal health care program requirements. At a minimum, the Policies and Procedures also shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. CCH's compliance with Federal health care program requirements regarding the accurate coding, preparation, and submission of claims;
- c. CCH's compliance with Federal health care program requirements regarding the provision of hospice services;
- d. CCH's compliance with Federal health care program requirements regarding proper and accurate documentation of medical records;
- e. the expectation that all Covered Persons are aware of relevant Federal health care program requirements and the personal obligation of each individual involved in the medical documentation process to ensure that such records are accurate;
- f. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures under this Section III.B.2, and the terms of this CIA; and

- g. CCH's performance of periodic hospice billing, coding, and clinical quality reviews and audits.

Throughout the term of this CIA, CCH shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

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), CCH shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, a description of the revisions shall be communicated to all affected Covered Persons and any revised or new Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *Training Plan.* Within 120 days after the Effective Date, CCH shall develop a written plan (Training Plan) that outlines the steps CCH will take to ensure that:

- a. all Covered Persons receive adequate training regarding CCH's CIA requirements and Compliance Program, including the Code of Conduct;
- b. all Billing, Coding, and Reimbursement Covered Persons receive adequate training regarding: (i) the Federal health care program requirements regarding the accurate coding, preparation, and submission of claims; (ii) policies, procedures, and other requirements applicable to the documentation of medical records; (iii) the personal obligation of each individual involved in the claims submission process to ensure that his or her activities with respect to the claims are accurate and appropriate; (iv) applicable reimbursement statutes, regulations, and program requirements and directives governing the provision of hospice services; (v) the legal sanctions for violations of the Federal health care program requirements; (vi) examples of

proper and improper claims submission practices; and (vii) examples of proper and improper coding practices; and

- c. all Clinical Services Covered Persons receive adequate training regarding: (i) policies, procedures, and other requirements applicable to the documentation of medical records; (ii) the personal obligation of each individual involved in patient care to ensure that medical records are complete and accurate; (iii) the personal obligation of each individual involved in patient care to ensure that care is appropriate, delivered in accordance with the hospice plan of care, and meets professionally recognized standards of care; (iv) applicable reimbursement statutes, regulations, and program requirements and directives; (v) the legal sanctions for violations of the Federal health care program requirements; and (vi) examples of proper and improper medical record documentation practices.

The Training Plan shall include information regarding the training topics, the categories of Covered Persons and Relevant Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of CCH's Training Plan, OIG will notify CCH of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, CCH may implement its Training Plan. CCH shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Governing Authority Member Training.* Within 90 days after the Effective Date, CCH shall provide at least two hours of training to each member of the Governing Authority. This training shall address CCH's CIA requirements and Compliance Program (including the Code of Conduct), the corporate governance responsibilities of Governing Authority members, and the responsibilities of Governing Authority members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of hospice Governing Authority members, including the risks, oversight areas, and strategic approaches to conducting oversight of a hospice entity. This training may be conducted by an outside compliance expert hired by the Governing Authority and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Governing Authority shall receive the Governing Authority Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Certification.* 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.

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

5. *Update of Training Plan.* CCH shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements; any issues discovered during internal audits, the Compliance Program Review, or the Claims Review; and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to CCH's Training Plan, OIG will notify CCH of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, CCH may implement the revised Training Plan.

6. *Computer-Based Training.* CCH may provide the training required under this CIA through appropriate computer-based training approaches. If CCH chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, CCH 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.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. *Claims Review.* The IRO shall review coding, billing, and claims submission to the Medicare and state Medicaid programs for hospice services rendered by CCH of New York and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) the Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (Validation Review). CCH shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of CCH's final Annual Report shall be initiated no later than one year after CCH's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify CCH of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, CCH may request a meeting with OIG to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. CCH agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with CCH 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.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to CCH a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D; and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, CCH shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished by CCH of New York to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process should include: (1) a process for identifying and prioritizing risks; (2) developing remediation plans in response to those risks, including internal auditing and monitoring of the identified risk areas; and (3) tracking results to assess the effectiveness of the remediation plans. The risk assessment and internal review process should require compliance, legal, and department leaders, at least annually, to evaluate and identify risks associated with the submission of claims for items and services furnished by CCH of New York to Medicare and Medicaid program beneficiaries and develop and implement specific plans to address and mitigate the identified risks. The risk assessment and internal review work plans shall be developed annually. CCH shall implement the risk assessment and internal review work plans and track the implementation of the work plans. CCH shall maintain the risk assessment and internal review process for the term of the CIA. Copies of any internal audit reports developed pursuant to the risk assessment and internal review process shall be made available to OIG upon request.

F. Disclosure Program

Within 90 days after the Effective Date, CCH shall establish a Disclosure Program that includes a mechanism (*e.g.*, a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CCH's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. CCH shall appropriately publicize the existence of the disclosure mechanism (*e.g.*, via periodic e-mails to Covered Persons or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

(1) permits a determination of the appropriateness of the alleged improper practice; and
(2) provides an opportunity for taking corrective action, CCH 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 and shall record each disclosure in the disclosure log within 48 hours of receipt of the disclosure. The disclosure log shall include a 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.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, or suspended from participation 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, or suspended.
- 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.* CCH shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. CCH 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 such Covered Persons to disclose whether they are Ineligible Persons.
- b. CCH shall screen all Covered Persons against the Exclusion Lists within 90 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. CCH shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

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

3. *Removal Requirement.* If CCH has actual notice that a Covered Person has become an Ineligible Person, CCH shall remove such Covered Person from responsibility for, or involvement with, CCH'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 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 CCH 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, CCH 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.

H. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, CCH shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to CCH conducted or brought by a governmental entity or its agents involving an allegation that CCH 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. CCH shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Repayment of Overpayments

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

2. *Overpayment Policies and Procedures.* Within 120 days after the Effective Date, CCH shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

a. If, at any time, CCH identifies any Overpayment, CCH shall repay the Overpayment to the appropriate payor (*e.g.*, Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 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. If not yet quantified, within 60 days after identification, CCH 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.

b. 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.

J. 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. a matter that a reasonable person would consider a probable violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations;
- d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- e. the filing of a bankruptcy petition by CCH Group or CCH of New York.

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

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

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by CCH to identify and quantify the Overpayment; and
- d. a description of CCH's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, CCH shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of CCH's actions taken to correct the Reportable Event and prevent it from recurring; and

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

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, the impact or potential impact on Federal health care program beneficiaries, and any legal and Federal health care program authorities implicated;
- b. a description of CCH's action taken to correct the Reportable Event;
- c. any further steps CCH plans to take to address the Reportable Event and prevent it from reoccurring; and
- d. a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies.

6. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion Lists screening that CCH completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was discovered; and

- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

7. *Reportable Events under Section III.J.1.e.* For Reportable Events under Section III.J.1.e, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

8. *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 CCH 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.3 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 CCH identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then CCH is not required by this Section III.J.8 to submit the Reportable Event to CMS through the SRDP.

K. Cooperation with Government Investigations

Upon reasonable notice, CCH Group and CCH of New York shall cooperate with all OIG investigations and understand that full cooperation includes: (1) prompt and truthful disclosure to OIG of all matters relating to any Federal or state health care law investigation, prosecution, or other enforcement action, related to the Covered Conduct described in the Settlement Agreement; and (2) truthful testimony in any administrative hearing and/or court proceeding. CCH Group and CCH of New York, upon reasonable notice, will make reasonable efforts to facilitate access to, and encourage the cooperation of, their directors, officers, and employees for interviews and testimony, and will furnish to the OIG, upon reasonable request, all documents and records in their possession, custody, or control relating to the Covered Conduct. Section III.K shall not require CCH Group's or CCH of New York's waiver of attorney-client and work product protections. Nothing in this Section III.K shall be construed as a waiver of any applicable attorney-client or work product privileges.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit, or Location

In the event that, after the Effective Date, CCH proposes to sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, CCH shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit, or location. This notification shall include a description of the business, 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 the business, business unit, or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit, or Location

In the event that, after the Effective Date, CCH changes locations or closes or terminates management of a business, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, CCH shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change, closure, or termination of management of the business, business unit, or location.

C. Purchase or Establishment of New Business, Business Unit, Location, or Management Arrangement

In the event that, after the Effective Date, CCH purchases or establishes a new business, business unit, location, or management arrangement related to the furnishing of items or services that may be reimbursed by Federal health care programs, CCH shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit, location, or management arrangement. This notification shall include the address of the new business, business unit, location, or management arrangement; its phone number and fax number; the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which CCH currently submits claims. Each new business, business unit, location, or management arrangement and all Covered Persons at each new business, business unit, location, or management arrangement shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, CCH 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.1, 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.2;
3. the name, address, phone number, and position description of the Chief Quality Officer required by Section III.A.3, and a summary of other non-quality assurance job responsibilities the Chief Quality Officer may have;
4. the names of the Governing Authority members who are responsible for satisfying the Governing Authority compliance obligations described in Section III.A.4;
5. the information regarding the Compliance Expert specified in Section III.A.5.b;
6. the names and positions of the Certifying Employees required by Section III.A.6;
7. a copy of CCH's Code of Conduct required by Section III.B.1;
8. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);
9. the Training Plan required by Section III.C.1 and a description of the Governing Authority training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
10. 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 CCH and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to CCH;

11. a description of the risk assessment and internal review process required by Section III.E;

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

13. a certification that CCH has conducted the screening required by Section III.G regarding Ineligible Persons, or a description of why CCH cannot provide such a certification;

14. a copy of CCH's policies and procedures regarding the identification, quantification, and repayment of Overpayments required by Section III.I;

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

16. a description of CCH's corporate structure, including identification of any parent and sister companies, subsidiaries, affiliated entities, and their respective lines of business, as well as any individual owners; and

17. the certifications required by Section V.C.

B. Annual Reports

CCH shall submit to OIG annually a report with respect to the status of, and findings regarding, CCH's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer required by Section III.A.1; any change in the membership of the Compliance Committee described in Section III.A.2; any change in the identity, position description, or other non-quality assurance job responsibilities of the Chief Quality Officer required by Section III.A.3; any change in the Governing Authority members who are responsible for satisfying the

Governing Authority compliance obligations described in Section III.A.4; and any change in the group of Certifying Employees described in Section III.A.6;

2. the dates of each report made by the Compliance Officer or Chief Quality Officer to the Governing Authority (written documentation of such reports shall be made available to OIG upon request);

3. the Governing Authority resolution required by Section III.A.4 and a description of the documents and other materials reviewed by the Governing Authority, as well as any additional steps taken, in its oversight of the Compliance Program and in support of making the resolution;

4. for the first, third, and fifth Reporting Periods, a copy of the Compliance Program Review Report prepared by the Compliance Expert pursuant to Section III.A.5.a.v;

5. a summary of any significant changes or amendments to CCH's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy);

6. a copy of CCH's Training Plan developed under Section III.C and, to the extent not explicitly stated in the Training Plan, the following information regarding each type of training: a description of the training, including a summary of the topics covered, the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which CCH ensures that all Covered Persons and Relevant Covered Persons receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request;

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

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

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

10. a certification from the IRO regarding its professional independence and objectivity with respect to CCH;

11. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;

12. a copy of CCH's internal review work plans, and a list of all reviews completed during the Reporting Period pursuant to Section III.E;

13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

14. a certification that CCH has completed the screening required by Section III.G regarding Ineligible Persons;

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

16. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

17. 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;

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

19. a summary describing any audits conducted during the applicable Reporting Period by a Medicare or state Medicaid program contractor, or any government entity or contractor, involving a review of Federal health care program claims, and CCH's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

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

21. 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

1. *Certifying Employees.* In each Annual Report, CCH shall include the certifications of Certifying Employees as required by Section III.A.6.

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer; Chief Executive Officer of CCH Group; and Chief Executive Officer of CCH of New York that:

- a. to the best of his or her knowledge, except as otherwise described in the report, CCH [or CCH of New York] is in compliance with all of the requirements of this CIA; and
- b. 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.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officers of CCH Group and CCH of New York that, to the best of their knowledge, CCH Group and CCH of New York have complied with their obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

CCH 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. CCH 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

Compassionate Care Hospice Group, Ltd.:

Milton Heching, Chief Executive Officer
200 Lanidex Plaza, Suite 2101
Parsippany, NJ 07054
Telephone: 973.402.4712
Facsimile: 973.402.4725

With a copy to:

Jennifer O'Neill, General Counsel
Compassionate Care Hospice
200 Lanidex Plaza, Suite 2101
Parsippany, NJ 07054
Telephone: 973.402.4712
Facsimile: 973.402.4725

Sean Cenawood
Dentons US LLP
1221 Avenue of the Americas
New York, NY 10020
Telephone: 212.398.4867
Facsimile: 212.768.6800

Compassionate Care Hospice of New York, LLC:

Judith Grey, Member
CCH of New York
369 East 148th Street
Bronx, NY 10455
Telephone: 718.601.6694
Facsimile: 718.601.4520

With a copy to: Jennifer O'Neill, General Counsel
Compassionate Care Hospice
200 Lanidex Plaza, Suite 2101
Parsippany, NJ 07054
Telephone: 973.402.4712
Facsimile: 973.402.4725

Sean Cenawood
Dentons US LLP
1221 Avenue of the Americas
New York, NY 10020
Telephone: 212.398.4867
Facsimile: 212.768.6800

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, CCH 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), 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 CCH's

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, CCH 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 CCH fails to establish and implement any of the following obligations as described in Sections III and IV:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a Chief Quality Officer;
- d. the Governing Authority compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review, and the preparation of a Compliance Program Review Report;
- e. the management certification obligations;
- f. a written Code of Conduct;
- g. written Policies and Procedures;
- h. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Governing Authority Members;
- i. a risk assessment and internal review process as required by Section III.E;
- j. a Disclosure Program;
- k. Ineligible Persons screening and removal requirements;
- l. notification of Government investigations or legal proceedings;
- m. policies and procedures regarding the repayment of Overpayments;
- n. the repayment of Overpayments as required by Section III.I;
- o. reporting of Reportable Events; and

p. disclosure of changes to business units or locations.

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 CCH fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

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

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of CCH 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 CCH fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to CCH stating the specific grounds for its determination that CCH has failed to comply fully and adequately with the CIA obligation(s) at issue and steps CCH shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after CCH 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

CCH 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 CCH 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 CCH 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 CCH 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 CCH of: (a) the failure to comply; and (b) OIG's exercise of 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 after the receipt of the Demand Letter, CCH 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 CCH elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CCH 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 CCH 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by CCH to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;
- 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, 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 CCH constitutes an independent basis for CCH's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that CCH has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify CCH of: (a) the 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.* CCH shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) CCH has begun to take action to cure the material breach; (ii) CCH is pursuing such action with due diligence; and (iii) CCH has provided to OIG a reasonable timetable for curing the material breach.

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

Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, CCH 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 CCH 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, CCH 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. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 CCH was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. CCH 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 CCH to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless CCH 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 whether CCH was in material breach of this CIA and, if so, whether:

- a. CCH cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following CCH's receipt of the Notice of Material Breach: (i) CCH had begun to take action to cure the material breach; (ii) CCH pursued such action with due diligence; and (iii) CCH provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for CCH, only after a DAB decision in favor of OIG. CCH's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude CCH 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 CCH 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. CCH shall waive its rights 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 CCH, CCH 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

CCH 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 between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of CCH's obligations under this CIA based on a certification by CCH that it is no longer providing health care items or services that

will be billed to any Federal health care program and that it 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 CCH is relieved of its CIA obligations, CCH will be required to notify OIG in writing at least 30 days in advance if it 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, OIG shall evaluate whether the CIA will be reactivated or modified as to CCH.

D. The undersigned signatories for CCH represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

E. 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 COMPASSIONATE CARE HOSPICE GROUP, LTD.

/Milton Heching/

1-26-15

MILTON HECHING
Chief Executive Officer

DATE

ON BEHALF OF COMPASSIONATE CARE HOSPICE OF NEW YORK, LLC

/Judith Grey/

1/26/15

JUDITH GREY
Member

DATE

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

/Robert K. DeConti/

1/30/15

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

DATE

/Kaitlyn L. Dunn/

1/27/15

KAITLYN L. DUNN
Associate Counsel
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

1. CCH 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 the information identified in Section V.A.10 of the CIA or any additional information submitted by CCH in response to a request by OIG, whichever is later, OIG will notify CCH if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CCH may continue to engage the IRO.

2. If CCH 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, CCH shall submit the information identified in Section V.A.10 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 CCH at the request of OIG, whichever is later, OIG will notify CCH if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CCH may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements applicable to hospice services and in the general requirements of the Federal health care program(s) from which CCH of New York 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 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 Claims Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;
3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority (*e.g.*, Medicare contractor);
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 defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

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

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

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

- a. Overpayment: The amount of money CCH of New York has 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 claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.
- b. Paid Claim: A claim for hospice services submitted by or on behalf of CCH of New York and for which CCH of New York has received reimbursement from the Medicare or Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- d. 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 Paid Claims in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims for services rendered by CCH of New York (Discovery Sample). The Paid Claims shall be randomly selected in proportion to the total volume of Paid Claims in the Population accounted for by each of CCH of New York's branch offices. The Paid Claims shall be reviewed based on the supporting documentation available at CCH's office(s) or under CCH's 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, CCH should, as appropriate, further analyze any errors identified in the Discovery Sample. CCH recognizes that OIG or another 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) from the respective universe using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at CCH's offices or under CCH's 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, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from CCH to the appropriate Federal health care program payor (e.g., Medicare contractor) for appropriate follow-up by that payor.

4. *Systems Review.* If the Discovery Sample identifies an Error Rate of 5% or greater, CCH's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of CCH's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, 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); and

- b. for each claim in the Discovery Sample and Full 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.

5. *Other Requirements*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or the Full Sample (if applicable), and CCH shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or the Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from CCH after the IRO has completed its initial review of the Discovery Sample or the Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the 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 Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which CCH cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by CCH of New York for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

- c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample and Full Sample) discussed in this Appendix B, the Paid 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 Discovery Sample or the Full Sample).

6. *Repayment of Identified Overpayments.* CCH of New York shall repay within 60 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3, above, in accordance with payor refund policies. CCH of New York shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix B for each Claims Review performed. The following information shall be included in the Claims Review Report for the Discovery Sample and the Full Sample (if applicable).

1. *Claims Review Methodology*

- a. Claims Review Population. A description of the Population subject to the Claims Review.
- b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- c. 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).
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by Section A.5.a, above.

2. *Statistical Sampling Documentation*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
- c. A description or identification of the statistical sampling software package used to select the sample and determine the size of the Full Sample, if applicable.

3. *Claims Review Findings*

a. Narrative Results

- i. A description of CCH’s 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 or on behalf of CCH of New York (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 CCH of New York.
- iii. Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).

- iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.
- v. Error Rate in the Discovery Sample and the Full Sample.
- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: 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), and the dollar difference between the allowed amount reimbursed by the payor and the correct allowed amount.
- vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to CCH's billing and coding systems based on the findings of the Claims 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 CCH's billing systems and processes;
- b. the strengths and weaknesses in CCH's coding systems and processes; and
- c. possible improvements to CCH's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

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.