CORPORATE INTEGRITY AGREEMENT

BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

TWIN OAKS NURSING HOME, INC.

I. PREAMBLE

Twin Oaks Nursing Home, Inc. ("Twin Oaks") 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 Twin Oaks, its directors, officers, employees, physicians and other health care professionals, and contractors and agents 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"). Twin Oaks' compliance with the terms and conditions in this CIA shall constitute an element of Twin Oaks' present responsibility with regard to participation in the Federal health care programs.

Further, Twin Oaks acknowledges its accountability for the health and safety of its patients and residents. The employees, contractors, and agents covered under this CIA are those who: (1) perform patient care or resident care duties; (2) make assessments of patients or residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, patient care, resident care, reimbursement, policies and procedures, or this CIA; or (5) perform any function that relates to or is covered by this CIA (hereinafter, "Covered Persons").

II. TERM OF THE CIA

The period of the compliance obligations assumed by Twin Oaks under this CIA shall be 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 of this CIA executes the CIA. Sections VII, VIII, IX, X and XI shall remain in effect until Twin Oaks submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

Twin Oaks shall establish a compliance program that includes the following elements.

A. <u>Compliance Officer, Committees, and Internal Audit or Review Functions.</u>

- Oaks 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 Twin Oaks (*i.e.*, not subordinate to Twin Oaks' general counsel or chief financial officer), shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Twin Oaks, 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 Twin Oaks 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, Twin Oaks shall notify the OIG, in writing, within fifteen (15) days of such a change.
- 2. Compliance Committee. To the extent not already established, Twin Oaks shall establish a Quality Assurance Compliance Committee within 120 days of the effective date of this CIA. The purpose of this Compliance Committee shall be to address issues concerning quality of care at Twin Oaks. At a minimum, the Committee shall include the Compliance Officer, the Chief Medical Officer, and the senior executives responsible for clinical operations for the nursing home, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA that relate to quality of care in the nursing facility.
- 3. Internal Audit and Review Functions. Within 120 days of the effective date of this CIA, Twin Oaks shall 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 Twin Oaks 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 120 days of the effective date of this CIA, Twin Oaks shall establish a Code of Conduct and distribute it to all Covered Persons. Twin Oaks shall make adherence to the Code of Conduct an element in evaluating the performance of Covered Persons. The Code of Conduct shall, at a minimum, set forth:
 - a. Twin Oaks' 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 Center for Medicare and Medicaid Services ("CMS") (or other appropriate regulatory agencies) and/or fiscal intermediaries or carriers;
 - b. Twin Oaks' requirement that all of its Covered Persons shall be expected to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Twin Oaks's own policies and procedures (including the requirements of this CIA);
 - c. the requirement that all of Twin Oaks' Covered Persons shall be expected to report internally, within 30 days, suspected violations of any statute, regulation, directive, or guideline applicable to Federal health care programs or of Twin Oaks' own policies and procedures; if there are credible allegations of patient harm, such report shall be made immediately;

- d. the possible consequences to both Twin Oaks and any Covered Person of failure to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Twin Oaks' own policies and procedures or of failure to report such non-compliance; and
- e. the right of all Covered Persons to use the confidential disclosure program, as well as Twin Oaks' commitment to confidentiality and non-retaliation with respect to disclosures.

Within 120 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Twin Oaks' Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after the commencement of their appointment, employment, or contract or within 120 days of the effective date of the CIA, whichever is later.

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

- 2. Policies and Procedures. Within 120 days of the effective date of this CIA, Twin Oaks shall develop and initiate implementation of written Policies and Procedures regarding the operation of Twin Oaks' 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, Twin Oaks' Policies and Procedures shall specifically address:
 - a. Measures designed to ensure that Twin Oaks 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 Twin Oaks complies with all requirements applicable to Medicare's Prospective Payment System ("PPS") for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set ("MDS") as specified by the Resident Assessment Instrument User's Manual; ensuring that Twin Oaks is appropriately and accurately using the current Resource Utilization Groups

- ("RUG") classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;
- c. Measures designed to ensure the coordinated interdisciplinary approach to providing care to nursing home residents, including, but not limited to, resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; protection from harm procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; activities of daily living ("ADL") care; therapy services; quality of life, including accommodation of needs and activities; and assessment of resident competence to make treatment decisions;
- d. Measures designed to ensure that Twin Oaks 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 Twin Oaks 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 Twin Oaks 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;
- h. Measures designed to ensure that Twin Oaks adequately supervises, monitors and safeguards all residents, including those with histories of exhibiting behaviors that cause injury to themselves or others;
- i. Measures designed to ensure that residents shall be protected from being victimized by other aggressive residents;

- j. Measures designed to ensure that staff members provide residents with appropriate basic care services that meet the residents' individual needs:
- k. 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;
- 1. Measures designed to ensure that Twin Oaks 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;
- m. Measures designed to ensure that Twin Oaks 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;
- n. 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;
- o. Measures designed to ensure that appropriate physicians' orders are obtained and followed before physical restraints are used;
- p. 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;
- q. Measures designed to ensure that residents receive adequate preventive, chronic, routine, acute, follow-up, and emergency medical care in accordance with generally accepted standards of care, and that residents receive the necessary health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Such measures shall include the following:

- i. Physicians promptly obtain and review all laboratory and test results, document the responses in the residents' charts and take appropriate actions to address any abnormal results;
- ii. Physicians complete monthly notes in the residents' charts on a timely basis;
- iii. Physicians do not rely inappropriately on telephone orders in treating residents;
- iv. Physicians address promptly residents' significant or undesirable weight loss and personally provide continual follow-up until the situation is adequately addressed;
- v. Health care of all diabetic residents comports with generally accepted medical practice;
- vi. All individuals with seizure disorders are provided with adequate and appropriate seizure management in accordance with accepted professional standards of care and with adequate and appropriate seizure documentation and with adequate and appropriate diagnostic techniques;
- vii. Residents currently receiving anti-convulsant medication, receive the type of medication(s) that is (are) appropriate and effective for the type of seizure and represents the fewest number of medications appropriate for effective seizure management;
- viii. There are a sufficient number of neurology consult hours to meet the needs of the residents and to provide each resident with a seizure disorder with a neurology review every 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.
- r. 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;
- s. Measures designed to ensure that discharges are made without regard to financial status or reimbursement source;
- t. 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;
- u. Measures that specify that if the director of nursing (or other person who is making staffing decisions at the facility) 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;

- v. Measures designed to minimize the number of individuals working at any Twin Oaks facility who are on a temporary assignment or not employed by Twin Oaks. 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;
- w. Measures designed to ensure that clinical assessments are made without regard to the reimbursement amount;
- x. Measures designed to ensure that all residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;
- y. 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;
- z. 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 facility, and the individuals responsible for such compliance at the district, regional, and corporate level;
- aa. Measures designed to ensure cooperation by Twin Oaks and its employees, contractors, and agents with the Monitor in the performance of his or her duties as set forth *infra*; and
- bb. 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, audits performed by the Independent Review Organization, or Monitor's reports) are promptly and appropriately investigated and, if the investigation substantiates compliance issues, Twin Oaks 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 Twin Oaks has corrected the survey

deficiencies noted and has achieved substantial compliance with the Medicare and Medicaid conditions of participation.

Twin Oaks 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 120 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all appropriate Covered Persons. Compliance staff or supervisors shall be available to explain any and all policies and procedures.

C. Training and Education.

- 1. General Training. Within 120 days of the effective date of this CIA, Twin Oaks shall provide at least 2 hours of training to each Covered Person. This general training shall explain Twin Oaks':
 - a. Corporate Integrity Agreement requirements;
 - b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
 - c. Code of Conduct.

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

New Covered Persons shall receive the general training described above within 10 days of the beginning of their employment or within 120 days after the effective date of this CIA, whichever is later. After the first year of the CIA, every Covered Person shall receive at least 1 hour of such general training on an annual basis.

2. Specific Training. Within 120 days of the effective date of this CIA, each Covered Person who is involved directly or indirectly in the delivery of patient or resident care

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 Twin Oaks and this CIA. Twin Oaks 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 Twin Oaks for more than a 30 day period, regardless of how many days during that period the person is actually present in the facility, must complete the training requirements set forth herein.

(including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions) ("Relevant Covered Person") shall receive at least 3 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 assessment of the resident's competence to make treatment decisions.

New Relevant Covered Persons shall receive this training within 10 days of the beginning of their employment or contract or within 120 days of the effective date of this CIA, whichever is later. If a new relevant Covered Person has any responsibility for the delivery of patient or resident care, then prior to completing this specific training, a Twin Oaks Relevant Covered Person who has completed the substantive training shall review all of the untrained person's work.

After the first year of the CIA, every Relevant Covered Person shall receive 2 hours of such specific training on an annual basis.

In addition, each facility shall conduct periodic training on an "as needed" basis (but at least annually) on those quality of care issues identified by the Compliance Committee. In determining what training should be performed, the Committee 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 provided to all Relevant Covered Persons. 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 Covered Person shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the

date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

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

<u>Independent Monitor</u>. After consultation with the OIG, Twin Oaks has agreed to engage, within 30 days of execution of this CIA, Nancy K. Ray, Ed.D and Natalie J. Russo, R.N., M.A. (hereinafter collectively referred to as the "Monitor") to monitor Twin Oaks' implementation of the CIA. 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.

- 1. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
 - a. Twin Oaks' 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;
 - b. Twin Oaks' response to quality of care issues, which shall include an assessment of:
 - i. Twin Oaks' ability to identify the problem;
 - ii. Twin Oaks' ability to determine the scope of the problem, including, but not limited to, whether the problem is isolated or systemic;
 - iii. Twin Oaks' ability to create a corrective action plan to respond to the problem;
 - iv. Twin Oaks' ability to execute the corrective action plan;
 - v. Twin Oaks' ability to evaluate whether the assessment, corrective action plan and execution of that plan were effective, reliable, and thorough.
 - vi. Twin Oaks' development and implementation of corrective action plans and the timeliness of such actions; and

vii. Twin Oaks' 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 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 Twin Oaks and set forth in this CIA.

2. The Monitor shall have:

- a. immediate access to facility, 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 CHSRA quality indicators; (2) internal or external surveys or reports; (3) hotline complaints; (4) resident satisfaction surveys; (5) staffing data in the format requested by the Monitor, including reports of the facility where more than 10 percent of the staff are hired on a temporary basis; (6) reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment; (7) reports of any incident involving a patient or resident that prompts a full internal investigation; (8) patient or resident records; (9) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (10) any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA; and
- c. immediate access to patients, residents, and staff for interviews outside the presence of Twin Oaks supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident or patient.

3. Twin Oaks shall:

a. ensure the Monitor's immediate access to the facility, individuals, and documents Twin Oaks is required to maintain pursuant to this CIA and/or as a participant in the Federal health care programs, and assist in obtaining full cooperation by its current Covered Persons;

- b. provide the Monitor a report within 48 hours regarding any of the following occurrences:
 - i. Deaths or injuries related to use of restraints;
 - ii. Deaths or injuries related to use of psychotropic medications;
 - iii. Suicides;
 - iv. Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines);
 - v. Fires, storm damage, flooding, major equipment failures at the facility;
 - vi. Strikes or other work actions:
 - vii. Manmade disasters that pose a threat to residents (e.g., toxic waste spills); and
 - viii. 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.

- c. assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, their families and Twin Oaks;
- d. provide access to current residents, patients, their families, and Twin Oaks; and
- e. provide to its Quality Assurance Compliance Committee copies of all documents and reports provided to the Monitor.
- 4. The Monitor shall respect the legal rights, privacy, and dignity of all residents, patients, and employees.
- 5. It is the intent of the parties to this CIA that the Monitor and Twin Oaks work cooperatively together to assure compliance with this CIA and to improve the quality of care at Twin Oaks.

- 6. In performing the functions as set forth herein, the Monitor shall seek to work collaboratively with Twin Oaks and consult with designated Twin Oaks representatives and independent physicians and other health care professionals, where appropriate. In connection with each review, the Monitor shall advise Twin Oaks orally, except if inappropriate, and in writing, if appropriate, concerning the status of its compliance efforts, any steps that he or she believes Twin Oaks should take to enhance its performance, and whether Twin Oaks' performance is satisfactory.
- 7. The Monitor shall charge a usual and customary rate for his or her fees and expenses. Twin Oaks shall be responsible for all costs reasonably incurred by the Monitor relating directly to this matter, including, but not limited to, travel expenses, consultants, administrative and other personnel, office supplies and equipment. Such costs, including consultant fees, may not exceed \$50,000 annually. Twin Oaks shall pay the Monitor within 20 calendar days of submission of his or her invoices. Twin Oaks shall have the right to audit the Monitor's invoices and to present to the OIG any challenge to the appropriateness of expenses incurred. In the event that the OIG agrees with Twin Oaks as to the challenged amount, Twin Oaks shall be entitled to a refund of the amount at issue from the Monitor. Such refund shall be paid by the Monitor within 20 calendar days of notification by the OIG as to its decision.
- 8. The Monitor shall visit Twin Oaks approximately once every three months until the CIA is terminated or at more or less frequent intervals at the option of the Monitor, depending upon Twin Oaks' performance under this CIA and depending upon the Monitor's needs in performing his or her functions under the CIA. In the event that the OIG determines that Twin Oaks has made satisfactory progress in implementing the CIA, it may in its sole discretion reduce the frequency of the Monitor's visits to twice a year.
- 9. Twin Oaks shall have the right to present its position to the OIG with respect to any reports issued by the Monitor. The OIG, the Monitor and Twin Oaks shall meet at least semi-annually, and more often, if appropriate, to discuss the status of Twin Oaks' compliance with the terms of this CIA. Except as otherwise provided herein, the Monitor may confer and correspond with Twin Oaks and the OIG on an *ex parte* basis.
- 10. The Monitor shall submit reports within 48 hours (or earlier if necessary to protect the health and safety of a patient or resident or otherwise mandated by law) to OIG, Twin Oaks, the state survey agency,² and any other appropriate regulatory or law enforcement entity, any time he or she has concerns regarding the health or safety of the residents or patients and such concerns create an obligation to report under Federal, state, or local law or professional licensing standards.

²As defined in 42 CFR § 488.1 (2000).

- 11. The Monitor shall provide quarterly reports to Twin Oaks and OIG concerning the findings made to date.
- 12. The Monitor shall submit to OIG and Twin Oaks an annual report representing an accounting of its costs throughout the year.
- 13. The Monitor is not bound by any other agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state survey agency.
- 14. The Monitor must promptly report to appropriate regulatory or law enforcement entities when warranted.
- 15. If the Monitor has concerns about corrective action plans that are not being enforced or systemic problems that could affect Twin Oaks' ability to render quality care to its patients and residents, then the Monitor shall: 1) report such concerns in writing to an interagency Consortium consisting of representatives of OIG, CMS, the Department of Justice, and the state survey agency; and 2) provide notice and a copy of the report to the President and CEO of Twin Oaks.
- 16. If the Monitor resigns or if the OIG approves of the removal of the Monitor for any reason prior to the termination of the CIA, Twin Oaks shall, after consultation with and receiving approval from the OIG, engage another Monitor with the same functions and authorities.

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

Within 90 days of the effective date of the CIA, Twin Oaks shall establish a 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 Twin Oaks' 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. Twin Oaks 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 its facility.

The 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, Twin Oaks shall conduct an internal review of the

allegations set forth in such a disclosure and ensure that proper follow-up is conducted, including that the inappropriate or improper practice ceases immediately.

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each allegation received, 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. Twin Oaks shall not hire or engage as health care service providers any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Twin Oaks shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

In addition, Twin Oaks 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 of the effective date of this CIA, Twin Oaks will review its list of current employees and contractors against the Exclusion Lists. Thereafter, Twin Oaks will review the list annually. If Twin Oaks has notice that an employee or contractor has become an Ineligible Person, Twin Oaks will remove such person from responsibility for, or involvement with, Twin Oaks' 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 Twin Oaks 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, Twin Oaks 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 of discovery, Twin Oaks 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 Twin Oaks 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. Twin Oaks shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. <u>New Business Units or Locations</u>

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

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within 120 days after the effective date of this CIA, Twin Oaks shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:
- 1. the name, address, phone number and position description of all individuals in positions described in section III.A;
 - 2. the program for internal audits and reviews required in section III.A;
 - 3. a copy of Twin Oaks' Code of Conduct required by section III.B.1;
 - 4. the summary of the Policies and Procedures required by section III.B.2;
- 5. a description of the training programs required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;

- 6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been made available to all pertinent Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
 - c. all Covered Persons have completed the training and executed the certification required by section III.C.
- 7. a description of the disclosure program required by Section III.E;
- 8. a summary of personnel actions (other than hiring) taken pursuant to section III.F; and
- 9. a list of all of Twin Oaks' 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>. Twin Oaks shall submit to OIG an Annual Report with respect to the status and findings of Twin Oaks' 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 committee's structure or charter, or any change in the internal audit and review program;
 - 2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1;
 - b. all Covered Persons have completed the training and executed the certification required by section III.C; and
 - c. Twin Oaks has effectively implemented all plans of correction related to problems identified under this CIA, Twin Oaks' 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 findings of any audit or review, and a summary of the corrective action taken under the program for internal audits and reviews;
- 5. Twin Oaks' response/corrective action plan to any issues raised by the Monitor;
- 6. a copy of the disclosure log required by section III.E (excluding any calls that relate solely to human resources issues);
- 7. a description of any personnel action (other than hiring) taken by Twin Oaks 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 Twin Oaks has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information; and
- 9. a description of all changes to the most recently provided list (as updated) of Twin Oaks' locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each locations' Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and 90 days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by Twin Oaks' President and Chief Executive Officer that, except as otherwise described in the applicable report: (1) Twin Oaks 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 has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful. Each Report shall also include a resolution (or its equivalent) from Twin Oaks' Board of Directors certifying that he has reviewed the Annual Report and agree with the statements made therein.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Civil Recoveries Branch - Compliance Unit

Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

Cohen Building, Room 5527 330 Independence Avenue, SW

Washington, DC 20201 Phone 202.619.2078 Fax 202.205.0604

Twin Oaks:

Twin Oaks Nursing Home, Inc.

506 West 5th Street LaPlace, LA 70068

Attn: Guy Burch, Compliance Officer

Ph: 985-652-9538 Fax: 985-652-8949

With a copy to:

Twin Oaks Nursing Home, Inc. 3127 Harvard Avenue, Suite 201

Metairie, LA 70006

Attn: Henry Burch, President and CEO

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 Twin Oaks' books, records, and other documents and supporting materials and/or conduct an onsite review of Twin Oaks' operations for the purpose of verifying and evaluating: (a) Twin Oaks' compliance with the terms of this CIA; and (b) Twin Oaks' compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Twin Oaks 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 Twin Oaks' employees, contractors, or agents who consent to be interviewed at the individuals's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, contractor, or agent and OIG. Twin Oaks agrees to assist OIG in contacting and arranging interviews with such employees, contractors, or agents

upon OIG's request. Twin Oaks' employees, and the contractors and agents may elect to be interviewed with or without a representative of Twin Oaks present.

VIII. DOCUMENT AND RECORD RETENTION

Twin Oaks shall maintain for inspection all documents and records relating to compliance with this CIA for six years (or longer if otherwise required by law).

IX. <u>Disclosures</u>

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

Twin Oaks 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 Twin Oaks 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 Twin Oaks with prompt written notification of such determination ("Noncompliance Notice"). Twin Oaks will have 35 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; (2) demonstrate that to the OIG's satisfaction that the alleged breach for which the OIG seeks specific performance cannot be cured within the 35 day period, but that: (i) Twin Oaks has begun to take action to cure the failure to comply; (ii) Twin Oaks is pursuing such action with due diligence; and (iii) Twin Oaks has provided to OIG a reasonable timetable for curing the alleged breach for which the OIG seeks specific performance; or (3) to reply in writing that Twin Oaks disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge ("ALJ"), pursuant to the provisions set forth in section X.E of this CIA. The purpose of the hearing is to determine whether Twin Oaks has failed to comply with the CIA and whether Twin Oaks 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, Twin Oaks 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 effective date of this CIA and concluding at the end of the term of this CIA, Twin Oaks fails to have in place any of the following:
 - a. a Compliance Officer;
 - b. Compliance Committee;
 - c. a program for performing internal audits and reviews;
 - d. written Code of Conduct;
 - e. written Policies and Procedures;
 - f. a requirement that Covered Persons be trained; and
 - g. a 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 Twin Oaks 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 Twin Oaks employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Twin Oaks' 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 Twin Oaks can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that Twin Oaks fails to grant access) for each day Twin Oaks 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 Twin Oaks of the failure to comply) for each day Twin Oaks 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 Twin Oaks, the OIG shall state the specific grounds for its determination that the Twin Oaks has failed to comply fully and adequately with the CIA obligation(s) at issue. A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1- 4 or 6 of this section.
- 6. A Stipulated Penalty of \$1,000 (which shall begin to accrue 10 days after the date OIG provides notice to Twin Oaks of the failure to comply) for each day Twin Oaks fails to comply fully and adequately with any obligation of this CIA. In its notice to Twin Oaks, the OIG

shall state the specific grounds for its determination that Twin Oaks has failed to comply fully and adequately with the CIA obligation(s) at issue. A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section. With respect to the Stipulated Penalty provision described in this Section X(B)(6) only, the OIG shall not seek a Stipulated Penalty if Twin Oaks demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10 day period, but that: (i) Twin Oaks has begun to take action to cure the failure to comply; (ii) Twin Oaks is pursuing such action with due diligence; and (iii) Twin Oaks has provided to OIG a reasonable timetable for curing the alleged breach for which the OIG seeks the Stipulated Penalty.

C. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that Twin Oaks has failed to comply with any of the obligations described in section X.B and determining that Stipulated Penalties are appropriate, OIG shall notify Twin Oaks by personal service or certified mail of: (a) Twin Oaks' 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 of the date of the Demand Letter, Twin Oaks 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.E. In the event Twin Oaks elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Twin Oaks 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.

- 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 Twin Oaks 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 2 business days after Twin Oaks 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 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 Twin Oaks 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. <u>Exclusion for Material Breach of this CIA</u>

- 1. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Twin Oaks constitutes an independent basis for Twin Oaks' 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 Twin Oaks has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Twin Oaks by certified mail of: (a) Twin Oaks' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion ("Notice of Material Breach and Intent to Exclude").
- 2. Opportunity to cure. Twin Oaks shall have 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. Twin Oaks is in full compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach with this CIA;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 35 day period, but that: (i) Twin Oaks has begun to take action to cure the material breach; (ii) Twin Oaks is pursuing such action with due diligence; and (iii) Twin Oaks has provided to OIG a reasonable timetable for curing the material breach.
- 3. Exclusion Letter. If at the conclusion of the 35 day period, Twin Oaks fails to satisfy the requirements of section X.C.2, OIG may exclude Twin Oaks from participation in the Federal health care programs. OIG will notify Twin Oaks in writing of its determination to excluded Twin Oaks ("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 Twin Oaks is excluded under the provisions of this CIA, Twin Oaks 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 Twin Oaks;
 - 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 fund the Monitor in accordance with section III.D.

E. <u>Dispute Resolution</u>

- 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, Twin Oaks shall be afforded certain review rights comparable to those set forth in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the specific performance, Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, an action for specific performance, a demand for payment of Stipulated Penalties, or an action for exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), a request for a hearing involving specific performance or Stipulated Penalties shall be made within fifteen (15) days of the date of the Demand Letter, and a request for a hearing involving exclusion shall be made within 30 days of the date of the Exclusion Letter.
- 2. Specific Performance Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for specific performance of CIA provisions shall be: (a) whether, at the time specified in the Noncompliance Notice, Twin Oaks was in full and timely compliance with the obligations of this CIA for which the OIG seeks specific performance; (b) whether Twin Oaks failed to cure; and (c) whether the obligations for which the OIG seeks specific performance could not be cured within the 35 day period, but that by the end of that period: (i) Twin Oaks had begun to take action to cure the failure to comply; (ii) Twin Oaks was and is pursuing such action with due diligence; and (iii) Twin Oaks had provided to OIG a reasonable timetable for curing the alleged breach, which is being followed. Twin Oaks 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, Twin Oaks shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision notwithstanding that Twin Oaks 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 Twin Oaks was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance; and (c) with respect to a Stipulated Penalty authorized under Section X(B)(6), whether failure to comply could not be cured within the ten-day period, but that by the end of that period: (i) Twin Oaks had begun to take action to cure the failure to comply; (ii) Twin Oaks was and is pursuing such action with due diligence; and (iii) Twin Oaks had provided to OIG a reasonable timetable for curing the alleged breach, which is being followed. Twin Oaks 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 Twin Oaks to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision notwithstanding that Twin Oaks 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 Twin Oaks was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that (i) Twin Oaks has begun to take action to cure the material breach, (ii) Twin Oaks is pursuing such action with due diligence, and (iii) Twin Oaks 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. Twin Oaks' election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Twin Oaks 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 Twin Oaks 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 Twin Oaks 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 Twin Oaks' 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 Twin Oaks;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and\
- D. The undersigned Twin Oaks signatory represents and warrants that he is 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 TWIN OAKS NURSING HOME, INC.

Henry J. Burch, President and CEO

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

By:

Lewis Morris, Assistant Inspector General for Legal Affairs, Office of Inspector General,

U. S. Department of Health and Human Services

Date: 10/29/01

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