

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

I. PREAMBLE

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

Subsequent to the period relating to the Covered Conduct described in the Settlement Agreement with the United States, Odyssey was acquired by Gentiva Health Services, Inc. (Parent or Gentiva) and Odyssey, as a wholly owned subsidiary of Gentiva, and Odyssey's hospices are now operational and organizational components of a single hospice division within Gentiva referred to herein as Odyssey Hospice. Accordingly, although Odyssey is the party to the Settlement Agreement with the United States and this CIA, and the party responsible for ensuring implementation of the CIA, the undertakings of this CIA will, for operational and organizational consistency purposes, relate to the entirety of Odyssey Hospice even though neither Gentiva nor certain of the hospice entities and hospices within Odyssey Hospice are alleged by the United States to have engaged in the Covered Conduct described in the Settlement Agreement with the United States.

Gentiva established a voluntary compliance program ("Compliance Program") in 1994 to which Odyssey Hospice is now subject. The Compliance Program currently includes, among other things, a Compliance Officer, a Code of Business Ethics and Conduct, written policies and procedures, a disclosure program that allows for the confidential disclosure and investigation of potential compliance violations, screening measures for Ineligible Persons (as defined in Section III.F.1.a below), regular compliance training to all employees, various compliance auditing programs, and oversight from Gentiva's Board of Directors. Gentiva's Compliance Program was and continues to be aimed at Gentiva's goal of promoting the highest standards of professionalism, ethics and

integrity in the conduct of Gentiva's and the Odyssey Hospice's business practices. Gentiva will continue to operate its Compliance Program throughout the term of this CIA. Gentiva may modify its Compliance Program as appropriate (subject to the terms of this CIA), but Odyssey Hospice shall ensure that during the term of this CIA it complies with the obligations of Odyssey Hospice set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Odyssey Hospice 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, unless otherwise specified. 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) Odyssey Hospice's final annual report; or (2) any additional materials submitted by Odyssey Hospice pursuant to OIG's request, whichever is later.

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

1. "Odyssey Hospice" includes Odyssey and all hospices owned or operated by Odyssey or Parent.
2. "Covered Persons" includes:
 - a. all owners, officers, directors, and employees of Odyssey and Odyssey Hospice;
 - b. all contractors, subcontractors, agents, Parent employees, and other persons (including medical directors and associate medical directors) whose job responsibilities involve, either directly or in a supervisory role, the provision of patient care items or services or the performance of billing or coding functions on behalf of Odyssey Hospice, excluding Parent's financial services unit employees whose responsibilities with respect to Odyssey Hospice are limited to the ministerial tasks of submitting and tracking claims and vendors whose sole connection with Odyssey Hospice is selling or otherwise

providing medical supplies or equipment to Odyssey Hospice and who do not bill the Federal health care programs for such medical supplies or equipment; and

- c. all Parent officers or employees whose job responsibilities involve, directly or indirectly, the provision of legal, compliance, or audit services to Odyssey Hospice.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

3. Relevant Covered Persons include:

- a. “Relevant Hospice Benefit Covered Persons” includes all Covered Persons whose job responsibilities involve (either directly or in a supervisory role) determining whether Odyssey Hospice patients meet the requirements for continuous care services.
- b. “Relevant Hospice Marketing Covered Persons” includes all Covered Persons whose job responsibilities involve (either directly or in a supervisory role) marketing the hospice benefit, specifically including but not limited to those marketing to physicians, hospitals, skilled nursing facilities, nursing facilities, beneficiaries, beneficiary family members, and beneficiary representatives.

4. “Continuous care services” means hospices services provided on a continuous basis for as much as 24 hours a day during periods of crisis to maintain the beneficiary at home, as defined at 42 C.F.R. § 418.204(a).

III. CORPORATE INTEGRITY OBLIGATIONS

Parent has and shall maintain a Compliance Program. Odyssey Hospice shall participate in and comply with Parent's Compliance Program, which for Odyssey Hospice shall, at a minimum, contain the following elements:

A. Compliance Officer and Committee

1. *Compliance Officer.* Odyssey Hospice has and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Parent, shall report directly to the President of Odyssey Hospice, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of Parent's Board of Directors (Board), and shall be authorized to report on such matters to Parent's Board Audit Committee at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of Odyssey or Parent. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Odyssey Hospice as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Odyssey Hospice shall report to OIG, in writing, any change in the identity 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.* Odyssey Hospice has and shall maintain a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). 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 Odyssey Hospice's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Odyssey Hospice 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. *Board Audit Committee Compliance Obligations.* Parent's Board has appointed and shall maintain an Audit Committee of the Board (the Board Audit Committee). The Board Audit Committee shall be responsible for the review and oversight of matters related to Odyssey Hospice's compliance with Federal health care program requirements and the obligations of this CIA.

The Board Audit Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Parent's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. ensuring that Odyssey Hospice adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and Federal health care program requirements; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board Audit Committee summarizing its review and oversight of Odyssey Hospice's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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

If the Board is unable to provide such a conclusion in the resolution, the Board 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.

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

B. Written Standards

1. *Code of Business Ethics and Conduct.* Parent has and shall maintain for the term of the CIA a written Code of Business Ethics and Conduct to which Odyssey Hospice is subject. Odyssey Hospice shall make the promotion of, and adherence to, the Code of Business Ethics and Conduct an element in evaluating the performance of all employees. The Code of Business Ethics and Conduct shall, at a minimum, set forth:

- a. Odyssey Hospice'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. Odyssey Hospice's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Parent's own Policies and Procedures;
- c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Odyssey Hospice, suspected violations of any Federal health care program requirements or of Parent's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and Odyssey Hospice's commitment to nonretaliation and to maintain, as appropriate,

confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Parent's Code of Business Ethics and Conduct to which Odyssey Hospice is subject. New Covered Persons shall receive the Code of Business Ethics and Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Odyssey Hospice shall periodically review the Code of Business Ethics and Conduct to determine if revisions are appropriate and shall recommend to Parent any necessary revisions based on such review. If Parent rejects these recommendations, Odyssey Hospice shall report its recommendations and the basis for Parent's rejection within 30 days after Parent rejects Odyssey Hospice's recommendations. Any revised Code of Business Ethics and Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Business Ethics and Conduct within 30 days after the distribution of the revised Code of Business Ethics and Conduct.

2. *Policies and Procedures.* Odyssey Hospice represents that its Parent has implemented written Policies and Procedures regarding the operation of its compliance program to which Odyssey Hospice is subject, including the compliance program requirements outlined in this CIA and Odyssey Hospice's compliance with Federal health care program requirements. At a minimum, the Policies and Procedures address and shall continue to address:

- a. the subjects relating to the Code of Business Ethics and Conduct identified in Section III.B.1;
- b. the OIG's Compliance Program Guidance for Hospice;
- c. Federal health care program requirements relating to the coverage of hospice services and the eligibility requirements for such coverage, including requirements relating to the initial admission of patients, eligibility of continued stay patients (*i.e.*, patients who have received

more than six continuous months of hospice care), and eligibility for continuous care services; and

- d. Federal health care program requirements relating to the documentation of eligibility for hospice services and the services provided, and relating to the preparation and submission of accurate claims for such services.

The Policies and Procedures are made available online and shall continue to be made available online to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education

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

- a. Odyssey Hospice's CIA requirements; and
- b. Parent's Compliance Program to which Odyssey Hospice is subject, including the Code of Business Ethics and Conduct.

Covered Persons who have received two hours of General Training no earlier than 60 days before the Effective Date shall be deemed to have met this requirement. New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive Specific Training in addition to the General Training required above.

- a. Relevant Hospice Benefit Covered Persons shall receive three hours of Specific Training that covers the following topics:
 - i. the Federal health care program requirements regarding the hospice benefit, including eligibility, certification, and recertification, with specific focus on the requirements for continuous care services;
 - 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 such claims are accurate;
 - 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 claims submission practices.

After receiving the initial Specific Training described in this section, each Relevant Hospice Benefit Covered Person shall receive at least two hours of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

- b. Relevant Hospice Marketing Covered Persons shall receive two hours of Specific Training that covers the following topics:
 - i. the Federal health care program requirements regarding the hospice benefit, including eligibility,

- certification, and recertification, with specific focus on the requirements for continuous care services;
- ii. applicable reimbursement statutes, regulations, and program requirements and directives;
- iii. the requirements of Anti-Kickback Statute;
- iv. examples of violations of the Anti-Kickback Statute; and
- v. the legal sanctions for violations of the Federal health care program requirements.

After receiving the initial Specific Training described in this section, each Relevant Hospice Marketing Covered Person shall receive at least one hour of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

- c. Relevant Covered Persons who have received the pertinent Specific Training no earlier than 60 days before the Effective Date shall be deemed to have satisfied this requirement. New Relevant Covered Persons shall receive Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

3. *Board Member Training.* Within 90 days after the Effective Date, Parent shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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

4. *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.

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

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

7. *Computer-based Training.* Odyssey Hospice may provide the training required under this CIA through appropriate computer-based training approaches. If Odyssey Hospice 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. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Odyssey Hospice shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the Verification Reviews and the Unallowable Cost Review 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.

2. *Eligibility Review.* Odyssey Hospice’s Eligibility Review Team, composed of individuals listed in Appendix B, shall review the eligibility of Odyssey Hospice’s Medicare beneficiaries for the hospice services those Medicare beneficiaries received and shall prepare an Eligibility Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Verification Review.* The IRO shall perform a Verification Review of Odyssey Hospice’s Eligibility Reviews and shall prepare a Verification Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

4. *IRO Assumption of Eligibility Review.* Following its review of any of Odyssey Hospice’s Annual Reports, if, in its sole discretion, OIG determines that the

Eligibility Reviews performed by the Eligibility Review Team fail to conform with the requirements of the CIA, OIG can require that future Eligibility Reviews be conducted by the IRO.

5. *Unallowable Cost Review.* For the first Reporting Period, the IRO shall conduct a review of Odyssey's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Odyssey has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable costs analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Odyssey or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

6. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed (Unallowable Cost Review Report). The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether Odyssey has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

7. *Retention of Records.* The IRO and Odyssey Hospice shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Odyssey Hospice, and those exchanged between the Eligibility Review Team and any individuals who are not on the Eligibility Review Team) related to the reviews.

8. *Validation Review.* In the event OIG has reason to believe that: (a) Odyssey Hospice's Eligibility Review, Verification Review, or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the Eligibility Review Team's or

IRO's findings or the Eligibility Review, Verification Review, or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Eligibility Review, Verification Review, or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Eligibility Review, Verification Review, or Unallowable Cost Review results are inaccurate (Validation Review). Odyssey Hospice 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 the Odyssey Hospice's final Annual Report shall be initiated no later than one year after Odyssey Hospice's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Odyssey Hospice 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, Odyssey Hospice may request a meeting with OIG to: (a) discuss the results of any Eligibility Review, Verification Review, or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Eligibility Review, Verification Review, or Unallowable Cost Review or to correct the inaccuracy of the Eligibility Review, Verification Review, or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Odyssey Hospice agrees to provide any additional information as may be requested by OIG under this Section III.D.8 in an expedited manner. OIG will attempt in good faith to resolve any Eligibility Review, Verification Review, or Unallowable Cost Review issues with Odyssey Hospice 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.

9. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Odyssey Hospice 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. Disclosure Program

Prior to the Effective Date, Odyssey Hospice established and shall maintain for the term of the CIA 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 Odyssey Hospice'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. Odyssey Hospice has and shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall 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, Odyssey Hospice shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

F. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

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

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

- a. Odyssey Hospice 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. Odyssey Hospice shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Odyssey Hospice shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.F affects Odyssey Hospice’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Odyssey Hospice understands that items or services furnished by excluded persons are not payable by Federal health care programs

and that Odyssey Hospice may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Odyssey Hospice meets the requirements of Section III.F.

3. *Removal Requirement.* If Odyssey Hospice has actual notice that a Covered Person has become an Ineligible Person, Odyssey Hospice shall remove such Covered Person from responsibility for, or involvement with, Odyssey Hospice'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 Odyssey Hospice has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, Odyssey Hospice shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

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

H. Repayment of Overpayments

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

2. *Repayment of Overpayments*

- a. If, at any time, Odyssey Hospice identifies or learns of any Overpayment, Odyssey Hospice shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 30 days after identification, Odyssey Hospice 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.

I. Reportable Events

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

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable

to any Federal health care program for which penalties or exclusion may be authorized;

- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- d. the filing of a bankruptcy petition by Odyssey or Parent or any corporate entity that owns or operates hospices within Odyssey Hospice.

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

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made at the same time as the repayment to the payor required in Section III.H, and shall include:

- a. a copy of the notification and repayment to the payor required in Section III.H.2;
- b. a description of the steps taken by Odyssey Hospice to identify and quantify the Overpayment;
- c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- d. a description of Odyssey Hospice's actions taken to correct the Reportable Event; and
- e. any further steps Odyssey Hospice plans to take to address the Reportable Event and prevent it from recurring.

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Odyssey Hospice's actions taken to correct the Reportable Event;
- c. any further steps Odyssey Hospice plans to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Odyssey Hospice to identify and quantify the Overpayment.

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

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Odyssey Hospice 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.H.2 that require repayment to the payor of any identified Overpayment within 30 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.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location

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

B. Purchase or Establishment of New Unit or Location

In the event that, after the Effective Date, Odyssey Hospice purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Odyssey Hospice shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, 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 Odyssey Hospice currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Odyssey Hospice shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. a copy of Parent's Code of Business Ethics and Conduct required by Section III.B.1;
4. the number of individuals required to complete the Code of Business Ethics and Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);
5. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);
6. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

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

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (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 Odyssey Hospice or Parent and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Odyssey Hospice and Parent;

9. a description of the process by which Odyssey Hospice fulfills the requirements of Section III.F regarding Ineligible Persons;

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

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

12. the certifications required by Section V.C.

B. Annual Reports

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

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

2. the Board Audit Committee resolution required by Section III.A.3;
3. a summary of any changes or amendments to Parent's Code of Business Ethics and Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Business Ethics and Conduct;
4. the number of individuals required to complete the Code of Business Ethics and Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);
5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);
6. the following information regarding each type of training required by Section III.C:
 - a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
 - b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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. Odyssey Hospice'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 Odyssey Hospice or Parent 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 Odyssey Hospice and Parent;
11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;
12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. 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;
13. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);
14. any changes to the process by which Odyssey Hospice fulfills the requirements of Section III.F regarding Ineligible Persons;
15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
16. a description of all changes to the most recently provided list of Odyssey Hospice's locations (including addresses) as required by Section V.A.10; 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 Odyssey Hospice currently submits claims; and

17. the certifications required by Section V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

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

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

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

D. Designation of Information

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

Odyssey and Odyssey Hospice:

Patrick Cunningham
Vice President Hospice Compliance
Gentiva® Health Services
3350 Riverwood Parkway, Suite 1400
Atlanta, GA 30339
Telephone: 770-951-6489
Facsimile: 913-814-4388

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, Odyssey Hospice 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 or request copies of Odyssey

Hospice's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Odyssey Hospice's locations for the purpose of verifying and evaluating: (a) Odyssey Hospice's compliance with the terms of this CIA; and (b) Odyssey Hospice's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Odyssey Hospice to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Odyssey Hospice's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Odyssey Hospice shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Odyssey Hospice's employees may elect to be interviewed with or without a representative of Odyssey Hospice present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Odyssey 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, Odyssey Hospice 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 Odyssey Hospice fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board Audit Committee compliance obligations;
- d. a written Code of Business Ethics and Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings; and
- j. reporting of Reportable Events.

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 Odyssey Hospice fails to engage and use an IRO, as required in Section III.D, Appendix A, Appendix C, and Appendix B if applicable under Section III.D.4.

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 Odyssey Hospice 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 Odyssey Hospice fails to submit any Eligibility Review Report, Verification Review Report, or Unallowable Cost Review Report in accordance with the requirements of Section III.D, Appendix B, and Appendix C.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Odyssey Hospice 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 Odyssey Hospice fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Odyssey Hospice stating the specific grounds for its determination that Odyssey Hospice has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Odyssey Hospice shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Odyssey Hospice 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

Odyssey Hospice 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 Odyssey Hospice fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Odyssey Hospice receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Odyssey Hospice 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 Odyssey Hospice of: (a) Odyssey Hospice's 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, Odyssey Hospice 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 Odyssey Hospice elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Odyssey Hospice 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 Odyssey Hospice has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Odyssey Hospice to report a Reportable Event, take corrective action, and 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, Appendix C, and Appendix B if applicable under Section III.D.4.

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

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

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Odyssey Hospice fails to satisfy the requirements of Section X.D.3, OIG may exclude Odyssey Hospice from participation in the Federal health care programs. OIG shall notify Odyssey Hospice in writing of its determination to exclude Odyssey Hospice. (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 Odyssey Hospice's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Odyssey Hospice 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 Odyssey Hospice 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, Odyssey Hospice shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event

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

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Odyssey Hospice was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Odyssey Hospice shall have the burden of proving Odyssey Hospice's 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 Odyssey Hospice to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Odyssey Hospice requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether Odyssey Hospice was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Odyssey Hospice had begun to take action to cure the material breach within that period; (ii) Odyssey Hospice has pursued and is pursuing such action with due diligence; and (iii) Odyssey Hospice provided to OIG within that period a reasonable timetable for curing the material breach and Odyssey Hospice has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Odyssey Hospice, only after a DAB decision in favor of OIG. Odyssey Hospice's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Odyssey Hospice 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 Odyssey Hospice 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. Odyssey Hospice shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Odyssey Hospice, Odyssey Hospice 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

Odyssey, Odyssey Hospice, and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Odyssey Hospice.

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

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

D. OIG may agree to a suspension of Odyssey Hospice's obligations under this CIA based on a certification by Odyssey Hospice 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 Odyssey Hospice is relieved of its CIA

obligations, Odyssey Hospice will be required to notify OIG in writing at least 30 days in advance if Odyssey Hospice 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.

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

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

ON BEHALF OF ODYSSEY HEATHCARE, INC. AND ODYSSEY HOSPICE

<u> /John Camperlengo/</u>	<u> 2/6/2012</u>
JOHN CAMPERLENGO General Counsel Odyssey Healthcare, Inc.	DATE
<u> /Gary W. Eiland/</u>	<u> 2/7/2012</u>
GARY W. EILAND (as to form only) King & Spalding, LLP Counsel to Odyssey Healthcare, Inc.	DATE

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

/Gregory E. Demske/

2/13/2012

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

DATE

/Laura E. Ellis/

2/9/2012

LAURA E. ELLIS
Senior 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. Odyssey Hospice 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.8 of the CIA or any additional information submitted by Odyssey Hospice in response to a request by OIG, whichever is later, OIG will notify Odyssey Hospice if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Odyssey Hospice may continue to engage the IRO.

2. If Odyssey Hospice 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, Odyssey Hospice shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Odyssey Hospice at the request of OIG, whichever is later, OIG will notify Odyssey Hospice if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Odyssey Hospice may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Verification Review, the Eligibility Review if required by OIG under Section III.D.4 of the CIA, and the Unallowable Cost Review who have expertise in the clinical, billing, and other standards and requirements of the hospice industry and Federal health care programs hospice eligibility requirements;

2. assign individuals to design and select the Verification Review, and the Eligibility Review, if applicable, sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the Verification Review, and the Eligibility Review, if applicable, of patient records who are licensed registered nurses or

physicians (“Eligibility Reviewers”) with demonstrated hospice experience or expertise; 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 Verification Review, Eligibility Review, if applicable, and Unallowable Cost Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare rules and applicable hospice eligibility guidance in making assessments in the Verification Review, or Eligibility Review if applicable;

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

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

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

D. IRO Independence and Objectivity

The IRO must perform the Verification Review, and the Eligibility Review, if applicable, in a professionally independent and objective fashion, as defined in the Government Auditing Standards (July 2007 Revision) issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO.* If Odyssey Hospice terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Odyssey Hospice 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. Odyssey Hospice must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

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 Odyssey Hospice to engage a new IRO in accordance with Paragraph A of this Appendix. Odyssey Hospice must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

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

APPENDIX B

ELIGIBILITY REVIEW

A. Eligibility Review. The Eligibility Review Team shall perform the Eligibility Review annually to cover each of the five Reporting Periods. Subject to the IRO Verification Review and Section III.D.4 of the CIA, as applicable, the Eligibility Review Team shall perform all components of each Eligibility Review.

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

- a. Eligibility Review Team: A team of internal auditors within Odyssey Hospice consisting of the Compliance Officer, the internal review team of Odyssey Hospice, and an outside consultant.
 - i. The Eligibility Review team members who review the patient records and the outside consultant shall be licensed registered nurses or physicians with demonstrated hospice experience, or expertise.
 - ii. The Eligibility Review Team shall assign individuals to design and select the Eligibility Review sample who are knowledgeable about the appropriate statistical sampling techniques.
- b. Overpayment: The amount of money Odyssey Hospice has received in excess of the amount due and payable under any Federal health care program requirements.
- c. Patient: A Medicare patient for whom Odyssey Hospice submitted a claim.
- d. Paid Claim: A claim submitted by Odyssey Hospice and for which Odyssey Hospice has received reimbursement from the Medicare program.
- e. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Eligibility Review.

- f. 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 under payments identified in the sample from all gross Overpayments identified in the sample.

2. *Discovery Sample*. The Eligibility Review Team shall randomly select two hospices from each region within Odyssey Hospice for a total of 10 hospices. The Eligibility Review Team shall randomly select and review a sample of 50 Paid Claims from each hospice paid during the 12-month period covered by the Eligibility Review (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Odyssey Hospice's office or under Odyssey Hospice's control, including the Patient's medical record, and eligibility criteria regulations and guidance, to determine whether a certification was made for the period in which the claim was filed that the Patient had a terminal diagnosis and whether the evidence in the medical record supports the terminal diagnosis. If the Paid Claim includes continuous care services, the Eligibility Review Team shall determine whether evidence in the record supports a determination that the Patient was eligible for continuous care services. For any Paid Claim in which the Eligibility Review Team determines that no certification was made, that the evidence in the record does not support the terminal diagnosis, or that the evidence in the record does not support a determination that the Patient was eligible for continuous care services, the Eligibility Review Team shall review all prior and subsequent claims for the Patient to determine whether a certification was made that the Patient had a terminal diagnosis, whether the evidence in the record supports the terminal diagnosis, and whether the evidence in the record supports eligibility for continuous care services if Odyssey Hospice submitted any claim for continuous care services.

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

3. *Full Sample*. If a Discovery Sample for a hospice indicates that the Error Rate is 5% or greater, the Eligibility Review Team shall select an additional sample of Paid Claims (Full Sample) from that hospice using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Eligibility

Review Team shall perform the same review for the Paid Claims selected for the Full Sample as it performed for the Discovery Sample. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the Eligibility Review Team 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 Eligibility Review Team selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Odyssey Hospice to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

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

5. *Other Requirements*

- a. Supplemental Materials. The Eligibility Review Team shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Odyssey Hospice shall furnish such documentation and materials to the Eligibility Review Team prior to the Eligibility Review Team initiating its review of the Discovery Sample or Full Sample (if applicable). If the Eligibility Review Team accepts any supplemental documentation or materials from Odyssey Hospice after the Eligibility Review Team has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the Eligibility Review Team shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the Eligibility Review Team gave to the Supplemental Materials in its review. In addition, the Eligibility Review Team shall include a narrative in the Eligibility Review Report describing the process by which the Supplemental Materials were accepted

and the Eligibility Review Team's reasons for accepting the Supplemental Materials.

- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Odyssey Hospice cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Odyssey Hospice 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(s) and Full Sample(s)) discussed in this Appendix, 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 Full Sample).

6. *Repayment of Identified Overpayments*. Odyssey Hospice shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Odyssey Hospice shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

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

- 1. *Eligibility Review Methodology*
 - a. Eligibility Review Population. A description of the Population subject to the Claims Review.
 - b. Eligibility Review Objective. A clear statement of the objective intended to be achieved by the Eligibility Review.
 - c. Source of Data. A description of the specific documentation relied upon by the Eligibility Review Team when performing the Eligibility 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 Eligibility Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by 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 Eligibility Review Team.
- 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 Full Sample size, if applicable.

3. *Eligibility Review Findings*

- a. Narrative Results
 - i. A description of Odyssey Hospice’s eligibility-determination system(s), including the identification, by position description, of the personnel involved in eligibility decisions and including any regional or hospice-level systems, policies, or procedures that differ from Odyssey Hospice’s corporate systems, policies, and procedures.
 - ii. A narrative explanation of the Eligibility Review Team’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Eligibility 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 Eligibility Review Team determined that the Paid Claims submitted by Odyssey Hospice (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 Odyssey Hospice.
 - iii. Total dollar amount of all Overpayments in the sample.
 - iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.
 - v. Error Rate in the sample.
 - vi. A spreadsheet of the Eligibility Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date(s) of service, the correct allowed amount (as determined by the Eligibility Review Team), and the dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The Eligibility Review Team's report shall include any recommendations for improvements to Odyssey Hospice's eligibility-determination system based on the findings of the Eligibility Review.

4. *Systems Review Findings*. The Eligibility Review Team shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the Eligibility Review Team's observations, findings, and recommendations regarding suggested improvements to the system(s) and the process(es) used to determine eligibility.

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

APPENDIX C

VERIFICATION REVIEW

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

1. *Definitions*. For the purposes of the Verification Review, the definitions in Section A.1 of Appendix B of the CIA shall be used.

2. *Discovery Sample*.

- a. The IRO shall randomly select 50 Paid Claims from the 500 Paid Claims selected by the Eligibility Review Team in the Discovery Samples. The IRO shall review the Paid Claims selected by the Eligibility Review Team. The Paid Claims shall be reviewed based on the documentation and materials gathered by the Eligibility Review Team, supplemented as necessary as described in Sections A.4.b and A.4.c below, to determine whether a certification was made for the period in which the claim was filed that the Patient had a terminal diagnosis and whether the evidence in the medical record supports the terminal diagnosis. If the Paid Claim includes continuous care services, the IRO shall determine whether evidence in the record supports a determination that the Patient was eligible for continuous care services.
- b. For any Paid Claim in which the Eligibility Review Team determined that no certification was made, that the evidence in the record does not support the terminal diagnosis, or that the evidence in the record does not support a determination that the Patient was eligible for continuous care services, the IRO shall review all prior and subsequent Patient claims in the Reporting Period to determine whether a certification was made that the Patient had a terminal diagnosis, whether the evidence in the record supports the terminal diagnosis, and whether the evidence in the record supports eligibility for continuous care services if Odyssey Hospice submitted any claim for continuous care services, using the documentation and materials gathered by the Eligibility Review Team, supplemented as necessary as described in Sections A.4.b and A.4.c below.

- c. For any Paid Claim for which the IRO disagrees with the Eligibility Team determination that a certification was made for the period in which the claim was filed that the Patient had a terminal diagnosis, that the evidence in the medical record supports a terminal diagnosis, or, if applicable, that the evidence in the record supports a determination that the Patient was eligible for continuous care services, the IRO shall review all prior and subsequent Patient claims in the Reporting Period to determine whether a certification was made that the Patient had a terminal diagnosis, whether the evidence in the record supports the terminal diagnosis, and whether the evidence in the record supports eligibility for continuous care services if Odyssey Hospice submitted any claim for continuous care services.

3. *Full Sample.* If the Eligibility Review Team performs a Full Sample, the IRO shall randomly select 10 percent of the Paid Claims comprising the Full Sample. The IRO shall perform the same review for the Paid Claims selected for the Full Sample as it performed for the Discovery Sample. 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 Eligibility Review Team selected the Full Sample Paid Claims using the seed number generated by the Discovery Sample.

4. *Other Requirements*

- a. Verification Review Materials. The Eligibility Review Team shall provide all documents and materials used in its review of the Discovery Sample and, if applicable, the Full Sample, prior to the IRO initiating its review. For any prior and subsequent Patient claims reviewed under Section A.2.c above, the IRO shall request all documentation and materials required for its review of the claims and Odyssey Hospice shall furnish such documentation and materials to the IRO prior to the IRO initiating that portion of its review.
- b. Supplemental Record Documentation. If the IRO requests or accepts any supplemental documentation from Odyssey Hospice or the Eligibility Review Team (Supplemental Record Documentation), the IRO shall identify in the Verification Review Report the Supplemental Record Documentation, the date the Supplemental Record

Documentation was requested or accepted, and the relative weight the IRO gave to the Supplemental Record Documentation in its review. In addition, the IRO shall include a narrative in the Verification Review Report describing the process by which the Supplemental Record Documentation was requested or accepted and the IRO's reasons for requesting or accepting the Supplemental Documentation.

- c. Supplemental Verification Materials. If the IRO relies on any materials that the Eligibility Review Team did not use in its Eligibility Review (Supplemental Verification Materials), the IRO shall identify the Supplemental Verification Materials (e.g., 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) and the IRO's reasons for using the Supplemental Verification Materials.
- d. Paid Claims without Supporting Documentation. Any Paid Claim for which Odyssey Hospice cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Odyssey Hospice for such Paid Claim shall be deemed an Overpayment.

5. *Repayment of Identified Overpayments.* Odyssey Hospice shall repay within 30 days any Overpayment(s) identified by the IRO in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Odyssey Hospice shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

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

1. *Verification Review Methodology*

- a. Verification Review Population. A description of the Population subject to the Claims Review.

- b. Verification Review Objective. A clear statement of the objective intended to be achieved by the Verification Review.
- c. Source of Data. A description of the Verification Review Materials that the Eligibility Review Team, and, for claims reviewed under Section A.2.c above, Odyssey Hospice, provided.
- d. Review Protocol. A narrative description of how the Eligibility Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Record Documentation and Supplemental Verification Materials as required by Sections A.4.b and A.4.c, above.

2. *Eligibility Review Findings*

a. Narrative Results

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

ii. A narrative description of the differences, if any, between the Eligibility Review Team's and the IRO's findings and supporting rationale.

iii. The IRO's observations and recommendations on the Eligibility Review Team's performance of the Eligibility Review.

b. Quantitative Results

i. Total number and percentage of instances in which the IRO's determination regarding whether the Paid Claims submitted by Odyssey Hospice (Claim Submitted) differed from what should have been the correct claim (Correct Claim) (IRO Results) was different than the Eligibility Review Team's determination (Eligibility Review Team Results), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the IRO Results differed from the Eligibility Review Team Results and in which such difference resulted in an Overpayment to Odyssey Hospice.

iii. The IRO Results' total dollar amount of all Overpayments in the sample, and the difference from the Eligibility Review Team Results' total dollar amount of all Overpayments in the sample.

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

v. Error Rate in the sample.

vi. A spreadsheet of the Verification Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date(s) of service, the allowed amount reimbursed by the payor, the allowed amount as determined by the Eligibility Review Team, the correct allowed amount as determined by the IRO, and the dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Odyssey Hospice's eligibility-determination system based on the findings of the Verification Review.

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