

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
HARBOR SENIOR CONCEPTS, LLC,
DELORES MOYER,
JOEL MOYER, AND
K. JONATHAN MOYER**

I. PREAMBLE

Harbor Senior Concepts, LLC, Delores Moyer, Joel Moyer, and K. Jonathan Moyer (collectively "Harbor") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Harbor is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Harbor under this CIA shall be 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Harbor's final annual report; or (2) any additional materials submitted by Harbor 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 Harbor; and
- b. all contractors, subcontractors, agents, and other persons who: (1) perform resident care duties; (2) make assessments of residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, resident care, reimbursement, policies and procedures, or this CIA; or (5) perform any function that relates to or is covered by this CIA, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions.

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

Any nonemployee private caregivers and/or attending physicians hired by any resident or the family or friends of any resident of Harbor are not Covered Persons, regardless of the hours worked per year in Harbor.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer, Committee, Board of Directors, and Internal Audit Program.

1. *Compliance Officer.* Prior to the Effective Date, Harbor appointed an individual to serve as its Compliance Officer. Harbor maintains and shall continue to maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health

care program requirements. The Compliance Officer shall be a member of senior management of Harbor, shall report directly to the Chief Executive Officer of Harbor, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Harbor, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Harbor as well as for any reporting obligations created under this CIA. The Compliance Officer shall also ensure that Harbor is appropriately addressing and correcting quality of care problems. 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.

Harbor 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 the change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Harbor shall appoint a Quality Assurance Compliance Committee (hereinafter "Compliance Committee"). The purpose of this committee shall be to address issues concerning quality of care. The Compliance Committee shall, at a minimum, include the Compliance Officer, representatives from among senior personnel responsible for clinical operations and quality of care, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA. 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). The Compliance Committee shall meet, at a minimum, every three months. For each scheduled Compliance Committee meeting, senior management of Harbor shall report to the Compliance Committee on the adequacy of care being provided by Harbor and senior representatives from Harbor's facilities shall be chosen, on a rotating and random basis, to report to the Compliance Committee on the adequacy of care being provided at their facilities. Attendance at such committee meetings by such senior management may be via conference phone or video conferencing equipment although in person attendance is the desired and intended form of attendance.

Harbor shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance

Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors.* The Board of Directors shall provide oversight on quality of care issues. The Board of Directors shall: (a) review the adequacy of Harbor's system of internal controls, quality assurance monitoring, and resident care; (b) ensure that Harbor's response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified; and (c) ensure that Harbor adopts and implements policies and procedures that are designed to ensure that each individual cared for by Harbor receives care that meets professionally recognized standards of care. The individuals who serve on the Board of Directors shall be readily available to the Compliance Officer and the Monitors required under this CIA to respond to any issues or questions that might arise.

The names of the Board members and the charter provisions pertaining to the Board of Directors' quality of care oversight responsibilities shall be provided to OIG within 90 days after the Effective Date. When new members are appointed, or the quality of care oversight responsibilities or authorities of the Board of Directors are substantially changed, Harbor shall notify OIG, in writing, within 15 days of such a change.

4. *Internal Audit Program.* Within 90 days after the Effective Date, Harbor shall create a program for performing internal quality audits and reviews (hereinafter "Internal Audit Program"). The Internal Audit Program shall:

- a. make findings of whether the residents at Harbor are receiving the quality of care and quality of life consistent with basic care, treatment, and protection from harm standards, including, but not limited to, Wis. Admin. Code DHS Chapter 83 (governing Community Based Residential Facilities) and any other applicable federal and state statutes, regulations, and directives;
- b. make findings of whether the Policies and Procedures mandated by Section III.B of this CIA are created, implemented, and enforced;
- c. make findings of whether training is performed in accordance with Section III.C of this CIA;
- d. make findings of whether Disclosure Program (as described in Section III.E of this CIA) disclosure are appropriately investigated;

e. make findings of whether the reporting obligations are complied with in accordance with Sections III.H and I of this CIA; and

f. make findings of whether action plans are developed in response to the Monitor's recommendations and are timely created, implemented, and enforced.

B. Written Standards.

1. *Code of Conduct.* Within 90 days after the Effective Date, Harbor shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Harbor 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. Harbor'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. Harbor's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Harbor's own Policies and Procedures;

c. the requirement that all of Harbor's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Harbor, suspected violations of any Federal health care program requirements or of Harbor's own Policies and Procedures; if there are credible allegations of resident harm, such report shall be made immediately and shall be complete, full, and honest; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and Harbor'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 Harbor'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.

Harbor 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 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 30 days after the distribution of the revised Code of Conduct.

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

- a. measures designed to ensure that Harbor fully complies with Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, Wis. Admin. Code DHS Chapter 83, and any other state or local statutes, regulations, directives, or guidelines that address quality of care in Community Based Residential Facilities;
- b. measures designed to ensure the coordinated interdisciplinary approach to providing care, including, but not limited to the following areas addressed in Wis. Admin. Code DHS Chapter 83: individualized resident assessment and service planning; activities; medical services; nursing care; personal care; mental health; and independent living skills;
- c. measures designed to ensure that Harbor complies with the resident admissions and retention limitations set forth in Wis. Admin. Code DHS § 83.06;
- d. measures designed to ensure that residents with dementia are provided daily structured activities;

- e. Measures designed to ensure compliance with state staffing requirements;
- f. measures designed to inform Covered Persons of the staffing requirements of federal and state law and to inform Covered Persons during orientation and other training required by the CIA that staffing levels are a critical aspect of resident care, and that, if any person has a concern about the level of staffing, there are many avenues available to report such concerns, including, but not limited to, the Administrator, Harbor's Disclosure Program (described in Section III.E of this CIA), individuals at the regional or corporate level, or directly to the Compliance Officer or Monitor;
- g. measures designed to minimize the number of individuals working on a temporary assignment or not employed by Harbor (not including those persons who are included in the definition of Covered Persons) and measures designed to create and maintain a standardized system to track the number of individuals who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Harbor or the Monitor;
- h. measures designed to ensure that all residents are served in the least restrictive environment and most integrated setting appropriate to their needs, as required by applicable state statute;
- i. measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes, regulations, and the CIA, by including such adherence as a significant factor in determining the compensation to the Administrator and the individuals responsible for such compliance;
- j. measures designed to ensure cooperation by Harbor and its Covered Persons with the Monitor in the performance of his or her duties as set forth in Section III.D of this CIA;
- k. measures designed to ensure that compliance issues are identified internally (e.g., through reports to supervisors, complaints received through the Disclosure Program, internal audits, resident satisfaction surveys, facility-specific key indicators, or internal surveys) or externally (e.g., through survey agency reports, consultants, or the

Monitor's Reports) and are promptly and appropriately investigated and, that if the investigation substantiates compliance issues, Harbor implements effective and timely action plans and monitors compliance with such plans;

l. measures designed to ensure that contractors, subcontractors, and agents that fall within the ambit of Covered Persons are appropriately supervised to ensure that they are acting within the parameters of Harbor's Policies and Procedures and the requirements of Federal health care programs;

m. measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews under the Internal Audit Program required by Section III.A;

n. nonretaliation policies and methods for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by Section III.E of this CIA;

o. disciplinary guidelines to reflect the Code of Conduct requirements as specified in Section III.B.1 of this CIA; and

p. measures designed to ensure that Harbor has a system to require and centrally collect reports relating to incidents, accidents, abuse, and neglect. The reports required under this system shall be of a nature to allow the Compliance Committee meaningful information to be able to determine: (1) if there is a quality of care problem; and (2) the scope and severity of the problem.

Within 90 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 those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. The Policies and Procedures shall be available to OIG upon request.

At least annually (and more frequently, if appropriate), Harbor shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the Effective Date of any revisions, any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

All training required in this section shall be competency-based. Specifically, the training must be developed and provided in such a way as to focus on Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Covered Person has learned as a result of the training.

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

- a. CIA requirements; and
- b. Harbor's Compliance Program.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, Harbor shall initiate the provision of Specific Training to each Covered Person who is involved directly or indirectly in the delivery of resident care (including individuals who are responsible for quality assurance, setting policies and procedures, or making staffing decisions). Such Covered Persons shall receive at least eight hours of Specific Training pertinent to their responsibilities in addition to the General Training required above and the Specific Training shall be complete within one year after the Effective Date of the CIA. This Specific Training shall include:

- a. The coordinated interdisciplinary approach to providing care to residents, including, but not limited to, individualized resident assessment and service planning; abuse and neglect policies and reporting procedures; medication management; appropriate mental health services; resident rights and restraint use; complaint investigation and corrective actions; personal care; independent living skills; and quality of life, including activity planning.

New Covered Persons who are involved directly or indirectly in the delivery of resident care shall begin receiving this training within 10 days after the start of their employment or contract or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Covered Person involved indirectly or directly in resident care shall receive at least eight hours of Specific Training in each subsequent Reporting Period.

3. *Periodic Training.* In addition to the General and Specific Training described above, Harbor shall provide Periodic Training to all Covered Persons who are responsible for resident care on quality of care issues identified by the Compliance Committee. This periodic training shall be provided on an "as needed" basis, but shall be provided at least semi-annually. In determining what training should be performed, the Compliance Committee shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by private agencies, any internal surveys, and the findings, reports, and recommendations of the Monitor. Such training shall be for a minimum of four hours annually.

4. *Certification.* Each Covered Person 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 and documentation evidencing that the individual attained competency in the required training areas. These shall be made available to OIG, upon request.

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

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

7. *Computer-based Training.* Harbor may provide the training required under this CIA through appropriate computer-based training approaches. If Harbor 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. Independent Monitor

Within 60 days after the Effective Date, Harbor shall retain an appropriately qualified monitoring team (the "Monitor"), selected by OIG after consultation with Harbor. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor's obligations under this CIA. The Monitor may confer and correspond with Harbor or OIG individually or together. The Monitor and Harbor shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, until after the date of OIG's CIA closure letter to Harbor. The Monitor is not an agent of OIG.

Harbor shall be responsible for all reasonable costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. The Monitor shall charge a reasonable amount for its fees and expenses. Failure to pay the Monitor within 30 calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CIA and shall subject Harbor to one or more of the remedies set forth in Section X; provided, however, that nothing in this section shall prevent or prohibit Harbor from bringing disputed bills to OIG's attention as provided in Section III.D.5 herein.

The Monitor may be removed by OIG at its sole discretion. If the Monitor resigns or is removed for any other reasons prior to the termination of the CIA, Harbor shall retain another Monitor selected by OIG, with the same functions and authorities.

1. *Scope of Monitor's review.* The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:

- a. Harbor's internal quality control systems, including, but not limited to:
 - i. whether the systems in place to promote quality of care and to respond to quality of care issues are operating in a timely and effective manner;
 - ii. whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and

- iii. whether the training programs are effective, thorough, and competency-based.
- b. Harbor's response to quality of care issues, which shall include an assessment of:
- i. Harbor's ability to identify the problem;
 - ii. Harbor's ability to determine the scope of the problem, including, but not limited to, whether the problem is isolated or systemic;
 - iii. Harbor's ability to conduct a root cause analysis;
 - iv. Harbor's ability to create an action plan to respond to the problem;
 - v. Harbor's ability to execute the action plan; and
 - vi. Harbor's ability to monitor and evaluate whether the assessment, action plan, and execution of that plan was effective, reliable, and thorough.
- c. Harbor's proactive steps to ensure that each resident receives care in accordance with:
- i. professionally recognized standards of health care;
 - ii. the rules and regulations set forth in Wis. Admin. Code DHS Chapter 83;
 - iii. State and local statutes, regulations, and other directives or guidelines; and
 - iv. the Policies and Procedures adopted by Harbor, including those implemented under Section III.B of this CIA; and
- d. Harbor's compliance with staffing requirements.

2. *Monitor's access rights.* The Monitor shall have:

a. immediate access to Harbor, at any time and without prior notice, to assess compliance with this CIA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;

b. immediate access to:

i. internal or external surveys or reports;

ii. Disclosure Program complaints;

iii. resident satisfaction surveys;

iv. staffing data in the format requested by the Monitor;

v. reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment;

vi. reports of any incident involving a resident that prompts a full internal investigation;

vii. resident records;

viii. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and

ix. any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA;

c. immediate access to residents, and Covered Persons for interviews outside the presence of Harbor supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident.

3. *Baseline Systems Assessment.* Within 60 days after the Monitor is retained by Harbor or 120 days after the Effective Date of the CIA, whichever is later, the Monitor shall:

- a. complete an assessment of the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1, and
- b. submit a written report to Harbor, OIG, and the Wisconsin Department of Health and Family Services, Bureau of Assisted Living that sets forth, at a minimum:
 - i. a summary of the Monitor's activities in conducting the assessment;
 - ii. the Monitor's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1; and
 - iii. the Monitor's recommendations to Harbor as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1.

In conducting this assessment, the Monitor shall visit four of Harbor's facilities (selected by the Monitor) and, at a minimum, observe quality assurance meetings, care planning meetings, a Compliance Committee meeting, and a Board of Director Committee meeting, interview key employees, review relevant documents, and observe resident care.

4. *Systems Improvements Assessments.* On a quarterly basis, the Monitor shall re-assess the effectiveness, reliability, and thoroughness of the systems described in Section III.D.1. For the first Reporting Period, the Monitor shall perform assessments for each quarter or portion of a quarter not covered by the Baseline Systems Assessment described in Section III.D.3. For each subsequent Reporting Period, the Monitor shall perform four quarterly assessments. No later than 30 days after the end of each quarter, the Monitor shall submit a written report, to Harbor, OIG, and the Wisconsin Department of Health and Family Services, Bureau of Assisted Living that sets forth, at a minimum:

- a. a summary of the Monitor's activities in conducting the assessment;

- b. the Monitor's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1;
- c. the Monitor's recommendations to Harbor as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1; and
- d. the Monitor's assessment of Harbor's response to the Monitor's prior recommendations.

In conducting these assessments, the Monitor shall visit two of Harbor's facilities (selected by the Monitor) and, at a minimum, observe quality assurance meetings, care planning meetings, a Compliance Committee meeting, and the quality of care oversight portion of a Board of Directors meeting, interview key employees, review relevant documents, and observe patient care. The Monitor may also want to have regular telephone calls with Harbor and any of its poorer performing facilities. As part of each Systems Improvement Assessment, the Monitor shall assess Harbor's response to recommendations made in prior written assessment reports.

5. *Harbor's Obligations.* Harbor shall:

- a. within 30 days after receipt of each written report of the Baseline Systems Assessment or Systems Improvement Assessments, submit, to both OIG and the Monitor, a written response to each of the Monitor's recommendations: (1) indicating that Harbor has substantially implemented the recommendation; (2) setting forth an action plan detailing how and when Harbor will substantially implement the recommendation; or (3) setting forth the reasons why Harbor has not substantially implemented the recommendation or created an action plan;
- b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
 - i. Deaths or injuries related to use of restraints;
 - ii. Deaths or injuries related to use of psychotropic medications;

- iii. Suicides;
- iv. Deaths or injuries related to abuse or neglect (as defined in the applicable federal guidelines);
- v. Fires, storm damage that poses a threat to residents or otherwise may disrupt the care provided, flooding, or major equipment failures at Harbor;
- vi. Strikes or other work actions that could affect resident care;
- vii. Man-made disasters that pose a threat to residents (e.g., toxic waste spills); and
- viii. Any other incident that involves or causes actual harm to a resident when such incident is required to be reported to any local, state, or federal government agency.

Each such report shall contain the full name, social security number, and date of birth of the resident(s) involved, the date of death or incident, and a brief description of the events surrounding the death or incident.

- c. provide to its Compliance Committee and its Board of Director Committee copies of all documents and reports provided to the Monitor;
- d. pay the Monitor's bills within 30 days of receipt. While Harbor must pay all the Monitor's bills within 30 days, Harbor may bring any disputed Monitor's Costs or bills to OIG's attention;
- e. ensure the Monitor's immediate access to the facilities, residents, Covered Persons, and documents, and assist in obtaining full cooperation by its current employees, contractors, and agents;
- f. provide access to current residents and provide contact information for their families and guardians consistent with the rights of such

individuals under state or federal law, and not impede their cooperation with the Monitor;

g. assist in locating and, if requested, attempt to obtain cooperation from past employees, contractors, agents, and residents and their families;

h. provide the last known contact information for former residents and their families, or guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation; and

i. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Harbor under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.

6. *The Monitor's Obligations.* The Monitor shall:

a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons and residents;

b. abide by the legal requirements of Harbor to maintain the confidentiality of each resident's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from resident clinical records, to OIG, and, when legally or professionally required, reporting to other agencies;

c. at all times act reasonably in connection with its duties under the CIA, including when requesting information from Harbor;

d. submit bills to Harbor on a consolidated basis no more than once per month and submit at the end of each Reporting Period, to both Harbor and OIG, a report representing an accounting of its costs throughout that Reporting Period;

e. if the Monitor has concerns about action plans that are not being enforced by Harbor or systemic problems that could affect Harbor's ability to render quality care to its residents, then the Monitor shall:

i. report such concerns in writing to OIG; and

ii. simultaneously provide notice and a copy of the report to Harbor's Compliance Committee;

f. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to OIG and to Harbor;

g. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, Wisconsin's Department of Health and Family Services. Likewise, such private or governmental agencies shall not be bound by the Monitor's findings or conclusions. Nothing in the previous sentence, however, shall preclude OIG or Harbor from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor, in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

h. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Harbor; and

i. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures, and forms obtained in connection with its duties under this CIA and not comment publicly concerning its findings except to the extent authorized by OIG.

E. Disclosure Program.

Within 90 days after the Effective Date, Harbor shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Harbor's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Harbor shall 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, Harbor shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practices places resident at risk of harm, then Harbor will ensure that that practice ceases immediately and that appropriate action is taken.

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 sent to the Monitor not less than monthly.

F. Ineligible Persons.

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

a. an “Ineligible Person” shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

a. Harbor shall screen all prospective and current 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. Harbor shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

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

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

4. *Pending Charges and Proposed Exclusions.* If Harbor has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, Harbor 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 or resident or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Harbor shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Harbor conducted or brought by a governmental entity or its agents involving an allegation that Harbor 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. Harbor 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.

In addition, within 15 days after notification, Harbor shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., Joint Commission).

H. Repayment of Overpayments.

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

2. *Repayment of Overpayments.*

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

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

I. Reportable Events.

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

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations; or
- d. a matter that a reasonable person would consider likely to render Harbor insolvent.

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

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall include:

- a. a copy of the notification and repayment to the payor;
- b. a description of the steps taken by Harbor to identify and quantify the Overpayment;

- c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- d. a description of Harbor's actions taken to correct the Reportable Event; and
- e. any further steps Harbor plans to take to address the Reportable Event and prevent it from recurring.

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

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

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, the impact or potential impact on Federal health care program beneficiaries, and any legal and Federal health care program authorities implicated;
- b. a description of Harbor's action taken to correct the Reportable Event;

- c. any further steps Harbor plans to take to address the Reportable Event and prevent it from reoccurring; and
- d. a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies.

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

- a. a complete description of the Reportable Event;
- b. a description of Harbor's action taken to ensure that the Reportable Event does not adversely impact resident care; and
- c. any further steps Harbor plans to take to address the Reportable Event.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

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

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Harbor 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, Harbor shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number and/or supplier number, and the name and address of the contractor that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Harbor proposes to sell any or all of its business units or locations that are subject

to this CIA, Harbor shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Harbor 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 and positions of the members of the Board of Directors and the charter provisions covering the Board of Directors' quality of care oversight responsibilities required by Section III.A;
4. a description of the Internal Audit Program required by Section III.A;
5. a copy of Harbor's Code of Conduct required by Section III.B.1;
6. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be make available to OIG upon request);
7. 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);

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

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

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

10. a description of the process by which Harbor 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 overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

12. a list of all of Harbor'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 Medicaid and Medicare provider number(s), if applicable; and the name and address of each Medicaid and Medicare contractor, if applicable, to which Harbor currently submits claims;

13. a description of Harbor'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. Harbor shall submit to OIG annually a report with respect to the status of, and findings regarding, Harbor'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; any change in the membership of the Compliance Committee or Board of Directors and any change to the charter provisions pertaining to the Board of Directors' quality of care oversight responsibilities 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;

3. a summary of findings under Harbor's Internal Audit Program and a summary of any corrective action taken under that program;

4. 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);

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

a. a description of the initial and annual training, including the targeted audience, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

6. a summary of Harbor's responses and action plans related to the issues and recommendations raised by the Monitor pursuant to Section III.D;

7. a copy of the disclosure log required under Section III.E (excluding any calls that relate solely to human resources issues);

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

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

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

11. 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;

12. a description of all changes to the most recently provided list of Harbor's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicaid and Medicare provider number(s), if applicable; and the name and address of each Medicaid and Medicare contractor, if applicable, to which Harbor currently submits claims; and

13. 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.

Within 180 days of the submission of each Annual Report, Harbor shall participate in an in-person meeting with a representative of OIG to review Harbor's performance under the CIA. OIG, in its discretion, may waive this meeting requirement.

C. Certifications. The Implementation Report and each Annual Report shall include:

1. certifications by the President, Chief Operating Officer, and Compliance Officer under the penalty of perjury, that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, Harbor 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.
2. a resolution (or its equivalent) from Harbor's Board of Directors certifying that they have reviewed the Report and agree with the statements made therein.

D. Designation of Information. Harbor 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. Harbor 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

Harbor:

Tammi Moyer, Compliance Officer
Harbor Senior Concepts, LLC
6405 Century Ave., Suite 104
Middleton, WI 53652
Telephone: 608.836.5070
Facsimile: 888.236.4832

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Harbor's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Harbor's locations for the purpose of verifying and evaluating: (a) Harbor's compliance with the terms of this CIA; and

(b) Harbor's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Harbor 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 Harbor'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. Harbor shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Harbor's employees may elect to be interviewed with or without a representative of Harbor present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Harbor prior to any release by OIG of information submitted by Harbor pursuant to its obligations under this CIA and identified upon submission by Harbor as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Harbor shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

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

A. Specific Performance of CIA Provisions. If OIG determines that Harbor is failing to comply with a provision or provisions of this CIA and decides to seek specific performance of any of these provisions, OIG shall provide Harbor with prompt written notification of such determination (hereinafter referred to as "Noncompliance Notice"). Harbor shall have 35 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to

comply; or (2) reply in writing that Harbor disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge (ALJ), pursuant to the provisions set for in Section X.F of this CIA. The purpose of the hearing is to determine whether Harbor has failed to comply with the CIA and whether Harbor shall be required to implement the particular provisions at issue.

B. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Harbor 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 Harbor 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 Board of Directors with responsibility for quality of care oversight;
- d. an Internal Audit Program;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons in the manner required by Section III.C;
- h. retention of a Monitor;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;

k. notification of Government investigations or legal proceedings; and

l. reporting of Reportable Events.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Harbor 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.

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

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Harbor as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

5. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Harbor employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Harbor's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, 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 (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Harbor can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

6. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Harbor fails to pay a Monitor, as required in Section III.D.

7. A Stipulated Penalty of \$2,500 for each day Harbor fails to comply fully and adequately with any of its obligations with respect to the Monitor, as set forth in Section III.D. OIG shall provide notice to Harbor stating the specific grounds for its determination that Harbor has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Harbor shall take to

comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Harbor receives this notice from OIG of the failure to comply.)

8. A Stipulated Penalty of \$1,000 for each day Harbor fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Harbor stating the specific grounds for its determination that Harbor has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Harbor shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Harbor 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 1-7 of this Section.

C. Timely Written Requests for Extensions. Harbor 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 Harbor 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 Harbor 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.

D. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Harbor has failed to comply with any of the obligations described in Section X.B and after determining that Stipulated Penalties are appropriate, OIG shall notify Harbor of: (a) Harbor'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, Harbor 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.F. In the event Harbor elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Harbor 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.E.

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.E.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Harbor has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.E, below.

E. Exclusion for Material Breach of this CIA.

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

- a. a repeated or flagrant violation of any obligation under this CIA, including, but not limited to, the obligations addressed in Section X.B;
- b. a failure by Harbor to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
- c. a failure to respond to a Noncompliance Notice concerning Specific Performance in accordance with Section X.A;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D; or

- e. a failure to retain, pay, use, or reasonably respond to the recommendations of the Monitor 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 Harbor constitutes an independent basis for Harbor's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Harbor has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Harbor of: (a) Harbor'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"). The exclusion may be directed at one or more of Harbor's facilities or corporate entities, depending upon the facts of the breach.

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Harbor fails to satisfy the requirements of Section X.E.3, OIG may exclude Harbor from participation in the Federal health care programs. OIG shall notify Harbor in writing of its determination to exclude Harbor (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.F, below, the exclusion shall go into effect 30 days after the date of Harbor'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, Harbor may apply for

reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-3004.

F. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Harbor of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Harbor 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 specific performance, Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand specific performance, payment of Stipulated Penalties, or 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 specific performance or 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. *Specific Performance 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 specific performance of CIA provisions shall be:

- a. whether, at the time specified in the Noncompliance Notice, Harbor was in full and timely compliance with the obligations of this CIA for which OIG seeks specific performance; and
- b. whether Harbor failed to cure.

Harbor 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 specific performance. If the ALJ agrees with OIG, Harbor shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless Harbor 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, Harbor shall take the actions OIG deems necessary to cure within 20 days after the DAB issues its decision.

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

4. *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 Harbor 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) Harbor had begun to take action to cure the material breach within that period; (ii) Harbor has pursued and is pursuing such action with due diligence; and (iii) Harbor provided to OIG within that period a reasonable timetable for curing the material breach and Harbor 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 Harbor, only after a DAB decision in favor of OIG. Harbor's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Harbor 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 Harbor 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. Harbor 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 Harbor, Harbor shall be reinstated effective on the date of the original exclusion.

5. *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

Harbor and OIG agree as follows:

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

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

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

D. OIG may agree to a suspension of Harbor's obligations under this CIA based on a certification by Harbor 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 Harbor is relieved of its CIA obligations, Harbor will be required to notify OIG in writing at least 30 days in advance if Harbor plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

E. The undersigned Harbor signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he

is signing this CIA in his official capacity and that he is authorized to execute this CIA.

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

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

/Gregory E. Demske/

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

4/9/10
DATE

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____ AMOUNT OF CHECK
 \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

| | | |
|---|--|---|
| <u>Billing/Clerical Error</u> 01 - Corrected Date of Service 02 - Duplicate 03 - Corrected CPT Code 04 - Not Our Patient(s) 05 - Modifier Added/Removed 06 - Billed in Error 07 - Corrected CPT Code | <u>MSP/Other Payer Involvement</u> 08 - MSP Group Health Plan Insurance 09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including Black Lung 12 - Veterans Administration | <u>Miscellaneous</u> 13 - Insufficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 - Other (Please Specify) |
|---|--|---|