### CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
WOODBINE HEALTHCARE AND REHABILITATION CENTRE

### I. PREAMBLE

Woodbine Healthcare and Rehabilitation Centre ("Woodbine") 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 that Woodbine complies 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"). Woodbine's compliance with the terms and conditions in this CIA shall constitute an element of its present responsibility with regard to participation in the Federal health care programs.

Woodbine acknowledges its accountability for the health and safety of Woodbine's patients and residents. The requirements imposed upon Woodbine by this CIA are also imposed on all of Woodbine's management and parent organizations to the extent that they perform functions related to Woodbine, all of whom are collectively referred to herein as "Woodbine." The persons covered by this CIA are all Woodbine employees, managers, and agents¹ who: (1) perform patient care or resident care duties related to residents of Woodbine; (2) make assessments of patients or residents of Woodbine that affect treatment decisions or reimbursement; (3) make decisions or provide oversight about this CIA or about staffing, patient care, resident care, reimbursement, policies and procedures related to Woodbine (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions); or (4) perform any function that relates to or is covered by this CIA (hereinafter collectively referred to as "Covered Persons").

<sup>&</sup>lt;sup>1</sup>For purposes of this CIA, "agents" shall include anyone retained on a contractual or less than full time basis to do any of the four functions listed in the definition of "Covered Persons."

#### II. TERM OF THE CIA

The period of the compliance obligations assumed by Woodbine under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA ("Effective Date"). Sections VII, VIII, IX, X and XI shall remain in effect until Woodbine submits all information required by OIG as part of the final Annual Report.

## III. CORPORATE INTEGRITY OBLIGATIONS

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

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

- 1. Compliance Officer. Woodbine has appointed 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 an individual independent of Woodbine's Administrator with authority to exercise senior level managerial responsibilities over the Administrator. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Woodbine 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, Woodbine shall notify the OIG, in writing, within fifteen (15) days after such a change.
- 2. Compliance Committee. Woodbine shall establish a Quality Assurance Compliance Committee within ninety (90) days after the Effective Date of this CIA. The purpose of this Compliance Committee shall be to address issues concerning quality of care at Woodbine. At a minimum, the Committee shall include the Compliance Officer or his or her designee, Woodbine's Administrator, its Medical Director, its 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 at Woodbine.

- 3. Internal Audit and Review Functions. Within ninety (90) days after the Effective Date of this CIA, Woodbine shall have created a program for performing internal audits and reviews of Woodbine. The internal audits and reviews shall:
  - a. make findings of whether the patients and residents at Woodbine 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. Part 483;
  - 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 the reporting obligations are complied with in accordance with this CIA; and
  - e. make findings of whether corrective action plans are timely created, implemented, and enforced.

#### B. Written Standards.

- 1. Code of Conduct. Within ninety (90) days after the Effective Date of this CIA, Woodbine shall establish a Code of Conduct and distribute it to all Covered Persons. Woodbine shall make adherence to the Code of Conduct an element in evaluating the performance of contractors, agents, and employees. The Code of Conduct shall, at a minimum, set forth:
  - a. Woodbine's commitment to full compliance with all statutes, regulations, directives, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Centers for Medicare and Medicaid Services ("CMS") (or other appropriate regulatory agencies) and/or fiscal intermediaries or carriers;

- b. Woodbine's requirement that all of its Covered Persons shall be expected to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Woodbine's own policies and procedures (including the requirements of this CIA);
- c. the requirement that all of Woodbine's Covered Persons shall be expected to report, within thirty (30) days, suspected violations of any statute, regulation, directive, or guideline applicable to Federal health care programs or of Woodbine's own policies and procedures; if there are credible allegations of patient harm, such report shall be made immediately;
- d. the possible consequences to Woodbine and any Covered Person of failure to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Woodbine's 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 Woodbine's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days after the Effective Date of the CIA, 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 Woodbine's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their appointment, employment, or contract or within ninety (90) days after the Effective Date of the CIA, whichever is later.

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

2. Policies and Procedures. Within ninety (90) days after the Effective Date of this CIA, Woodbine shall develop and initiate implementation of written Policies and Procedures regarding the operation of Woodbine's compliance program and their 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, these Policies and Procedures shall specifically address:

- a. Measures designed to ensure that Woodbine 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 and 483, and any applicable other state or local statutes, regulations, directives, or guidelines that address quality of care in nursing homes;
- b. Measures designed to ensure that Woodbine 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;
- 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; and assessment of resident competence to make treatment decisions;
- d. 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;
- e. Measures designed to minimize the use of individuals at any Woodbine facility who are from a temporary agency or not employed by Woodbine (not including those individuals who are included in the definition of Covered Persons) and measures designed to create and maintain a standardized system to track the number of individuals at each facility who

fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Woodbine and/or the Monitor;

- f. Measures designed to ensure that clinical assessments are made without regard to the reimbursement amount;
- g. Measures designed to ensure that all residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;
- h. 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;
- i. 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 Woodbine's Administrator and other individuals responsible for such compliance at the district, regional, and corporate level;
- j. Measures designed to ensure cooperation by Woodbine and its Covered Persons with the Monitor in the performance of his or her duties as set forth in section III.D *infra*;
- k. Measures designed to ensure that compliance issues identified internally (e.g., through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CHSRA quality indicators, hospital key indicators, or internal surveys) or externally (e.g., through CMS or state survey agency reports, consultants, or Monitor's reports) are promptly and appropriately investigated and, if the investigation substantiates compliance issues, Woodbine assesses the nature and scope of the problems, implements appropriate corrective action plans, and monitors compliance with such plans;
- 1. Measures designed to ensure that Woodbine has a system to require and centrally collect reports relating to incidents,

accidents, abuse and neglect. The reports required under this system shall be of nature to allow the Quality Assurance Committees meaningful information to be able to determine: 1) if there is a quality of care problem; and 2) the scope and severity of the problem;

- m. Measures designed to inform Covered Persons of the staffing requirements of Federal and state law;
- n. Measures to inform Covered Persons during orientation and during other training required by this CIA that staffing levels are a critical aspect of patient and resident care, and, if any person has a concern about the level of staffing that there are many avenues available to each individual to report such concerns, including, but not limited to, the Administrator, the Hotline (as described in Section III. E. of this CIA), individuals at the district, regional, or corporate level, or directly to the Compliance Officer or Monitor;
- o. Measures designed to ensure compliance with the completion of accurate clinical assessments as required by applicable Federal law (see, e.g., 42 C.F.R. § 483.20);
- p. Measures designed to ensure compliance with the completion of accurate clinical assessments as required by applicable Federal law (see, e.g., 42 C.F.R. § 483.20);
- q. Measures designed to ensure that compliance issues are identified internally (e.g., through reports of abuse or neglect, financial data, reports to supervisors, Hotline or other complaints, internal audits or reviews, patient and resident satisfaction surveys, CHSRA quality indicators, staff turnover data, or internal surveys) or externally (e.g., consultants, audits performed by the IRO, or the Monitor's reports) and are promptly and appropriately investigated and, if the investigation substantiates compliance issues, Woodbine implements effective and timely corrective action plans and monitors compliance with such plans; and

r. Measures designed to effectively collect and analyze staffing data, including staff to patient or resident ratio and staff turnover.

Woodbine shall assess and update as necessary the Policies and Procedures, as appropriate. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days after 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. <u>Training and Education</u>.

- . 1. General Training. Within ninety (90) days after the Effective Date of this CIA, Woodbine shall provide at least one (1) hour of training to each Covered Person.<sup>2</sup> This general training shall explain Woodbine's:
  - a. Corporate Integrity Agreement requirements;
  - b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
  - c. Code of Conduct.

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

New Covered Persons shall receive the general training described above within ten (10) days after the beginning of their employment or within ninety (90) days after the Effective Date of this CIA, whichever is later. Every Covered Person shall receive such general training on an annual basis.

<sup>&</sup>lt;sup>2</sup>Any non-employee who is hired on a temporary basis (regardless of whether he or she is considered an "agent") is required to follow the policies and procedures of the facility, Woodbine, and this CIA. Woodbine 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 Woodbine for more than for more than a thirty (30) day period, regardless of how many days during that period the person is actually present in the facility, must complete the training requirements set forth herein.

- 2. Specific Training. In addition to the general training required above, within ninety (90) days after the Effective Date of this CIA, each Covered Person shall receive sufficient and effective training on the policies and procedures set forth in Section III.B, including, but not limited to:
  - a. policies, procedures, and other requirements applicable to the documentation of medical records; and
  - b. the coordinated interdisciplinary approach to providing care to residents, including, but not limited to, resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; ADL care; therapy services; quality of life, including accommodation of needs and activities; and assessment of the resident's competence to make treatment decisions.

Affected new Covered Persons shall receive this training within ten (10) days after the beginning of their employment or contract or within ninety (90) days after the Effective Date of this CIA, whichever is later. If a Covered Person has any responsibility for the delivery of patient or resident care, then prior to completing this specific training, Covered Person who has completed the substantive training shall review all of the untrained person's work.

Every Covered Person shall receive such specific training on an annual basis.

In addition, each facility shall conduct periodic effective training on an "as needed" basis on those quality of care issues identified by the Compliance Committee. In determining what training should be performed, these Committees will review the complaints received, satisfaction surveys, staff turnover data, any state or Federal surveys, including those performed by the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") or other such private agencies, any internal surveys, and the CHSRA quality indicators. Such training will be provided to all Covered Persons. Woodbine shall implement mechanisms to evaluate the individual's competence with respect to the training received.

Training materials shall be made available to OIG upon request. Persons providing the training must have 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. Review Procedures.

- 1. Independent Monitor. Within sixty (60) days after the Effective Date of this CIA, Woodbine shall appoint an appropriately qualified Monitor, approved by the OIG, which approval shall not be unreasonably withheld. The Monitor shall charge a usual and customary rate for his or her fees and expenses. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor's obligations under this CIA. Woodbine shall be responsible for all fees and expenses incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. Woodbine shall enter into a contract with the Monitor that establishes an annual cap on the dollar amount for the Monitor's fees and expenses consistent with the terms of the CIA. Woodbine may be obligated to pay the Monitor in excess of the annual cap if special circumstances arise that require the Monitor to expend additional resources to fulfill her duties under the CIA. The Monitor may be removed solely at the discretion of the OIG, which discretion shall not be unreasonably withheld. If the Monitor resigns or if the OIG approves the Monitor's removal for any reason prior to the termination of the CIA, Woodbine shall appoint another Monitor, after approval by the OIG, with the same functions and authorities.
  - a. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
    - i. Woodbine's internal quality control systems, including, but not limited to, whether the systems in place to promote quality of care and to respond to quality of care issues are acting in a timely and effective manner; whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and whether the training programs are effective and thorough;
    - ii. Woodbine's response to quality of care issues, which shall include an assessment of:
      - (A) Woodbine's ability to identify the problem;

- (B) Woodbine's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;
- (C) Woodbine's ability to create a corrective action plan to respond to the problem;
- (D) Woodbine's ability to execute the corrective action plan;
- (E) Woodbine's ability to evaluate whether the assessment, corrective action plan and execution of that plan was effective, reliable, and thorough.
- iii. Woodbine'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 Woodbine and set forth in this CIA.
- b. *Access*. The Monitor shall have access at any time and without prior notice to:
  - i. Woodbine;
  - ii. The following types of documents: (A) the CMS quality indicators; (B) internal or external surveys or reports; (C) Woodbine's hotline complaints; (D) resident or patient satisfaction surveys; (E) staffing data in the format requested by the Monitor, including but not limited to reports setting forth the staff to patient ratios, temporary staffing levels, and staff turnover data, as well as reports where temporary agency staff constitutes more than ten percent of the nursing and direct care staff; (F) incident, accident, abuse, neglect or death reports; (G) reports of incidents involving a patient or resident that prompt a full internal investigation; (H) patient or resident records; (I) financial data; (J) self-evaluative reports including, but not limited to, those from medical review committees, quality assurance committees, or peer review

committees; and (K) any other pre-existing data, including the reconfiguring of existing data that the Monitor may determine relevant to fulfilling the duties required under this CIA in the format requested by the Monitor, to the extent practicable; and

iii. patients, residents, and staff for interviews outside the presence of Woodbine supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident or patient.

### c. Woodbine's Obligations. Woodbine shall:

- i. Not impede the Monitor's access to Woodbine (pursuant to the provisions of this CIA) and shall provide any requested documentation within the time frame specified by the Monitor, subject to any extensions and modifications requested by Woodbine and granted by the Monitor;
- ii. Assist in contacting and arranging interviews of Covered Persons, and not impede the cooperation by such individuals;
- iii. Provide access to current residents or patients and contact information for their families and guardians, in a manner consistent with the rights of such individuals under State or Federal law, and not impede their cooperation;
- iv. Provide the last known contact information for former Covered Persons, and not impede the cooperation from such individuals, including, but not limited to, refraining from placing confidentiality requirements in termination agreements that would limit such cooperation;
- v. Provide the last known contact information for former residents, patients, their families, or guardians consistent with the rights of such individuals under State or Federal law, and not impede their cooperation;

- vi. Address any written recommendation made by the Monitor either by substantially implementing the Monitor's recommendations or by explaining in writing why it has elected not to do so;
- vii. Pay the Monitor's bills for Monitor's Costs pursuant to the terms of Woodbine's contract with the Monitor. Woodbine may bring any disputed Monitor's Costs or bills to OIG's attention;
- viii. Not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Woodbine under this Agreement; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others; and
- ix. Provide the Monitor a report within forty-eight hours of any of the following occurrences:
  - (A) Deaths or injuries related to use of restraints;
  - (B) Deaths or injuries related to use of psychotropic medications;
  - (C) Suicides;
- (D) Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines); and
- (E) Any other incident involving a resident that prompts a full internal investigation.

Each such report shall contain the full name, social security number, and date of birth of the resident, the date of the occurrence, and a brief description of the events surrounding the occurrence.

d. The Monitor's Obligations. The Monitor shall:

- i. Respect the legal rights, privacy, and dignity of all Covered Persons, residents, and patients;
- ii. Promptly report to appropriate regulatory or law enforcement entities when warranted. Where independently required by applicable law or professional licensing standard to report any finding to an appropriate regulatory or law enforcement authority, simultaneously submit copies of such reports to OIG and to Woodbine;
- iii. At all times act reasonably in connection with its duties under the CIA, including when requesting information from Woodbine;
- iv. Provide quarterly reports to Woodbine and OIG concerning the findings made to date;
- v. Submit bills to Woodbine on a consolidated basis no more than once per month, and submit an annual summary representing an accounting of its costs throughout the year to Woodbine and to OIG. Woodbine shall have the opportunity to review such bills and bring any issue of disputed bills or costs to the attention of OIG;
- vi. Not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. Monitor's reports may prompt an investigation by the state survey agency, but they are not intended to nor can they supplant a state survey agency investigation. The parties agree that HHS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or findings from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Woodbine. Woodbine shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or findings from the Monitor as evidence

in any of these proceedings. Nothing in the previous sentence, however, shall preclude the OIG or Woodbine from using any material generated by the Monitor, or any opinions, testimony, or findings from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other fora not explicitly excluded in this subsection;

vii. Abide by the legal requirements of Woodbine to maintain the confidentiality of each resident's personal and clinical records, and to maintain confidential and not to disclose the records of Woodbine's Compliance Committee and self-evaluative reports including, but not limited to, those from medical review committees, quality assurance committees or peer review committees. Nothing in the prior sentence, however, shall limit or affect the Monitor's obligation to provide information, including information from patient and resident clinical records, to the OIG, and, when legally or professionally required, reporting to other agencies;

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

ix. The Monitor shall visit each covered facility as often as the Monitor believes it necessary to perform its functions. In the event that the OIG determines that Woodbine has made satisfactory progress in implementing the CIA, the OIG may in its sole discretion reduce the frequency of the Monitor's visits.

#### e. Miscellaneous Provisions.

- i. The Monitor may confer and correspond with Woodbine and OIG on an *ex parte* basis at any time.
- ii. The Monitor shall not control, manage or operate Woodbine.

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

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

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Woodbine shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted, including that the inappropriate or improper practice ceases immediately.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation concerning Woodbine 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 monthly.

# 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, suspended, 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, debarred, suspended, or otherwise declared ineligible.

2. Screening Requirements. Woodbine shall not hire or engage as Covered Persons any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Woodbine shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists will hereinafter be referred to as the "Exclusion Lists").

In addition, Woodbine shall require employees to disclose immediately any debarment, exclusion or other event that causes the employee to become an Ineligible Person.

- 3. Review and Removal Requirement. Within ninety (90) days after the Effective Date of this CIA, Woodbine will review its list of current employees and contractors against the Exclusion Lists. Thereafter, Woodbine will review the list semi-annually. If Woodbine has notice that an employee or contractor has become an Ineligible Person, Woodbine will remove such person from responsibility for, or involvement with, Woodbine's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.
- 4. Pending Charges and Proposed Exclusions. If Woodbine 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, Woodbine shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and will not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.
- G. <u>Notification of Proceedings</u>. Within thirty (30) days after discovery, Woodbine 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 Woodbine 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. Woodbine shall also provide written notice to OIG within thirty (30) days after the

resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### IV. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within one hundred and twenty (120) days after the Effective Date of this CIA, Woodbine 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 Woodbine's 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 confidential disclosure program required by section III.E; and
  - 8. a summary of personnel actions (other than hiring) taken pursuant to section III.F.

- B. <u>Annual Reports</u>. Woodbine shall submit to OIG an Annual Report with respect to the status and findings of Woodbine's compliance activities over the one-year period covered by the Annual Report. Each Annual Reports shall include:
  - 1. any change in the identity or position description of individuals in positions described in section III.A, a change in any of the committees' structure or charter, or any change in the internal audit and review program;
  - 2. a certification by the Compliance Officer that:
    - a. all 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. Woodbine has effectively implemented all plans of correction related to problems identified under this CIA, Woodbine's Compliance Program, or internal audits.
  - 3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
  - 4. a summary of the findings of such audit or review, and a summary of the corrective action taken under the program for internal audits and reviews;
  - 5. Woodbine's response/corrective action plan to any issues raised by the Monitor;
  - 6. a copy of the confidential disclosure log required by section III.E (excluding any calls that relate solely to human resources issues);
  - 7. a description of any personnel action (other than hiring) taken by Woodbine 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

Woodbine 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 summary describing any corrective action plan to address the probable violations of law identified in section III.G.

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

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by Woodbine's Compliance Officer, under penalty of perjury, that: (1) Woodbine is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance 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.
- D. <u>Designation of Information</u>: Woodbine shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Woodbine shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

### IV. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch

Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

Cohen Building, Room 5527 330 Independence Avenue, SW

Washington, DC 20201 Phone 202.619.2078 Fax 202.205.0604

Woodbine:

Kent Fosha

Executive Vice President/Compliance Officer

Centennial HealthCare

400 Perimeter Center Terrace, Suite 650

Atlanta, GA 30346 Phone: 770 730 1175 Fax: 770 730 1375

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

#### VII. DOCUMENT AND RECORD RETENTION

Woodbine shall maintain for inspection all documents and records relating to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

#### VIII. 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 Woodbine prior to any release by OIG of information submitted by Woodbine pursuant to its obligations under this CIA and identified upon submission by Woodbine as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Woodbine 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. With respect to the disclosure of information, Woodbine shall have the rights set forth in 45 C.F.R. § 5.65(d). The OIG shall protect confidential information under the FOIA rules to the greatest extent allowed by law.

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as a waiver by Woodbine of Woodbine's attorney-client, work product, peer review, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Woodbine's obligation to comply with the provisions of this CIA.

### IX. Breach and Default Provisions

Woodbine 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 Woodbine 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 Woodbine with prompt written notification of such determination ("Noncompliance Notice"). Woodbine will have thirty (30) days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) to reply in writing that it disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge ("ALJ"), pursuant to the provisions set for in section IX.E of this CIA. The purpose of the hearing is to determine whether Woodbine has failed to comply with the CIA and whether Woodbine 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, Woodbine 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 ninety (90) days after the Effective Date of this CIA and concluding at the end of the term of this CIA, Woodbine fails to have in place any of the following:
  - a. Compliance Officer;
  - b. Compliance Committee;
  - c. program for performing internal audits and reviews;
  - d. written Code of Conduct;
  - e. written Policies and Procedures;
  - f. training program; and
  - g. Confidential Disclosure Program.
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Woodbine 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 Woodbine employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Woodbine's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Woodbine can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.H) as to the status of the person).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that Woodbine fails to grant access) for each day Woodbine fails to grant access to the information or documentation as required in section V of this CIA.
- 5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date OIG provides notice to Woodbine of the failure to comply) for each day Woodbine fails to comply fully and adequately with any obligation of this CIA. In its notice to Woodbine, the OIG shall state the specific grounds for its determination that Woodbine has failed to comply fully and adequately with the CIA obligation(s) at issue.

#### C. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that Woodbine has failed to comply with any of the obligations described in section X.B and determining that Stipulated Penalties are appropriate, OIG shall notify Woodbine by personal service or certified mail of: (a) Woodbine'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 after the date of the Demand Letter, Woodbine shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event Woodbine elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Woodbine cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

- 2. Timely Written Requests for Extensions. Woodbine 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 Woodbine 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 Woodbine 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

- 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 Woodbine;
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section IX.B of this CIA;
- c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section IX.B above; or
- d. a failure to fund the Monitor in accordance with section III.D.

# E. Dispute Resolution

- 1. Review Rights. Upon the OIG's delivery to Woodbine of its Noncompliance Notice or Demand Letter or its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Woodbine 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 after the date of the Demand Letter, and a request for a hearing involving exclusion shall be made within thirty (30) days after the date of the Exclusion Letter.
- 2. Specific Performance Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for specific performance of CIA provisions shall be: (a) whether, at the time specified in the Noncompliance Notice, Woodbine was in full and timely compliance with the obligations of this CIA for which the OIG seeks specific performance; and (b) whether Woodbine failed to cure. Woodbine 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, Woodbine shall take the actions OIG deems necessary to cure within (20) days after the ALJ issues such a decision notwithstanding that Woodbine 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 Woodbine was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Woodbine 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 Woodbine to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Woodbine 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 Woodbine was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 30-day period, but that (i) Woodbine has begun to take action to cure the material breach, (ii) Woodbine is pursuing such action with due diligence, and (iii) Woodbine 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. Woodbine's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Woodbine 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 Woodbine 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 Woodbine 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.
- 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 Woodbine's compliance with applicable Federal and state health care program requirements.

### XI. EFFECTIVE AND BINDING AGREEMENT

- A. This CIA shall be binding on the successors, assigns, and transferees of Woodbine;
- 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 Woodbine 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 WOODBINE HEALTHCARE AND REHABILITATION CENTRE:

Kent l	Focha

Executive Vice President/Compliance Officer

Denise Crosby Administrator

William Cowden

Counsel for Woodbine

121302 DATE

Mar. 25, 2002

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

Office of Inspector General

U. S. Department of Health and Human Services