

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

**I. PREAMBLE**

Odyssey HealthCare, Inc., and its wholly-owned subsidiaries, (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, among others, the United States.

Odyssey has an established corporate compliance program (Compliance Program), which preceded the execution of this CIA. The Compliance Program includes written policies and procedures, numerous education and training programs, ongoing compliance monitoring mechanisms and auditing functions for employees and agents to report incidents of noncompliance in an anonymous and confidential manner, disciplinary actions for individuals violating Odyssey policies and procedures, oversight by the Odyssey Compliance Officer and its Board of Directors Compliance Committee. Odyssey will continue to operate its Compliance Program throughout the term of this CIA. The Compliance Program may be modified, as appropriate, which modifications shall be consistent with this CIA.

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

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

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

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

1. "Odyssey" or the "Company" means Odyssey HealthCare, Inc. and its wholly-owned subsidiaries.
2. "Covered Persons" includes:
  - a. owners (other than shareholders who: 1) have an ownership interest of less than 5%; and 2) acquired the ownership interest through public trading), officers, directors, employees, and medical directors of Odyssey; and
  - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Odyssey (but not including Hospital Covered Contractors).

With the exception of medical directors, this term does not include part-time or per diem employees, contractors, subcontractors, agents, or other persons who are not reasonably expected to work on behalf of Odyssey for more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work on behalf of Odyssey for more than 160 hours during the calendar year.

3. "Relevant Covered Persons" includes Regional Clinical Directors, Regional Clinical Trainers, Compliance Liaisons, and other individuals who are engaged directly (or in a supervisory role) in the determination of whether Odyssey patients meet applicable benefit eligibility requirements and guidelines included in the Clinical Review Protocol, including, but not limited to: Interdisciplinary Team Members, Clinical Reviewers, Medical Directors, General Managers, and CQI Managers.
4. "Hospital Covered Contractors" shall mean any acute care hospital, skilled nursing facility or nursing home that Odyssey contracts with and

pays to provide (a) general inpatient care to Odyssey's patients during acute periods, (b) respite care, or (c) room and board services in connection with routine home care.

### III. CORPORATE INTEGRITY OBLIGATIONS

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

#### A. Compliance Officer and Committee.

1. *Compliance Officer.* To the extent not completed prior to the Effective Date, within 90 days after the Effective Date, Odyssey shall appoint an individual to serve as its full-time dedicated Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of this CIA and Federal health care programs. The Compliance Officer shall be a member of senior management of Odyssey, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Compliance Committee of the Board of Directors of Odyssey, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer, although he or she may report to those individuals for administrative purposes from time-to-time. The Compliance Officer shall be responsible for managing a compliance department that shall monitor Odyssey's day-to-day compliance activities engaged in by as well as for any reporting obligations created under this CIA.

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

2. *HealthCare Compliance Committee.* To the extent not already completed prior to the Effective Date, within 90 days after the Effective Date, Odyssey shall appoint a HealthCare Compliance Committee (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 the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Odyssey 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 its duties under this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* To the extent not already completed prior to the Effective Date, within 90 days after the Effective Date, Odyssey shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Distribution may include publishing the Code of Conduct on Odyssey's intranet or other internal web site available to all employees and Covered Persons. If Odyssey uses such an electronic distribution method, it must notify the individuals of the distribution of the Code of Conduct in that manner and it must monitor the distribution to ensure that all appropriate individuals receive the revised Code of Conduct. Odyssey shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Odyssey's commitment to full compliance with all applicable Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Odyssey's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Odyssey's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of Odyssey's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Odyssey suspected violations of any

Federal health care program requirements or of Odyssey's own Policies and Procedures;

d. the possible consequences to both Odyssey and Covered Persons of failure to comply with Federal health care program requirements and with Odyssey's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and Odyssey'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, that he or she has received, read, understood, and shall abide by Odyssey's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Odyssey shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions to the Code of Conduct are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 60 days after the distribution of the revised Code of Conduct.

## *2. Hospital Covered Contractor Requirements.*

Odyssey shall make available a copy of its Code of Conduct to each Hospital Covered Contractor that (1) furnishes general inpatient or respite care to patients who remain as Odyssey patients (*i.e.*, who are not discharged following the initiation of the inpatient or respite care) or (2) provides room and board services to its residents who are Odyssey hospice patients. Odyssey shall request each such Hospital Covered Contractor to make available a copy of the Odyssey Code of Conduct to its employees and/or agents that it believes are reasonably expected to provide care to Odyssey patients for more than 160 hours in any calendar year. Upon the execution of a new Hospital Covered Contractor agreement or an amendment to an existing Hospital Covered

Contractor agreement, Odyssey shall confirm that the Hospital Covered Contractor has its own compliance program.

3. *Policies and Procedures.* To the extent not already completed prior to the Effective Date, within 120 days after the Effective Date, Odyssey shall implement written Policies and Procedures regarding the operation of Odyssey's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1; and
- b. OIG's Compliance Program Guidance for Hospice; and
- c. Odyssey's internal Billing Review Protocol (Billing Protocol), Clinical Sampling Plan for Admissions and Long Length of Stay Review Protocols (Clinical Review Protocol), and Systems Review Protocol (Systems Protocol).

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to the respective Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Odyssey shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to the Policies and Procedures at issue.

#### C. Training and Education.

Prior to the Effective Date, Odyssey had established compliance training programs for all its Covered Persons and agrees that it shall continue to conduct appropriate training programs that meet the CIA requirements.

Odyssey provides training on a regular basis to its employees and medical directors concerning a variety of regulatory and compliance topics. The training required by this

CIA need not be separate and distinct from the regular training Odyssey provides, but instead may be fully integrated into regular training. The Compliance Officer, with prior approval of the OIG, shall be responsible for determining how many hours of regular training shall be credited toward the general and specific training requirements of this CIA.

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

- a. CIA requirements; and
- b. Odyssey's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. Each Covered Person shall receive reasonable and appropriate General Training annually (Refresher Training). Such Refresher Training shall reinforce the importance of Odyssey's Compliance Program and shall address material changes in Federal health care program requirements, changes in Odyssey's compliance policies and procedures, and other relevant compliance-related topics. Notwithstanding the above, Odyssey will not have to provide General Training to Covered Persons who received general compliance training that meets the requirements of this Section III.C.1 within the six month period prior to the Effective Date in the event Odyssey distributes to those Covered Persons a detailed memorandum explaining the CIA requirements. To the extent a Covered Person is on a leave of absence when the required training is offered, the Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

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

- a. Federal health care program requirements regarding the hospice benefit;

- b. policies, procedures, and other requirements applicable to the documentation of medical records;
- c. applicable reimbursement statutes, regulations, and program requirements and directives; and
- d. the legal sanctions for violations of the Federal health care program requirements.

Relevant Covered Persons shall receive this training within 60 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An Odyssey employee who has completed the Specific Training shall adequately supervise a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

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

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. Copies of these certifications shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the hospice benefits.

5. *Update of Training.* Odyssey shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements related to hospice, significant issues discovered during internal audits, the Independent Verification Organization (IVO) Review and any other relevant information.



6. *Computer-based Training.* Odyssey may provide the training required under this CIA through appropriate computer-based training approaches. If Odyssey 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. All applicable references to “hours” in this section shall mean “normative hours,” as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Verification Organization. Within 90 days after the Effective Date, Odyssey shall retain an entity (or entities), such as an accounting, auditing, or consulting firm to perform reviews to assist Odyssey in assessing and evaluating its clinical admission and discharge practices. Each IVO retained by Odyssey shall have expertise in the billing, coding, reporting, and other requirements of the hospice industry, including the requirements of the Federal health care program(s) from which Odyssey seeks reimbursement. Each IVO shall assess, along with Odyssey, whether it can perform the IVO review in a professionally independent fashion taking into account any other business relationships or engagements that may exist. The IVO(s) review shall address and analyze Odyssey’s Clinical Review Protocol described below, and shall analyze whether Odyssey sought payment for certain unallowable costs (“Unallowable Cost Review”).

b. Frequency of IVO Review. The IVO Review shall be performed annually and shall cover each of the Reporting Periods. Odyssey shall perform all components of the Clinical Review Protocol review, subject to Section III.D.2. The IVO shall perform a verification review, described in Section III.D.1.c, below.

c. IVO Verification Review. The IVO shall conduct a verification review of 30 of the sampling units reviewed by Odyssey pursuant to its Clinical Review Protocol (“Verification Review”). The Verification Review shall involve the random selection by the IVO of 15 records selected from the Admissions Reviews and 15 records selected from the Long Length of Stay

Reviews, as described in Section III.D.2.a below.

As part of Odyssey's Annual Report, the IVO shall submit a report in connection with its verification that the requirements outlined in Section III.D and in Appendices A and B to this CIA have been satisfied and shall report the findings of the Verification Review performed (the "Verification Review Report"), described in Section III.D.3 to Odyssey.

d. IVO Reviews. Following its review of any of Odyssey's Annual Reports, if, in its sole discretion, OIG determines that Odyssey's Clinical Review Protocol internal reviews did not meet the Clinical Review Protocol terms, OIG can require that all aspects of future Reviews conducted be done by the IVO.

e. Frequency of Unallowable Cost Review. The IVO shall perform the Unallowable Cost Review for the first Reporting Period.

f. Retention of Records. The IVO and Odyssey shall retain and make available to OIG, upon request, all pertinent work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IVO and Odyssey) related to its Clinical Review Protocol reviews.

2. *Internal Reviews*. Prior to the Effective Date, Odyssey established a Clinical Review Protocol, as submitted to OIG on April 29, 2006. The applicable procedures and reporting requirements under this CIA are outlined in Appendices A and B as it pertains to the Clinical Review Protocol.

a. Clinical Review Protocol Procedures.

The Clinical Review Protocol ("Clinical Protocol") shall be conducted to determine whether Medicare beneficiaries meet hospice clinical criteria. The Clinical Protocol reviews shall be conducted annually and shall focus on two timeframes: 1) initial admission; and 2) the most recent recertification period for long length of stay patients. Odyssey shall randomly select 16 Medicare-certified hospice programs from a universe of all Odyssey hospice programs. Odyssey shall randomly select two

programs from each of its eight regions.

i. Admissions Review: For each of the 16 selected programs, Odyssey shall create a list of all the Medicare beneficiaries who were admitted to that program in the prior calendar year. Odyssey shall then randomly select 10 patients from each list creating a final sample of 160 Medicare beneficiaries. The sampling unit for selected new admission patients is the initial certification.

ii. Long Length of Stay Review: Odyssey shall also identify Medicare beneficiaries at each of the 16 selected locations who were Odyssey patients during the Clinical Review Period and who received uninterrupted services from Odyssey for 210 days or more. Odyssey shall then randomly select 10 Long Length of Stay Patients from each of the selected programs which will result in a total review of up to 160 certification periods. The sampling unit for selected long length of stay patients is the most recent recertification period.

iii. Qualifications of Reviewers: The Clinical Protocol reviews shall be conducted by licensed nurses or physicians (“Clinical Reviewers”) with demonstrated hospice experience or expertise. To ensure independence of the Clinical Protocol reviews, the Clinical Reviewers shall not review their own clinical decisions and shall not review patients from their own facility. Any proposed changes to the Clinical Protocol shall be submitted to the OIG for prior approval.

b. Repayment of Identified Overpayments. In accordance with Section III.H.1, Odyssey shall repay within 30 days any overpayment(s) identified in the Internal Reviews, regardless of the Error Rate, to the appropriate Federal health care program payor (Payor) and in accordance with Payor refund policies. Odyssey shall make available to the OIG any and all documentation that reflects the refunds, if any, of overpayment(s) to each Payor.

3. *Verification Review Report*. The IVO shall prepare a report (Verification Review Report) based upon Odyssey's internal Clinical Protocol reviews. The Verification Review Report shall include the IVO's findings, consistent with Appendix B, with respect to: (a) whether Odyssey has generally implemented the Clinical Protocol

described in Section III.D.2.a; (b) specific findings as to whether Odyssey has complied with the Clinical Protocol; (c) any observations, findings, and recommendations on possible improvements to Odyssey's clinical policies, procedures, and systems; and (d) a narrative explanation of the IVO's findings and supporting rationale (including reasons for errors, patterns noted, concerns relating to the eligibility or appropriateness of hospice patients etc.) regarding the Clinical Protocol Internal Reviews.

4. *Unallowable Cost Review.* The IVO shall conduct a review of Odyssey's compliance with the unallowable cost provisions of the Settlement Agreement.

a. The IVO 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 cost 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 of its subsidiaries. To the extent 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 IVO will determine if such adjustments were proper. In making this determination, the IVO 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.

5. *Unallowable Cost Review Report.* The IVO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IVO's findings and supporting rationale regarding the Unallowable Costs 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.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) the Verification Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) Odyssey and/or the IVO's findings or Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the

Verification Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or review results are inaccurate (“Validation Review”). Odyssey agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Odyssey’s final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Odyssey of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Odyssey may request a meeting with the OIG to discuss the results of any Verification Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Verification Review or Unallowable Cost Review or to correct inaccuracies of the Verification Review or the Unallowable Cost Review; and/or propose alternatives to the proposed Validation Review. Odyssey agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Verification Review or Unallowable Cost Review with Odyssey 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 the OIG.

*7. Independence Certification.* The IVO shall include in its report(s) to Odyssey a certification or sworn affidavit that it has evaluated its professional independence with regard to the Clinical Protocol Review and that it has concluded that it was, in fact, independent.

#### E. Disclosure Program

Prior to the Effective Date, Odyssey established and shall continue to maintain 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’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 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 shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties

Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

c. "Screened Persons" include prospective and current owners (other than shareholders who: 1) have an ownership interest of less than 5%; and 2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of Odyssey.

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

a. Odyssey shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. Odyssey shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Odyssey shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Odyssey to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Odyssey has actual notice that a Screened Person has become an Ineligible Person, Odyssey shall remove such person from responsibility for, or involvement with, Odyssey's business operations related to Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Odyssey has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, Odyssey shall take appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days once the matter is known by senior management, Odyssey shall notify OIG in writing of any ongoing investigation or legal proceeding known to Odyssey conducted or brought by a governmental entity or its agents involving an allegation that Odyssey 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. To the extent OIG was not involved in the matter or legal proceeding, Odyssey shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Overpayments.*

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

b. Reporting of Overpayments. If, at any time, Odyssey identifies or learns of any Overpayment, Odyssey shall notify the Payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the Payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Odyssey



shall repay the Overpayment to the appropriate Payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Odyssey shall notify the Payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the Payor shall be done in accordance with the Payor's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the Payor should be handled in accordance with such policies and procedures.

## 2. *Reportable Events.*

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

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

b. Reporting of Reportable Events. If Odyssey 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 shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the

notification to the Payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the Payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

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

iii. a description of Odyssey's actions taken to correct the Reportable Event; and

iv. any further steps Odyssey plans to take to address the Reportable Event and prevent it from recurring.

#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date, Odyssey changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Odyssey shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

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

A. Implementation Report. Within 150 days after the Effective Date, Odyssey 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 Odyssey's Code of Conduct required by Section III.B.1;

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

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

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

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

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

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

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

8. the following information regarding the IVO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Odyssey and the IVO; and (d) the proposed start and completion dates of the IVO Verification Review of Clinical Protocol Internal Reviews and of Unallowable Costs.

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

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

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any Federal health care program Overpayments relating to items or services furnished, ordered or prescribed by an Ineligible Person;

12. a list of all of Odyssey's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Odyssey currently submits claims;

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

14. the certifications required by Section V.C.

B. Annual Reports. Odyssey shall submit to OIG annually a report with respect to the status of, and findings regarding, Odyssey's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

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

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

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

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

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

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

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

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IVO's engagement letter (if applicable);

6. Odyssey's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. summary and description of any and all current and prior engagements and agreements between Odyssey and the IVO, if different from what was submitted as part of the Implementation Report;

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

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

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories, as applicable to Odyssey: Medicare and Medicaid (report each

applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the Payor do not need to be included in this aggregate Overpayment report;

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

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

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Odyssey in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any Federal health care program Overpayments relating to items or services furnished, ordered or prescribed by an Ineligible Person;

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

15. a description of all changes to the most recently provided list of Odyssey's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Odyssey currently submits claims; and

16. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

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

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Odyssey 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, based on such inquiry, believes that the information in the Report is accurate and truthful; and

3. Odyssey has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal healthcare 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 following the Settlement Agreement effective date; (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 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 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:

Odyssey HealthCare, Inc.  
Attn: Chief Compliance Officer  
Attn: General Counsel  
717 North Harwood  
Suite 1500  
Dallas, TX 75201

Telephone: 214.922.9711  
Facsimile: 214.245.3336

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, email attachment, 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.

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



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

Odyssey shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law).

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Odyssey prior to any release by OIG of information submitted by Odyssey pursuant to its obligations under this CIA and identified upon submission by Odyssey as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Odyssey 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 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 fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;

- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements; and
- h. Notification of Government investigations or legal proceedings.

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

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

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

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Odyssey 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 fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Odyssey, stating the specific grounds for its determination that Odyssey has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Odyssey shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 30 days after Odyssey 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 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 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 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 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 of: (a) Odyssey's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Odyssey 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 elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Odyssey cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or

otherwise set a standard for OIG's decision that Odyssey has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

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

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

3. *Opportunity to Cure.* Odyssey 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 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 has begun to take action to cure the material breach; (ii) Odyssey is pursuing such action with due diligence; and (iii) Odyssey 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 fails to satisfy the requirements of Section X.D.3, OIG may exclude Odyssey from participation in the Federal health care programs. OIG shall notify Odyssey in writing of its determination to exclude Odyssey (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Odyssey’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 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 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 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 was

in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Odyssey shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Odyssey to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Odyssey 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 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 had begun to take action to cure the material breach within that period; (ii) Odyssey has pursued and is pursuing such action with due diligence; and (iii) Odyssey provided to OIG within that period a reasonable timetable for curing the material breach and Odyssey 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, only after a DAB decision in favor of OIG. Odyssey's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Odyssey 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 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 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, Odyssey shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Odyssey and OIG agree as follows:

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

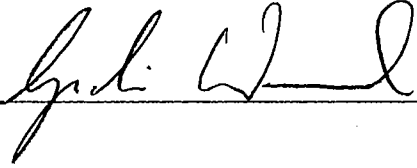
B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

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

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

E. The undersigned Odyssey 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.

ON BEHALF OF ODYSSEY HEALTHCARE, INC.

  
\_\_\_\_\_

7/6/06  
\_\_\_\_\_

BY:

DATE

Gadi Weinreich  
Howard J. Young  
Elizabeth McCubrey  
SONNENSCHNAIN NATH & ROSENTHAL LLP  
Counsel for Odyssey HealthCare, Inc.

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W. Bradley Bickham  
VP and General Counsel  
Odyssey HealthCare, Inc. and its wholly-owned subsidiaries

DATE

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\_\_\_\_\_

DATE



ON BEHALF OF ODYSSEY HEALTHCARE, INC.

\_\_\_\_\_  
BY:

Gadi Weinreich  
Howard J. Young  
Elizabeth McCubrey  
SONNENSCHNEN NATH & ROSENTHAL LLP  
Counsel for Odyssey HealthCare, Inc.

\_\_\_\_\_  
DATE

W. Bradley Bickham

W. Bradley Bickham  
VP and General Counsel  
Odyssey HealthCare, Inc. and its wholly-owned subsidiaries

7/6/2006

DATE

\_\_\_\_\_  
DATE

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



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

7/6/06

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DATE

**APPENDIX A  
INDEPENDENT VERIFICATION ORGANIZATION**

A. IVO Engagement.

Odyssey shall engage an IVO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IVO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IVO, OIG will notify Odyssey if the IVO is unacceptable. Absent notification from OIG that the IVO is unacceptable, Odyssey may continue to engage the IVO.

If Odyssey engages a new IVO during the term of the CIA, this IVO shall also meet the requirements of this Appendix. If a new IVO is engaged, Odyssey shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IVO. Within 30 days after OIG receives written notice of the identity of the selected IVO, OIG will notify Odyssey if the IVO is unacceptable. Absent notification from OIG that the IVO is unacceptable, Odyssey may continue to engage the IVO.

B. IVO Qualifications.

The IVO shall:

1. assign individuals to conduct the Clinical Protocol Verification Review and Unallowable Cost Review engagement who have expertise in the clinical, billing and other standards and requirements of hospice and in the general requirements of the Federal health care program(s) from which Odyssey seeks reimbursement; and
2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IVO Responsibilities.

The IVO shall:

1. perform each Clinical Protocol Verification Review and Unallowable Cost Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare rules and consider applicable hospice eligibility guidelines in making assessments of the Clinical Review Protocols reviews;
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 inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IVO Independence/Objectivity.

The IVO must perform the Verification Reviews in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IVO and Odyssey.

E. IVO Removal/Termination.

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

2. *OIG Removal of IVO.* In the event OIG has reason to believe that the IVO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Odyssey to engage a new IVO in accordance with Paragraph A of this Appendix.

Prior to requiring Odyssey to engage a new IVO, OIG shall notify Odyssey in writing 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 may request a meeting with OIG to discuss any aspect of the IVO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Odyssey shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IVO with Odyssey prior to requiring Odyssey to terminate

the IVO. However, the final determination as to whether or not to require Odyssey to engage a new IVO shall be made at the sole discretion of OIG.

**APPENDIX B**  
**VERIFICATION REVIEW REPORT**

A. The IVO shall prepare a report based upon the Internal Reviews performed (Verification Review Report).

B. *Verification Review Report Findings:*

The following information shall be included in the IVO's Verification Review Report:

1. the IVO's findings with respect to whether Odyssey has generally implemented the Clinical Protocol described in Section III.D.2;
2. specific findings as to whether Odyssey has complied with the Clinical Protocol described in Section III.D.2;
3. the IVO's observations, findings, and recommendations on possible improvements to Odyssey's policies, procedures, and systems in place to ensure that Odyssey is in compliance with its Clinical Protocol; and
4. a narrative explanation of the IVO's findings and supporting rationale (including reasons for errors, patterns noted, concerns relating to the eligibility or appropriateness of hospice patients, etc.) regarding the Internal Reviews.

C. *Credentials.* The names and credentials of the individuals who prepared the IVO Internal Review Reports.