CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
DAYBREAK VENTURE, LLC AND DAYBREAK PARTNERS, LLC

I. PREAMBLE

Daybreak Venture, LLC and Daybreak Partners, LLC (Provider) 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 promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Provider is entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), Daybreak established a voluntary corporate compliance program (the Compliance Program). Daybreak’s Compliance Program includes a Chief Compliance Officer, Compliance Committee, Code of Conduct, written policies and procedures, a disclosure program, screening measures, regular compliance training for employees, and various compliance auditing programs. Daybreak shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Daybreak may modify its Compliance Program as appropriate, but, at a minimum, Daybreak shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

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

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B. This CIA applies to any long term care facility in which Provider has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any long term care facility that is managed by Provider.

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

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

1. “Covered Persons” includes:
   a. all owners, officers, directors, and employees of Provider;
   b. all owners, officers, directors, and employees of any corporation, subsidiary, affiliate, joint venture, or other organization or entity in which Provider, or its individual owners, own 5% or more or have a controlling interest at any time during the term of the CIA and that operates a long term care facility, or any long term care facility that Provider or its individual owners operate or have a management contract or arrangement to provide management and/or 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
   c. all contractors, subcontractors, agents, and other persons who: (1) are involved directly or indirectly in the delivery of resident resident care; (2) make assessments of residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, 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. Any nonemployee private caregivers and/or attending physicians hired by any resident or the family or friends of any resident of Provider are not Covered Persons, regardless of the hours worked per year in Provider.

2. "Relevant Covered Persons" includes all Covered Persons who: (1) are involved directly or indirectly in the delivery of resident care; (2) make assessments of residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, 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.

III. CORPORATE INTEGRITY OBLIGATIONS

Provider shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer, Compliance Committee, and Board of Directors

1. Compliance Officer. Within 90 days after the Effective Date, Provider shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer must have sufficient compliance and quality assurance experience to effectively oversee the implementation of the requirements of this CIA. The Compliance Officer shall be an employee and a member of senior management of Provider, shall report directly to the Chief Executive Officer of Provider, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Provider, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer’s reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer shall not be or be subordinate to the General Counsel, Chief
Financial Officer, or Chief Operating Officer, or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Provider. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Provider, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer’s reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Provider and any reporting obligations created under this CIA, and ensuring that Provider is appropriately identifying and correcting quality of care problems.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

Provider shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. **Compliance Committee.** Within 90 days after the Effective Date, Provider shall appoint a Quality Assurance Compliance Committee (hereinafter “Compliance Committee”).

a. **General Responsibilities.** The purpose of this committee shall be to support the Compliance Officer in fulfilling his/her responsibilities (e.g., developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care; monitoring the day-to-day compliance
activities engaged in by Provider; monitoring any reporting obligations created under this CIA; and ensuring that Provider is appropriately identifying and correcting quality of care problems. The Compliance Committee shall, at a minimum, include the Compliance Officer, representatives from among senior personnel responsible for clinical operations and quality of care, human resources, operations including the Vice President of Clinical Services, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee.

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, senior management of Provider shall report to the Compliance Committee on the adequacy of care being provided by Provider and senior representatives from Provider's facilities shall be chosen, on a rotating and random basis, to report to the Compliance Committee on the adequacy of care being provided at their facilities. The minutes of the Compliance Committee meetings shall be made available to the OIG upon request.

Provider shall report to OIG, in writing, any changes in the composition of the Compliance Committee, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after the change.

b. **Staffing Responsibilities.** The Compliance Committee shall assess the nursing staffing provided at Provider and make recommendations regarding how to improve such staffing. The Compliance Committee shall consult with nurse managers, RNs, LPNs, and certified nursing aides (CNAs) from each facility and the Independent Monitor required under Section III.D of
this CIA regarding staffing at each facility. In consultation with the Independent Monitor required under Section III.D of this CIA, the Compliance Committee shall:

i. review the development and implementation of the staffing-related policies and procedures required by Section III.B.2.f of the CIA.

ii. assess on an on-going basis whether Provider is providing the quantity, quality, and composition of nursing staff necessary to meet resident needs at each of its facilities;

iii. make recommendations as to how Provider can improve the quantity, quality, and composition of nursing staff necessary to meet resident needs;

iv. identify obstacles related to the recruitment, retention, and training of nursing staff at each of Provider’s facilities; and

v. make recommendations as to how Provider can improve the recruitment, retention, and training of nursing staff.

c. Quality of Care Review Program. The Compliance Committee shall ensure that, within 120 days after the Effective Date, Provider establishes and implements a program for performing internal quality audits and reviews (hereinafter “Quality of Care Review Program”). The Quality of Care Review Program shall make findings as to:

i. whether the residents at Provider are receiving the quality of care for residential settings and quality of life consistent with professionally recognized standards of care, 42 C.F.R. Part 483, and any other applicable federal and state
d. **Quality of Care Dashboard.** The Compliance Committee, in consultation with the Monitor required under Section III.D of this CIA, shall create and implement a “Quality of Care Dashboard” (Dashboard), which will function as a performance scorecard for Provider. Quality indicator data shall be collected and reported on the Dashboard. Within 120 days after the Effective Date, the Compliance Committee shall: (1) identify and establish the overall quality improvement goals for Provider based on its assessment of [Provider’s] quality of care risk areas; (2) identify and establish the quality indicators related to those goals that Provider will monitor through the Dashboard; and (3) establish performance metrics for each quality indicator. The Compliance Committee shall measure, analyze, and track the performance metrics for the quality indicators on a monthly basis, monitoring progress towards the quality improvement goals. At least semi-annually, the Compliance Committee shall review the quality indicators to determine if revisions are appropriate and shall make any necessary revisions based on such review.
3. Board of Directors Compliance Obligations. Within 90 days after the Effective Date, Provider shall create a committee as part of its Board of Directors (hereinafter “Board of Directors Committee”).

a. General Responsibilities. The purpose of the Board of Directors Committee shall be to review and provide oversight of matters related to Provider’s compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care. The individuals who serve on the Board of Directors Committee shall be readily available to the Compliance Officer and the Monitor required under Section III.D of this CIA to respond to any issues or questions that might arise. The Board of Directors Committee shall, at a minimum:

i. meet at least quarterly to review and oversee Provider’s Compliance Program, including, but not limited to, the performance of the Compliance Officer and the Compliance Committee;

ii. review the adequacy of Provider’s system of internal controls, quality assurance monitoring, and resident care;

iii. ensure that Provider’s response to state, federal, internal, and external reports of quality of care problems is complete, thorough, and resolves the problem(s) identified;

iv. ensure that Provider adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care;

v. review and respond to the Dashboard and ensure that Provider implements effective
responses when potential quality problems are indicated on the Dashboard or when quality indicators show that Provider is not meeting its established goals.

b. For each Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of Provider’s Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Provider’s compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Provider’s compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Provider. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to the OIG upon request.

b. **Board Resolution.** For the Implementation Report required under Section V.A and for each Reporting Period of the CIA, the Board of Directors shall adopt a resolution (consistent with the bylaws for adopting resolutions) summarizing the Board of Directors Committee’s review and oversight of Provider’s compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care. Each individual member of the Board of Directors Committee shall sign a statement indicating that he or
she agrees with the resolution. At a minimum, the resolution shall include the following language:

“\[quote\]The Board of Directors has made a reasonable inquiry into the operations of Provider’s Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. The Board of Directors has also provided oversight on quality of care issues. Based on its inquiry and review, the Board of Directors has concluded that, to the best of its knowledge, Provider has implemented an effective Compliance Program and Provider is in compliance with the requirements of the CIA, the Federal health care programs, and professionally recognized standards of care.\[quote\]"

In support of making the resolution below during each Reporting Period, Provider submit to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of Provider’s compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care.

If the Board of Directors is unable to provide such a conclusion in the resolution, the Board of Directors shall include in the written resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to ensure that Provider implements an effective Compliance Program at Provider.

Provider shall report to OIG, in writing, any changes in the composition of the Board of Directors Committee, or any actions or changes that would affect the Board of Directors Committee’s ability to perform the duties
necessary to meet the obligations in this CIA, within 15 days after such a change.

4. Management Certifications. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Provider employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Provider department is in compliance with applicable Federal health care program requirements, with the obligations of this CIA, and with professionally recognized standards of healthcare. These Certifying Employees shall include, at a minimum, the following: the Administrator and the Director of Nursing of each long term care facility referred to in Section II(B) of this CIA. For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, professionally recognized standards of healthcare, and Provider policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of Provider is in compliance with all applicable Federal health care program requirements, the obligations of the Corporate Integrity Agreement, and professionally recognized standards of healthcare. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, Provider shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

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1. **Code of Conduct.** Within 90 days after the Effective Date, Provider shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Provider shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

   a. Provider's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

   b. Provider's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Provider's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

   c. the requirement that all of Provider's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Provider, suspected violations of any Federal health care program requirements or of Provider's own Policies and Procedures;

   d. the requirement that all of Provider's Covered Persons shall immediately report to the Compliance Officer, or other appropriate individual designated by Provider, credible allegations of resident harm and such report shall be complete, full, and honest;

   e. the possible consequences to both Provider and Covered Persons of failure to comply with Federal health care program requirements and with Provider's own Policies and Procedures and the failure to report such noncompliance; and

   f. the right of all individuals to use the Disclosure Program described in Section III.E of this CIA, and Provider's commitment to nonretaliation and to
maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Provider’s Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Provider shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. **Policies and Procedures.** Within 90 days after the Effective Date, Provider shall develop and implement written Policies and Procedures regarding the operation of Provider’s compliance program, including the compliance program requirements outlined in this CIA, Provider’s compliance with Federal health care program requirements. Throughout the term of this CIA, Provider shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

At a minimum, the Policies and Procedures shall address:

- **a.** the compliance program requirements outlined in this CIA;

- **b.** the 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 Provider is appropriately and accurately using the current Resource Utilization Groups (RUG) classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;

- **c.** compliance with the completion of accurate clinical assessments as required by applicable Federal law,
which shall include: (1) that all 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;

d. compliance with Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5, 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 other state or local statutes, regulations, directives, or guidelines that address quality of care in nursing homes, as well as professionally recognized standards of health care;

e. the coordinated interdisciplinary approach to providing care, including but not limited to the following areas addressed in 42 C.F.R. § 483:

i. resident rights;
ii. admission, transfer, and discharge rights;
iii. resident behavior and facility practices;
iv. quality of life;
v. resident assessment;
vi. quality of care;
vii. nursing services;
viii. dietary services;
ix. physician services;
x. specialized rehabilitative services;
xi. dental services;
xii. pharmacy services;
xiii. infection control;
xiv. physical environment; and
xv. administration.

f. staffing, including, but not limited to:
i. ensuring that nursing staff levels are sufficient to meet residents’ needs, as required by Federal and state laws, including, but not limited to, 42 C.F.R. § 483.30 (nursing services);

ii. a measurable, acuity-based staffing protocol that includes resident needs-based direct care nurse staffing per patient day scaled requirements for each class of nursing staff (e.g., RNs, LPNs, CNAs) and the methodology for establishing the per patient day requirements;

iii. ensuring that Covered Persons are informed of the staffing requirements of Federal and state law, that staffing levels are a critical aspect of 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; and

iv. minimizing the number of individuals working on a temporary assignment or not employed by Provider (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 who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Provider or the Monitor.

g. capital improvements, including but not limited to a process to ensure that Provider and its nursing facilities address facility maintenance and repairs, equipment adequacy, supplies, and make necessary capital expenditures to provide a habitable
environment and to protect the health and safety of residents, personnel, and the public in a timely manner consistent with their obligations under the Nursing Home Reform Act, OBRA 1987, Pub. L. 100-203 § 4203 (amending Social Security Act § 1818(g), (h)), and its regulations.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. The Policies and Procedures shall be available to OIG upon request.

At least annually (and more frequently, if appropriate), Provider shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. Training Plan. Within 90 days after the Effective Date, Provider shall develop a written plan (Training Plan) that outlines the steps Provider will take to ensure that: (a) all Covered Persons receive adequate training regarding Provider’s CIA requirements and Compliance Program, including the Code of Conduct and (b) all Relevant Covered Persons receive adequate training regarding: (i) policies, procedures, and other requirements applicable to the documentation of medical records; (ii) the policies implemented pursuant to Section III.B.2 of this CIA, as appropriate for the job category of each Relevant Covered Person; (iii) the coordinated interdisciplinary approach to providing care and related communication between disciplines; (iv) the personal obligation of each individual involved in resident care to ensure that care is appropriate and meets professionally recognized standards of care; (v) examples of proper and improper care; and (vi) reporting requirements and legal sanctions for violations of the Federal health care program requirements. The Training Plan shall also include training to address quality of care problems identified by the Compliance Committee. In determining what training should be performed, the Compliance Committee shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by CMS survey and its agents the Joint Commission or other such private agencies, any
internal surveys, the CMS quality indicators, and the findings, reports, and recommendations of the Monitor required under Section III.D of this CIA.

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

The Training Plan shall include information regarding the training topics, the categories of Covered Persons and Relevant Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG’s receipt of Provider’s Training Plan, OIG will notify Provider of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, Provider may implement its Training Plan. Provider shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. **Board Member Training.** Within 90 days after the Effective Date, Provider shall provide at least two hours of training to each member of the Board of Directors. This training shall address the Provider’s CIA requirements and Compliance Program (including the Code of Conduct), the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG’s guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. **Certification.** Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.
4. **Qualifications of Trainer.** Persons providing the training shall be knowledgeable about the subject area.

5. **Update of Training Plan.** Provider shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to Provider's Training Plan, OIG will notify Provider of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, Provider may implement the revised Training Plan.

6. **Computer-based Training.** Provider may provide the training required under this CIA through appropriate computer-based training approaches. If Provider chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. **Independent Monitor**

Within 60 days after the Effective Date, Provider shall retain an appropriately qualified monitoring team (the "Monitor"), selected by OIG after consultation with Provider. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor's obligations under this CIA. The Monitor may confer and correspond with Provider or OIG individually or together. The Monitor and Provider shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, until after the date of OIG's CIA closure letter to Provider or six months after the expiration of this CIA, whichever is later.

The Monitor is not an agent of OIG. However, the Monitor may be removed by OIG at its sole discretion. If the Monitor resigns or is removed for any other reasons prior to the termination of the CIA, Provider shall retain, within 60 days of the resignation or removal, another Monitor selected by OIG, with the same functions and authorities.

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

a. Provider’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 problems 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, thorough, and competency-based.

b. Provider’s response to quality of care issues, which shall include an assessment of:

i. Provider’s ability to identify the problem;

ii. Provider’s ability to determine the scope of the problem, including, but not limited to, whether the problem is isolated or systemic;

iii. Provider’s ability to conduct a root cause analysis;

iv. Provider’s ability to create an action plan to respond to the problem;

v. Provider’s ability to execute the action plan; and

vi. Provider’s ability to monitor and evaluate whether the assessment, action plan, and
execution of that plan was effective, reliable, and thorough.

c. Provider’s proactive steps to ensure that each resident receives care in accordance with:

i. professionally recognized standards of health care;

ii. the rules and regulations set forth in 42 C.F.R. Part 483;

iii. State and local statutes, regulations, and other directives or guidelines; and

iv. the Policies and Procedures adopted by Provider, including those implemented under Section III.B of this CIA;

d. Provider’s compliance with staffing requirements;

e. Provider’s ability to analyze outcome measures, such as the CMS Quality Indicators, and other data;

f. Provider’s Quality of Care Review Program required under Section III.A.2.c of this CIA;

g. Provider’s Quality of Care Dashboard required under Section III.A.2.d of this CIA; and

h. Provider’s ability to identify and correct physical plant problems, including the implementation and effectiveness of the capital improvements process required under Section III.B.2.g of this CIA.

2. Access. The Monitor shall have:

a. immediate access to Provider, 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:

i. the CMS quality indicators;

ii. internal or external surveys or reports;

iii. Disclosure Program complaints;

iv. resident satisfaction surveys;

v. staffing data in the format requested by the Monitor, including reports detailing when more than 10 percent of Provider’s staff are hired on a temporary basis;

vi. reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment;

vii. reports of any falls;

viii. reports of any incident involving a resident that prompts a full internal investigation;

ix. resident records;

x. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and

xi. any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA;

c. immediate access to residents, and Covered Persons for interviews outside the presence of Provider
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.

3. **Baseline Systems Assessment.** Within 120 days after the Effective Date of the CIA, the Monitor shall:

   a. complete an assessment of the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1;

   b. in conducting this assessment, visit Provider’s facilities (selected by the Monitor) and, at a minimum, observe quality assurance meetings, observe corporate compliance meetings, observe care planning meetings, observe Board of Directors Committee meetings, interview key employees, review relevant documents, and observe resident care; and

   c. submit a written report to Provider and OIG that sets forth, at a minimum:

      i. a summary of the Monitor’s activities in conducting the assessment;

      ii. the Monitor’s findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1; and

      iii. the Monitor’s recommendations to Provider as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1.

4. **Systems Improvements Assessments.** On a quarterly basis, the Monitor shall:
a. re-assess the effectiveness, reliability, and thoroughness of the systems described in Section III.D.1;

b. assess Provider’s response to recommendations made in prior written assessment reports;

c. in conducting these assessments, visit Provider’s facilities (selected by the Monitor) and, at a minimum, observe quality assurance meetings, observe corporate compliance meetings, observe care planning meetings, observe Board of Directors Committee meetings, interview key employees, review relevant documents, and observe resident care (the Monitor may also want to have regular telephone calls with Provider and any of its poorer performing facilities); and

d. submit a written report to Provider and OIG that sets forth, at a minimum:

   i. a summary of the Monitor’s activities in conducting the assessment;

   ii. the Monitor’s findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1;

   iii. the Monitor’s recommendations to Provider as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1; and

   iv. the Monitor’s assessment of Provider’s response to the Monitor’s prior recommendations.

The Monitor shall perform assessments for each quarter after the Baseline Systems Assessment. The Monitor shall submit written reports no later than 30 days after the end of the relevant quarter to Provider and OIG.
5. **Financial Obligations of Provider and the Monitor.**

a. Provider shall be responsible for all reasonable costs incurred by the Monitor in connection with this engagement, including, but not limited to, labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).

b. Provider shall pay the Monitor's bills within 30 days of receipt. Failure to pay the Monitor within 30 calendar days of submission of the Monitor's invoice for services previously rendered shall constitute a basis to impose stipulated penalties or exclude Provider, as provided under Section X of this CIA. While Provider must pay all of the Monitor's bills within 30 days, Provider may bring any disputed Monitor's Costs or bills to OIG's attention.

c. The Monitor shall charge a reasonable amount for its fees and expenses, and shall submit monthly invoices to Provider with a reasonable level of detail reflecting all key category costs billed.

d. The Monitor shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to Provider and to OIG by the submission deadline of Provider's Annual Report. This report shall reflect, on a cumulative basis, all key category costs included on monthly invoices.

6. **Additional Provider Obligations.** Provider shall:

a. As a condition of retaining the Monitor, Provider shall require the Monitor to enter into a subcontract with an individual or entity, approved by OIG, that can create objective and independent Quality Indicator data analysis reports of the type described in the attached Appendix A;
b. within 30 days after receipt of each written report of the Baseline Systems Assessment or Systems Improvement Assessments, submit a written response to OIG and the Monitor to each recommendation contained in those reports stating what action Provider took in response to each recommendation or why Provider has elected not to take action based on the recommendation;

c. 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 Provider;

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, if applicable, the full name, social security number, and date of birth of the residents involved, the date of death or incident, and a brief description of the events surrounding the death or incident.

d. provide to its Compliance Committee and Board of Directors Committee copies of all documents and reports provided to the Monitor;

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

f. provide access to current residents 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;

g. assist in locating and, if requested, attempt to obtain cooperation from past employees, contractors, agents, and residents and their families;

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

7. Additional Monitor 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, and residents;

b. abide by the legal requirements of Provider 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 resident clinical records, to OIG, and, when legally or professionally required, to other agencies;

c. at all times act reasonably in connection with its duties under the CIA including when requesting information from Provider;

d. if the Monitor has concerns about action plans that are not being enforced or systemic problems that could affect Provider’s ability to render quality care to its residents, then the Monitor shall:

i. report such concerns in writing to OIG; and

ii. simultaneously provide notice and a copy of the report to Provider’s Compliance Committee and Board of Directors Committee referred to in Section III.A of this CIA;

e. 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 OIG and to Provider;

f. not be bound by any other private or governmental agency’s findings or conclusions, including, but not limited to, Joint Commission, 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 Provider, and Provider 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 OIG or Provider 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;

\[
g. \quad \text{abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Provider; and}
\]

\[
h. \quad \text{except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures, and forms obtained in connection with its duties under this CIA and not comment publicly concerning its findings except to the extent authorized by OIG.}
\]

E. Disclosure Program

Within 90 days after the Effective Date, Provider 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 disclosing individual’s chain of command, any identified issues or questions associated with Provider’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. Provider 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).

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 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, Provider shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practices places residents at risk of harm, then Provider will ensure that that practice ceases immediately and that appropriate action is taken.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within 48 hours of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

The disclosure log shall be sent to the Monitor required under Section III.D of this CIA not less than monthly.

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, or suspended from participation 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 scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or suspended.

b. “Exclusion Lists” include:

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

ii. the General Services Administration’s System for Award Management (available through the Internet at http://www.sam.gov).

2. **Screening Requirements.** Provider shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

   a. Provider shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

   b. Provider shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter.

   c. Provider shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

Nothing in Section III.F affects Provider’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Provider understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Provider may be liable for
overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Provider meets the requirements of Section III.F.

3. **Removal Requirement.** If Provider has actual notice that a Covered Person has become an Ineligible Person, Provider shall remove such Covered Person from responsibility for, or involvement with, Provider’s business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person’s compensation or the items or services furnished, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

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

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

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

In addition, within 15 days after notification, Provider shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., Joint Commission) relating to quality of care issues.

H. **Repayment of Overpayments**
1. **Definition of Overpayments.** For purposes of this CIA, an "Overpayment" shall mean the amount of money Provider has received in excess of the amount due and payable under any Federal health care program requirements.

2. **Repayment of Overpayments**

   a. If, at any time, Provider identifies or learns of any Overpayment, Provider shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 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. If not yet quantified, within 60 days after identification, Provider 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.

   b. 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.

I. **Reportable Events**

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

   a. a substantial Overpayment;

   b. 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;

c. 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;

d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

e. insolvency or a matter that a reasonable person would consider likely to render Provider insolvent.

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

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

3. Reportable Events under Section III.I.1.a. For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment and shall include:

   a. a description of the steps taken by Provider to identify and quantify the Overpayment;

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

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c. a description of Provider’s actions taken to correct the Reportable Event; and 
d. any further steps Provider plans to take to address the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Provider shall provide OIG with a copy of the notification and repayment to the payor required in Section III.H.2.

4. Reportable Events under Section III.I.1.b and d. For Reportable Events under Section III.I.1.b and d, the report to OIG shall include:

   a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
   b. a description of Provider’s actions taken to correct the Reportable Event;
   c. any further steps Provider plans to take to address the Reportable Event and prevent it from recurring; and
   d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Provider to identify and quantify the Overpayment.

5. Reportable Events under Section III.I.1.c. For Reportable Events under Section III.I.1.c, the report to OIG shall include:

   a. a complete description of the Reportable Event, including the relevant facts, persons involved, the impact or potential impact on Federal health care program beneficiaries, and any legal and Federal health care program authorities implicated;
   b. a description of Provider’s action taken to correct the Reportable Event;
c. any further steps Provider plans to take to address the Reportable Event and prevent it from reoccurring; and

d. a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies.

6. Reportable Events under Section III.I.1.e. For Reportable Events under Section III.I.1.e, the report to OIG shall include:

a. a complete description of the Reportable Event;

b. a description of Provider’s action taken to ensure that the Reportable Event does not adversely impact resident care;

c. any further steps Provider plans to take to address the Reportable Event; and

d. if the Reportable Event involves the filing of a bankruptcy petition, documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. Reportable Events Involving the Stark Law. Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Provider to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If Provider identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Provider is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

IV. Successor Liability: Changes to Business Units or Locations

A. Sale of Business, Business Unit or Location.

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In the event that, after the Effective Date, Provider proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, Provider shall notify OIG of the proposed sale at least 30 days prior to the sale of such business, business unit or location. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business, business unit or location, unless otherwise determined and agreed to in writing by OIG.

B. Change or Closure of Business, Business Unit or Location.

In the event that, after the Effective Date, Provider changes locations or closes a business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Provider shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit or location.

C. Purchase or Establishment of New Business, Business Unit or Location.

In the event that, after the Effective Date, Provider purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Provider shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location’s Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Provider currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Provider shall submit a written report to OIG summarizing the status of its
implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. the names of the Board members who are responsible for satisfying the Board of Directors Committee compliance obligations described in Section III.A;

4. a description of the Quality of Care Review Program required by Section III.A.2.c;

5. a description of the Dashboard required by Section III.A.2.d;

6. a copy of Provider’s Code of Conduct required by Section III.B.1;

7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

8. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to OIG upon request);

9. the following information regarding each type of training required by Section III.C:

   a. a description of such training, including the targeted audience, the categories of personnel required to participate in the training, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

10. a description of the Disclosure Program required by Section III.E;

11. a description of the process by which Provider fulfills the requirements of Section III.F regarding Ineligible Persons;

12. a list of all of Provider’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 and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Provider currently submits claims;

13. a description of Provider’s corporate structure, including identification of any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business;

14. the certifications required by Section V.C; and

15. a copy of the Board of Directors Committee Resolution required by Section III.A.3.b.

B. Annual Reports. Provider shall submit to OIG annually a report with respect to the status of, and findings regarding, Provider’s compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee or Board of Directors Committee described in Section III.A;
2. the dates of each report made by the Compliance Officer and Compliance Committee to the Board of Directors (written documentation of such reports shall be made available to OIG upon request);

3. a summary of activities and findings under Provider’s Quality of Care Review Program and a summary of any corrective action taken in response to any problems identified through its Quality of Care Review Program as required by Section III.A.2.c;

4. a summary of the Compliance Committee’s measurement, analysis, and tracking of the performance metrics included in Provider’s Dashboard, Provider’s progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes, and activities, assessments, recommendations, and findings related to staffing and Provider’s response to those findings;

5. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution including a copy of the Compliance Program Review Report;

6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG, upon request);

7. a summary of any significant changes or amendments to Provider’s Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

8. a copy of Provider’s Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and
the process by which Provider ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request;

9. Provider's response and action plan(s) related to any written recommendations of the Monitor pursuant to Section III.D;

10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs and delivery of resident care (the complete disclosure log shall be made available to OIG upon request);

11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

12. a certification that Provider has completed the screening required by Section III.F regarding Ineligible Persons;

13. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

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

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a description of all changes to the most recently provided list of Provider's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the
name and address of each Medicare and state Medicaid program contractor to which Provider currently submits claims; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG 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, Provider shall participate in an in-person meeting with a representative of OIG to review Provider’s performance under the CIA. OIG, in its discretion, may waive this meeting requirement.

C. Certifications

1. Certifying Employees. In each Annual Report, Provider shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Compliance Officer and Chief Executive Officer. The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

   a. to the best of his or her knowledge, except as otherwise described in the report, Provider is in compliance with all of the requirements of this CIA; and

   b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

D. Designation of Information. Provider 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. Provider shall refrain from identifying any information as exempt from
disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. **NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

**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
Telephone: 202.619.2078
Facsimile: 202.205.0604

**Provider:**
Michael Rich
Jackie Stephens
Daybreak Venture LLC
401 N Elm St,
Denton, TX 76201
Phone: (940) 297-1230 OR (888)983-4310
Fax: (940) 999-5054

James Holloway
Ober Kaler
1401 H Street, NW
Suite 500
Washington, DC 20005
Phone: (202) 326-5045
Fax: (202) 336-5245
Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Provider may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Provider’s books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Provider’s locations for the purpose of verifying and evaluating: (a) Provider’s compliance with the terms of this CIA; and (b) Provider’s compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Provider 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 Provider’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 OIG. Provider shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG’s request. Provider’s employees may elect to be interviewed with or without a representative of Provider present.

VIII. DOCUMENT AND RECORD RETENTION

Provider shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA, for 6 years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS’s FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Provider prior to any release by OIG of information submitted by Provider pursuant to its obligations under this CIA and
identified upon submission by Provider as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Provider shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. **Breach and Default Provisions**

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

A. **Specific Performance of CIA Provisions.** If OIG determines that Provider 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 Provider with prompt written notification of such determination. (This notification shall be referred to as the “Noncompliance Notice.”) Provider shall have 30 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that Provider disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge (ALJ), pursuant to the provisions set forth in Section X.F of this CIA.

B. **Stipulated Penalties for Failure to Comply with Certain Obligations.** As a contractual remedy, Provider and OIG hereby agree that failure to comply with certain obligations as 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 Provider fails to establish and effectively implement any of the following obligations as described in Section III:

   a. a Compliance Officer;

   b. a Compliance Committee;

   c. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review and the preparation
of a Compliance Program Review Report, as required by Section III.A.3;

d. a Quality of Care Review Program;

e. a Dashboard;

f. a written Code of Conduct;

g. written Policies and Procedures;

h. the training of Covered Persons, Relevant Covered Persons, and Board Members in the manner required by Section III.C;

i. retention of a Monitor;

j. a Disclosure Program;

k. Ineligible Persons screening and removal requirements;

l. notification of Government investigations or legal proceedings; and

m. reporting of Reportable Events.

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 Provider fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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

4. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Provider as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

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5. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Provider fails to pay a Monitor, as required in Section III.D.5.

6. A Stipulated Penalty of $2,500 for each day Provider fails to comply fully and adequately with any of its obligations with respect to the Monitor, including, but not limited to, the obligation to adequately and timely respond to any written recommendation of the Monitor, as set forth in Section III.D.6. OIG shall provide notice to Provider stating the specific grounds for its determination that Provider has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Provider shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Provider receives this notice from OIG of the failure to comply.)

7. A Stipulated Penalty of $1,000 for each day Provider fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Provider stating the specific grounds for its determination that Provider has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Provider shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Provider receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

C. **Timely Written Requests for Extensions.** Provider 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 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 Provider fails to meet the revised deadline set by OIG. 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 three business days after Provider receives 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.

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D. Payment of Stipulated Penalties

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

2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, Provider shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS ALJ to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.F. In the event Provider elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Provider cures, to 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

4. Independence from Material Breach Determination. Except as set forth in Section X.E.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Provider has materially breached this CIA, which decision shall be made at 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

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b. a failure by Provider to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Sections III.H and III.I;

c. a violation of any obligation under this CIA that has a material impact on the quality of resident care;

d. a failure to respond to a Noncompliance Notice concerning specific performance in accordance with Section X.A;

e. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D; or

f. a failure to retain, pay, or use the Monitor, or failure to respond to the recommendations of 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 Provider constitutes an independent basis for Provider's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Provider has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Provider of: (a) Provider's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude."). The exclusion may be directed at one or more of Provider's facilities or corporate entities, depending upon the facts of the breach.

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

   a. the alleged material breach has been cured; or

   b. the alleged material breach cannot be cured within the 30-day period, but that: (i) Provider has begun to take action to cure the material breach; (ii) Provider is
pursuing such action with due diligence; and (iii) Provider has provided to OIG a reasonable timetable for curing the material breach.

4. **Exclusion Letter.** If, at the conclusion of the 30-day period, Provider fails to satisfy the requirements of Section X.E.3, OIG may exclude Provider from participation in the Federal health care programs. OIG shall notify Provider in writing of its determination to exclude Provider. (This letter shall be referred to 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 Provider’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Provider 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 OIG’s delivery to Provider of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Provider shall be afforded certain review rights comparable to the ones that are provided 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, OIG’s determination to demand specific performance, 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 after receipt of the Demand Letter and the 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, Provider was in full and timely compliance

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with the obligations of this CIA for which OIG seeks specific performance; and

b. whether Provider failed to cure.

Provider shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to specific performance. If the ALJ agrees with OIG, Provider shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless Provider 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 OIG, Provider shall take the actions 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 Provider was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Provider shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Provider to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Provider 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 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 whether Provider was in material breach of this CIA and, if so, whether:

a. Provider cured such breach within 30 days of its receipt of the Notice of Material Breach; or
b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following Provider’s receipt of the Notice of Material Breach: (i) Provider had begun to take action to cure the material breach; (ii) Provider pursued such action with due diligence; and (iii) Provider 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 favorable to OIG, or, if the ALJ rules for Provider, only after a DAB decision in favor of OIG. Provider’s election of its contractual right to appeal to the DAB shall not abrogate OIG’s authority to exclude Provider upon the issuance of an ALJ’s decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Provider may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Provider 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 Provider, Provider 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.

XI. Effective and Binding Agreement

Provider and OIG agree as follows:

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

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
C. OIG may agree to a suspension of Provider’s obligations under this CIA based on a certification by Provider that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If Provider is relieved of its CIA obligations, Provider will be required to notify OIG in writing at least 30 days in advance if Provider plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Provider’s responsibility to follow all applicable Federal health care program requirements or (2) the government’s right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Provider signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

F. 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 PROVIDER

/Michael Rich/

Michael Rich
Chief Executive Officer/General Partner
DAYBREAK VENTURE, LLC
DAYBREAK PARTNERS, LLC

9/26/16

DATE

/James P. Holloway/

James P. Holloway
Ober Kaler Grimes & Shriver, PC
Counsel for Daybreak Venture, LLC
and Daybreak Partners, LLC

9/27/16

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

/Robert K. DeConti/ 9/30/16

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Nancy W. Brown/ 9/27/16

NANCY W. BROWN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services
Appendix A to CIA - Data Analysis Subcontract Description

1. Under the Monitor’s subcontract with a data analysis expert, as required by Section III.D of the CIA, the data analysis expert shall provide, at a minimum, the following reports to the Monitor and Provider on a quarterly basis:

   a. Facility Reports: a summary report for Provider, showing facility-level quality indicator (QI) values and information on the MDS assessments underlying these values.

   b. Facility Comparison Reports: a summary table that includes QI values for each facility covered by the CIA and allows Provider to compare the QI values among the facilities.

   c. Peer Comparison Reports: a summary report comparing Provider’s QI values to the QI values of an appropriate peer comparison group.

   d. Resident Reports: if the data is available to the data analysis expert, a resident-level report showing which QI values were triggered by each resident in the Facility Report.

2. The data analysis expert will provide the Monitor with a QI User Guide, which will describe the format and contents of the reports listed above and provide QI definitions in terms of the underlying MDS assessment items.