

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
HARBOR HEALTHCARE AND REHABILITATION CENTER**

I. PREAMBLE

Harbor Healthcare and Rehabilitation Center (Harbor) 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 its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f) (hereinafter collectively referred to as the "Federal health care programs"). Contemporaneously with this CIA, Harbor is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Harbor under this CIA shall be three (3) years from the Effective Date of this CIA (unless otherwise specified). The Effective Date of this CIA shall be the date on which the final signatory executes this CIA (Effective Date). Sections VII, VIII, IX, X, and XI shall remain in effect until Harbor submits all information required by OIG as part of the final Annual Report.

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

1. *Harbor*: the nursing facility presently located at 301 Ocean View Blvd., Lewes, DE 19958 with provider number 085034001.

2. *Covered Persons*:

a. all owners, officers, directors, and employees of Harbor, any corporation, subsidiary, affiliate, joint venture or other organization or entity in which Harbor owns 5% or more or has a controlling interest, or

which Harbor operates or has a management contract or arrangement to provide management and administrative services that gives it control over the day-to-day operations over the organization or entity; and

b. all contractors, subcontractors, agents, and other persons who, on a regular basis (*i.e.*, more often than two weeks over a 52-week period) on behalf of Harbor: (1) perform patient care or resident care duties; (2) make assessments of patients or residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit or review functions relating to quality of care; (4) make decisions or provide oversight about staffing, patient care, 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 (excluding the Monitor).

Notwithstanding the above, 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 at Harbor.

III. CORPORATE INTEGRITY OBLIGATIONS

Harbor shall establish a compliance program that includes the following elements.

A. Compliance Officer, Committees, and Internal Audit or Review Functions.

1. *Compliance Officer.* To the extent not already established, Harbor shall appoint a Compliance Officer, who 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 the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of Harbor, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Harbor, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to Harbor's general counsel or chief financial officer. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Harbor to further its compliance objectives as well as any reporting obligations created under this CIA. The Compliance Officer shall also ensure that quality of care problems are being appropriately addressed and corrected. In the event a new Compliance Officer is appointed during the term of this CIA, Harbor shall notify the OIG, in writing, within fifteen (15) days of such a change.

2. *Compliance Committee.* To the extent not already established, Harbor shall establish a Quality Assurance Compliance Committee within one hundred twenty (120) days after the Effective Date. The purpose of this Compliance Committee shall be to address issues concerning quality of care at Harbor's nursing homes. This committee shall: (a) review the adequacy of Harbor's system of internal controls, quality assurance monitoring, and patient 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 at Harbor receives the highest practicable physical, mental, and psychosocial level of care attainable. At a minimum, the Committee shall include the Compliance Officer, the Medical Director, the Nursing Home Administrator, the Director of Nursing, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA that relate to quality of care in the nursing facility.

3. *Internal Audit and Review Functions.* To the extent not already established, Harbor shall, within one hundred twenty (120) days after the Effective Date, create a program for performing internal quality audits and reviews. The internal audits and reviews shall:

- a. make findings of whether the patients and residents of 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, 42 C.F.R. Parts 482 and 483 and any other Federal and state statutes, regulations, and directives;
- b. make findings of whether the policies and procedures mandated by this CIA are created, implemented, and enforced;
- c. make findings of whether training is performed in accordance with this CIA;
- d. make findings of whether hotline complaints are appropriately investigated;
- e. make findings of whether all falls policies and protocols are adhered to;
- f. make findings of whether the reporting obligations are complied with in accordance with this CIA; and

- g. make findings of whether corrective action plans are timely created, implemented, and enforced.

B. Written Standards.

1. *Code of Conduct.* Within one hundred twenty (120) days after the Effective Date, Harbor shall establish a Code of Conduct and distribute it to all Covered Persons. Harbor shall make adherence to the Code of Conduct an element in evaluating the performance of Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. Harbor's commitment to full compliance with all statutes, regulations, directives, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Centers for Medicare and Medicaid Services (CMS) (or other appropriate regulatory agencies) and/or fiscal intermediaries or carriers;
- b. Harbor's requirement that all of its Covered Persons shall be expected to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Harbor's own policies and procedures (including the requirements of this CIA);
- c. the requirement that all of Harbor's Covered Persons shall be expected to report, within thirty (30) days, suspected violations of any statute, regulation, directive, or guideline applicable to Federal health care programs or of Harbor's own policies and procedures; if there are credible allegations of patient harm, such report shall be made immediately and shall be complete, full, and honest;
- d. the possible consequences to both Harbor and any Covered Person of failure to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Harbor's own policies and procedures or of failure to report such non-compliance; and

- e. the right of all Covered Persons to use the disclosure program, as well as Harbor's commitment to confidentiality and nonretaliation with respect to disclosures.

Within one hundred twenty (120) days after the Effective Date, to the extent not already accomplished, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Harbor's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their appointment, employment, or contract or within one hundred twenty (120) days after the Effective Date, whichever is later.

Harbor shall annually review the Code of Conduct and shall make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Covered Persons shall certify on an annual basis that they have received, read, understood and will abide by the Code of Conduct.

2. *Policies and Procedures.* Within one hundred twenty (120) days after the Effective Date, Harbor shall develop and implement written Policies and Procedures regarding the operation of Harbor's compliance program and its compliance with all Federal and state health care statutes, regulations, directives, and guidelines, including the requirements of the Federal health care programs. At a minimum, Harbor's Policies and Procedures shall specifically address:

- a. Measures designed to ensure that Harbor fully complies with Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424, 482, and 483, and any other state or local statutes, regulations, directives, or guidelines that address quality of care in nursing homes;
- b. Measures designed to ensure that Harbor complies with all requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as specified by the Resident Assessment Instrument User's Manual; ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups (RUG) classification system; and ensuring the

accuracy of billing and cost report preparation policies and procedures;

- c. Measures designed to ensure the coordinated interdisciplinary approach to providing care to nursing home residents, including, but not limited to the following areas addressed in 42 C.F.R. § 483: resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; protection from harm procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; activities of daily living (ADL) care; therapy services; quality of life, including accommodation of needs and activities; and assessment of resident competence to make treatment decisions;
- d. Measures designed to ensure that Harbor has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans;
- e. Measures designed to ensure compliance with the completion of accurate clinical assessments as required by applicable Federal law, which shall include: (1) that all patient and resident care information be recorded in ink or permanent print; (2) that corrections shall only be made in accordance with accepted health information management standards; (3) that erasures shall not be allowable; and (4) that clinical records may not be rewritten or destroyed to hide or otherwise make a prior entry unreadable or inaccessible;
- f. Measures designed to ensure that staffing needs are decided first and foremost upon achieving the level of care for Harbor's patients and residents required by federal and state laws, including, but not limited to, 42 C.F.R. § 483.30 (nursing facilities);
- g. Measures that specify that if the director of nursing (or other person who is making staffing decisions at the facilities) disagrees with a staffing determination that is not in compliance with state

or federal regulations or the CIA and that significantly affects patient care made by the Administrator or other individuals at the corporate level, and is unable to resolve the issue through the normal chain of responsibility, then that person must immediately call the hotline and the Monitor. Nothing in this subsection prohibits or prevents such person from contacting the hotline or the Monitor without first going through the normal chain of responsibility;

- h. Measures designed to inform Covered Persons of the staffing requirements of federal and state law;
- i. Measures to inform Covered Persons during orientation and during other training required by this CIA that staffing levels are a critical aspect of patient and 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, the Hotline (as described in Section III.E of the CIA), individuals at the corporate level, or directly to the Compliance Officer or Monitor;
- j. Measures designed to minimize the number of individuals working at any Harbor facility who are 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 at each facility who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identify by Harbor or the Monitor;
- k. Measures designed to ensure that all residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;
- l. 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 Administrators of the facilities, and the individuals responsible for such compliance at the corporate level;

- m. 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 *infra*;
- n. Measures designed to ensure that compliance issues are identified internally (*e.g.*, through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CMS quality indicators, facility-specific key indicators, or internal surveys) or externally (*e.g.*, through CMS or state survey agency reports, consultants, or Monitor's Reports) and are promptly and appropriately investigated and, if the investigation substantiates compliance issues, Harbor implements effective and timely corrective action plans and monitors compliance with such plans;
- o. Measures designed to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred;
- p. 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;
- q. Measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews;
- r. Nonretaliation policies and method for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by Section III.E.;
- s. Disciplinary guidelines to reflect the Code of Conduct requirements as specified in Section III.B.1; and
- t. Measures designed to ensure that Harbor has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. The reports required under this system shall be of a nature to allow the Quality Assurance Committees 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.

Harbor shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures shall be provided to OIG in the Implementation Report. The Policies and Procedures shall be available to OIG upon request.

Within one hundred twenty (120) days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all appropriate Covered Persons. Compliance staff or supervisors shall be available to explain any and all policies and procedures.

C. Training and Education.

1. *General Training.* Within one hundred twenty (120) days after the Effective Date, Harbor shall provide at least two (2) hours of training to each Covered Person.¹ This general training shall explain Harbor's:

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

New Covered Persons shall receive the general training described above within ten (10) days of the beginning of their employment or contract, or within one hundred twenty (120) days after the Effective Date, whichever is later. Every Covered Person shall receive such general training on an annual basis.

¹Any nonemployee who is hired on a temporary basis (regardless of whether he or she is considered a "Covered Contractor") is required to follow the policies and procedures of the facility, Harbor, and this CIA. Harbor shall ensure that there is sufficient supervision to ensure that a temporary nonemployee is acting within the parameters of such policies and procedures. Any temporary nonemployee who works in Harbor facilities for more than a thirty (30) day period, regardless of how many days during that period the person is actually present in the facility, must complete the training requirements set forth herein.

2. *Specific Training.* Within one hundred twenty (120) days after the Effective Date, each Covered Person who is involved directly or indirectly in the delivery of patient or resident care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions) shall receive at least eight (8) hours of training in addition to the general training required above.² This training shall include a discussion of the policies and procedures set forth in Section III.B, including, but not limited to:

- a. Policies, procedures, and other requirements applicable to the documentation of medical records; and
- b. The coordinated interdisciplinary approach to providing care to residents, including, but not limited to, resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; ADL care; therapy services; quality of life, including accommodation of needs and activities; and assessment of the resident's competence to make treatment decisions.

Affected new Covered Persons shall receive this training within ten (10) days of the beginning of their employment or contract or within one hundred twenty (120) days after the Effective Date of this CIA, whichever is later. If a new Covered Person has any responsibility for the delivery of patient or resident care, then prior to completing this specific training, a Harbor Covered Person who has completed the substantive training shall review all of the untrained person's work.

Every Covered Person shall receive such specific training on an annual basis.

In addition, each facility shall conduct periodic training on an "as needed" basis (but at least semi-annually) on those quality of care issues identified by the Compliance Committee. In determining what training should be performed, these Committees shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other such private agencies, any internal surveys, and the CMS quality indicators. Such training shall be for a minimum of four (4) hours. Such training shall be provided to all Covered Persons at the facility who are responsible

² Specific training conducted within six months before the Effective Date of the CIA shall count toward satisfying this initial training requirement

for patient or resident care. Each individual trained shall be required to complete a comprehension test to ensure that the individual has learned the material being presented. These comprehension tests shall be maintained and made available to the OIG and the monitor upon request.

3. *Certification.* Each Covered Person shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

All training materials shall be made available to OIG upon request. Persons providing the training must have sufficient expertise in the subject area.

D. Independent Monitor

Within sixty (60) days after the Effective Date, Harbor shall retain an appropriately qualified Monitor approved by the OIG. 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 and OIG on an *ex parte* basis. Harbor shall be responsible for all 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 his or her fees and expenses. Failure to pay the Monitor within thirty (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 VI *infra*. The Monitor may be removed solely at the discretion of the OIG. If the Monitor resigns or is removed for any reason prior to the termination of the CIA, Harbor shall retain another Monitor, after approval by the OIG, with the same functions and authorities.

1. 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:

(1) whether the systems in place to promote quality of care and to respond to quality of care issues are acting in a timely and effective manner;

- (2) 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
 - (3) whether the training programs are effective and thorough;
- b. Harbor's response to quality of care issues, which shall include an assessment of:
- (1) Harbor's ability to identify the problem;
 - (2) Harbor's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;
 - (3) Harbor's ability to create a corrective action plan to respond to the problem;
 - (4) Harbor's ability to execute the corrective action plan; and
 - (5) Harbor's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough;
- c. Harbor's development and implementation of corrective action plans and the timeliness of such actions;
- d. Harbor's proactive steps to ensure that each patient and resident receives care in accordance with:
- (1) basic care, treatment and protection from harm standards;
 - (2) the rules and regulations set forth in 42 C.F.R. Parts 482 and 483;
 - (3) state and local statutes, regulations, and other directives or guidelines; and
 - (4) the policies and procedures adopted by Harbor and set forth in this CIA.

2. The Monitor shall have:
 - a. immediate access to facilities, 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: (1) the CMS quality indicators; (2) internal or external surveys or reports; (3) hotline complaints; (4) resident satisfaction surveys; (5) staffing data in the format requested by the Monitor, including reports of any facility where more than ten (10) percent of the staff are hired on a temporary basis; (6) reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment; (7) reports of any falls; (8) reports of any incident involving a patient or resident that prompts a full internal investigation; (9) patient or resident records; (10) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (11) any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA; and
 - c. immediate access to patients, residents, and staff 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 or patient.

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

- a. ensure the Monitor's immediate access to the facilities, individuals, and documents, and assist in obtaining full cooperation by its current employees, contractors and agents;
- b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
 - (1) Deaths or injuries related to use of restraints;
 - (2) Deaths or injuries related to use of psychotropic medications;

- (3) Suicides;
- (4) Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines);
- (5) Fires, storm damage, flooding, or major equipment failures at any facility;
- (6) Strikes or other work actions;
- (7) Manmade disasters that pose a threat to residents (e.g., toxic waste spills); and
- (8) Any other incident involving a resident that prompts a full internal investigation.

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. assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, and their families;
- d. provide access to current residents and patients, and contact information for their families and guardians, and not impede their cooperation with the Monitor;
- e. provide to its Quality Assurance Compliance Committee copies of all documents and reports provided to the Monitor;
- f. provide the last known contact information for former residents, patients, their families, or guardians consistent with the rights of such individuals under state or Federal law, and not impede their cooperation;
- g. address any written recommendation made by the Monitor either by substantially implementing the Monitor's recommendations or by explaining in writing why it has elected not to do so;

any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Harbor, and Harbor shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude the 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;

g. abide by the legal requirements of Harbor's facilities 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 patient and resident clinical records, to the OIG, and, when legally or professionally required, reporting to other agencies;

h. 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 the OIG; and

i. visit Harbor as often as the Monitor believes it necessary to perform its functions.

E. Disclosure Program.

To the extent not already established, within one hundred twenty (120) 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 reporting 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 or the applicable standard of care. 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 such as the lobby, dining rooms, activity rooms, waiting rooms) of each of its facilities.

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 the information in such a way as to elicit 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 such a disclosure and ensure that proper follow-up is conducted, including that the inappropriate or improper practice ceases immediately.

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each allegation received (whether anonymous or not), the status of the respective investigations, and any corrective action taken in response to the investigation. The disclosure log shall be sent to the Monitor not less than weekly and shall be made available to the OIG upon request.

F. Ineligible Persons.

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

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

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

c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of Harbor.

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

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

b. Harbor shall screen all Screened Persons against the Exclusion Lists within one hundred twenty (120) days after the Effective Date and on an annual basis thereafter.

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

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

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

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

rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Proceedings. Within thirty (30) days of 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 thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that Harbor purchases or establishes new business units after the Effective Date, Harbor shall notify OIG of this fact within thirty (30) days after the date after purchase or establishment. This notification shall include the type of facility, location of the new operation(s), phone number, fax number, Federal health care program Harbor number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each Harbor number. All such new business units and their employees, contractors, and agents at such locations shall be subject to the requirements in this CIA that apply to new Covered Persons (*e.g.*, completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and fifty (150) 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. This Implementation Report shall include:

1. the name, address, phone number and position description of all individuals in positions described in section III.A;
2. the program for internal audits and reviews required in section III.A;
3. a copy of Harbor's Code of Conduct required by section III.B.1;
4. the summary of the Policies and Procedures required by section III.B.2;

5. a description of the training programs required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been made available to all pertinent Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
 - c. all Covered Persons have completed the training and executed the certification required by section III.C.
7. a description of the disclosure program required by section III.E;
8. a summary of personnel actions taken pursuant to section III.F; and
9. a list of all of Harbor's locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program Harbor identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each Harbor identification number.

B. Annual Reports. Harbor shall submit to OIG an Annual Report with respect to the status and findings of Harbor's compliance activities over the one year period covered by the Annual Report. Each Annual Reports shall include:

1. any change in the identity or position description of individuals in positions described in section III.A, a change in any of the committees' structure or charter, or any change in the internal audit and review program;
2. certification by the Compliance Officer that:
 - a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1;

- b. all Covered Persons have completed the training and executed the certification required by section III.C; and
 - c. Harbor has effectively implemented all plans of correction related to problems identified under this CIA, Harbor's Compliance Program, or internal audits.
 3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (*e.g.*, change in contractor policy);
 4. a list of audits and reviews undertaken, a summary of the findings of each such audit or review, and a summary of the corrective action taken under the program for internal audits and reviews;
 5. Harbor's response/corrective action plan to any issues raised by the Monitor;
 6. a copy of the disclosure log required by section III.E (excluding any calls that relate solely to human resources issues);
 7. a description of any personnel action (other than hiring) taken by Harbor as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;
 8. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Harbor has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information; and
 9. a description of all changes to the most recently provided list (as updated) of Harbor's locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program Harbor identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each Harbor identification number.

The first Annual Report shall be received by the OIG no later than one year and sixty (60) days after the Effective Date. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by Harbor's Chief Executive Officer, under penalty of perjury, that: 1) Harbor is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and 2) the Chief Executive Officer has reviewed the Report and has made reasonable inquiry regarding its content and believe that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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
Phone: (202) 619-2078
Fax: (202) 205-0604

Harbor: Lisa MacLennan, NHA
Corporate Compliance Officer
Harbor Healthcare & Rehabilitation Center
Three Mill Road, Suite 200
Wilmington, DE 19806
Phone: (302) 427-8181
Fax: (302) 427-9826

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 photocopy Harbor's books, records, and other documents and supporting materials and/or conduct an onsite review of Harbor's operations for the purpose of verifying and evaluating: 1) Harbor's compliance

with the terms of this CIA; and 2) 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 employee, contractor, or agent and OIG. Harbor agrees to assist OIG in contacting and arranging interviews with such employees, contractors, or agents upon OIG's request. Harbor's employees, and the contractors and agents 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 compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act (FOIA) procedures, set forth in 45 C.F.R. Part 5, the 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, commercial or financial information and privileged and confidential under the FOIA rules. Harbor shall refrain from identifying any information as trade secrets, commercial, or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Harbor is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

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 (Noncompliance Notice). Harbor shall have thirty five (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 XI.E 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 agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (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, beginning one hundred and twenty (120) days after the Effective Date and concluding at the end of the term of this CIA, 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 program for performing internal audits and reviews;
- d. a written Code of Conduct;
- e. Written Policies and Procedures;
- f. The training of Covered Persons;
- g. Retention and payment of a Monitor; and
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements; and
- j. Notification of Government investigations or legal proceedings.

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

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that Harbor fails to grant access) for each day Harbor fails to grant access to the information or documentation as required in section VII of this CIA.

4. A Stipulated Penalty of \$5,000 (which shall begin to accrue ten (10) days after the date OIG provides notice to Harbor of the failure to comply) for each day Harbor fails to comply fully and adequately with an obligation of this CIA that is widespread or systemic in nature or reflective of a pattern or practice. In its notice to Harbor, the OIG shall state the specific grounds for its determination that the Harbor has failed to comply fully and adequately with the CIA obligation(s) at issue.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date OIG provides notice to Harbor of the failure to comply) for each day Harbor fails to comply fully and adequately with any obligation of this CIA. In its notice to Harbor, the OIG shall state the specific grounds for its determination that the Harbor has failed to comply fully and adequately with the CIA obligation(s) at issue.

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of [Provider] 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 \$2,500 (which shall begin to accrue ten (10) days after the date OIG provides notice to Harbor of the failure to comply) for each day Harbor fails to comply fully and adequately with any of its obligation with respect to the Monitor, as set forth in section III.D.3. In its notice to Harbor, the OIG shall state the specific grounds for its determination that the Harbor has failed to comply fully and adequately with the CIA obligation(s) at issue.

C. 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 determining that Stipulated Penalties are appropriate, OIG shall notify Harbor by personal service or certified mail of: (a) Harbor's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, Harbor shall either: a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or b) request a hearing before an HHS ALJ to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event Harbor elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Harbor cures, to the 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.

2. *Timely Written Requests for Extensions.* Harbor may 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 as agreed to by the OIG-approved extension. 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 two (2) business days after Harbor receives OIG's written denial of such request or when the original obligation becomes due, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

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

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Harbor has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *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, as defined in 42 U.S.C. § 1320a-7b(f). Upon a determination by OIG that Harbor has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Harbor by certified mail of: a) Harbor's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (Notice of Material Breach and Intent to Exclude). The exclusion may be directed at one or more facilities or corporate entities, depending upon the facts of the breach.

2. *Opportunity to cure.* Harbor shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

- a. Harbor is in full compliance with this CIA;
- b. The alleged material breach has been cured; or
- c. The alleged material breach cannot be cured within the thirty five (35) day period, but that: (1) Harbor has begun to take action to

cure the material breach; (2) Harbor is pursuing such action with due diligence; and (3) Harbor has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, Harbor fails to satisfy the requirements of section X.C.2, OIG may exclude Harbor from participation in the Federal health care programs. OIG shall notify Harbor in writing of its determination to excluded Harbor (Exclusion Letter). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. If Harbor is excluded under the provisions of this CIA, Harbor may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

- a. a failure to meet an obligation under the CIA that has a material impact on the quality of care rendered to any residents or patients of Harbor;
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.B of this CIA;
- c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
- d. a failure to retain, pay or use the Monitor in accordance with section III.D.

E. Dispute Resolution

1. *Review Rights.* Upon the 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 the obligation of this CIA, Harbor shall be afforded certain review rights comparable to those set forth 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, an action for specific performance, a demand for payment of Stipulated Penalties, or an action for exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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), a request for a hearing involving specific performance or Stipulated Penalties shall be made within fifteen (15) days of the date of the Demand Letter, and a request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

2. *Specific Performance Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 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 the 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. If the ALJ finds for the OIG, Harbor shall take the actions OIG deems necessary to cure within (20) days after the ALJ issues such a decision notwithstanding that Harbor may request review of the ALJ decision by the DAB.

3. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 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 the 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. If the ALJ finds for the 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 twenty (20) days after the ALJ issues such a decision notwithstanding that Harbor may request review of the ALJ decision by the DAB.

4. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 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) the alleged material breach cannot be cured within the 35 day period, but that (1) Harbor has begun to take action to cure the material breach, (2) Harbor is pursuing such action with due diligence, and (3) Harbor has 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 that is favorable to the OIG. Harbor's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Harbor upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Harbor may request review of the ALJ decision by the DAB.

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 and Harbor agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

6. *Review by Other Agencies.* Nothing in this CIA shall affect the right of CMS or any other federal or state agency to enforce any statutory or regulatory authorities with respect to Harbor's compliance with applicable state and Federal health care program requirements.

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

C. 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.

ON BEHALF OF HARBOR HEALTHCARE & REHABILITATION CENTER

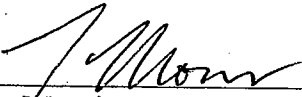
Annette Vecchiarelli, NHA
Annette Vecchiarelli
Executive Director & Administrator

Oct 25, 2005
DATE

Adam Balick
Adam Balick, Esq.
Counsel for Harbor

Oct 28, 2005
DATE

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



Lewis Morris
Chief Counsel to the Inspector General
U. S. Department of Health and Human Services

9/8/05
DATE