

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
SERENITY HOSPICE AND PALLIATIVE CARE**

**I. PREAMBLE**

Serenity Hospice and Palliative Care (Serenity) 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, Serenity is entering into a Settlement Agreement with the United States.

Serenity has an established corporate compliance program (“Compliance Program”), which preceded the execution of this CIA, and which applies in all aspects to Serenity. The Compliance Program includes written policies and procedures, 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 Serenity’s policies and procedures, and oversight by Serenity’s Compliance Officer and its Compliance Committee. Serenity will continue to operate its Compliance Program throughout the term of this CIA, and shall ensure that Serenity complies with each requirement herein. The Compliance Program may be modified, as appropriate, which modifications shall be consistent with this CIA.

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

A. The period of the compliance obligations assumed by Serenity under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

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

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

1. "Covered Persons" includes:

- a. all owners, officers, directors, and employees of Serenity;
- b. officers, directors, and employees of Serenity who are responsible for the management or oversight of Serenity, including but not limited to the Certifying Employees (defined in Section III.A.4 below); and
- c. all contractors, subcontractors, agents, and other persons who provide patient care items or services or management services or who perform billing or coding functions on behalf of Serenity, excluding vendors whose sole connection with Serenity is selling or otherwise providing medical supplies or equipment to Serenity and who do not bill the Federal health care programs for such medical supplies or equipment.

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

2. "Relevant Covered Persons" includes Covered Persons involved in the delivery of patient care items or services, eligibility determinations for hospice care and the appropriate Level of Care, the marketing of hospice services, and/or the preparation or submission of claims for reimbursement from any Federal health care program.

3. "Level of Care" means one of the four categories of care reimbursed under the Medicare hospice benefit, which consist of:

- a. Routine Home Care: When an individual who has elected to receive hospice care is at home and is not

receiving continuous care.

- b. **Continuous Home Care:** When an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Continuous home care is only furnished during brief periods of crisis (as defined in 42 C.F.R. 418.204(a)) and only as necessary to maintain the terminally ill at home.
- c. **Inpatient Respite Care:** When an individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.
- d. **General Inpatient Care:** When an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

4. "Long Length of Stay" means a Serenity patient who during a Reporting Period received uninterrupted services from Serenity for 210 days or more.

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

Serenity has and shall continue to maintain the aforementioned Compliance Program. Serenity shall continue to participate in and comply with its Compliance Program which shall, at a minimum, include the following elements:

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

1. *Compliance Officer.* Serenity has and shall maintain an employee in the position of Compliance Officer for term of this CIA. The Compliance Officer shall be a member of senior management of Serenity, shall report directly to the Chief Executive Officer of Serenity, and shall not be or be subordinate to the General Counsel or Chief Financial Officer of Serenity or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Serenity. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making on-site visits to Serenity periodically throughout the CIA's term;
- c. making periodic (at least quarterly) reports regarding compliance matters directly to the Governing Body of Serenity, and shall be authorized to report on such matters to the Governing Body at any time. Written documentation of the Compliance Officer's reports to the Governing Body shall be made available to OIG upon request; and
- d. monitoring the day-to-day compliance activities engaged in by Serenity 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.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, Serenity shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., 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 Serenity risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Serenity 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. *Governing Body's Compliance Obligations.* Serenity's Governing Body, which currently has three members, shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

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

- a. meeting at least quarterly to review and oversee Serenity's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Governing Body summarizing its review and oversight of Serenity compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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

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

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain employees of Serenity (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Chief Executive Officer for Serenity; the Director of Clinical Services; the Medical Director; and the Billing Coordinator. For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and SERENITY policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of SERENITY is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

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

B. Written Standards

1. *Code of Ethics.* Serenity has and shall maintain for the term of the CIA a Code of Ethics to which Serenity is subject. Within 90 days after the Effective

Date, Serenity shall update its Code of Ethics, and distribute in person or electronically the revised copy to all Covered Persons. Serenity shall make the performance of job responsibilities in a manner consistent with the Code of Ethics an element in evaluating the performance of all employees. The Code of Ethics shall, at a minimum, set forth:

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

Serenity shall review the Code of Ethics at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Ethics shall be distributed at least annually to all Covered Persons, either in person or electronically.

2. *Policies and Procedures.* Serenity represents that it has developed and implemented written Policies and Procedures regarding the operation of its Compliance Program, including the compliance program requirements outlined in this CIA and Serenity compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall continue to address:

- a. Eligibility for hospice services, including upon initial admission, recertification, and for continued stay (i.e., patients who have received more than six months of hospice care);

- b. The role of physicians in making eligibility determinations; and
- c. Documentation of eligibility for hospice services and the services provided, and relating to the preparation and submission of accurate claims for such services.

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

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

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

C. Training and Education

1. *Training Plan.* Serenity represents that it has developed, and shall maintain, a written plan (Training Plan) that outlines the steps Serenity will take to ensure that: (a) all Covered Persons receive adequate training regarding Serenity's CIA requirements and Compliance Program, including the Code of Ethics and (b) all Relevant Covered Persons receive adequate training regarding: (i) the Federal health care program requirements regarding the accurate coding and submission of hospice claims; (ii) the Federal health care program requirements regarding hospice benefit, including eligibility upon initial admission and at recertification for continued stay; (iii) Serenity Policies and Procedures applicable to the documentation of medical records; (iv) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (v) reimbursement statutes, regulations, and program requirements and directives applicable to Serenity hospice operations; (vi) the legal sanctions for violations of the Federal health care program requirements; and (vii) examples of proper and improper eligibility determinations, documentation, and hospice claims submission practices.

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

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

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

3. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain a copy of the certifications, along with a copy of all course materials.

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

5. *Update of Training Plan.* Serenity shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised

Training Plan. Within 30 days of OIG's receipt of any updates or revisions to Serenity's Training Plan, OIG will notify Serenity of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, Serenity may implement the revised Training Plan.

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

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Serenity shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Serenity shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Serenity) related to the reviews.

2. *Claims Review.* The IRO shall review Serenity's coding, billing, and claims submission to the Medicare program and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) Serenity's Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate

(Validation Review). Serenity shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of a Claims Review submitted as part of Serenity's final Annual Report shall be initiated no later than one year after Serenity final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Serenity 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, Serenity may request a meeting with OIG to: (a) discuss the results of any Claims Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. Serenity agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with Serenity prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

E. Risk Assessment and Internal Review Process

Serenity has and shall maintain a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of hospice claims for items and services furnished to Medicare program beneficiaries. The risk assessment and internal review process should include: (1) a process for identifying and prioritizing risks, (2) developing remediation plans in response to those risks, including internal auditing and monitoring of the identified risk areas, and (3) tracking results to assess the effectiveness of the remediation plans. The risk assessment and internal review process should require compliance, legal and department leaders, at least annually, to evaluate and identify risks associated with the submission of claims for items and services furnished to Medicare beneficiaries and develop and implement specific plans to address and mitigate the identified risks. The risk assessment and internal review work plans shall be developed annually. Serenity shall implement the risk assessment and internal review work plans and track the implementation of the work plans. Serenity shall maintain the risk assessment and internal review process for the

term of the CIA. Copies of any internal audit reports developed pursuant to the risk assessment and internal review process shall be made available to OIG upon request.

F. Disclosure Program

Serenity represents that it currently has mechanisms in place which enables 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 Serenity'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. In addition to the current mechanisms, within 90 days of the Effective Date, Serenity shall also install a toll-free compliance telephone line, as well as a link on its website, whereby members of the public may also make comments regarding compliance at Serenity. Serenity shall appropriately publicize the existence of the new 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, Serenity shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two (2) business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

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

- a. an "Ineligible Person" shall include an individual or entity who:
  - i. is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or suspended.
- b. "Exclusion Lists" include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration's System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* Serenity has and shall maintain screening requirements to ensure that all prospective and current Covered Persons are not Ineligible Persons. Serenity shall continue to conduct the following screening requirements.

- a. Serenity 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. Serenity shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. Serenity shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

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

3. *Removal Requirement.* If Serenity has actual notice that a Covered Person has become an Ineligible Person, Serenity shall remove such Covered Person from responsibility for, or involvement with, Serenity 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 Serenity 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 Serenity shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

#### H. Notification of Government Investigation or Legal Proceedings

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

I. Repayment of Overpayments

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

2. *Overpayment Policies and Procedures.* Serenity has developed and implemented written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

- a. If, at any time, Serenity identifies any Overpayment to Serenity, Serenity shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, Serenity shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies.
- b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

J. Reportable Events

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

- a. a substantial Overpayment;

- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Serenity.

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

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

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

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

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

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

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

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

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Persons employment or contractual relationship;
- c. a description of the Exclusion Lists screening that Serenity completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the

Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

- d. a description of how the Reportable Event was discovered; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.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.

7. *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 Serenity to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If Serenity identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Serenity is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

##### **A. Sale of Business, Business Unit or Location.**

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

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

In the event that, after the Effective Date, Serenity changes locations or closes a business, business unit or location that are subject to this CIA related to the furnishing of items or services that may be reimbursed by Federal health care programs, Serenity 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 business, business unit or location.

**C. Purchase or Establishment of New Business, Business Unit or Location**

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

**V. IMPLEMENTATION AND ANNUAL REPORTS**

**A. Implementation Report**

Within 120 days after the Effective Date, Serenity 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. the names of the Governing Body members who are responsible for satisfying the Governing Body's compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Serenity's Code of Ethics required by Section III.B.1;
6. 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);
7. the Training Plan required by Section III.C.1 and a description of the Governing Body's training required by Section III.C.2 (including a summary of the topics covered, the length of the training; and when the training was provided);
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 Serenity and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Serenity;
9. a description of the risk assessment and internal review process required by Section III.E;
10. a description of the Disclosure Program required by Section III.F;
11. a certification that Serenity has conducted the screening required by Section III.G regarding Ineligible Persons, or a description of why Serenity cannot provide such a certification;
12. a copy of Serenity's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;
13. a list of all of Serenity's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Serenity currently submits claims;

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

15. the certifications required by Section V.C.

B. Annual Reports

Serenity shall submit to OIG annually a report with respect to the status of, and findings regarding, Serenity 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; any change in the membership of the Compliance Committee described in Section III.A, any change in the members of the Governing Body who are responsible for satisfying the Governing Body's compliance obligations described in Section III.A.3, and any change in the group of Certifying Employees described in Section III.A.4;

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

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

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

5. a copy of Serenity's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which Serenity ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;
7. Serenity'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;
8. a summary and description of any and all current and prior engagements and agreements between Serenity and the IRO (if different from what was submitted as part of the Implementation Report);
9. a certification from the IRO regarding its professional independence and objectivity with respect to Serenity;
10. a. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;
11. a copy of Serenity's internal review work plans, and a list of all reviews completed during the Reporting Period pursuant to Section III.E;
12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);
13. a certification that Serenity has completed the screening required by Section III.G regarding Ineligible Persons;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;
16. 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: Medicare, 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;

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

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

19. a description of all changes to the most recently provided list of Serenity's locations (including addresses) as required by Section V.A.13; 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 Serenity currently submits claims; and

20. the certifications required by Section V.C.

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

### C. Certifications

1. *Certifying Employees.* In each Annual Report, Serenity shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer of Serenity that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Serenity is in compliance with all of the requirements of this CIA; and

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

3. *Chief Executive Officer.* The first Annual Report shall include a certification by the Chief Executive Officer of Serenity that, to the best of his or her knowledge, Serenity 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

Serenity 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. Serenity 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

SERENITY:  
Kelli Casady  
Chief Compliance Officer  
Serenity Hospice and Palliative Care  
2999 N. 44<sup>th</sup> Street, Suite 225  
Phoenix, AZ 85018  
Telephone: 602-216-2273  
Facsimile: 602-443-5398  
E-Mail: [k.casady@serenityhospice.com](mailto:k.casady@serenityhospice.com)

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, Serenity may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

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

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

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

## **X. BREACH AND DEFAULT PROVISIONS**

Serenity 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, Serenity 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 Serenity fails to establish and implement any of the following obligations as described in Sections III and IV:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Governing Body's compliance obligations;
- d. the management certification obligations;
- e. a written Code of Ethics;

- f. written Policies and Procedures;
- g. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Governing Body Members;
- h. a risk assessment and internal review process as required by Section III.E;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. policies and procedures regarding the repayment of Overpayments;
- m. the repayment of Overpayments as required by Section III.I;
- n. reporting of Reportable Events; and
- o. disclosure of changes to business units or locations.

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

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

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

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

Serenity 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 business day after Serenity 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 Serenity receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

**C. Payment of Stipulated Penalties**

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

D. Exclusion for Material Breach of this CIA

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Serenity to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

- d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Serenity constitutes an independent basis for Serenity's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Serenity has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Serenity of: (a) Serenity'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.* Serenity shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Serenity fails to satisfy the requirements of Section X.D.3, OIG may exclude Serenity from participation in the Federal health care programs. OIG shall notify Serenity in writing of its determination to exclude Serenity. (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 Serenity receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Serenity 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 Serenity 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, Serenity shall be afforded certain review

rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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

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

- a. Serenity cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following Serenity receipt of the Notice of Material Breach:
  - (i) Serenity had begun to take action to cure the material breach;
  - (ii) Serenity pursued such action with due diligence;

and (iii) Serenity provided to OIG a reasonable timetable for curing the material breach.

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

Serenity and OIG agree as follows:

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

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

C. OIG may agree to a suspension of Serenity's obligations under this CIA based on a certification by Serenity 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 Serenity is relieved of its CIA obligations, Serenity will be required to notify OIG in writing at least 30 days in advance if Serenity 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.

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

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

ON BEHALF OF SERENITY

/Shawn McAfee/

SHAWN MCAFFEE  
Chief Executive Officer  
Serenity

/Ashley Adams/

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ASHLEY ADAMS  
Counsel for Serenity

9-8-2015  
DATE

September 4, 2015  
DATE

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

/Robert K. DeConti/

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

9/23/15  
DATE

/Gregory J. Wellins/

GREGORY J. WELLINS  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

9-11-15  
DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

#### A. IRO Engagement

1. Serenity 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 Serenity in response to a request by OIG, whichever is later, OIG will notify Serenity if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Serenity may continue to engage the IRO.

2. If Serenity 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, Serenity 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 Serenity at the request of OIG, whichever is later, OIG will notify Serenity if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Serenity may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in hospice eligibility and medical necessity, and the billing, coding, reporting, and other requirements of the Medicare hospice benefit and in the general requirements of the Federal health care program(s) from which Serenity seeks reimbursement;

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

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have

maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines and applicable hospice eligibility guidance in making assessments in the Claims Review;
3. if in doubt of the application of a particular Medicare and Medicaid policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);
4. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *Provider and IRO.* If Serenity terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Serenity 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. Serenity must engage a new IRO in

accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Serenity to engage a new IRO in accordance with Paragraph A of this Appendix. Serenity must engage a new IRO within 60 days of termination of the IRO.

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

## APPENDIX B

### CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The Claims Review shall consist of two components: an Eligibility Review and an Appropriate Level of Services Review.

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

- a. Overpayment: The amount of money Serenity has received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.4 of this Appendix B.
- b. Admissions Eligibility Population: The Admissions Eligibility Population shall be defined as all Medicare beneficiaries admitted to Serenity during the Reporting Period for whom claims were submitted and reimbursed.
- c. Long-Length-of-Stay Population: The Long-Length-of-Stay Population shall be defined as all Medicare beneficiaries who received uninterrupted services from Serenity for 210 days or more during the Reporting Period and for whom Serenity submitted claims and received reimbursement.
- d. Eligibility Review Error Rate: The Error Rate for the Eligibility Review shall be the percentage of Medicare beneficiaries determined to be ineligible for the hospice benefit in the sample of Medicare beneficiaries. The Overpayment shall be all claims submitted for services provided to the ineligible Medicare beneficiaries.

- e. Level of Services: One of the four categories of care reimbursed under the Medicare hospice benefit, which consist of:
  - i. Routine Home Care – when a patient is at home and is not receiving Continuous Care services;
  - ii. Continuous Care – when a patient is at home and receives services that consist predominantly of nursing care on a continuous basis for brief periods of crisis and as necessary to maintain the terminally ill at home. See 42 C.F.R. § 418.204;
  - iii. Inpatient Respite Care –when a patient receives care at an approved facility on a short term basis for respite; and
  - iv. General Inpatient Care – when a patient receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.
  
- f. Appropriate Level of Services Review Error Rate: The Error Rate for the Appropriate Level of Services Review shall be the percentage of net Overpayments identified in the sample of Medicare beneficiaries. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

2. *Eligibility Review Procedures.* The Eligibility Review shall consist of two components. The Admissions Eligibility Component shall include the beneficiary's first admission for hospice services and the initial election period for hospice services, which includes the first Certification or Recertification of Terminal

Illness and Face-to-Face encounter, if applicable. The Long-Length-of-Stay Eligibility Component shall include election periods beginning with the first recertification.

- a. Admissions Eligibility Component: The IRO shall select a statistically valid random sample of 50 Medicare beneficiaries from the Admissions Eligibility Population.
- b. Long-Length-of-Stay Eligibility Component: The IRO shall select a statistically valid random sample of 50 Medicare beneficiaries from the Long-Length-of-Stay Population.

The Medicare beneficiaries chosen for the Admissions Eligibility Component and the Long-Length-of-Stay Eligibility Component shall comprise the Discovery Sample. (The Medicare beneficiaries selected may comprise less than 100 beneficiaries because some Medicare beneficiaries may be selected for both components.)

The IRO shall review the medical records of the beneficiaries in the Admissions Eligibility Component sample to determine whether the beneficiaries were eligible for hospice services at the time of admission. The IRO shall review the medical records of the beneficiaries in the Long-Length-of-Stay Eligibility Component sample to determine whether the beneficiaries were eligible for hospice services during their most recent recertification period. The medical records of the Medicare beneficiaries selected for the Admissions Eligibility Component and the Long-Length-of-Stay Eligibility Component shall be reviewed based on the supporting documentation available at Serenity or under Serenity control and applicable hospice statutes, regulations, and guidance to determine whether the Medicare beneficiary was eligible for the hospice benefit during the periods under review.

3. *Appropriate Level of Services Review Procedures*. The Appropriate Level of Services Review shall consist of a documentation review to ensure that the appropriate Level of Services was properly documented, and properly submitted to and reimbursed by Medicare. This Review will be completed for each beneficiary in the Admissions Eligibility Component sample who was determined to be eligible for hospice services and for each beneficiary in the Long-Length-of-Stay Eligibility Component sample who was determined to be eligible to continue to receive hospice services.

The scope of review shall include but not be limited to documentation to determine if the Medicare beneficiaries received appropriate hospice care in accordance with Medicare requirements and guidelines including those relating to informed consents,

plan of care, physician orders, skilled nursing notes, and Level-of-Services compliance. Documentation will be reviewed to ensure the appropriateness of the Level of Services billed and reimbursed.

If both Error Rates (as defined above) for the Discovery Sample are less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Serenity should, as appropriate, further analyze any errors identified in the Discovery Sample. Serenity recognizes that OIG or another HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review claims submitted by Serenity for which Serenity has received reimbursement from the Medicare or Medicaid program included in the Discovery Sample or any other segment of the universe.)

4. *Full Sample.* If the Discovery Sample indicates that either Error Rate is 5% or greater, the IRO shall select an additional sample of Medicare beneficiaries (Full Sample) using commonly accepted sampling methods. The medical records for the Medicare beneficiaries selected for the Full Sample shall be reviewed based on supporting documentation available at Serenity or under Serenity control and applicable billing and coding regulations and guidance to determine if the beneficiary was eligible upon admission and eligible for subsequent recertifications and, if eligible, whether the Level of Service billed to Medicare was appropriate. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Medicare beneficiaries sampled as part of the Discovery Sample, and the corresponding findings for those Medicare beneficiaries, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Medicare beneficiaries using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. If the Discovery Sample is larger than the number of beneficiaries needed for a Full Sample, then the Discovery Sample shall be treated as the Full Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Serenity to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

5. *Systems Review.* If either Error Rate for the Discovery Sample is 5% or greater, Serenity IRO shall also conduct a Systems Review with respect to the applicable review. The Systems Review shall consist of the following:

- a. a review of Serenity's systems and processes for determining and documenting a Medicare beneficiary's eligibility for the hospice benefit, including the processes for certification and recertification of beneficiaries, and how those systems and processes were implemented at Serenity;
- b. a review of Serenity's systems and processes for determining and documenting the medical necessity for the Level of Services provided to a Medicare beneficiary implemented, and how those systems and processes were implemented at Serenity; and
- c. for each Medicare beneficiary determined to be ineligible for the hospice benefit or to receive a Level of Services that was not medically necessary (e.g., continuous care), the IRO shall perform a detailed review of the system(s) and process(es) that resulted in Serenity erroneous determination that the beneficiary was eligible for the hospice benefit or that medical necessity existed for the Level of Services provided, to identify any problems or weaknesses that may have resulted in the identified error(s). The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) for determining eligibility for the hospice benefit or medical necessity for the Level of Services provided.

6. *Other Requirements*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the medical records of the Medicare beneficiaries selected as part of the Discovery Sample or Full Sample (if applicable), and Serenity shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Serenity after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental

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

- b. Claims without Supporting Documentation. Any claim for which Serenity cannot produce documentation sufficient to support the claim shall be considered an error and the total reimbursement received by Serenity for such claim shall be deemed an Overpayment. Replacement sampling for claims or Medicare beneficiaries 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 Medicare beneficiaries 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).

7. *Repayment of Identified Overpayments.* Serenity shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. Serenity shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

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

- 1. *Eligibility and Appropriate Level of Services Reviews Methodology*

- a. Review Population. A description of the Admission Eligibility Population and the Long Length of Stay Population.
  - b. Review Objective. A clear statement of the objective intended to be achieved by the Eligibility Review and the Appropriate Level of Services Review.
  - c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Eligibility Review and the Appropriate Level of Services 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 and the Appropriate Level of Services Review were conducted and what was evaluated.
  - e. Supplemental Materials. A description of any Supplemental Materials as required by A.6.a., above.
2. *Statistical Sampling Documentation*
- a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
  - b. A description or identification of the statistical sampling software package used to select the Samples.
3. *Review Findings*
- a. Narrative Results

i. A description of Serenity's hospice eligibility certification, recertification, and determination of appropriate Level of Service processes, including the identification, by position description, of the personnel involved.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, concerns relating to the eligibility for hospice or appropriateness of hospice services, etc.) regarding the Eligibility Review and Appropriate Level of Services Review.

b. Quantitative Results

i. Total number and percentage of instances in which the IRO determined that the documentation for a Medicare beneficiary did not support that the beneficiary was eligible for the Medicare hospice benefit or did not support that the beneficiary received the appropriate Level of Services based on medical necessity, regardless of the effect on the payment.

ii. Total number and percentage of instances in which the documentation for a Medicare beneficiary did not support that the beneficiary was eligible for the Medicare hospice benefit or did not support that the appropriate Level of Services was provided and in which such difference resulted in an Overpayment to Serenity.

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

iv. Error Rates for the Review.

v. A spreadsheet of the Review results that includes the following information for each Medicare beneficiary: Federal health care program billed, beneficiary health insurance claim number, date(s) of service, allowed amount reimbursed by payor, correct allowed amount (as determined by the IRO),

dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

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

- a. the strengths and weaknesses in Serenity's systems and processes for the certification and recertification of eligibility for the Medicare hospice benefit;
- b. possible improvements to Serenity's systems and processes for the certification and recertification of eligibility for the Medicare hospice benefit to address the specific identified problems or weaknesses;
- c. the strengths and weaknesses in Serenity's systems and processes for the determination of medical necessity for the Level of Services provided; and
- d. possible improvements to Serenity's systems and processes for the determination of medical necessity for the Level of Services to be provided to address the specific identified problems or weaknesses.

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