

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**LIFE CARE CENTER OF LAWRENCEVILLE**  
**AND**  
**LIFE CARE CENTERS OF AMERICA, INC.**

**I. PREAMBLE**

Life Care Center of Lawrenceville (Lawrenceville) and Life Care Centers of America (Life Care) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote their compliance with the requirements of Medicare, Medicaid and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f) (hereinafter collectively referred to as the “Federal health care programs”) in the operation of Lawrenceville. Contemporaneously with this CIA, Lawrenceville and Life Care are entering into a Stipulated Consent Order with the United States, and this CIA is incorporated by reference into the Stipulated Consent Order.

**II. TERM AND SCOPE OF CIA**

A. The period of the compliance obligations assumed by Lawrenceville and Life Care under this CIA shall be five (5) years from the Effective Date of this CIA (unless otherwise specified). The Effective Date of this CIA shall be the date on which the final signatory executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

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

C. The scope of this CIA shall be governed by the following definition of the term “Covered Persons,” which shall include:

1. all owners, officers, directors, and employees of Lawrenceville;
2. all owners, officers, directors, associates, and employees of Life Care who have job functions that pertain to Lawrenceville; and
3. all contractors, subcontractors, agents, and other persons who, on a regular basis (*i.e.*, more often than two weeks over a 52-week period) on behalf of Life Care or Lawrenceville: (1) perform patient care or resident care duties with respect to Lawrenceville; (2) make assessments of patients or residents of Lawrenceville that affect treatment decisions or reimbursement; (3) perform billing, coding, audit or review functions relating to quality of care at Lawrenceville; (4) make decisions or provide oversight about staffing, patient care, resident care, reimbursement, policies and procedures that pertain to Lawrenceville; or (5) perform any function that relates to or is covered by this CIA, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions.

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

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

### **III. COMPLIANCE OBLIGATIONS**

Life Care represents that it currently operates a compliance program, known as the Integrity Services Program, that applies to Lawrenceville and all other Life Care operations. Life Care further represents that its Integrity Services Program include all the elements set forth in this section III of the CIA. Life Care agrees that during the term of this CIA, it will maintain its Integrity Services Program to include the elements set forth in this section III of the CIA.

#### **A. Program Infrastructure.**

1. *Integrity Services Officer.* Life Care shall appoint an experienced professional to serve as its compliance officer, known as the Integrity Services Officer. The Integrity Services Officer is responsible for developing and implementing policies,

procedures and practices designed to promote compliance by all Covered Persons with Life Care's Code of Conduct, the requirements set forth in this CIA and the requirements of the Federal health care programs. The Integrity Services Officer shall be a member of senior management of Life Care and shall be responsible for making quarterly reports regarding compliance matters directly to the Chief Executive Officer of Life Care and Life Care's Board of Directors. The Integrity Services Officer is authorized to report directly to the Board of Directors at any time. The Integrity Services Officer shall not be the general counsel or chief financial officer. Nor shall the Integrity Services be subordinate to the general counsel or chief financial officer. The Integrity Services Officer shall be responsible for monitoring the day-to-day activities engaged in by Lawrenceville to further its compliance objectives as well as any reporting obligations created under this CIA. The Integrity Services Officer shall also ensure that quality of care problems related to Lawrenceville are being appropriately addressed and corrected. In the event a new Integrity Services Officer is appointed during the term of this CIA, Life Care shall notify OIG, in writing, within fifteen (15) days of such a change. As part of his or her job functions, the Integrity Services Officer shall verify:

- a. whether the patients and residents of Lawrenceville are receiving the quality of care and quality of life consistent with basic care, treatment, and protection from harm standards, including but not limited to, 42 C.F.R. Parts 482 and 483 and any other applicable Federal and state statutes, regulations, and directives;
- b. whether the policies and procedures mandated by this CIA are created, implemented, and enforced at Lawrenceville;
- c. whether training is performed in accordance with this CIA;
- d. whether complaints are appropriately investigated;
- e. whether the reporting obligations are complied with in accordance with this CIA; and
- f. whether corrective action plans are timely created, implemented, and enforced.

The Integrity Services Officer shall also perform such other internal reviews as necessary to confirm that this CIA is being appropriately implemented. These verifications shall be made in writing and maintained by the Integrity Services Officer.

2. *Performance Improvement Committee.* Prior to this CIA, Lawrenceville established a clinical quality assurance committee known as the

Performance Improvement Committee. The purpose of this Performance Improvement Committee shall be to address issues concerning quality of care at Lawrenceville. At a minimum, the Committee shall include the Integrity Services Officer or his or her designee, the Medical Director, Lawrenceville's Executive Director, the Director of Nursing, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA that relate to quality of care. The minutes of these meetings shall be delivered for review within 48 hours to the Integrity Services Officer.

3. *Internal Review Function.* Prior to this CIA, Life Care represents that it has established an internal review program pursuant to which the Performance Improvement Committee performs internal quality compliance reviews on clinical and nonclinical facility issues. The Performance Improvement Committee's internal reviews shall:

a. make findings of whether the patients and residents of Lawrenceville are receiving the quality of care and quality of life consistent with basic care, treatment, and protection from harm standards, including but not limited to, 42 C.F.R. Parts 482 and 483 and any other applicable Federal and state statutes, regulations, and directives;

b. make findings of whether the policies and procedures mandated by this CIA are created, implemented, and enforced at Lawrenceville;

c. make findings of whether training is performed in accordance with this CIA;

d. make findings of whether complaints are appropriately investigated;

e. make findings of whether the facility reporting obligations are complied with in accordance with this CIA; and

f. make findings of whether facility corrective action plans are timely created, implemented, and enforced.

The Performance Improvement Committee shall also perform such other internal reviews as necessary to confirm that this CIA is being appropriately implemented. These verifications shall be made in writing and maintained by the Integrity Services Officer.

## **B. Written Standards.**

1. *Code of Conduct.* Life Care has established a Code of Conduct that applies to all Covered Persons. The Code of Conduct shall be reviewed by the Integrity Services Officer to confirm that it meets the requirements set forth herein.

a. *Contents:* The Code of Conduct shall, at a minimum, include:

(I) Life Care's commitment to full compliance with all statutes, regulations, directives and guidelines applicable to Federal health care programs;

(ii) Life Care's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Life Care's Policies and Procedures (including the requirements of this CIA);

(iii) the requirement that all Covered Persons shall be expected to report suspected violations of Life Care's Policies and Procedures, any Federal health care program requirements, or the requirements of this CIA (including Section IV.E.2.b.ii relating to incidents, accidents, and abuse reports);

(iv) the possible consequences to Lawrenceville, Life Care and to any Covered Person for failure to comply with Life Care's Policies and Procedures or Federal health care program requirements, or for failure to report such non-compliance; and

(v) the right of all individuals to use the Confidential Disclosure System, as well as Life Care's commitment to confidentiality and non-retaliation with respect to disclosures as set forth in its anonymous reporting policy.

b. *Distribution and Certification.* Life Care shall continue to require that the Code of Conduct be distributed to all Covered Persons. Within ninety (90) days after the Effective Date, to the extent not already accomplished, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Life Care's Code of Conduct. New Covered Persons who work at Lawrenceville shall receive the Code of Conduct and shall complete the required certification within two weeks after the commencement of their appointment, employment, or contract or within ninety (90) days after the Effective Date, whichever is later. New Covered Persons who work at Life Care corporate headquarters or elsewhere other than at Lawrenceville shall receive the Code of Conduct and shall complete the required certification within thirty days after the commencement of their appointment,

employment, or contract or within ninety (90) days after the Effective Date, whichever is later.

Life Care shall annually review the Code of Conduct and will revise or supplement it as necessary. Life Care shall distribute revisions or supplements of the Code of Conduct to Covered Persons as they occur. Covered Persons shall certify that they have received, read, understood and will abide by the Code of Conduct after each such revision.

2. *Policies and Procedures.* Life Care has developed written Policies and Procedures regarding its Integrity Services Program and its compliance with relevant Federal and state requirements, including, but not limited to, the requirements of Federal health care programs. These Policies and Procedures apply to Lawrenceville and all Covered Persons. Life Care shall continue to assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. The Policies and Procedures shall be made available to OIG within ninety (90) days after the Effective Date of this CIA. To the extent not already accomplished, Life Care shall confirm that the relevant portions of its Policies and Procedures are available to the appropriate Covered Persons within ninety (90) days after the Effective Date of this CIA. Integrity Services staff or supervisors shall continue to be available to explain any and all Policies and Procedures.

Within ninety (90) days after the Effective Date of this CIA, Life Care shall review and analyze its Policies and Procedures to confirm that Life Care has developed and implemented appropriate Policies and Procedures that, at a minimum, specifically address:

a. Measures designed to ensure that Life Care and Lawrenceville fully comply 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 Life Care and Lawrenceville comply with all requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as specified by the Resident Assessment Instrument User's Manual; ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups (RUG) classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;

c. Measures designed to ensure the coordinated interdisciplinary approach to providing care to nursing home residents, including, but not limited to the following areas addressed in 42 C.F.R. § 483: resident assessment and care planning; nutrition; diabetes care; wound care; infection control; fall prevention, recovery, and assessment; abuse and neglect policies and reporting procedures; protection from harm procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; activities of daily living (ADL) care; therapy services; quality of life, including accommodation of needs and activities; and assessment of resident competence to make treatment decisions;

d. Measures designed to ensure that Life Care and Lawrenceville have an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans;

e. Measures designed to ensure compliance with the completion of accurate clinical assessments as required by applicable Federal law, which shall include: (1) that all patient and resident care information be recorded in ink or permanent print; (2) that corrections shall only be made in accordance with accepted health information management standards; (3) that erasures shall not be allowable; and (4) that clinical records may not be rewritten or destroyed to hide or otherwise make a prior entry unreadable or inaccessible;

f. Measures designed to ensure that staffing needs are decided first and foremost upon achieving the level of care for Life Care's and Lawrenceville's patients and residents required by federal and state laws, including, but not limited to, 42 C.F.R. § 483.30 (nursing facilities);

g. Measures that specify that if the director of nursing (or other person who is making staffing decisions at the facilities) disagrees with a staffing determination that is not in compliance with state or federal regulations or the CIA and that significantly affects patient care made by the Executive Director or other individuals at the regional, divisional or corporate level, and is unable to resolve the issue through the normal chain of responsibility, then that person must immediately call the hotline and the Monitor. Nothing in this subsection prohibits or prevents such person from contacting the hotline or the Monitor without first going through the normal chain of responsibility;

h. Measures designed to inform Covered Persons of the staffing requirements of federal and state law;

i. Measures to inform Covered Persons during orientation and during other training required by this CIA that staffing levels are a critical aspect of patient and resident care, and that if any person has a concern about the level of staffing, there are many avenues available to report such concerns, including, but not limited to, the Executive Director, the Hotline, individuals at the regional, divisional, or corporate level, or directly to the Integrity Services Officer or Monitor;

j. Measures designed to minimize the number of individuals working at Lawrenceville who are on a temporary assignment or not employed by Lawrenceville (not including those persons who are included in the definition of Covered Persons) and measures designed to create and maintain a standardized system to track the number of individuals at Lawrenceville who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Lawrenceville or the Monitor;

k. Measures designed to ensure that all Lawrenceville residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;

l. Measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes, regulations, and the CIA, by including such adherence as a significant factor in evaluating the performance and compensation of the Executive Director and the director of nursing of Lawrenceville, and the individuals responsible for such compliance at the regional, divisional and corporate level;

m. Measures designed to ensure cooperation by Lawrenceville, Life Care, and their Covered Persons with the Independent Monitor in the performance of his or her duties as set forth *infra*;

n. Measures designed to ensure that compliance issues are identified internally (*e.g.*, through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CMS quality indicators, facility-specific key indicators, or internal surveys) or externally (*e.g.*, through CMS or state survey agency reports, consultants, or Monitor's Reports) and are promptly and appropriately investigated and, that if the investigation substantiates compliance issues, Lawrenceville implements effective and timely corrective action plans and monitors compliance with such plans;

o. Measures designed to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred;



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

q. Measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews;

r. Nonretaliation policies and method for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by this CIA;

s. Disciplinary guidelines to reflect the Code of Conduct requirements as specified in this CIA; and

t. Measures designed to ensure that Life Care and Lawrenceville have a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. The reports required under this system shall be of a nature to allow the Performance Improvement Committee meaningful information to be able to determine: 1) if there is a quality of care problem; and 2) the scope and severity of the problem.

### **C. Training and Education.**

Lawrenceville and Life Care shall continue to conduct training programs that meet the requirements of this CIA. Persons providing the training must be knowledgeable about the subject area covered by the training.

1. *General Training.* Within ninety (90) days after the Effective Date of this CIA, Lawrenceville and Life Care shall provide general training to each Covered Person. This general training shall explain:

a. the CIA requirements;

b. Life Care's Integrity Services Program (including the Policies and Procedures as they pertain to general compliance issues); and

c. Life Care's Code of Conduct.

These training materials shall be made available to OIG, upon request. New Covered Persons shall receive the general training described above during orientation, but

not later than thirty (30) days after the beginning of their employment or within ninety (90) days after the Effective Date of this CIA, whichever is later. Each year, every Covered Person shall receive such general training on an annual basis.

2. *Specific Training.* Within ninety (90) days after the Effective Date of this CIA, Lawrenceville and Life Care shall initiate specific training of certain designated Covered Persons, as set forth in this Paragraph. Covered Persons who are involved directly or indirectly in the delivery of resident care at Lawrenceville (including individuals who are responsible for performance improvement, setting policies or procedures, or making staffing decisions) shall receive at least eight hours of specific training pertinent to their responsibilities (as described below) in addition to the general training required above. This training, which shall be completed within one (1) year after the Effective Date of this CIA and conducted at least annually thereafter, shall include a discussion of the policies and procedures set forth in Section III.B, including, but not limited to:

a. the documentation of accurate information regarding services rendered to Medicare beneficiaries and/or Medicaid recipients, including, but not limited to, the requirements for an accurate clinical assessment, if relevant to the person's duties;

b. policies, procedures, and other requirements applicable to the documentation of medical records, if relevant to the person's duties;

c. the personal obligation of each individual involved in the resident care processes to confirm that such records are accurate;

d. applicable Federal health care program requirements, including requirements relating to quality of care, if relevant to the person's duties;

e. the legal sanctions for improper submissions to Federal health care programs; and

f. if relevant to the person's duties, the coordinated interdisciplinary approach to providing care to residents, including, but not limited to, resident assessment and the requirements of 42 C.F.R. Part 483.

New Covered Persons working at Lawrenceville shall have begun to receive this training within thirty (30) days after the beginning of their employment, and shall have completed this specific training within ninety (90) days after the beginning of their employment. New Covered Persons involved in the delivery of resident care shall be adequately supervised by trained employees until they have completed the specific

training relevant to their duties or as allowed by their license or certification.

In addition to the specific training described above, Lawrenceville and Life Care shall conduct periodic training on an “as needed” basis (but at least semi-annually) on those quality of care issues identified by the Performance Improvement Committee. In determining what training should be performed, the Committee shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other such private agencies, any internal surveys, the CMS quality indicators, and the findings, reports and recommendations of the Monitor appointed pursuant to section III.D. Such training shall be for a minimum of four (4) hours total annually. Such training shall be provided to all Covered Persons at the facility who are responsible for patient or resident care.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Integrity Services Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG upon request.

4. *Prior Training.* Training of any type provided to affected Covered Persons within six (6) months prior to the Effective Date of this CIA that meets the requirements of Section IV.E.3.b shall be deemed to meet the time frame obligation imposed by this Paragraph.

#### **D. Independent Monitor.**

1. *Appointment and Costs.* Within sixty (60) days after the Effective Date of this CIA, Life Care and Lawrenceville shall engage an appropriately qualified monitoring team (collectively the “Monitor”), appointed by the OIG after consultation with Life Care and Lawrenceville. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor’s obligations under this CIA. The Monitor shall charge a reasonable amount for his or her fees and expenses, which shall not exceed \$125,000.00 per year unless the OIG, after consultation with Lawrenceville and Life Care, determines that circumstances necessitate additional expenditures. Life Care and Lawrenceville shall be responsible for all reasonable costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, and out of pocket expenses. Failure to pay the Monitor within thirty (30) calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CIA and shall subject Life Care and Lawrenceville to one or more of the remedies set forth in Section

V. *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, Life Care and Lawrenceville shall retain another Monitor appointed by the OIG, with the same functions and authorities. At the end of 36 months after the Effective Date of this CIA, the OIG will review the need for a Monitor and, in its sole discretion, the OIG may release Lawrenceville and Life Care from the remaining 24 months of the Monitor obligations set forth in this CIA. The OIG's decision whether to release Lawrenceville from its Monitor obligations is non-reviewable.

2. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:

a. Life Care's and Lawrenceville's internal quality control systems, including, but not limited to:

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

(2) whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and

(3) whether the training programs are effective and thorough.

b. Life Care's and Lawrenceville's response to quality of care issues at Lawrenceville, which shall include an assessment of:

(1) Life Care's and Lawrenceville's ability to identify the problem;

(2) Life Care's and Lawrenceville's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;

(3) Life Care's and Lawrenceville's ability to create a corrective action plan to respond to the problem;

(4) Life Care's and Lawrenceville's ability to execute the corrective action plan; and

(5) Life Care's and Lawrenceville's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.

c. Life Care's and Lawrenceville's development and implementation of corrective action plans and the timeliness of such actions;

d. Life Care's and Lawrenceville'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 Life Care and Lawrenceville and set forth in this CIA.

3. *The Monitor shall have:*

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

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

c. immediate access to patients, residents, and Covered Persons for interviews outside the presence of Life Care's and Lawrenceville 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.

4. *Life Care's and Lawrenceville's Obligations.* Life Care and Lawrenceville shall:

- a. ensure the Monitor's immediate access to Life Care and Lawrenceville, individuals, and documents, and assist in obtaining full cooperation by Covered Persons;
- b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
  - (1) Deaths or injuries related to use of restraints;
  - (2) Deaths or injuries related to use of psychotropic medications;
  - (3) Suicides;
  - (4) Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines);
  - (5) Fires, storm damage, flooding, or major equipment failures at Lawrenceville;
  - (6) Strikes or other work actions;
  - (7) Manmade disasters that pose a threat to residents (*e.g.*, toxic waste spills); and
  - (8) Any other incident that involves or causes actual harm to a resident when such incident prompts a full internal investigation. Each such report shall contain the full name, social security number, and date of birth of the resident(s) involved, the date of death or incident, and a brief description of the events surrounding the death or incident.
- c. assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, and their families;
- d. provide access to current residents and patients, and contact

information for their families and guardians, and not impede their cooperation with the Monitor;

e. provide to the Performance Improvement Committee copies of all documents and reports provided to the Monitor;

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

g. address any written recommendation made by the Monitor either by substantially implementing the Monitor's recommendations or by explaining in writing why they have elected not to do so;

h. pay the Monitor's bills within 30 days of receipt. While Life Care and Lawrenceville must pay all the Monitor's bills within 30 days, Life Care and Lawrenceville may bring any disputed Monitor's Costs or bills to OIG's attention; and

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

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

a. respect the legal rights, privacy, and dignity of all Covered Persons, residents, and patients;

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

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

d. simultaneously provide quarterly reports to Life Care, Lawrenceville and OIG concerning the findings made to date. The Monitor may confer and correspond with Lawrenceville and OIG on an *ex parte* basis;

e. submit bills to Life Care and Lawrenceville on a consolidated

basis no more than once per month, and submit an annual summary representing accounting of its costs throughout the year to Life Care and Lawrenceville and to OIG. The Monitor shall submit to Life Care, Lawrenceville and the OIG an annual report representing an accounting of its costs throughout the year;

f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Lawrenceville, and Life Care and Lawrenceville 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 Life Care and Lawrenceville from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

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

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

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

j. visit Life Care and Lawrenceville as often as the Monitor believes it necessary to perform its functions; and

k. If the Monitor has concerns about corrective action plans



that are not being enforced or systemic problems that could affect Life Care's and Lawrenceville's ability to render quality care to patients and residents of Lawrenceville, then the Monitor shall: a) report such concerns in writing to an interagency Consortium consisting of representatives of OIG, CMS, the Department of Justice, and the state survey agency; and b) provide notice and a copy of the report to Life Care's Board of Directors.

**E. Disclosure System.**

Life Care has established a Disclosure System applicable to Lawrenceville and all Covered Persons, which includes a toll-free telephone Hotline. The Disclosure System enables any individual to disclose to the Integrity Services Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Life Care's policies, practices or procedures with respect to quality of care or to a Federal health care program. Life Care shall continue to publicize the existence of the Hotline, and, at a minimum, shall post it prominently throughout Lawrenceville and publicize it in training and newsletters to employees.

The Disclosure System shall continue to emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Integrity Services Officer (or designee) shall gather all relevant information from the disclosing individual. The Integrity Services 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, Lawrenceville shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Integrity Services Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

**F. Ineligible Persons.**

1. *Definitions.* For purposes of this CIA:
  - a. "Ineligible Person" shall include an individual or entity who:

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

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

b. "Exclusion Lists" include:

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

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

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

2. *Screening Requirements.* Life Care and Lawrenceville shall ensure that all Screened Persons are not Ineligible Persons, by continuing the following screening requirements.

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

b. Life Care and Lawrenceville shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

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

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

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

#### **G. Notification of Government Investigation or Legal Proceedings.**

Within 30 days after discovery, Life Care and Lawrenceville shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Life Care and Lawrenceville conducted or brought by a governmental entity or its agents involving an allegation that Life Care or Lawrenceville 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. Life Care and Lawrenceville shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

#### **H. Reporting.**

##### 1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Lawrenceville or Life Care has received in excess of the amount due and payable under any Federal health care program requirements for services rendered to residents of Lawrenceville.

b. *Reporting of Overpayments.* If, at any time, Lawrenceville or Life Care identifies or learns of any Overpayment, Lawrenceville or Life Care shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification

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

2. *Reportable Events.*

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

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

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

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

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

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

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

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

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

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

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

In the event that, after the Effective Date, Lawrenceville changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Life Care and Lawrenceville shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

##### **A. Implementation Report.**

Within one hundred and twenty (120) days after the Effective Date of this CIA, Lawrenceville and Life Care shall submit a written report to OIG summarizing the status of their 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 this CIA, and a summary of other noncompliance job responsibilities the Integrity Services Officer may have;

2. the program for internal reviews required in this CIA;

3. a copy of Life Care's Code of Conduct required by this CIA;

4. the number of individuals required to complete the Code of Conduct certification required by this CIA, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

5. the summary of the Policies and Procedures required by this CIA;

6. the following information regarding each type of training required by this CIA:

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

ii. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the Disclosure Program required by this CIA;

8. a description of the process by which Lawrenceville fulfills the requirements of this CIA A regarding Ineligible Persons;

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

10. a list of all of Lawrenceville's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider

number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Lawrenceville currently submits claims;

11. a description of Lawrenceville's and Life Care's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

12. the certifications required by this CIA.

**B. Annual Reports.**

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

1. any change in the identity or position description of individuals in positions described in this CIA, a change in any of the committees' structure or charter, any change in the internal review program, or any change in the quality of care infrastructure;

2. the number of individuals required to complete the Code of Conduct certification required by this CIA, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

3. the following information regarding each type of training required by this CIA:

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

b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

4. a summary of the findings of all reviews undertaken by the Performance Improvement Committee, and a summary of the corrective actions taken under the program for internal reviews;

5. Life Care's and Lawrenceville's response/corrective action plan to any issues raised by the Monitor;

6. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Life Care or Lawrenceville has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to this CIA. 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;

7. a summary of Reportable Events (as defined in this CIA) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

8. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

9. a summary of the disclosures in the disclosure log required by this CIA that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. any changes to the process by which Life Care and Lawrenceville fulfills the requirements of this CIA regarding Ineligible Persons; and

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

The first Annual Report shall be received by OIG no later than one (1) year and one hundred and twenty (120) 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. Certifications.** The Implementation Report and Annual Reports shall



include a certification by the Integrity Services Officer, under penalty of perjury, that:

1. Life Care and Lawrenceville are in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and

2. the Integrity Services Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing subsequent to the Effective Date 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  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Lawrenceville and Life Care: Patricia Combs, R.N.  
Interim Integrity Services Officer  
Life Care Centers of America, Inc.  
3001 Keith Street, NW  
Cleveland, TN 37320-3480  
Telephone: 423.473.5598  
Facsimile: 423.339.8318

Life Care and Lawrenceville shall provide OIG with any changes to the above information within thirty (30) days of any such change. Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received.

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

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

Life Care and Lawrenceville shall maintain for inspection all documents and records relating to compliance with this CIA, one (1) 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 Life Care and Lawrenceville prior to any release by OIG of information submitted by Life Care and Lawrenceville pursuant to their obligations under this CIA and identified upon submission by Life Care or Lawrenceville as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Life Care and Lawrenceville 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. OIG BREACH AND DEFAULT REMEDIES**

In addition to and as an independent alternative to the United States' judicial

enforcement remedies set forth in the Stipulated Consent Order, the OIG may seek one or more of the following contractual remedies for breach of the CIA. The contractual remedies set forth below need not be exhausted prior to the United States' exercise of one of the judicial enforcement remedies set forth in the Stipulated Consent Order.

**A. Stipulated Penalties for Failure to Comply with Certain Obligations.**

As a contractual remedy, Life Care and Lawrenceville and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the OIG's imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Life Care or Lawrenceville fails to maintain any of the following obligations as described in this CIA:

- a. an Integrity Services Officer;
- b. a program for performing internal reviews;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a Training Program for Covered Persons;
- f. a Disclosure Program;
- g. retention and payment of a Monitor;
- h. Ineligible Persons screening and removal requirements; or
- i. notification of government investigations or legal

proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Life Care or Lawrenceville fails to meet any of the deadlines (or any extension granted by OIG) to submit the Implementation Report or the Annual Reports to OIG.

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

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

5. A Stipulated Penalty of \$5,000 (which shall begin to accrue ten (10) days after the date OIG provide notice to Life Care of the failure to comply) for each day Life Care or Lawrenceville 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 the notice to Life Care, the OIG shall state the specific grounds for their determination that Life Care or Lawrenceville has failed to comply fully and adequately with the CIA obligation(s) at issue.

6. A Stipulated Penalty of \$2,500 (which shall begin to accrue ten (10) days after the date OIG provide notice to Life Care of the failure to comply) for each day Life Care or Lawrenceville fails to comply fully and adequately with any of its obligations under the CIA, including those with respect to the Monitor. In the notice to Life Care, the OIG shall state the specific grounds for its determination that Life Care or Lawrenceville has failed to comply fully and adequately with the CIA obligation(s) at issue.

#### **B. Payment of Stipulated Penalties**

1. *Demand Letter.* Upon a finding that Life Care or Lawrenceville has failed to comply with any of the obligations described in Section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Life Care by personal service or certified mail of: (a) Life Care or Lawrenceville'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, Life Care 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 this CIA. In the event Life Care elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Life Care cures, to the OIG's satisfaction, the alleged breach in dispute; however, the payment of such accrued Stipulated Penalties shall not be required until the ALJ determination. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall cause the penalty to be final, due and pending.

2. *Timely Written Requests for Extensions.* Life Care or Lawrenceville 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 Life Care or Lawrenceville 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 Life Care or Lawrenceville 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 Life Care or Lawrenceville 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.

### C. Exclusion for Material Breach

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Life Care or Lawrenceville constitutes an independent basis for Life Care's or Lawrenceville'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 Life Care or Lawrenceville has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Life Care and Lawrenceville by certified mail of: a) Life Care or Lawrenceville's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (Notice of Material Breach and Intent to Exclude). Depending upon the facts of the breach, the OIG, in its sole discretion, may direct the exclusion at Lawrenceville or Life Care.

2. *Opportunity to cure.* Life Care and Lawrenceville 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. Life Care and Lawrenceville are in full compliance with this CIA;
- b. The alleged material breach has been cured; or
- c. The alleged material breach cannot be cured within the thirty

five (35) day period, but that: (1) Life Care or Lawrenceville has begun to take action to cure the material breach; (2) Life Care or Lawrenceville is pursuing such action with due diligence; and (3) Life Care or Lawrenceville 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, Life Care and/or Lawrenceville fail to satisfy the requirements of this CIA, OIG may exclude Life Care and/or Lawrenceville from participation in the Federal health care programs. OIG shall notify Life Care and/or Lawrenceville in writing of their determination to exclude Life Care and/or Lawrenceville (Exclusion Letter). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. If Life Care or Lawrenceville is excluded under the provisions of this CIA, Life Care or Lawrenceville 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 CIA that has a material impact on the quality of care rendered to any residents or patients of Lawrenceville;
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C above; or
- d. a failure to retain, pay or use the Monitor in accordance with this CIA.

#### **D. Dispute Resolution**

1. *Review Rights.* Upon the OIG's delivery to Life Care or Lawrenceville of its Demand Letter or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Life Care and Lawrenceville 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 Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, an action for 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©, a request for a hearing involving 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. *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 Life Care and Lawrenceville were in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Life Care and Lawrenceville shall have the burden of proving their 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 Life Care or Lawrenceville to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Life Care or Lawrenceville may request review of the ALJ decision by the DAB.

3. *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 Life Care or Lawrenceville was in material breach of this CIA; b) whether such breach was continuing on the date of the Exclusion Letter; and c) the alleged material breach cannot be cured within the 35 day period, but that (1) Life Care or Lawrenceville has begun to take action to cure the material breach, (2) Life Care or Lawrenceville is pursuing such action with due diligence, and (3) Life Care or Lawrenceville 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. Life Care or Lawrenceville's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude

Life Care or Lawrenceville 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 Life Care or Lawrenceville may request review of the ALJ decision by the DAB.

4. *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 Life Care and Lawrenceville agree to waive any right they may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

5. *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 Life Care and Lawrenceville's compliance with applicable state and Federal health care program requirements.

#### **XI. EFFECTIVE AND BINDING AGREEMENT**

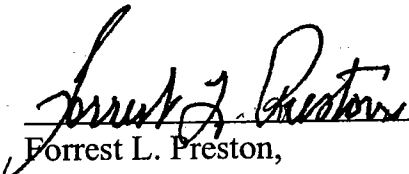
A. This CIA shall be binding on the successors, assigns, and transferees of Lawrenceville and Life Care;

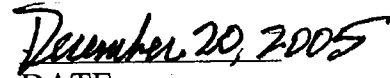
B. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

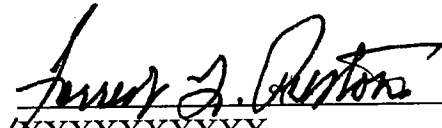
C. The undersigned Lawrenceville and Life Care signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

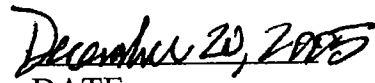


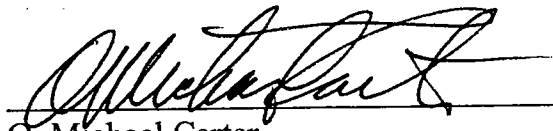
ON BEHALF OF LAWRENCEVILLE AND LIFE CARE

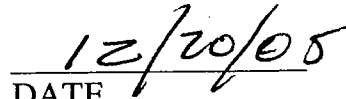
  
\_\_\_\_\_  
Forrest L. Preston,  
Individually and as  
Chairman and CEO of Life Care Centers of America, Inc.

  
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DATE


  
\_\_\_\_\_  
XXXXXXXXXXXX  
Life Care Centers of Lawrenceville

  
\_\_\_\_\_  
DATE

  
\_\_\_\_\_  
O. Michael Carter,  
Counsel for Life Care and Lawrenceville

  
\_\_\_\_\_  
DATE

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



\_\_\_\_\_  
LEWIS MORRIS  
Chief Counsel to the Inspector General  
U. S. Department of Health and Human Services

12/20/05  
DATE