CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
GENERAL LIVING CENTERS, INC.

I. PREAMBLE

General Living Centers, Inc. ("GLC") is a Louisiana nonprofit corporation with its principal business located at 8585 Picardy Avenue, Baton Rouge, Louisiana 70809. Until May 1, 2003, GLC operated Regency Place Nursing Home. GLC does not currently have an ownership interest in, or operate, a nursing home or assisted living facility that receives reimbursement from Medicare, Medicaid, or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs"). GLC currently operates a pharmacy.

GLC 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 GLC, subsidiaries and affiliates in which GLC has an ownership interest, and contractors, directors, employees, agents, physicians, and other health care professionals of GLC and such subsidiaries and affiliates with the requirements of Federal health care programs. GLC's compliance with the terms and conditions in this CIA shall constitute an element of GLC's present responsibility with regard to participation in the Federal health care programs. As of the time of execution of this CIA, GLC represents that it does not have an ownership interest in, or operate, a nursing home or assisted living facility that bills Federal health care programs.

GLC acknowledges its accountability for the health and safety of its patients and residents. The requirements imposed upon GLC by this CIA are also imposed on all subsidiaries and affiliates in which GLC has an ownership interest (which are collectively referred to herein as "GLC"). The employees, contractors, and agents covered under this

General Living Centers, Inc. CIA

EXHIBIT 1

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 (hereinafter referred to as "Covered Persons"). Notwithstanding the above, the term "Covered Persons" does not include part-time, temporary or *per diem* employees, agents or other individuals 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.

II. TERM OF THE CIA

The period of the obligations assumed by GLC under this CIA shall be seven (7) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA ("Effective Date"). Sections VII, VIII, IX, X, and XI shall remain in effect until GLC submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

If, at any time during the term of this CIA, GLC obtains an ownership interest in, or operates a nursing home or assisted living facility that receives reimbursement from any Federal health care program, then GLC shall establish a compliance program that includes the following elements in this Section III. An ownership interest, for the purposes of this CIA, shall include, but not be limited to, "ownership or control interest," as that phrase is defined in Section 1124(a)(3) of the Social Security Act. 42 U.S.C. § 1320a-3(a)(3). (The date on which GLC either obtains an ownership interest in, or begins to operate, a nursing home or assisted living facility that receives reimbursement from any Federal health care program shall hereinafter be referred to as the "Springing Date.") The obligations under the following Section III shall remain in effect only for the period during which GLC has an ownership interest in or operates a nursing home or assisted living facility that receives reimbursement from any Federal health care program.

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

- 1. Compliance Officer. Within 90 days after the Springing Date, GLC 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 GLC (i.e., not subordinate to GLC's general counsel or chief financial officer), shall make regular (at least quarterly) reports regarding compliance matters directly to the Chief Executive Officer and/or to the Board of Directors of GLC, 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 GLC 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, GLC shall notify the OIG, in writing, within 15 days after such a change.
- 2. Compliance Committee. GLC shall establish a Quality Assurance Compliance Committee within 90 days after the Springing Date. The purpose of this Compliance Committee shall be to address issues concerning quality of care at GLC'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 (if applicable), 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. GLC 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 GLC's system of internal controls, quality assurance monitoring, and patient care; (b) ensure that GLC'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 GLC adopts and implements policies and procedures that are designed to ensure that each individual cared for at a GLC 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 90 days after the Springing Date of this CIA. When new members are appointed, or the responsibilities or authorities of the Board committee are substantially changed, GLC shall notify the OIG, in writing, within 15 days after such a change.

- 4. *Internal Audit and Review Functions*. GLC shall, within 90 days after the Springing Date, create a program for performing internal audits and reviews. The internal audits and reviews shall:
 - a. make findings of whether the patients and residents at GLC 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;
 - 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 90 days after the Springing Date of this CIA, GLC shall establish a Code of Conduct and distribute it to all directors, employees, contractors, and agents. GLC 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. GLC'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. GLC'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 GLC's own policies and procedures (including the requirements of this CIA);
 - c. the requirement that all of GLC's directors, employees, contractors, and agents shall be expected to report, within 30 days, suspected violations of any statute, regulation, directive, or guideline applicable to Federal health care programs or of GLC'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 GLC 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 GLC'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 GLC's commitment to confidentiality and non-retaliation with respect to disclosures.

Within 90 days after the Springing 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 GLC's Code of Conduct. New directors, employees, contractors, and agents shall receive the Code of Conduct and shall complete the required certification within 2 weeks after the commencement of their appointment, employment, or contract or within 90 days after the Springing Date of the CIA, whichever is later.

GLC will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within 30 days after 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 90 days after the Springing Date of this CIA, GLC shall develop and implement written Policies and Procedures regarding the operation of GLC'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, GLC's Policies and Procedures shall specifically address:
 - a. Measures designed to ensure that GLC 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 GLC complies with all

requirements applicable to Medicare's Prospective Payment System ("PPS") for skilled nursing facilities, including, but not limited to (i) ensuring the accuracy of the clinical data required under the Minimum Data Set ("MDS") as specified by the Resident Assessment Instrument User's Manual; (ii) ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups ("RUG") classification system; and (iii) 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 GLC 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 GLC 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 GLC 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 GLC 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 GLC 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 GLC 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 GLC 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 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 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 GLC facility who are on a temporary assignment or not employed by GLC, and measures designed to create and maintain a standardized system to track the number of individuals at each facility who fall within this category so that the number/proportion of, or changing trends in, such staff can be adequately identified by GLC and/or the Monitor. If the number of temporary staff is greater than 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 GLC and its employees, contractors, and agents with the Monitor in the performance of his or her duties as set forth *infra*;
- Measures designed to ensure that compliance issues identified cc. 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 CMS 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, GLC 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 CMS and state survey agency report and plan of correction and certify in writing to the appropriate government agency as to whether GLC has corrected the survey deficiencies noted and has achieved substantial compliance with the Medicare and Medicaid conditions of participation;

- dd. Measures designed to effectively collect and analyze staffing data, including staff-to-resident ratio and staff turnover;
- ee. 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 CMS or state survey agency reports, consultants, or monitor's reports) are promptly and appropriately investigated and, if the investigation substantiates compliance issues, GLC assesses the nature and scope of the problems, implements appropriate corrective action plans, and monitors compliance with such plans;
- ff. Measures designed to ensure that GLC has a system to require and centrally collect reports relating to incidents, accidents, abuse and neglect. The reports required under this system shall be of 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;
- gg. Measures designed to inform Covered Persons of the staffing requirements of federal and state law;
- hh. 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, if any person has a concern about the level of staffing that there are many avenues available to each individual to report such concerns, including, but not limited to, the Administrator, the Hotline (as described in Section III. E. of this CIA), individuals at the district, regional, or corporate level, or directly to the Compliance Officer or Monitor;

- ii. Measures designed to ensure compliance with the completion of accurate clinical assessments as required by applicable federal law (see, e.g., 42 C.F.R. § 483.20); and
- jj. Measures designed to ensure that compliance issues are identified internally (e.g., through reports of abuse or neglect, financial data, reports to supervisors, Hotline or other complaints, internal audits or reviews, patient and resident satisfaction surveys, CHSRA quality indicators, staff turnover data, or internal surveys) or externally (e.g., consultants, audits performed by the IRO, or the Monitor's reports) and are promptly and appropriately investigated and, if the investigation substantiates compliance issues, GLC implements effective and timely corrective action plans and monitors compliance with such plans.

GLC 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 90 days after the Springing 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.

C. Training and Education.

1. General Training. Within 90 days after the Springing Date of this CIA, GLC shall provide at least two hours of training to each director, employee, contractor, and agent.¹ This general training shall explain GLC's:

¹Any 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, GLC, and this CIA. GLC 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 GLC facilities for more than 160 hours in a calendar year must complete

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

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

New employees, contractors, and agents shall receive the general training described above within 10 days of the beginning of their employment or within 90 days after the Springing 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 90 days of the Springing 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 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;
 - 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

the training requirements set forth herein.

assessment of the resident's competence to make treatment decisions.

Affected new employees, contractors, or agents shall receive this training within 10 days after the beginning of their employment or contract or within 90 days after the Springing 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 GLC employee, contractor, or agent who has completed the substantive training shall review all of the untrained person's work.

Every employee, contractor, and agent 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 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. Review Procedures.

- 1. <u>Independent Monitor</u>. Within 60 days after the Springing Date of this CIA, GLC shall appoint an appropriately qualified monitoring team (the "Monitor"), approved by the OIG. The Monitor shall charge a usual and customary rate for his or her fees and expenses. 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. GLC shall be responsible for all fees and expenses incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. Failure to pay the Monitor within 30 calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CIA and shall subject GLC to one or more of the remedies set forth in Section XI *infra*. The Monitor may be removed solely at the discretion of the OIG. If the Monitor resigns or is removed for any reason prior to the termination of the CIA, GLC shall appoint another Monitor, after approval by the OIG, with the same functions and authorities.
 - a. The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:
 - i. GLC'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. GLC's response to quality of care issues, which shall include an assessment of:
 - (A) GLC's ability to identify the problem;
 - (B) GLC's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;

- (C) GLC's ability to create a corrective action plan to respond to the problem;
- (D) GLC's ability to execute the corrective action plan;
- (E) GLC's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.
- iii. GLC's development and implementation of corrective action plans and the timeliness of such actions;
- iv. GLC'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 GLC and set forth in this CIA.
- b. Access. The Monitor shall have access to:
 - i. Facilities, at any time and without prior notice;
 - ii. The following types of documents:
 - (A) The CMS quality indicators (for nursing facilities);
 - (B) Internal or external surveys or reports;
 - (C) GLC's hotline complaints;
 - (D) Resident or patient satisfaction surveys;

- (E) Staffing data in the format requested by the monitor, including but not limited to, reports setting forth the staff to patient ratios, temporary staffing levels, and staff turnover data, as well as reports of any facility where temporary agency staff constitutes more than ten percent of the nursing and direct care staff;
- (F) Incident, accident, abuse, neglect, or death reports;
- (G) Reports of incidents involving a patient or resident that prompt a full internal investigation;
- (H) Patient or resident records;
- (I) Financial data;
- (J) Self-evaluative reports including, but not limited to, those from medical review committees, quality assurance committees, or peer review committees; and
- (K) Any other pre-existing data, including the reconfiguring of existing data that the Monitor may determine relevant to fulfilling the duties required under this CIA in the format requested by the Monitor, to the extent practicable; and

iii. immediate access to patients, residents, and staff for interviews outside the presence of GLC 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. GLC's Obligations. GLC shall:

- i. Not impede the Monitor's access to its facilities (pursuant to the provisions of this CIA) and shall provide any requested documentation within the time frame specified by the Monitor, subject to any extensions and modifications requested by GLC and granted by the Monitor;
- ii. Assist in contacting and arranging interviews of Covered Persons, and not impede the cooperation by such individuals;
- iii. Provide access to current residents or patients and contact information for their families and guardians, in a manner consistent with the rights of such individuals under state or federal law, and not impede their cooperation;
- iv. Provide the last known contact information for former employees, contractors, and agents, and not impede the cooperation from such individuals, including, but not limited to, refraining from placing confidentiality requirements in termination agreements that would limit such cooperation;
- v. 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;
- vi. 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;
- vii. Pay the Monitor's bills for Monitor's costs within 30 days of receipt. While GLC must pay all the Monitor's bills within 30 days, GLC may bring any disputed Monitor's costs or bills to OIG's attention;

viii. 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 GLC under this Agreement; 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; and

viii. Provide the Monitor a report within forty-eight hours of 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); and
- (E) 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.

- d. The Monitor's Obligations. The Monitor shall:
 - i. Respect the legal rights, privacy, and dignity of all Covered Persons, residents, and patients;
 - ii. Promptly report to appropriate regulatory or law enforcement entities when warranted. Where independently required by applicable law or professional licensing standard

to report any finding to an appropriate regulatory or law enforcement authority, simultaneously submit copies of such reports to OIG and to GLC;

- iii. At all times act reasonably in connection with its duties under the CIA, including when requesting information from GLC;
- iv. Provide quarterly reports to GLC and OIG concerning the findings made to date;
- v. Submit bills to GLC 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 GLC and to OIG. GLC shall have the opportunity to review such bills and bring any issue of disputed bills or costs to the attention of OIG;
- vi. 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 GLC, and GLC 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 GLC 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 for not explicitly excluded in this subsection;

vii. Abide by the legal requirements of GLC's facilities to maintain the confidentiality of each resident's personal and clinical records, and to maintain confidential and not to disclose the records of GLC's Corporate Compliance Committee and self-evaluative reports including, but not limited to, those from medical review committees, quality assurance committees or peer review committees. Nothing in the prior sentence, 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;

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

ix. The monitor shall visit each covered facility as often as the monitor believes it necessary to perform its functions, and at least as often as once every two months.

- e. Miscellaneous Provisions.
 - i. The Monitor may confer and correspond with GLC and OIG on an *ex parte* basis at any time;
 - ii. If, after consulting with GLC, the Monitor has concerns about corrective action plans that are not being enforced or systemic or repeated problems that could impact GLC's ability to render quality care to its patients and residents, then the Monitor may: (A) report such concerns in writing to the Consortium, in care of OIG at the address set forth in Section

VI of this CIA (the Consortium consists of representatives of OIG, CMS, and the Department of Justice); and (B) provide notice and a copy of the report to the Compliance Officer and the Board Committee. GLC shall be provided an opportunity to respond to the Consortium concerning any such report. The Consortium shall seek to resolve any such dispute between the Monitor and GLC prior to OIG seeking any remedies pursuant to the terms of this CIA;

iii. The Monitor shall not control, manage, or operate GLC.

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

Within 90 days after the Springing Date of the CIA, GLC 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 GLC'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. GLC 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, GLC 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. GLC shall not hire or engage as healthcare service providers any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, GLC 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://oig.hhs.gov) (these lists will hereinafter be referred to as the "Exclusion Lists").

In addition, GLC 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 days after the Springing Date of this CIA, GLC will review its list of current employees and contractors against the Exclusion Lists. Thereafter, GLC will review the list semi-annually. If GLC has notice that an employee or contractor has become an Ineligible Person, GLC will remove such person from responsibility for, or involvement with, GLC'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 GLC 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, GLC 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 30 days after discovery, GLC 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 GLC 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. GLC 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 proceedings, if any.

IV. NOTIFICATION OF OWNERSHIP INTEREST OR OPERATION

If, at any time during the term of this CIA, GLC obtains an ownership interest in, or operates a nursing home or assisted living facility that receives reimbursement from any Federal health care program, then GLC shall notify OIG of this fact within 10 days of obtaining such ownership interest or beginning such operation.

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within 120 days after the Springing Date of this CIA, GLC 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 GLC'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 GLC'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. <u>Annual Reports</u>. GLC shall submit to OIG an Annual Report with respect to the status and findings of GLC'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. GLC has effectively implemented all plans of correction related to problems identified under this CIA, GLC'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. GLC'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 GLC 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

GLC 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 GLC'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 90 days after the Springing 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 GLC's President and Chief Executive Officer, under penalty of perjury, that: (1) GLC 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 GLC'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: 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, SW

Washington, DC 20201

Phone

202.619.2078

Fax

202.205.0604

GLC: Mary Saporito

Compliance Officer

General Living Centers, Inc.

8490 Picardy Avenue Baton Rouge, LA 70809 Phone 225.237-1588

Fax

225.237-1669

Email

Mary.Saporito@brgeneral.org

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

VIII. DOCUMENT AND RECORD RETENTION

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

GLC 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 GLC 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 GLC with prompt written notification of such determination ("Noncompliance Notice"). GLC will have 30 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 GLC 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 GLC has failed to comply with the CIA and whether GLC 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, GLC 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 120 days after the Springing Date of this CIA and concluding at the end of the term of this CIA, GLC 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 GLC 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 GLC employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, GLC'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 GLC 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 GLC fails to grant access) for each day GLC 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 10 days after the date OIG provides notice to GLC of the failure to comply) for each day GLC 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 GLC, the OIG shall state the

specific grounds for its determination that GLC 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 10 days after the date OIG provides notice to GLC of the failure to comply) for each day GLC fails to comply fully and adequately with any obligation of this CIA. In its notice to GLC, the OIG shall state the specific grounds for its determination that GLC has failed to comply fully and adequately with the CIA obligation(s) at issue.
- 7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of GLC as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.
- 8. A Stipulated Penalty of \$10,000 (which shall begin to accrue on the date that failure to comply began) for each day that GLC fails to meet the deadline, as set forth in Section IV. of this CIA, for notifying the OIG that GLC has obtained an ownership interest in, or began to operate, a nursing home or assisted living facility that receives reimbursement from any Federal health care program. In its notice to GLC, the OIG shall state the specific grounds for its determination that GLC 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 GLC has failed to comply with any of the obligations described in section X.B and determining that Stipulated Penalties are appropriate, OIG shall notify GLC by personal service or certified mail of: (a) GLC'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 15 days after the date of the Demand Letter, GLC 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 GLC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GLC 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. GLC 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 GLC 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 business days after GLC 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 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 GLC 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 GLC constitutes an independent basis for GLC'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 GLC has materially breached this CIA and that exclusion should be imposed, the OIG shall notify GLC by certified mail of: (a) GLC'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. GLC shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:
 - a. GLC is in full compliance with the obligations of the CIA cited as being the basis of the breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30 day period, but that: (i) GLC has begun to take action to cure the material breach; (ii) GLC is pursuing such action with due diligence; and (iii) GLC has provided to OIG a reasonable timetable for curing the material breach.
- 3. Exclusion Letter. If at the conclusion of the 30 day period, GLC fails to satisfy the requirements of section X.C.2, OIG may exclude GLC from participation in the Federal health care programs. OIG will notify GLC in writing of its determination to excluded GLC ("Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect 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 GLC is excluded under the provisions of this CIA, GLC 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 GLC;
 - 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 and use the Monitor in accordance with section III.D.

E. <u>Dispute Resolution</u>

- 1. Review Rights. Upon the OIG's delivery to GLC 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, GLC 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 15 days after the date of the Demand Letter, and a request for a hearing involving exclusion shall be made within 30 days after 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, GLC was in full and timely compliance with the obligations of this CIA for which the OIG seeks specific performance; and (b) whether GLC failed to cure. GLC 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, GLC shall take the actions OIG deems necessary to cure within twenty (20) days after the ALJ issues such a decision notwithstanding that GLC 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 GLC was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. GLC 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 GLC to pay Stipulated Penalties, such Stipulated Penalties shall become due and

payable 20 days after the ALJ issues such a decision notwithstanding that GLC 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 GLC 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 30-day period, but that (i) GLC has begun to take action to cure the material breach, (ii) GLC is pursuing such action with due diligence, and (iii) GLC 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. GLC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude GLC 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 20 days after the ALJ issues such a decision, notwithstanding that GLC 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 GLC 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 GLC'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 GLC;
- B. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

C. The undersigned GLC 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.				
General Living Centers, Inc. CIA				

ON BEHALF OF GLC

(i) Dum	R.	#	Luar
WILLIAM R.	HOLM	AN	

Chief Executive Officer

General Living Centers, Inc.

9 24 03 DATE

LEE C. KANTROW

Kantrow, Spaht, Weaver & Blitzer, A Professional Law Corporation

Counsel for General Living Centers, Inc.

9/25/03

DATE

MICHAEL'S. WALSH

Lee & Walsh

Counsel for General Living Centers, Inc.

DATE

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

LARRY (J. GOLDBER

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services