

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**CIENA HEALTHCARE MANAGEMENT, INC.,**  
**MOHAMMAD QAZI, ANIS KHAN, AND DENISE MAHNKE-PUGH**

**I. PREAMBLE**

Ciena Healthcare Management, Inc. ("Ciena"), Mohammad Qazi (Qazi), Anis Khan (Khan), and Denise Mahnke-Pugh (Pugh) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote their compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f) (hereinafter collectively referred to as the "Federal health care programs"). Contemporaneously with this CIA, Ciena, Qazi, Khan, and Pugh are entering into a Settlement Agreement with the United States.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Ciena, Qazi, Khan, and Pugh under this CIA shall be five years from the Effective Date of this CIA (unless otherwise specified). The Effective Date of this CIA shall be the date on which the final signatory executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period." This CIA applies to any long term care and/or hospice facility in which Ciena, Qazi, Kahn, or Pugh have an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any entity managed by Ciena (hereinafter "Ciena Facilities").

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

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. Qazi, Khan, Pugh, all owners, officers, directors, and employees of Ciena, any corporation, subsidiary, affiliate, joint

venture, or other organization or entity in which Ciena or its individual owners own 5% or more or have a controlling interest at any time during the term of the CIA and which operates a long term facility or hospice, or any long term care facility or hospice which Ciena or its individual owners operate or have a management contract or arrangement to provide management and administrative services that give any of them control over the day-to-day operations over the organization or entity at any time during the term of the CIA; and

b. all contractors, subcontractors, agents, and other persons who, on a regular basis (*i.e.*, more often than two weeks over a 52-week period) on behalf of Ciena: (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 relating to quality of care; (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, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions.

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

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

### **III. CORPORATE INTEGRITY OBLIGATIONS**

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

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

1. *Compliance Officer.* Within 90 days after the Effective Date, Ciena 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 Ciena, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Ciena, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall not be Ciena's general counsel or chief financial officer. Nor shall the Compliance Officer be subordinate to Ciena's general counsel or chief financial officer. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Ciena 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, Ciena shall notify the OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* To the extent not already established, Ciena shall establish a Quality Assurance Compliance Committee (hereinafter "Compliance Committee") within 90 days after the Effective Date. The purpose of this Compliance Committee shall be to address issues concerning quality of care at Ciena's Facilities. The Compliance Committee shall include, at a minimum, the Compliance Officer, representatives from among senior personnel responsible for clinical operations and quality of care, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA that relate to quality of care in the Ciena Facilities. For each scheduled Compliance Committee meeting, there shall be senior representatives from the Ciena Facilities, chosen on a rotating and random basis, to report to the Compliance Committee on the adequacy of care being provided at their facilities. Attendance at such committee meetings by such senior representatives may be via conference phone or video conferencing equipment although in person attendance is the desired and intended form of attendance. The Compliance Committee shall meet, at a minimum, every three months.

3. *Quality Assurance Monitoring Committee.* Ciena shall create a committee to provide oversight on quality of care issues (hereinafter the "Quality Assurance Monitoring Committee"). The Quality Assurance Monitoring Committee shall: (a) review the adequacy of Ciena's system of internal controls, quality assurance monitoring, and patient care; (b) ensure that Ciena's response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified; and (c) ensure that Ciena adopts and implements policies and

procedures that are designed to ensure that each individual cared for at a Ciena Facility receives the highest practicable physical, mental, and psychosocial level of care attainable. The individuals who serve on the Quality Assurance Monitoring Committee shall be readily available to the Compliance Officer and the Monitors required under this CIA to respond to any issues or questions that might arise. The names of the committee members and the mission statement for the committee shall be provided to the OIG within 90 days after the Effective Date. When new members are appointed, or the responsibilities or authorities of the Quality Assurance Monitoring Committee are substantially changed, Ciena shall notify the OIG, in writing, within 15 days of such a change.

4. *Internal Audit and Review Functions.* To the extent not already established, Ciena shall, within 90 days after the Effective Date, create a program for performing internal quality audits and reviews. The internal audits and reviews shall:

- a. make findings of whether the patients and residents at Ciena Facilities are receiving the quality of care and quality of life consistent with basic care, treatment, and protection from harm standards, including but not limited to, 42 C.F.R. Parts 482 and 483 and any other applicable federal and state statutes, regulations, and directives;
- b. make findings of whether the Policies and Procedures mandated by Section III.B of this CIA are created, implemented, and enforced;
- c. make findings of whether training is performed in accordance with Section III.C of this CIA;
- d. make findings of whether Disclosure Program (as described in Section III.E of this CIA) complaints are appropriately investigated;
- e. make findings of whether the reporting obligations are complied with in accordance with Section III.H of this CIA; and
- f. make findings of whether corrective action plans are timely created, implemented, and enforced.

B. Written Standards.

1. *Code of Conduct.* Within 90 days after the Effective Date, Ciena shall establish a Code of Conduct and distribute it to all Covered Persons. Ciena 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. Ciena'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. Ciena'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 Ciena's own policies and procedures (including the requirements of this CIA);
- c. the requirement that all of Ciena's Covered Persons shall be expected to report, within 30 days, suspected violations of any statute, regulation, directive, or guideline applicable to Federal health care programs or of Ciena's own policies and procedures; if there are credible allegations of patient harm, such report shall be made immediately and shall be complete, full, and honest;
- d. the possible consequences to both Ciena and any Covered Person of failure to comply with all statutes, regulations, directives, and guidelines applicable to Federal health care programs and with Ciena's own policies and procedures or of failure to report such non-compliance; and
- e. the right of all Covered Persons to use the Disclosure Program, described in Section III.E of this CIA, as well as Ciena's commitment to confidentiality and nonretaliation with respect to disclosures.

Within 90 days after the Effective Date, to the extent not already accomplished, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Ciena's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after the commencement of their appointment, employment, or contract or within 90 days after the Effective Date, whichever is later.

Ciena shall annually review the Code of Conduct and shall 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 90 days after the Effective Date, Ciena shall develop and implement written Policies and Procedures regarding the operation of Ciena's compliance program and its compliance with all federal and state health care statutes, regulations, directives, and guidelines, including the requirements of the Federal health care programs. At a minimum, Ciena's Policies and Procedures shall specifically address:

- a. Measures designed to ensure that Ciena fully complies with Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh 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 Ciena complies with all requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as specified by the Resident Assessment Instrument User's Manual; ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups (RUG) classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;
- c. Measures designed to ensure the coordinated interdisciplinary approach to providing care, including, but not limited to the following areas addressed in 42 C.F.R. § 483: resident assessment

and care planning; nutrition; diabetes care; wound care; infection control; fall prevention, recovery, and assessment; abuse and neglect policies and reporting procedures; protection from harm procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; activities of daily living (ADL) care; therapy services; quality of life, including accommodation of needs and activities; and assessment of resident competence to make treatment decisions;

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

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

f. Measures designed to ensure that nursing staff levels are sufficient to meet patients' and residents' needs, as required by federal and state laws, including, but not limited to, 42 C.F.R. § 483.30 (nursing facilities);

g. Measures that specify that, if the director of nursing (or other person who is making staffing decisions at the facilities) disagrees with a staffing determination that is not in compliance with state or federal regulations or the CIA and that significantly affects patient care made by the Administrator or other individuals at the district, region, or corporate level, and is unable to resolve the issue through the normal chain of responsibility, then that person must immediately contact the mechanism provided in Ciena's Disclosure Program (described in Section III.E of this CIA) and the Monitor. Nothing in this subsection prohibits or prevents such person from using the

Disclosure Program or contacting the Monitor without first going through the normal chain of responsibility;

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

i. Measures to inform Covered Persons during orientation and during other training required by this CIA that staffing levels are a critical aspect of patient and resident care, and that, if any person has a concern about the level of staffing, there are many avenues available to report such concerns, including, but not limited to, the Administrator, the Disclosure Program (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;

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

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

l. Measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes, regulations, and the CIA, by including such adherence as a significant factor in determining the compensation to Administrators and Directors of Nursing of the facilities, and the individuals responsible for such compliance at the district, regional, and corporate level;

m. Measures designed to ensure cooperation by Ciena and its Covered Persons with the Monitor in the performance of his or her duties as set forth in Section III.D of this CIA;



- n. Measures designed to ensure that compliance issues are identified internally (e.g., through reports to supervisors, complaints received through the Disclosure Program, internal audits, patient satisfaction surveys, CMS quality indicators, facility-specific key indicators, or internal surveys) or externally (e.g., through CMS or state survey agency reports, consultants, or the Monitor's Reports) and are promptly and appropriately investigated and, that if the investigation substantiates compliance issues, Ciena implements effective and timely corrective action plans and monitors compliance with such plans;
- o. Measures designed to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred;
- p. Measures designed to ensure that contractors, subcontractors, and agents that fall within the ambit of Covered Persons are appropriately supervised to ensure that they are acting within the parameters of Ciena's Policies and Procedures and the requirements of Federal health care programs;
- q. Measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews;
- r. Nonretaliation policies and methods for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by Section III.E of this CIA;
- s. Disciplinary guidelines to reflect the Code of Conduct requirements as specified in Section III.B.1 of this CIA;
- t. Measures designed to ensure that Ciena has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. The reports required under this system shall be of a nature to allow the Compliance Committee and the Quality Assurance Monitoring Committee meaningful information to be able to determine: (1) if there is a quality of care problem; and (2) the scope and severity of the problem;

- u. Measures that meet the requirements of Section 6032 of the Deficit Reduction Act;
- v. Measures designed to ensure that Ciena complies with state staffing requirements; and
- w. Measures that define the responsibilities and role of the corporate Medical Director and the facility Medical Directors.

At least annually, and more frequently if appropriate, Ciena shall assess and update, as necessary, the Policies and Procedures. A summary of the Policies and Procedures shall be provided to the OIG in the Implementation Report. The Policies and Procedures shall be available to the OIG upon request.

Within 90 days after the Effective Date, 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.

All training required in this section shall be competency-based. Specifically, training must be developed and provided in such a way as to focus on Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Covered Person has learned as a result of the training.

1. *General Training.* Within 90 days after the Effective Date, Ciena shall provide at least two hours of general competency-based training to each Covered Person.<sup>1</sup> This general training shall explain Ciena's:

- a. CIA requirements;

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<sup>1</sup>Any nonemployee who is hired on a temporary basis (regardless of whether he or she is considered a "Covered Person") is required to follow the policies and procedures of the facility, Ciena, and this CIA. Ciena shall ensure that there is sufficient supervision to ensure that a temporary nonemployee is acting within the parameters of such policies and procedures. Any temporary nonemployee who works in Ciena Facilities 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.

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

New Covered Persons shall receive the general training described above within 30 days of the beginning of their employment or contract, or within 90 days after the Effective Date, whichever is later. Every Covered Person shall receive such general training on an annual basis.

2. *Specific Training.* Within 90 days after the Effective Date, Ciena shall initiate specific competency-based training of each Covered Person who is involved directly or indirectly in the delivery of patient or resident care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions). Such Covered Persons shall receive at least eight hours of competency-based training pertinent to their responsibilities in addition to the general training required above. This training, which shall be completed within one year after the Effective Date of the CIA and conducted at least annually thereafter, shall include a discussion of the Policies and Procedures set forth in Section III.B of this CIA, 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; assessment of the resident's competence to make treatment decisions; and specialty care provided to medically-complex residents.

Affected new Covered Persons shall begin receiving this competency-based training within 10 days of the beginning of their employment or contract or within 90 days after the Effective Date of this CIA, whichever is later. If a new Covered Person has any responsibility for the delivery of patient or resident care, then, prior to completing this.

specific training, a Ciena Covered Person who has completed the substantive training shall review all of the untrained person's work.

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

3. *Periodic Training.* In addition to the specific competency-based training described above, each facility shall provide periodic competency-based training to all Covered Persons at the facility who are responsible for patient or resident care on the quality of care issues identified by the Quality Assurance Monitoring Committee and the Compliance Committee. This periodic training shall be provided on an "as needed" basis, but shall be provided at least semi-annually. In determining what training should be performed, the Quality Assurance Monitoring Committee and the Compliance Committee shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other such private agencies, any internal surveys, the CMS quality indicators, and the findings, reports and recommendations of the Monitor. Such training shall be for a minimum of four hours annually.

4. *Certification.* Each Covered Person shall certify, in writing, that he or she has successfully completed 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 and documentation evidencing that the Covered Persons attained competency in the required training areas. These shall be made available to the OIG upon request.

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

#### D. Independent Monitor

Within 60 days after the Effective Date, Ciena shall retain an appropriately qualified monitoring team (the "Monitor"), appointed by the OIG after consultation with Ciena. 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. Ciena shall be responsible for all reasonable costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. The Monitor shall charge a reasonable amount for his

or her fees and expenses. As a condition to retaining the Monitor, Ciena shall require the Monitor to enter into a subcontract with an individual or entity, approved by the OIG, that has the requisite expertise, capacity, and access to MDS data directly from CMS to perform quarterly Quality Indicator data analysis reports of the type described in the attached Appendix A. Failure to pay the Monitor within 30 calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CIA and shall subject Ciena to one or more of the remedies set forth in Section X; provided, however, nothing in this section shall prevent or prohibit Ciena from bringing disputed bills to the OIG's attention as provided in Section III.D.3.h herein. The Monitor may be removed solely at the discretion of the OIG. If the Monitor resigns or is removed for any reason prior to the termination of the CIA, Ciena shall retain another Monitor appointed by the OIG, with the same functions and authorities. The Monitor may confer and correspond with Ciena and the OIG on an ex parte basis.

1. The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:
  - a. Ciena's internal quality control systems, including, but not limited to:
    - i. whether the systems in place to promote quality of care and to respond to quality of care issues are operating in a timely and effective manner;
    - ii. 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
    - iii. whether the training programs are effective and thorough.
  - b. Ciena's response to quality of care issues, which shall include an assessment of:
    - i. Ciena's ability to identify the problem;

- ii. Ciena's ability to determine the scope of the problem, including, but not limited to, whether the problem is isolated or systemic;
  - iii. Ciena's ability to create a corrective action plan to respond to the problem;
  - iv. Ciena's ability to execute the corrective action plan; and
  - v. Ciena's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.
- c. Ciena's development and implementation of corrective action plans and the timeliness of such actions;
  - d. Ciena's proactive steps to ensure that each patient and resident receives care in accordance with:
    - i. basic care, treatment, and protection from harm standards;
    - ii. the rules and regulations set forth in 42 C.F.R. Parts 482 and 483;
    - iii. state and local statutes, regulations, and other directives or guidelines; and
    - iv. the Policies and Procedures adopted by Ciena and set forth in Section III.B of this CIA; and
  - e. Ciena's compliance with staffing requirements.
2. The Monitor shall have:
- a. immediate access to Ciena Facilities, at any time and without prior notice, to assess compliance with this CIA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;

b. immediate access to: (1) the CMS quality indicators; (2) internal or external surveys or reports; (3) Disclosure Program complaints; (4) resident satisfaction surveys; (5) staffing data in the format requested by the Monitor, including reports of any 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 falls; (8) reports of any incident involving a patient or resident that prompts a full internal investigation; (9) patient or resident records; (10) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (11) any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA; and

c. immediate access to patients, residents, and Covered Persons for interviews outside the presence of Ciena 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. Ciena's Obligations. Ciena shall:

a. ensure the Monitor's immediate access to the facilities, residents, Covered Persons, and documents, and assist in obtaining full cooperation by its current employees, contractors, and agents;

b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each 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 that poses a threat to residents or otherwise may disrupt the care provided, flooding, or major equipment failures at any facility;
- vi. Strikes or other work actions that could affect resident care;
- vii. Man-made disasters that pose a threat to residents (e.g., toxic waste spills); and
- viii. Any other incident that involves or causes actual harm to a resident when such incident is required to be reported to any local, state, or federal government agency.

Each such report shall contain the full name, social security number, and date of birth of the resident(s) involved, the date of death or incident, and a brief description of the events surrounding the death or incident.

- c. assist in locating and, if requested, attempt to obtain cooperation from past employees, contractors, agents, and residents, patients, and their families;
- d. provide access to current residents and patients and provide contact information for their families and guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation with the Monitor;
- e. provide to its Compliance Committee or its Quality Assurance Monitoring Committee copies of all documents and reports provided to the Monitor;
- f. provide the last known contact information for former residents, patients, their families, or guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation;



- g. address any written recommendation made by the Monitor, either by substantially implementing the Monitor's recommendations or by explaining in writing why Ciena has elected not to do so;
  - h. pay the Monitor's bills within 30 days of receipt. While Ciena must pay all the Monitor's bills within 30 days, Ciena may bring any disputed Monitor's Costs or bills to the OIG's attention; and
  - i. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Ciena under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.
4. The Monitor's Obligations. The Monitor shall:
- a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons, residents, and patients;
  - b. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to the OIG and to Ciena;
  - c. at all times act reasonably in connection with its duties under the CIA including when requesting information from Ciena;
  - d. simultaneously provide quarterly reports to Ciena and the OIG concerning the findings made to date;
  - e. submit bills to Ciena on a consolidated basis no more than once per month and submit an annual report representing an accounting of its costs throughout the year to Ciena and to the OIG;
  - f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions.

The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Ciena, and Ciena shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude the OIG or Ciena from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

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

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

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

j. visit each Ciena Facility as often as the Monitor reasonably believes it necessary to perform its functions; and

k. if the Monitor has concerns about corrective action plans that are not being enforced or systemic problems that could affect Ciena's ability to render quality care to its patients and residents, then the

Monitor shall: (a) report such concerns in writing to the OIG and (b) simultaneously provide notice and a copy of the report to Ciena's Quality Assurance Monitoring Committee referred to in Section III.A.3 of this CIA.

E. Disclosure Program.

Within 90 days after the Effective Date, Ciena shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with Ciena's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law or the applicable standard of care. Ciena shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas such as the lobby, dining rooms, activity rooms, waiting rooms).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, 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, Ciena shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practice places residents at risk of harm, then Ciena will ensure that that practice ceases immediately.

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each allegation received (whether anonymous or not), the status of the respective investigations, and any corrective action taken in response to the investigation. The disclosure log shall be sent to the Monitor not less than monthly and shall be made available to the OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an “Ineligible Person” shall include an individual or entity who:

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

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

b. “Exclusion Lists” include:

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

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

c. “Screened Persons” include prospective and current owners, officers, directors, employees, contractors, and agents of Ciena.

2. *Screening Requirements.* Ciena shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

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

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

- c. Ciena shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

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

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Ciena shall notify the OIG, in writing, of any ongoing investigation or legal proceeding known to Ciena conducted or brought by a governmental entity or its agents involving an allegation that Ciena 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. Ciena shall also provide written notice to the OIG within 30 days after the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the investigation or proceedings, if any. In addition, within 15 days after notification, Ciena shall notify the OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., JCAHO) regarding quality of care issues.

## H. Reporting.

### 1. *Overpayments.*

a. Definition of Overpayments. For purposes of this CIA, an “Overpayment” shall mean the amount of money Ciena has received in excess of the amount due and payable under any Federal health care program requirements.

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

### 2. *Reportable Events.*

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

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws

applicable to any Federal health care program for which penalties or exclusion may be authorized; or

iii. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations;

iv. a matter that a reasonable person would consider likely to render Ciena insolvent.

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

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

i. If the Reportable Event results in an Overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, the legal and

Federal health care program authorities implicated, and the potential impact, if any, on Federal health care program beneficiaries;

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

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

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

In the event that, after the Effective Date, Ciena, Qazi, Khan, and/or Pugh change locations or sell, close, purchase, or establish a new long term care or hospice facility, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ciena, Qazi, Khan and/or Pugh shall notify the OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new long term care or hospice facility, business unit, or location, phone number, fax number, Medicaid and Medicare Ciena number, Ciena identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicaid and Medicare number. Each new long term care or hospice facility, business unit, or location shall be subject to all the requirements of this CIA no later than 120 days after Ciena, Qazi, Khan, and/or Pugh assume control or ownership of the new facility or location.

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

A. **Implementation Report.** Within 120 days after the Effective Date, Ciena shall submit a written report to the 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 mission statement for the Quality Assurance Monitoring Committee required in Section III.A;



3. a description of the program for internal audits and reviews required in Section III.A;
4. a copy of Ciena's Code of Conduct required by Section III.B.1;
5. the summary of the Policies and Procedures required by Section III.B.2;
6. a description of the training programs required by Section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;
7. a certification by the Compliance Officer that:
  - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been made available to all pertinent 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.
8. a description of the Disclosure Program required by Section III.E;
9. a summary of personnel actions taken pursuant to Section III.F; and
10. a list of all of Ciena's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Ciena number(s), Ciena identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Ciena currently submits claims.

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

1. any change in the identity or position description of individuals in positions described in 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. Ciena has effectively implemented all plans of correction related to problems identified under this CIA, Ciena's Compliance Program, or internal audits.
3. notification of any changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);
4. a summary of the facilities audited or reviewed, a summary of the findings of such audit or review, and a summary of the corrective action taken under the program for internal audits and reviews;
5. Ciena'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 Ciena 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 Ciena has committed a crime or has engaged in fraudulent activities required to 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 of Ciena's locations (including addresses) as required by Section V.A.10; the corresponding

name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Ciena number(s), Ciena identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Ciena currently submits claims.

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

Within 180 days of the submission of each annual report, Ciena shall schedule and hold an in-person meeting with a representative of the OIG to review Ciena's performance under the CIA. The OIG, in its discretion, may waive this meeting requirement.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by Ciena's President and Chief Executive Officer, under penalty of perjury, that:

1. to the best of his or her knowledge, Ciena is in compliance with all of the requirements of this CIA; and

2. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believe that, upon such inquiry, the information is accurate and truthful. Each Report shall also include a resolution (or its equivalent) from Ciena's Board of Directors certifying that they have reviewed the Annual Report and agree with the statements made therein.

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

Unless otherwise stated in writing subsequent to the Effective Date, 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, S.W.  
Washington, DC 20201  
Phone: (202) 619-2078  
Fax: (202) 205-0604

Ciena: Mohammad Qazi  
Ciena Healthcare Management, Inc.  
4000 Town Center, Suite 380  
South field, MI 48075  
Phone: (248) 386-0300  
Fax: (248) 386-0314

## **VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Ciena's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Ciena's locations for the purpose of verifying and evaluating: (a) Ciena's compliance with the terms of this CIA; and (b) Ciena's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Ciena to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Ciena's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. Ciena shall assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Ciena's employees may elect to be interviewed with or without a representative of Ciena present.

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

Ciena shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

## **IX. DISCLOSURES**

Subject to HHS's Freedom of Information Act (FOIA) procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Ciena prior to any release by the OIG of information submitted by Ciena pursuant to its obligations under this CIA and identified upon submission by Ciena as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Ciena 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, Ciena shall have the rights set forth in 42 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

Ciena is expected to fully and timely comply with all of its CIA obligations.

A. Specific Performance of CIA Provisions. If the OIG determines that Ciena is failing to comply with a provision or provisions of this CIA and decides to seek specific performance of any of these provisions, the OIG shall provide Ciena with prompt written notification of such determination (hereinafter referred to as "Noncompliance Notice"). Ciena shall have 35 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that Ciena 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 X.F of this CIA. The purpose of the hearing is to determine whether Ciena has failed to comply with the CIA and whether Ciena shall be required to implement the particular provisions at issue.

B. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Ciena and the OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Ciena fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a Quality Assurance Monitoring Committee;
- d. a program for performing internal audits and reviews;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons in the manner required by Section III.C;
- h. retention and payment of a Monitor;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements; and
- k. notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Ciena fails to submit the Implementation Report or any Annual Reports to the OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$1,500 for each day Ciena fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Ciena fails to grant access.)

4. A Stipulated Penalty of \$1,000 for each day Ciena fails to comply fully and adequately with any obligation of this CIA. The OIG shall provide notice to Ciena stating the specific grounds for its determination that Ciena has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Ciena shall take to

comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Ciena receives this notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under the other subsections of this Section.

5. A Stipulated Penalty of \$5,000 for each day Ciena 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. The OIG shall provide notice to Ciena stating the specific grounds for its determination that Ciena has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Ciena shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Ciena receives this notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under the other Subsection of this Section.

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

7. A Stipulated Penalty of \$2,500 for each day Ciena fails to comply fully and adequately with any of its obligations with respect to the Monitor, as set forth in Section III.D.3. The OIG shall provide notice to Ciena stating the specific grounds for its determination that Ciena has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Ciena shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Ciena receives this notice from the OIG of the failure to comply.)

C. Timely Written Requests for Extensions. Ciena may, in advance of the due date, 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 the 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 Ciena fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the 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 three business days after Ciena receives the OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received

by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

D. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Ciena has failed to comply with any of the obligations described in Section X.B and after determining that Stipulated Penalties are appropriate, the OIG shall notify Ciena of: (a) Ciena's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Ciena 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.F. In the event Ciena elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Ciena 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.E.

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 the OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.E.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's decision that Ciena has materially breached this CIA, which decision shall be made at the OIG's discretion and shall be governed by the provisions in Section X.E, below

E. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:
  - a. a failure by Ciena to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;



- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.B;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D; or
- d. a failure to retain, pay or use the Monitor in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Ciena constitutes an independent basis for Ciena's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Ciena has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Ciena of: (a) Ciena's material breach; and (b) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude"). The exclusion may be directed at one or more of Ciena's Facilities or corporate entities, depending upon the facts of the breach.

3. *Opportunity to cure.* Ciena shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

- a. Ciena is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Ciena has begun to take action to cure the material breach; (ii) Ciena is pursuing such action with due diligence; and (iii) Ciena has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Ciena fails to satisfy the requirements of Section X.E.3, the OIG may exclude Ciena from participation in the Federal health care programs. The OIG shall notify Ciena in writing of its determination to excluded Ciena (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.F, below,

the exclusion shall go into effect 30 days after the date of Ciena's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Ciena may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

F. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Ciena of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Ciena 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, the OIG's determination to seek specific performance, demand payment of Stipulated Penalties, or seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS 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), the request for a hearing involving specific performance or Stipulated Penalties shall be made within 10 days of the date of the Demand Letter and a request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Specific Performance Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 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, Ciena was in full and timely compliance with the obligations of this CIA for which the OIG seeks specific performance; and (b) whether Ciena failed to cure. Ciena shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to specific performance. If the ALJ agrees with the OIG, Ciena shall take the actions the OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless Ciena requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of the OIG, Ciena shall take the actions the OIG deems necessary to cure within 20 days after the DAB issues its decision.

3. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only

issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Ciena was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Ciena shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this CIA and orders Ciena to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Ciena requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of the OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

4. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 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 Ciena was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Ciena had begun to take action to cure the material breach within that period; (ii) Ciena has pursued and is pursuing such action with due diligence; and (iii) Ciena provided to the OIG within that period a reasonable timetable for curing the material breach and Ciena has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for Ciena, only after a DAB decision in favor of the OIG. Ciena's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Ciena upon the issuance of an ALJ's decision in favor of the OIG. 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 Ciena may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. Ciena shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the

ALJ or DAB. If the DAB finds in favor of Ciena, Ciena shall be reinstated effective on the date of the original exclusion.

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.

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 Ciena's compliance with applicable state and Federal health care program requirements.

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

A. This CIA shall be binding on the successors, assigns, and transferees of Ciena. The OIG may decide to waive this successor liability provision upon receipt of verified proof to the OIG's satisfaction that Ciena has wholly divested itself of any interest or involvement, direct or indirect, in the transferred or assigned entity, that the successor is an independent entity unrelated in any manner to Ciena, that the successor has acquired its interest at fair market value in an arms' length transaction, and that the successor has policies, procedures, and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as well as a history of such compliance.


B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;


D. The undersigned signatories represent and warrant that they are authorized to execute this CIA on behalf of Ciena, Qazi, Khan, and Pugh. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

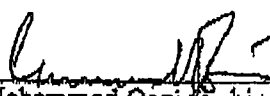
ON BEHALF OF CIENA HEALTHCARE MANAGEMENT, INC.

  
\_\_\_\_\_  
Mohammad Qazi  
Ciena Healthcare Management, Inc.


7/30/07  
DATE

  
\_\_\_\_\_  
Robert Ramsey III  
Counsel for Ciena Healthcare  
Management, Inc.

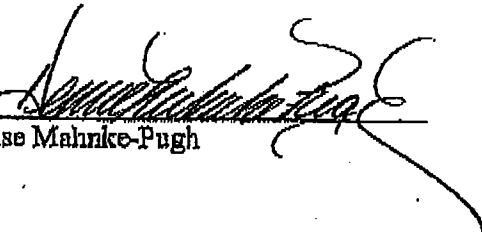
7/30/07  
DATE

  
\_\_\_\_\_  
Mohammad Qazi for himself

7/30/07  
DATE

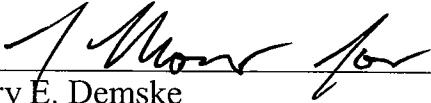
  
\_\_\_\_\_  
Anis Khan

7/30/07  
DATE

  
\_\_\_\_\_  
Denise Mahnke-Pugh

8/2/07  
DATE

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



\_\_\_\_\_  
Gregory E. Demske  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

7/24/07

\_\_\_\_\_  
DATE

## **Appendix A to CIA - Data Analysis Subcontract Description**

Below is a description of the kinds of reports to be provided under the Monitor's subcontract with a data analysis expert, as required by Section III.D of the CIA.

a. Facility Reports: a summary report for each facility covered by this CIA, showing facility-level quality indicator (QI) values and information on the MDS assessments underlying these values. The reports will provide the facility's QI ratios as well as information regarding the placement of these values within the distribution of results for appropriate comparison groups. Initially, two comparison groups will be available. The first comparison group will be all nursing facilities within the subcontractor's MDS assessment database. The second group will be all nursing facilities within Ciena. The subcontractor may make additional comparison groups available if such groups can be readily identified using the facility identification codes within the subcontractor's MDS assessment database.

b. Resident Reports: a resident-level report showing which QI numerators were triggered by each resident in the Facility Report tabulation.

c. Database Extracts: a facility-level database table of QI values for Ciena. This extract will be produced quarterly by the subcontractor and mailed to the Monitor on compact disc or DVD, along with a printed summary of the table contents. These tables will be in a format suitable for use in spreadsheets and/or simple database applications to allow the monitor to manipulate/rearrange the data supporting the QI reports.

d. Documentation: The subcontractor will provide the Monitor with a QI User Guide, which will describe the report format and contents, provide QI definitions in terms of the underlying MDS assessment items, and outline the QI tabulation process.

e. QI Report Distribution: The Facility and Resident reports will be produced quarterly by the subcontractor.

f. QI Analyses: Throughout the term of this subcontract, the subcontractor will analyze the available QI information relating to Ciena in an effort to refine and expand the information provided to the Monitor.

## OVERPAYMENT REFUND

### TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: \_\_\_\_\_  
 Contractor Deposit Control # \_\_\_\_\_ Date of Deposit: \_\_\_\_\_  
 Contractor Contact Name: \_\_\_\_\_ Phone # \_\_\_\_\_  
 Contractor Address: \_\_\_\_\_  
 Contractor Fax: \_\_\_\_\_

### TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

*Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.*

PROVIDER/PHYSICIAN/SUPPLIER NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 PROVIDER/PHYSICIAN/SUPPLIER # \_\_\_\_\_ CHECK NUMBER# \_\_\_\_\_  
 CONTACT PERSON: \_\_\_\_\_ PHONE # \_\_\_\_\_ AMOUNT OF CHECK  
 \$ \_\_\_\_\_ CHECK DATE \_\_\_\_\_

### REFUND INFORMATION

**For each Claim, provide the following:**

Patient Name \_\_\_\_\_ HIC # \_\_\_\_\_  
 Medicare Claim Number \_\_\_\_\_ Claim Amount Refunded \$ \_\_\_\_\_  
 Reason Code for Claim Adjustment: \_\_\_\_\_ (Select reason code from list below. Use one reason per claim)

*(Please list all claim numbers involved. Attach separate sheet, if necessary)*

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: \_\_\_\_\_*

**For Institutional Facilities Only:**

Cost Report Year(s) \_\_\_\_\_  
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

**For OIG Reporting Requirements:**

Do you have a Corporate Integrity Agreement with OIG?                      Yes                      No

**Reason Codes:**

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp. (Including Black Lung)	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		
07 - Corrected CPT Code		