CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

GUARDIAN POSTACUTE SERVICES, INC.

I. PREAMBLE

Guardian Postacute Services, Inc. ("Guardian") 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 ensure compliance by Guardian, subsidiaries and affiliates in which it has an ownership or control interest (as defined by 42 U.S.C. § 1320a-3(a)(3)), contractors, directors, employees, 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"). Guardian's compliance with the terms and conditions in this CIA shall constitute an element of Guardian's present responsibility with regard to participation in the Federal health care programs.

Further, Guardian acknowledges its accountability for the health and safety of its patients and residents. The requirements imposed upon Guardian by this CIA are also imposed on all of Guardian's subsidiaries and affiliates (which are collectively referred to herein as "Guardian"). The employees, contractors, and agents covered under this CIA are those who: (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; (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.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Guardian under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which judgment is entered against Guardian North Bay in the criminal case filed by the Santa Clara County District Attorney ("effective date"). Sections VII, VIII, IX, X and XI shall remain in effect until Guardian submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

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

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

- 1. Compliance Officer. Guardian 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 Guardian (*i.e.*, not subordinate to Guardian's general counsel or chief financial officer), shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Guardian, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Guardian 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, Guardian shall notify the OIG, in writing, within fifteen (15) days of such a change.
- 2. Compliance Committee. To the extent not already established, Guardian shall establish a Quality Assurance Compliance Committee within ninety (90) days after the effective date of this CIA. The purpose of this Compliance Committee shall be to address issues concerning quality of care at Guardian's nursing homes. At a minimum, the Committee shall include the Compliance Officer, the Chief Medical Officer, the President of the Nursing Home Division, the Vice President for Clinical Operations for nursing homes, representatives from each of the regions, 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 facilities. For each committee meeting, there shall be senior representatives from the facilities, chosen on a rotating and random basis, to report to the committee on the adequacy of care being provided at their facilities.

- 3. Board of Directors' Committee. Guardian 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 Guardian's system of internal controls, quality assurance monitoring, and patient care; (b) ensure that Guardian'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 Guardian adopts and implements policies and procedures that are designed to ensure that each individual cared for at a Guardian 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, the Monitors, and the Independent Review Organization(s) 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 of the effective date of this CIA. When new members are appointed, or the responsibilities or authorities of the Board committee are substantially changed, Guardian 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, Guardian shall, within ninety (90) days of the effective date of this CIA, create a program for performing internal audits and reviews. The internal audits and reviews shall:
 - 1. make findings of whether the patients and residents at Guardian 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 Federal and state statutes, regulations, and directives;
 - 2. make findings of whether the policies and procedures mandated by this CIA are created, implemented, and enforced;
 - 3. make findings of whether training is performed in accordance with this CIA;
 - 4. make findings of whether hotline complaints are appropriately investigated;

- 5. make findings of whether the reporting obligations are complied with in accordance with this CIA; and
- 6. make findings of whether corrective action plans are timely created, implemented, and enforced.

B. Written Standards.

- 1. Code of Conduct. Within ninety (90) days of the effective date of this CIA, Guardian shall establish a Code of Conduct and distribute it to all directors, employees, contractors, and agents. Guardian shall make adherence to the Code of Conduct an element in evaluating the performance of contractors, agents, and employees. The Code of Conduct shall, at a minimum, set forth:
 - a. Guardian'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 Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or fiscal intermediaries or carriers:
 - b. Guardian's requirement that all of its directors, employees, contractors, and agents shall be expected to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Guardian's own policies and procedures (including the requirements of this CIA);
 - c. the requirement that all of Guardian's directors, employees, contractors, and agents 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 Guardian's own policies and procedures; if there are credible allegations of patient harm, such report shall be made immediately;
 - d. the possible consequences to both Guardian and any director,

employee, contractor, or agent of failure to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Guardian's own policies and procedures or of failure to report such non-compliance; and

e. the right of all directors, employees, contractors, and agents to use the confidential disclosure program, as well as Guardian's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, to the extent not already accomplished, each director, employee, contractor, and agent shall certify, in writing, that he or she has received, read, understood, and will abide by Guardian's Code of Conduct. New directors, employees, contractors, and agents 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 of the effective date of the CIA, whichever is later.

Guardian will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Directors, employees, contractors, and agents 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 of the effective date of this CIA, Guardian shall develop and initiate implementation of written Policies and Procedures regarding the operation of Guardian'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, Guardian's Policies and Procedures shall specifically address:
 - a. Measures designed to ensure that Guardian 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 Guardian 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, 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 Guardian provides appropriate wound care (decubitus ulcer) treatment and appropriate nutrition for residents with wounds:
- e. Measures designed to ensure that Registered Dieticians accurately calculate all residents' ideal body weight, compare current body weight to the residents' usual body weight in order to determine an appropriate healthy weight range for each resident on a regular and consistent basis and clearly document such findings in the residents' charts;
- f. Measures designed to ensure that Guardian identifies and provides timely clinical responses to all "nutritionally at risk" and "nutritionally compromised" residents at the earliest possible time;
- g. Measures designed to ensure that Guardian obtains serum albumin levels for all residents at the time of admission for

- screening purposes, and as warranted thereafter to measure protein levels and performs prealbumins in accordance with professional standards;
- h. Measures designed to ensure that Guardian provides a safe and functional environment for all residents and that all residents are free from mistreatment, verbal, sexual, physical, and mental abuse, corporal punishment, involuntary seclusion, neglect, and misappropriation of property;
- i. Measures designed to ensure that Guardian adequately supervises, monitors and safeguards all residents, including those with histories of exhibiting behaviors that cause injury to themselves or others;
- j. Measures designed to ensure that residents shall be protected from being victimized by other aggressive residents;
- k. Measures designed to ensure that staff members provide residents with appropriate basic care services that meet the residents' individual needs;
- 1. Measures designed to ensure that all residents are positioned properly, receive proper oral care and are bathed as scheduled, in appropriate water temperatures and with sufficient frequency;
- m. Measures designed to ensure that Guardian provides residents with sufficient, meaningful activities both during the week and on the weekends to enable the residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being;
- n. Measures designed to ensure that Guardian provides an ongoing structured program of activities designed to meet the individual interests and physical, mental, and psychosocial well-being of each resident, and provides medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

- o. Measures designed to ensure that physical and chemical restraints are used only pursuant to accepted professional standards when less restrictive alternatives are not effective and that they are never used as punishment or for the convenience of staff;
- p. Measures designed to ensure that appropriate physicians' orders are obtained and followed before physical restraints are used;
- q. Measures designed to ensure that psychotropic medication is used only in accordance with accepted professional standards and only where there is an appropriate psychiatric or neuropsychiatric diagnosis, and that psychotropic medication is never used as punishment, in lieu of a training program, for behavior control or in lieu of a psychiatric or neuropsychiatric diagnosis or for the convenience of staff;
- r. Measures designed to ensure that residents receive adequate preventive, chronic, routine, acute, follow-up, and emergency medical care in accordance with generally accepted standards of care, and that residents receive the necessary health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Such measures shall include the following:
 - i. Physicians promptly obtain and review all laboratory and test results, document the responses in the residents' charts and take appropriate actions to address any abnormal results;
 - ii. Physicians complete monthly notes in the residents' charts on a timely basis;
 - iii. Physicians do not rely inappropriately on telephone orders in treating residents;
 - iv. Physicians address promptly residents' significant or undesirable weight loss and personally provide continual follow-up until the situation is adequately addressed;

- v. Health care of all diabetic residents comports with generally accepted medical practice;
- vi. All individuals with seizure disorders are provided with adequate and appropriate seizure management in accordance with accepted professional standards of care and with adequate and appropriate seizure documentation and with adequate and appropriate diagnostic techniques;
- vii. Residents currently receiving anti-convulsant medication, receive the type of medication(s) that is (are) appropriate and effective for the type of seizure and represents the fewest number of medications appropriate for effective seizure management;
- viii. There are a sufficient number of neurology consult hours to meet the needs of the residents and to provide each resident with a seizure disorder with a neurology review every six (6) months;
- ix. As indicated by accepted professional standards of care, in the event of a medical emergency involving a resident, including status epilepticus, facility staff will immediately call an ambulance, and will initiate appropriate emergency interventions while awaiting arrival of the ambulance prior to transport of the resident to the closest tertiary care facility;
- x. Physicians conduct comprehensive health care evaluations of all residents;
- xi. Physicians determine what specialized medical services are required for the residents and ensure that such services are timely provided whenever necessary to evaluate or treat the resident's medical problems;
- xii. An integrated medical plan of care for each resident exists;

- xiii. Each resident's medical status and progress in response to the resident's medical plan of care is regularly and adequately reviewed and all changes appropriately documented;
- xiv. Each resident's drug regimen is free from unnecessary drugs;
- xv. Adequate and appropriate interdisciplinary communication among relevant professionals, especially between and among physicians and nurses; and
- xvi. Physicians communicate with the pharmacist pertaining to therapeutic responses by residents to prescribed medications.
- s. Measures designed to ensure that residents receive adequate and appropriate nursing care, and that nurses perform their responsibilities in keeping with accepted professional standards of care by adequately identifying health care problems, notifying physicians of health care problems, monitoring and intervening to ameliorate such problems, and keeping appropriate records of residents' health care status;
- t. Measures designed to ensure that discharges are made without regard to financial status or reimbursement source;
- u. Measures designed to ensure that staffing needs decisions are based on the needs of the patients or residents at the facility and not upon financial concerns;
- v. 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 affects patient care made by the Administrator or other individuals at the district, region, or corporate level, then that person must immediately call the hotline and the Monitor;

- w. Measures designed to minimize the number of individuals working at any Guardian facility who are on a temporary assignment or not employed by Guardian. If the number of temporary staff is greater than ten (10) percent during any one shift, then a report shall be generated that explains why temporary staffing is required;
- x. Measures designed to ensure that clinical assessments are made without regard to the reimbursement amount;
- y. Measures designed to ensure that all residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;
- z. Disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues through the Confidential Disclosure Program required by section III.E;
- aa. Measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes, regulations, and in this 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 district, regional, and corporate level;
- bb. Measures designed to ensure cooperation by Guardian and its employees, contractors, and agents with the Monitor in the performance of his or her duties as set forth *infra*; and
- cc. Measures designed to ensure that compliance issues identified internally (e.g., through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CHSRA quality indicators, hospital key indicators, or internal surveys) or externally (e.g., through HCFA or state survey agency reports, consultants, audits performed by the Independent Review Organization, or monitor's reports) are promptly and appropriately investigated and, if the investigation substantiates compliance issues, Guardian assesses the nature and scope of the problems, implements

appropriate corrective action plans, and monitors compliance with such plans. Such measures shall include the requirement that the President and Chief Executive Officer review each HCFA and state survey agency report and plan of correction and certify in writing to the appropriate government agency as to whether Guardian has corrected the survey deficiencies noted and has achieved substantial compliance with the Medicare and Medicaid conditions of participation.

Guardian 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 will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all appropriate employees, contractors, and agents. Compliance staff or supervisors shall be available to explain any and all policies and procedures.

3. <u>Training and Education</u>.

1. General Training. Within ninety (90) days of the effective date of this CIA, Guardian shall provide at least two (2) hours of training to each director, employee,

contractor, and agent. This general training shall explain Guardian's:

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

These training material shall be made available to the OIG upon request.

New employees, contractors, and agents shall receive the general training described above within ten (10) days of the beginning of their employment or within ninety (90) days after the effective date of this CIA, whichever is later. Every employee, contractor and agent shall receive such general training on an annual basis.

- 2. Specific Training. Within ninety (90) days of the effective date of this CIA, each employee, contractor, or agent 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. 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:

Any non-employee who is hired on a temporary basis (regardless of whether he or she is considered an "agent") is required to follow the policies and procedures of the facility, Guardian, and this CIA. Guardian shall ensure that there is sufficient supervision to ensure that a temporary non-employee is acting within the parameters of such policies and procedures. Any temporary non-employee who works in Guardian 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.

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 employees, contractors, or agents shall receive this training within ten (10) days of the beginning of their employment or contract or within ninety (90) days of the effective date of this CIA, whichever is later. If a new employee, contractor, or agent has any responsibility for the delivery of patient or resident care, then prior to completing this specific training, a Guardian employee, contractor, or agent who has completed the substantive training shall review all of the untrained person's work.

Every employee, contractors, and agents 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 Board of Directors Committee and the Compliance Committee. In determining what training should be performed, these Committees will 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 CHSRA quality indicators. Such training will be for a minimum of four (4) hours. Such training will be provided to all employees, contractors, and agents at the facility who are responsible for patient or resident care. Each individual trained will be required to complete a comprehension test to ensure that the individual has learned the material being presented. These comprehension tests will be maintained and made available to the OIG and the monitor upon request.

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

3. Certification. Each employee, contractor, and agent 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.

D. <u>Review Procedures</u>.

- 1. <u>Independent Monitor</u>. Within sixty (60) days of the effective date of this CIA, the OIG shall appoint an appropriately qualified monitoring team (the "Monitor"), selected at its discretion (after consultation with Guardian). 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. Guardian 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.
 - a. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
 - i. Guardian's internal quality control systems, including, but not limited to, 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; 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 whether the training programs are effective and thorough;
 - ii. Guardian's response to quality of care issues, which shall include an assessment of:
 - (A) Guardian's ability to identify the problem;
 - (B) Guardian's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;
 - (C) Guardian's ability to create a corrective action plan to respond to the problem;
 - (D) Guardian's ability to execute the corrective action plan;

- (E) Guardian's ability to evaluate whether the assessment, corrective action plan and execution of that plan was effective, reliable, and thorough.
- iii. Guardian's development and implementation of corrective action plans and the timeliness of such actions;
- iv. Guardian'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 Guardian and set forth in this CIA.

b. The Monitor shall have:

- i. 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;
- ii. immediate access to: (1) the CHSRA 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 incident involving a patient or resident that prompts a full internal investigation; (8) patient or resident records; (9) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (10) any other data in the format the monitor determines relevant to fulfilling the duties required under this CIA; and

iii. immediate access to patients, residents, and staff for interviews outside the presence of Guardian 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.

c. Guardian shall:

- i. 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;
- ii. provide the Monitor a report within forty-eight hours regarding any of the following occurrences:
 - (A) Deaths or injuries related to use of restraints;
 - (B) Deaths or injuries related to use of psychotropic medications.
 - (C) Suicides;
 - (D) Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines),
 - (E) Fires, storm damage, flooding, major equipment failures at any facility;
 - (F) Strikes or other work actions;
 - (G) Manmade disasters that pose a threat to residents (e.g., toxic waste spills); and
 - (H) 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, the date of death or incident, and a brief description of the events surrounding the death or incident.

- iii. assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, their families and guardians;
- iv. provide access to current residents, patients, their families, and guardians; and
- v. 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.
- d. The Monitor shall respect the legal rights, privacy, and dignity of all residents, patients, and employees.
- e. The Monitor shall submit reports within forty-eight hours (or earlier if necessary to protect the health and safety of a patient or resident or otherwise mandated by law) to OIG, Guardian, the state survey agency,² and any other appropriate regulatory or law enforcement entity, any time he or she has concerns regarding the health or safety of the residents or patients and such concerns create an obligation to report under Federal, state, or local law or professional licensing standards.
- f. The Monitor shall provide quarterly reports to Guardian and OIG concerning the findings made to date.
- g. The Monitor shall submit to OIG and Guardian an annual report representing an accounting of its costs throughout the year.
- h. The Monitor is not bound by any other agency's findings or conclusions, including, but not limited to, JCAHO, HCFA, or the state survey agency.
- i. The Monitor must promptly report to appropriate regulatory or law enforcement entities when warranted.

²As defined in 42 CFR § 488.1 (1998).

- j. The Monitor may confer and correspond with Guardian and OIG on an *ex parte* basis.
- k. If the Monitor has concerns about corrective action plans that are not being enforced or systemic problems that could affect Guardian's ability to render quality care to its patients and residents, then the Monitor shall: 1) report such concerns in writing to an interagency Consortium consisting of representatives of OIG, HCFA, the Department of Justice, and the state survey agency; and 2) provide notice and a copy of the report to Guardian's Board of Directors Quality Assurance Monitoring Committee referred to *supra*.
- 1. The Monitor serves at the behest of the OIG and 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, OIG, at its sole discretion, shall appoint another Monitor with the same functions and authorities.

E. <u>Confidential Disclosure Program.</u>

Within ninety (90) days of the effective date of the CIA, Guardian shall establish a Confidential Disclosure Program that provides a toll-free compliance telephone line to enable employees, contractors, agents, patients, residents, family members, or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any issues or questions associated with Guardian's policies, practices, or procedures with respect to quality of care or a Federal health care program, believed by the individual to have violated Federal or state criminal, civil or administrative law or the applicable standard of care. Guardian shall publicize the existence of the hotline, and shall post notices of its existence prominently in the lobby and gathering areas (e.g., dining rooms, activity rooms, waiting rooms) of each of its facilities.

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, 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, Guardian 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 confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation. This log shall be sent to the Monitor not less than weekly.

F. <u>Ineligible Persons</u>.

- 1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services but has not yet been excluded, disbarred or otherwise declared ineligible.
- 2. Screening Requirements. Guardian shall not hire or engage as healthcare service providers any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Guardian shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

In addition, Guardian shall require employees to disclose immediately any debarment, exclusion or other event that makes the employee into an Ineligible Person.

3. Review and Removal Requirement. Within 90 (ninety) days of the effective date of this CIA, Guardian will review its list of current employees and contractors against the Exclusion Lists. Thereafter, Guardian will review the list semi-annually. If Guardian has notice that an employee or contractor has become an Ineligible Person, Guardian will remove such person from responsibility for, or involvement with, Guardian's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly

or indirectly, by Federal health care programs or otherwise with Federal funds 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 Guardian has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Guardian shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and will not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.
- G. <u>Notification of Proceedings</u>. Within thirty (30) days of discovery, Guardian shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Guardian 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. Guardian 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. <u>New Business Units or Locations</u>

In the event that Guardian purchases or establishes new business units after the effective date of this CIA, Guardian shall notify OIG of this fact within thirty (30) days of the date of 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 provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All employees, contractors, and agents at such locations shall be subject to the requirements in this CIA that apply to new employees, contractors, and agents (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within one hundred and twenty (120) days after the effective date of this CIA, Guardian 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 Guardian'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 employees, contractors, and agents;
 - b. all employees, contractors, and agents have completed the Code of Conduct certification required by section III.B.1; and
 - c. all employees, contractors, and agents have completed the training and executed the certification required by section III.C.
- 8. a description of the confidential 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 Guardian'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. Guardian shall submit to OIG an Annual Report with

respect to the status and findings of Guardian'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. a certification by the Compliance Officer that:
 - a. all employees, contractors, and agents have completed the annual Code of Conduct certification required by section III.B.1;
 - b. all employees, contractors, and agents have completed the training and executed the certification required by section III.C; and
 - c. Guardian has effectively implemented all plans of correction related to problems identified under this CIA, Guardian'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 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. Guardian'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 Guardian 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 Guardian 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;
- 9. a corrective action plan to address the probable violations of law identified in section III.H; and
- 10. a description of all changes to the most recently provided list (as updated) of Guardian's locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each locations' 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 of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by Guardian's President and Chief Executive Officer, under penalty of perjury, that: (1) Guardian 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 Guardian'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 of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
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, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Guardian:

Robert G. Peirce, President and CEO Guardian Postacute Services, Inc. 5725 Paradise Drive, Suite 900 Corte Madera, CA 94925

Phone: 415.945.2222 Fax: 415.927.6772

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

VIII. DOCUMENT AND RECORD RETENTION

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

Guardian 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 Guardian 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 Guardian with prompt written notification of such determination ("Noncompliance Notice"). Guardian will have thirty five (35) days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) to reply in writing that Guardian 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. This purpose of the hearing is to determine whether Guardian has failed to comply with the CIA and whether Guardian shall be required to implement the particular provisions at issue.
- B. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Guardian 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 of this CIA and concluding at the end of the term of this CIA, Guardian fails to have in place any of the following:

- a. a Compliance Officer;
- b. Compliance Committee;
- c. Compliance Committee of the Board of Directors;
- d. a program for performing internal audits and reviews;
- e. written Code of Conduct;
- f. written Policies and Procedures;
- g. a training program; and
- h. a Confidential Disclosure Program.
- 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 Guardian fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.
- 3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date that failure to comply began) for each day Guardian employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Guardian's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Guardian can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.H) as to the status of the person).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that Guardian fails to grant access) for each day Guardian fails to grant access to the information or documentation as required in section V of this CIA.
- 5. A Stipulated Penalty of \$5,000 (which shall begin to accrue ten (10) days after the date OIG provides notice to Guardian of the failure to comply) for each day Guardian 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 Guardian, the OIG shall state the specific grounds for its determination that the Guardian has failed to comply fully and adequately with the CIA obligation(s) at issue.
- 6. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date OIG provides notice to Guardian of the failure to comply) for each day

Guardian fails to comply fully and adequately with any obligation of this CIA. In its notice to Guardian, the OIG shall state the specific grounds for its determination that the Guardian 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 Guardian has failed to comply with any of the obligations described in section X.B and determining that Stipulated Penalties are appropriate, OIG shall notify Guardian by personal service or certified mail of: (a) Guardian'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, Guardian 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 administrative law judge ("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 Guardian elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Guardian 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. Guardian 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 Guardian 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 Guardian 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 Guardian 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 Guardian constitutes an independent basis for Guardian'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 Guardian has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Guardian by certified mail of: (a) Guardian'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. Guardian 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. Guardian 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: (i) Guardian has begun to take action to cure the material breach; (ii) Guardian is pursuing such action with due diligence; and (iii) Guardian 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, Guardian fails to satisfy the requirements of section X.C.2, OIG may exclude Guardian from participation in the Federal health care programs. OIG will notify Guardian in writing of its determination to excluded Guardian ("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 will also apply to all other Federal procurement and non-procurement programs. If Guardian is excluded under the provisions of this CIA, Guardian 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 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 Guardian;

- a. 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;
- b. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
- c. a failure to fund the Monitor in accordance with section III.D.

E. Dispute Resolution

- 1. Review Rights. Upon the OIG's delivery to Guardian of its
 Noncompliance Notice or Demand Letter or its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Guardian 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, Guardian was in full and timely compliance with the obligations of this CIA for which the OIG seeks specific performance; and (b) whether Guardian failed to cure. Guardian 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, Guardian shall take the actions OIG deems necessary to

cure within (20) days after the ALJ issues such a decision notwithstanding that Guardian 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 Guardian was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Guardian 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 Guardian to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Guardian 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 Guardian 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 (i) Guardian has begun to take action to cure the material breach, (ii) Guardian is pursuing such action with due diligence, and (iii) Guardian 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. Guardian's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Guardian 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 Guardian 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 Guardian 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 HCFA or any other Federal or State agency to enforce any statutory or regulatory

authorities with respect to Guardian's compliance with applicable Federal and state health care program requirements.

XI. EFFECTIVE AND BINDING AGREEMENT

- A. This CIA shall be binding on the successors, assigns, and transferees of Guardian, except for the two facilities subject to the divestiture agreement signed by the parties this same date;
- B. This CIA shall become final and binding on the date judgment is entered against Guardian North Bay in the criminal case filed by the Santa Clara County District Attorney;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
- D. The undersigned Guardian 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 GUARDIAN

Routher	5-24-00
ROBERT G. PEIRCE, President and CEO	DATE
Guardian Postacute Services, Inc.	
Kenneth J. Burgess / KENNETH L. BURGESS, Esq. / hr	5/24/00
KENNETH L. BURGESS, Esq.	DATE
Hooper, Lundy & Bookman	
Counsel for Guardian	
	•

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

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services