

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

**I. PREAMBLE**

Nazareth Enterprises, Inc., (hereinafter referred to as “Provider”) for itself and the “Covered Facilities” as identified in Section II.B below, hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by Provider, its “Covered Facilities,” their subsidiaries, affiliates, owners, directors, officers, employees, contractors, agents, physicians, and other health care professionals 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”).

On March 6, 2006, the OIG and Pleasant Care Corporation, SNF Properties, Inc., Ember Care Corporation, Atlas Care Enterprises, Inc., PCC Health Services, Inc., and Stockton Edison Health Care Corporation (hereinafter collectively referred to as “Pleasant Care”) entered into a Corporate Integrity Agreement (Pleasant Care CIA). Pursuant to Section XI.A. of the Pleasant Care CIA, the CIA is binding on all successors, assigns, and transferees of Pleasant Care. As of the date of this agreement, Provider has purchased the nursing home operations of two former Pleasant Care facilities. Based on Provider’s status as a successor, the OIG and Provider agree that Provider will be obligated by the terms and conditions of this CIA.

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

A. The period of the compliance obligations assumed by Provider 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). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. This CIA pertains to and covers the following nursing home facilities (hereinafter “Covered Facilities” or “Covered Facility”):

1. Yuba Skilled Nursing Center, Inc. currently located at 521 Lorel Way, Yuba City, CA 95991; and
2. Santa Cruz Skilled Nursing Center, Inc., located at 2990 Soquel Ave., Santa Cruz, CA 95062.

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

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

1. “Covered Persons” includes:
  - a. all owners, officers, directors, and employees of the Covered Facilities; and
  - b. all contractors, subcontractors, agents, and other persons of the Covered Facilities who, on a regular basis (*i.e.*, more often than two weeks over a 52-week period) on behalf of Provider: (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.

Notwithstanding the above, this term does not include part-time or *per diem* employees, contractors, subcontractors, agents, and other persons of the Covered Facilities 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.

Notwithstanding the above, any nonemployee private caregivers and/or attending physicians hired by any resident or the family or friends of any resident of a Covered Facility are not Covered Persons, regardless of the hours worked per year in a Provider facility.

Provider agrees that it will implement the provisions of this CIA at each of the Covered Facilities, and cause the Covered Persons at such Covered Facilities to comply with the terms of this CIA.

E. Subject to the provisions of this paragraph, it is expressly understood that this CIA shall not apply to any facility that is not a Covered Facility as identified in Section II.B above. If, after the effective date of this CIA and during the term of this CIA, Provider acquires ownership or control interests (as defined in 42 U.S.C. § 1320a-3(a)(3)) in any entity formerly owned and/or operated by Pleasant Care, such entity shall become a Covered Facility or Covered Person, if other than a nursing home, and be subject to this CIA.

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

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

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

1. *Compliance Officer.* Within ninety (90) days after the Effective Date, Provider 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 Provider, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Provider, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall not be Provider's general counsel or chief financial officer. Nor shall the Compliance Officer be subordinate to Provider's general counsel or chief financial officer. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Provider 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, Provider shall notify the OIG, in writing, within fifteen (15) days of such a change.

2. *Compliance Committee.* To the extent not already established, Provider shall establish a Quality Assurance Compliance Committee (hereinafter “Compliance Committee”) within ninety (90) days after the Effective Date. The purpose of this Compliance Committee shall be to address issues concerning quality of care at the Covered Facilities. The Board of Directors may determine to appoint itself or a committee of its members to serve as the Compliance Committee. At a minimum, the Committee shall 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 that relate to quality of care in the Covered Facilities. For each committee meeting, there shall be senior representatives from the Covered Facility, chosen on a rotating and random basis, to report to the committee on the adequacy of care being provided by the Covered Facility. The Compliance Committee shall meet, at a minimum, every three months.

3. *Board of Directors Committee.* Provider shall create a committee as part of its Board of Directors to provide oversight on quality of care issues (Quality Assurance Monitoring Committee). This committee shall: (a) review the adequacy of Provider’s system of internal controls, quality assurance monitoring, and patient care; (b) ensure that Provider’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 Provider adopts and implements policies and procedures that are designed to ensure that each individual cared for by a Covered Facility receives the highest practicable physical, mental, and psychosocial level of care attainable. The individuals who serve on this committee 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 for the committee shall be provided to the OIG within ninety (90) days after the Effective Date. When new members are appointed, or the responsibilities or authorities of the Board committee are substantially changed, Provider shall notify the OIG, in writing, within fifteen (15) days of such a change.

4. *Internal Audit and Review Functions.* To the extent not already established, Provider shall, within ninety (90) 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 at Provider’s Covered Facilities 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 applicable 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 the reporting obligations are complied with in accordance with this CIA; and
- f. make findings of whether corrective action plans are timely created, implemented, and enforced.

B. Written Standards.

1. *Code of Conduct.* Within ninety (90) days after the Effective Date, Provider shall establish a Code of Conduct and distribute it to all Covered Persons. Provider 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. Provider'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. Provider'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 Provider's own policies and procedures (including the requirements of this CIA);

- c. the requirement that all of Provider'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 Provider'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 Provider and any Covered Person of failure to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Provider'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 Provider's commitment to confidentiality and nonretaliation with respect to disclosures.

Within ninety (90) 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 Provider'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 ninety (90) days after the Effective Date, whichever is later.

Provider 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 ninety (90) days after the Effective Date, Provider shall develop and implement written Policies and Procedures regarding the operation of Provider'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, Provider's Policies and Procedures shall specifically address:

- a. Measures designed to ensure that Provider 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 Provider 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; fall prevention, recovery, and assessment; 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 Provider 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 Provider'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 Covered Facility) 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 district, region, or 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 district, regional, or corporate level, or directly to the Compliance Officer or Monitor;
- j. Measures designed to minimize the number of individuals working at any Covered Facility who are on a temporary assignment or not employed by Provider (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 Covered Facility who fall within this category so that the number/proportion of or



changing trends in such staff can be adequately identified by Provider 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 and Directors of Nursing of the Covered Facilities, and the individuals responsible for such compliance at the district, regional, and corporate level;
- m. Measures designed to ensure cooperation by Provider 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, that if the investigation substantiates compliance issues, Provider 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 Provider'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. No retaliation policies and methods 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;
- t. Measures designed to ensure that Provider 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; and
- u. Measures designed to ensure that Provider complies with California's staffing requirements set out in California Health and Safety Code section 1276.5.

Provider 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 ninety (90) 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 ninety (90) days after the Effective Date, Provider shall provide at least two (2) hours of general training to each Covered Person.<sup>1</sup> This general training shall explain Provider's:

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<sup>1</sup>Any nonemployee who is hired on a temporary basis (regardless of whether he or she is considered a "Covered Person") is required to follow the policies and procedures of the facility, Provider, and this CIA. Provider shall ensure that there is sufficient supervision to ensure that a

- 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 thirty (30) days of the beginning of their employment or contract, or within ninety (90) days after the Effective Date, whichever is later. Every Covered Person shall receive such general training on an annual basis.

2. *Specific Training.* Within ninety (90) days after the Effective Date, Provider shall initiate specific training of 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). Such Covered Persons shall receive at least eight (8) hours of training pertinent to their responsibilities in addition to the general training required above. This training, which shall be completed within one (1) year after the Effective Date of the CIA training and conducted at least annually thereafter, 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.

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temporary nonemployee is acting within the parameters of such policies and procedures. Any temporary nonemployee who works in Provider 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.

Affected new Covered Persons shall begin receiving this training within ten (10) days of the beginning of their employment or contract or within ninety (90) 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 Provider 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 to the specific training described above, each Covered Facility shall conduct periodic training on an "as needed" basis (but at least semi-annually) on those quality of care issues identified by the Board of Directors Committee and 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, the CMS quality indicators, and the findings, reports and recommendations of the Monitor. Such training shall be for a minimum of four (4) hours total annually. Such training shall be provided to all Covered Persons at the Covered Facilities who are responsible for patient or resident care.

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 five (5) days after the Effective Date, Provider shall retain the Long Term Care Institute located in Madison, Wisconsin, to serve as the Independent Monitor ("Monitor"). 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. Provider 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 his

or her fees and expenses. As a condition to retaining the Monitor, Provider shall require the Monitor to enter into a subcontract with an individual or entity, approved by the OIG, that has the requisite expertise, capacity and access to MDS data directly from CMS to perform quarterly Quality Indicator data analysis reports of the type described in the attached Appendix # 1. 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 Provider to one or more of the remedies set forth in Section X. 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, Provider shall retain another Monitor appointed by the OIG, with the same functions and authorities. The Monitor may confer and correspond with Provider and OIG on an *ex parte* basis.

1. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
  - a. Provider'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. Provider's response to quality of care issues, which shall include an assessment of:
    - (1) Provider's ability to identify the problem;
    - (2) Provider's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;
    - (3) Provider's ability to create a corrective action plan to respond to the problem;

- (4) Provider's ability to execute the corrective action plan; and
    - (5) Provider's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.
  - c. Provider's development and implementation of corrective action plans and the timeliness of such actions;
  - d. Provider'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 Provider and set forth in this CIA; and
  - e. Provider's compliance with California's staffing requirements set out in California Health and Safety Code section 1276.5.
- 2. The Monitor shall have:
  - a. immediate access to Covered 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 Covered 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 Covered Persons for interviews outside the presence of Provider 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. Nothing in this paragraph shall require Provider to breach or fail to perform any of its duties to its patients, residents, and Covered Persons under state and federal laws and regulations.

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

- a. ensure the Monitor's immediate access to the Covered 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 Covered 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 that involves or causes actual harm to a resident when such incident is required to be reported to the California Department of Health Services or any other 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. 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 or its Board of Director's Quality Assurance Monitoring 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;
- h. pay the Monitor's bills within 30 days of receipt. While Provider must pay all the Monitor's bills within 30 days, Provider may bring any disputed Monitor's Costs or bills to OIG's attention; 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 Provider 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.

4. *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, residents, and patients;
- b. 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 the OIG and to Provider;
- c. at all times act reasonably in connection with its duties under the CIA including when requesting information from Provider;
- d. simultaneously provide quarterly reports to Provider and OIG concerning the findings made to date;
- e. submit bills to Provider on a consolidated basis no more than once per month, and submit an annual summary representing an accounting of its costs throughout the year to Provider and to OIG. The Monitor shall submit to Provider and the OIG an annual report representing an accounting of its costs throughout the year;
- f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce 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 Provider,

and Provider 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 Provider 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 Provider 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. 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 Covered Facilities;

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 the OIG;

j. visit each Covered Facility as often as the Monitor believes it necessary to perform its functions; and

k. If the Monitor has concerns about corrective action plans that are not being enforced or systemic problems that could affect Provider's ability to render quality care to its patients and residents, then the Monitor shall: a) report such concerns in writing to the OIG and the California Bureau of Medi-Cal Fraud and Elder Abuse (BMFEA); and b) simultaneously provide notice and a copy of the report to Provider's Board of Directors Quality Assurance Monitoring Committee referred to *supra*.

E. Disclosure Program.

Within ninety (90) days after the Effective Date, Provider 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 Provider'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. Provider 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) at each of its Covered 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, Provider 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 monthly 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 Provider.

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

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

c. Provider 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) Provider to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Provider has actual notice that a Screened Person has become an Ineligible Person, Provider shall remove such person from responsibility for, or involvement with, Provider'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 Provider 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, Provider 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 Government Investigation or Legal Proceedings.

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

#### H. Reporting.

##### 1. *Overpayments.*

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

b. Reporting of Overpayments. If, at any time, Provider identifies or learns of any Overpayment, Provider shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Provider shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Provider shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

## 2. *Reportable Events*.

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

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

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

b. Reporting of Reportable Events. If Provider determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Provider shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

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

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

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

In the event that, after the Effective Date, a Covered Facility is sold, closed or purchased, or a Covered Facility changes location, 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, Provider shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or

establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

**V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within one hundred and twenty (120) days after the Effective Date, Provider 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 charter for the Board of Directors Committee required in section III.A;
3. the program for internal audits and reviews required in section III.A;
4. a copy of Provider's Code of Conduct required by section III.B.1;
5. the summary of the Policies and Procedures required by section III.B.2;
6. 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;
7. a certification by the Compliance Officer that:
  - a. the Policies and Procedures required by section III.B 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.



8. a description of the disclosure program required by section III.E;
9. a summary of personnel actions taken pursuant to section III.F; and
10. a list of all of Provider'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 provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

B. Annual Reports. Provider shall submit to OIG an Annual Report with respect to the status and findings of Provider's compliance activities over the one year period covered by the Annual Report. Each Annual Report 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. a 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. Provider has effectively implemented all plans of correction related to problems identified under this CIA, Provider'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 summary of the Covered Facilities audited or reviewed, a summary of the findings of such audit or review, and a summary of the corrective action taken under the program for internal audits and reviews;
5. Provider's response/corrective action plan to any issues raised by the Monitor;

6. a copy of the confidential 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 Provider 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 Provider 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 Provider'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 provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and ninety (90) 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 Provider's President and Chief Executive Officer, under penalty of perjury, that: 1) Provider is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and 2) the President and Chief Executive Officer have reviewed the Report and have made reasonable inquiry regarding its content and believe that, upon such inquiry, the information is accurate and truthful. Each Report shall also include a resolution (or its equivalent) from Provider's Board of Directors certifying that they have reviewed the Annual Report and agree with the statements made therein.

## **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

Provider: Compliance Officer  
800 South B Street, Suite 100  
San Mateo, CA 94401

## **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 Provider's books, records, and other documents and supporting materials and/or conduct an onsite review of Provider's operations for the purpose of verifying and evaluating: 1) Provider's compliance with the terms of this CIA; and 2) Provider's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Provider 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 Provider'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. Provider agrees to assist OIG in contacting and arranging interviews with such employees, contractors, or agents upon OIG's request. Provider's employees, and the contractors and agents may elect to be interviewed with or without a representative of Provider present.

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

Provider 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 Provider prior to any release by OIG of information submitted by Provider pursuant to its obligations under this CIA and identified upon submission by Provider as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Provider 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**

Provider 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 Provider 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 Provider with prompt written notification of such determination (Noncompliance Notice). Provider 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 Provider 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 Provider has failed to comply with the CIA and whether Provider shall be required to implement the particular provisions at issue.

B. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Provider 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, Provider 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;
- 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 Provider 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 Provider fails to grant access) for each day Provider 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 Provider of the failure to comply) for each day Provider 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 Provider, the OIG shall state the specific grounds for its determination that the Provider 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 Provider of the failure to comply) for each day Provider fails to comply fully and adequately with any obligation of this CIA. In its notice to Provider, the OIG shall state the specific grounds for its determination that the Provider 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 Provider of the failure to comply) for each day Provider fails to comply fully and adequately with any of its obligations with respect to the Monitor, as set forth in section III.D.3. In its notice to Provider, the OIG shall state

the specific grounds for its determination that the Provider 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 Provider has failed to comply with any of the obligations described in section X.B and determining that Stipulated Penalties are appropriate, OIG shall notify Provider by personal service or certified mail of: (a) Provider'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, Provider 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 Provider elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Provider 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.* Provider 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 Provider 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 Provider 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 Provider 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 Provider constitutes an independent basis for Provider'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 Provider has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Provider by certified mail of: a) Provider'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 of Provider's facilities or corporate entities, depending upon the facts of the breach.

2. *Opportunity to cure.* Provider 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. Provider 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) Provider has begun to take action to cure the material breach; (2) Provider is pursuing such action with due diligence; and (3) Provider 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, Provider fails to satisfy the requirements of section X.C.2, OIG may exclude Provider from participation in the Federal health care programs. OIG shall notify Provider in writing of its determination to excluded Provider (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 Provider is excluded under the provisions of this CIA, Provider 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 Provider;
  - 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 Provider 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, Provider 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, Provider was in full and timely compliance with the obligations of this CIA for which the OIG seeks specific



performance; and b) whether Provider failed to cure. Provider 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, Provider shall take the actions OIG deems necessary to cure within (20) days after the ALJ issues such a decision notwithstanding that Provider 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 Provider was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Provider 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 Provider to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Provider 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 Provider 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) Provider has begun to take action to cure the material breach, (2) Provider is pursuing such action with due diligence, and (3) Provider 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. Provider's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Provider 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 Provider 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 Provider 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 Provider'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 Provider. The OIG may decide to waive this successor liability provision upon receipt of verified proof to the OIG's satisfaction that Provider has wholly divested itself of any interest or involvement, direct or indirect, in the transferred or assigned entity, that the successor is an independent entity unrelated in any manner to Provider, that the successor has acquired its interest at fair market value in an arms' length transaction, and that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs, as well as a history of such compliance.

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

C. The undersigned Provider 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.

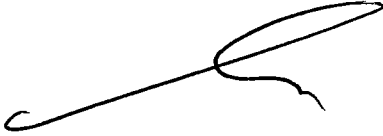
**ON BEHALF OF NAZARETH ENTERPRISES, INC.**



Mounir Kardosh  
Provider

1/16/08  
DATE

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



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

2/7/08  

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DATE

## **Appendix # 1 to CIA - Data Analysis Subcontract Description**

Below is a description of the kinds of reports to be provided under the Monitor's subcontract with a data analysis expert, as required by section III.D of the CIA.

a. Facility Reports: a summary report for facility, showing facility-level quality indicator (QI) values and information on the MDS assessments underlying these values. The reports will provide the facility's QI ratios as well as information regarding the placement of these values within the distribution of results for appropriate comparison groups. Initially, two comparison groups will be available. The first comparison group will be all nursing facilities within the subcontractor's MDS assessment database. The second group will be all nursing facilities within Provider. The subcontractor may make additional comparison groups available if such groups can be readily identified using the facility identification codes within the subcontractor's MDS assessment database.

b. Resident Reports: a resident-level report showing which QI numerators were triggered by each resident in the Facility Report tabulation.

c. Database Extracts: a facility-level database table of QI values for Provider. This extract will be produced quarterly by the subcontractor and mailed to the Monitor on CD, along with a printed summary of the table contents. These tables will be in a format suitable for use in spreadsheets and/or simple database applications to allow the monitor to manipulate/rearrange the data supporting the QI reports.

d. Documentation: The subcontractor will provide the Monitor with a QI User Guide, which will describe the report format and contents, provide QI definitions in terms of the underlying MDS assessment items, and outline the QI tabulation process.

e. QI Report Distribution: The Facility and Resident reports will be produced quarterly by the subcontractor.

f. QI Analyses: Throughout the term of this subcontract, the subcontractor will analyze the available QI information relating to Provider in an effort to refine and expand the information provided to the Monitor.