CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
EXTENDICARE HEALTH SERVICES, INC.
AND
THE PROGRESSIVE STEP CORPORATION

I. PREAMBLE

Extendicare Health Services, Inc. ("EHSI"), and The Progressive Step Corporation ("ProStep") (hereafter collectively referred to as "Extendicare") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote 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, Extendicare is entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), Extendicare established a voluntary corporate compliance program (the Compliance Program). Extendicare's Compliance Program includes a Chief Compliance Officer, Code of Conduct, written policies and procedures, a disclosure program, screening measures, regular compliance training for employees, and various compliance auditing programs. Extendicare's Canadian parent company, Extendicare, Inc., has a Board of Directors Quality and Compliance Committee. Extendicare shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Extendicare may modify its Compliance Program as appropriate, but, at a minimum, Extendicare 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 Extendicare 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."

B. This CIA applies to any long term care facility in which Extendicare has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), any long term care facility managed by Extendicare, and any Extendicare-owned supplier of rehabilitation therapy services to long-term care facilities. This CIA shall apply only to U.S. operations of Extendicare that are subject to U.S. Federal health care program requirements.

C. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Extendicare's final annual report; or (2) any additional materials submitted by Extendicare 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 who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and employees of Extendicare;

   b. all owners, officers, directors, and employees of any corporation, subsidiary, affiliate, joint venture, or other organization or entity in which Extendicare, 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 or supplies rehabilitation services to a long term care facility. This shall include any long term care facility that Extendicare or its individual owners 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 of 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 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 other function that relates to or is covered by this CIA.

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 guardians of any resident of Extendicare are not Covered Persons, regardless of the hours worked per year at Extendicare.

2. "Relevant Covered Persons" includes all Covered Persons who: (1) are involved directly or indirectly in the delivery of resident care; (2) are involved directly or indirectly in the delivery of rehabilitation therapy; (3) make assessments of residents that affect treatment decisions or reimbursement; (4) perform billing, coding, audit, or review functions; (5) make decisions or provide oversight about staffing, resident care, reimbursement, policies and procedures, or this CIA; or (6) perform any function that relates to or is covered by this CIA

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Responsibilities of Compliance Officer, Compliance Committee, Board of Directors, and Staffing Review Committee

1. *Compliance Officer*. Within 90 days after the Effective Date, Extendicare shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for 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. The Compliance Officer shall also be responsible for monitoring the day-to-day compliance activities engaged in by Extendicare and any reporting obligations created under this CIA. The Compliance Officer shall ensure that Extendicare adopts procedures and systems intended to identify and correct quality of care issues. 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 a member of senior management of Extendicare, shall report directly to the Chief Executive Officer of Extendicare, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Extendicare, 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 supervised legal counsel functions for Extendicare. 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.

Extendicare shall report to OIG, in writing, any changes 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, Extendicare 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 Extendicare; monitoring any reporting obligations created under this CIA; and ensuring that Extendicare is appropriately identifying and correcting quality of care issues). The Compliance Committee shall, at a minimum, include the Compliance Officer, the corporate Medical Director, representatives from among senior personnel responsible for clinical operations and quality of care, human resources, operations, 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 minutes of the Compliance Committee meetings shall be made available to OIG upon request.

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, senior management of Extendicare shall report to the Compliance Committee, on the adequacy of care being provided by Extendicare, and senior representatives from Extendicare'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. Attendance at such committee meetings by such senior management may be via conference phone or video conferencing equipment although in person attendance is the desired and intended form of attendance.

Extendicare 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. *Quality of Care Review Program*. The Compliance Committee shall ensure that, within 120 days after the Effective Date, Extendicare 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 be designed to determine:

i. whether the residents at Extendicare are receiving the quality of care and quality of life consistent with professionally recognized standards of care, 42 C.F.R. Part 483, and any other applicable federal and state statutes, regulations, and directives;

ii. whether Extendicare is effectively reviewing quality of care related incidents and completing root cause analyses;

iii. whether Extendicare's action plans in response to identified quality of care problems are appropriate, timely, implemented, and enforced; and

iv. whether Extendicare's nursing staff is of the quantity, quality, and composition necessary to consistently meet resident care needs.

c. *Quality of Care Dashboard*. The Compliance Committee, in consultation with the Monitor required under Section III.E. of this CIA, shall create and implement a "Quality of Care Dashboard" (Dashboard), which will function as a performance scorecard for Extendicare. Within 120 days after the Effective Date, the Compliance Committee shall: (1) identify and establish the overall quality improvement goals for Extendicare based on its assessment of Extendicare's quality of care risk areas; (2) identify

and establish the quality indicators related to those goals that Extendicare 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 Committee*. Within 90 days after the Effective Date, Extendicare 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 Extendicare's compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care. The Board of Directors Committee must include independent (i.e., non-executive) members. The individuals who serve on the Board of Directors Committee shall be readily available to the Compliance Officer and the Monitor required under 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 Extendicare's Compliance Program, including, but not limited to, the performance of the Compliance Officer and the Compliance Committee;

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

iii. confirm that Extendicare's response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified;

iv. confirm that Extendicare 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; and

v. monitor Extendicare's performance under to the Dashboard and ensure that Extendicare implements effective responses when potential quality issues are indicated on the Dashboard or when quality indicators show that Extendicare is not meeting its established goals.

Extendicare 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.

b. *Board of Directors Committee Resolution*. For the Implementation Report required under Section V.A and for each Reporting Period of the CIA, the Board of Directors Committee shall adopt a resolution (consistent with the bylaws for adopting resolutions) summarizing the Board of Directors Committee's review and oversight of Extendicare'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:

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

If the Board of Directors Committee is unable to provide such a conclusion in the resolution, the Board of Directors Committee 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 Extendicare implements an effective Compliance Program.

4. *Staffing Review Committee.* Within 90 days after the Effective Date, Extendicare shall establish a Staffing Review Committee (hereinafter "Staffing Committee"). The purpose of this committee shall be to assess the nursing staffing provided at Extendicare facilities and make recommendations regarding staffing. The Staffing Committee shall include at least the Compliance Officer and the Vice President of Clinical Services, and shall regularly solicit input from employees at every level of the organization, including direct care nursing staff. The Staffing Committee shall meet at least monthly and shall:

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

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

c. make recommendations as to how Extendicare can ensure the appropriate quantity, quality, and composition of nursing staff necessary to meet resident needs;

d. identify challenges related to the recruitment, retention, job satisfaction, and training of nursing staff at each of Extendicare's facilities;

e. make recommendations as to how Extendicare can address challenges related to the recruitment, retention, job satisfaction, and training of nursing staff; and

f. report quarterly to the Compliance Committee on the reviews, assessments, and recommendations set forth in this Section III.B.4 of this CIA.

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

B. Written Standards

1. *Code of Conduct*. Within 90 days after the Effective Date, Extendicare shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Extendicare 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. Extendicare'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. Extendicare's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Extendicare's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

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

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

e. the possible consequences to both Extendicare and Covered Persons of failure to comply with Federal health care program requirements and with Extendicare'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.F, and Extendicare'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 Extendicare'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.

Extendicare shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 90 days after the Effective Date, Extendicare shall implement written Policies and Procedures regarding the

operation of Extendicare's compliance program, including the compliance program requirements outlined in this CIA, Extendicare's compliance with Federal health care program requirements. 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 Extendicare 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, XIX, and XX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1, 1396-1396w-5, and 1397; 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;
xv. administration; and
xvi. mental health services.

f. staffing, including, but not limited to:

i. ensuring 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, resident needs and acuity-based protocol to determine appropriate direct care nursing staff levels and allocation for each class of nursing staff (*e.g.*, RNs, LPNs, CNAs);

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.F of this CIA), or directly to the Compliance Officer or Monitor; and

iv. minimizing the number of individuals working on a temporary assignment or not employed by Extendicare (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 Extendicare or the Monitor.

g. delivery, management, and oversight of rehabilitation therapy services, including, but not limited to, the requirements that skilled rehabilitation therapy:

i. be pursuant to physician orders

ii. be pursuant to an individualized plan of care including documented therapeutic goals;

iii. be consistent with the nature and severity of the resident's individual illness or injury;

iv. comply with accepted standards of medical practice;

v. be reasonable in terms of duration and quantity;

vi. be reasonable and necessary to improve a resident's current condition, to maintain the resident's current condition, or to prevent or slow further deterioration of the resident's condition.

vii. include only services that 1) require the skills of qualified technical or professional health personnel such as physical therapists, occupational therapists, and speech-language

pathologists; and 2) must be provided directly by or under the general supervision of these skilled rehabilitation personnel to assure the safety of the resident and to achieve the medically desired result; and

viii. include thorough and timely documentation sufficient to enable a reviewer to determine whether all the criteria above have been meet.

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), Extendicare shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education

1. *General Training*. Within 120 days after the Effective Date, Extendicare shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Extendicare's:

a. CIA requirements; and

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

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

For purposes of the General Training requirements, if Extendicare provided training on its Compliance Program that satisfies the requirements set forth in Section III.C.1 above, to Covered Persons within 90 days prior to the Effective Date, then OIG will credit that training for purposes of satisfying the applicable part of Extendicare's General Training obligations for the first Reporting Period of the CIA.

2. *Specific Training*. Within 120 days after the Effective Date, Extendicare shall initiate the provision of Specific Training to each Relevant Covered Person. Within the first Reporting Period, each Relevant Covered Person shall receive at least six hours of Specific Training pertinent to their responsibilities in addition to the General Training required above. This Specific Training shall include a discussion of:

a. policies, procedures, and other requirements applicable to the documentation of medical records;

b. the policies implemented pursuant to Section III.B.2 of this CIA, as appropriate for the job category of each Relevant Covered Person;

c. the coordinated interdisciplinary approach to providing care and related communication between disciplines;

d. the personal obligation of each individual involved in resident care to ensure that care is appropriate and meets professionally recognized standards of care;

e. examples of proper and improper care; and

f. reporting requirements and legal sanctions for violations of the Federal health care program requirements.

New Relevant Covered Persons shall begin receiving this training within 10 days after the start of their employment or contract (or becoming Relevant Covered Persons) or within 120 days after the Effective Date, whichever is later.

For purposes of satisfying the Specific Training described in this section, any Relevant Covered Person, as defined in Section II.C.2 who, during the 90 days prior to the Effective Date of this CIA, received training that meets the

requirements for Specific Training shall be considered to have completed the Specific Training requirements in Section III.C.2.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least six hours of Specific Training in each subsequent Reporting Period.

3. *Periodic Training*. In addition to the Specific Training described above, Extendicare shall provide four hours of Periodic Training to all Relevant Covered Persons annually on the quality of care issues 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 the Joint Commission or other such private agencies, any internal surveys, the CMS quality indicators, and the findings, reports, and recommendations of the Monitor.

4. *Competency Based Training.* All Specific and Periodic 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.

5. *Board Member Training*. Within 90 days after the Effective Date, Extendicare shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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.

6. *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 and documentation evidencing that the individual attained competency in the required training areas. These shall be made available to OIG, upon request.

7. *Qualifications of Trainer*. Persons providing the training shall be knowledgeable about the subject area.

8. *Update of Training.* Extendicare shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or by the Independent Monitor, and any other relevant information.

9. *Computer-based Training.* Extendicare may provide the training required under this CIA through appropriate computer-based training approaches. If Extendicare 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. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Extendicare shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. The IRO may retain additional personnel, including consultants, if needed to help meet the IRO's obligations under the CIA. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and Extendicare shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Extendicare) related to the reviews.

2. *Minimum Data Set (MDS) Review*. The IRO shall review Extendicare's coding, billing, and claims submission to Medicare Part A and the

reimbursement received (MDS Review) and shall prepare a MDS Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review*. In the event OIG has reason to believe that: (a) Extendicare's MDS Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or MDS Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the MDS Review complied with the requirements of the CIA and/or the findings or MDS Review are inaccurate (Validation Review). Extendicare shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Extendicare's final Annual Report shall be initiated no later than one year after Extendicare's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Extendicare of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Extendicare may request a meeting with OIG to: (a) discuss the results of any MDS Review submissions or findings; (b) present any additional information to clarify the results of the MDS Review or to correct the inaccuracy of the MDS Review; and/or (c) propose alternatives to the proposed Validation Review. Extendicare agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any MDS Review issues with Extendicare prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Extendicare a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Independent Monitor

Within 60 days after the Effective Date, Extendicare shall retain an appropriately qualified monitoring team (the "Monitor"), selected by OIG after consultation with Extendicare. 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 Extendicare or OIG individually or together. The Monitor and Extendicare 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 Extendicare 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, Extendicare shall retain, within 60 days of the resignation or removal, another Monitor selected by OIG, with the same functions and authorities.

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

a. Extendicare's internal quality control systems, including, but not limited to:

i. whether the systems in place to promote quality of care and to respond to quality of care issues are operating in a timely and effective manner;

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

iii. whether the training programs are effective, thorough, and competency-based.

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

i. Extendicare's ability to identify the issue;

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

iii. Extendicare's ability to conduct a root cause analysis;

iv. Extendicare's ability to create an action plan to respond to the issue;

v. Extendicare's ability to execute the action plan; and

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

c. Extendicare'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 Extendicare, including those implemented under Section III.B of this CIA;

d. Extendicare's Staffing Committee and compliance with staffing requirements;

e. Extendicare's rehabilitation therapy systems, which shall include an assessment of whether such systems ensure Extendicare:

i. provides only skilled rehabilitation therapy that is: (1) delivered pursuant to a physician's orders and to an individualized plan of care including documented therapy goals; (2) consistent with the nature and severity of the resident's individual illness or injury; (3) in

compliance with accepted standards of medical practice; (4) reasonable and necessary to improve a resident's current condition, to maintain the resident's current condition, or to prevent or slow further deterioration of the resident's condition; and (5) limited to services that require the skills of physical, speech, or occupational therapists, among other types of professionals and that must be provided directly by or under the general supervision of these skilled rehabilitation personnel to assure the safety of the resident and to achieve the medically desired result;

ii. complies with Medicare program requirements relating to the tracking of therapy minutes; and

iii. complies with all Medicare guidance on appropriate documentation of medical records.

f. Extendicare's ability to analyze outcome measures, such as the CMS Quality Indicators, and other data; and

g. Extendicare's Quality of Care Dashboard required under Section III.A.2.c. of this CIA.

2. *Access*. The Monitor shall have:

a. immediate access to Extendicare, 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 Extendicare's staff are hired on a temporary basis;

vi. reports of abuse, neglect, or any 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 Extendicare 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 60 days after the Monitor is retained by Extendicare or 120 days after the Effective Date of the CIA, whichever is later, the Monitor shall:

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

b. in conducting this assessment, visit Extendicare's facilities (selected by the Monitor) and, at a minimum, observe care planning meetings, interview key employees, review relevant documents, observe resident care; and observe corporate level committee meetings such as: Compliance Committee, Staffing Committee, and Board of Directors Committee meetings; and

c. submit a written report to Extendicare 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.E.1; and

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

b. assess Extendicare's response to recommendations made in prior written assessment reports;

c. in conducting this assessment, visit Extendicare's facilities (selected by the Monitor) and, at a minimum,

observe care planning meetings, interview key employees, review relevant documents, observe resident care; and observe corporate level committee meetings such as: Compliance Committee, Staffing Committee, and Board of Directors Committee meetings (the Monitor may also want to have regular telephone calls with Extendicare and any of its poorer performing facilities); and

b. submit a written report to Extendicare 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.E.1;

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

iv. the Monitor's assessment of Extendicare's response to the Monitor's prior recommendations.

For the first Reporting Period, the Monitor shall perform assessments for each quarter or portion of a quarter not covered by the Baseline Systems Assessment. For each subsequent Reporting Period, the Monitor shall perform quarterly assessments. 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 Extendicare and the Monitor*.

a. Extendicare 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. Extendicare 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 Extendicare, as provided under Section X of the CIA. While Extendicare must pay all of the Monitor's bills within 30 days, Extendicare 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 Extendicare 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 Extendicare and to OIG by the submission deadline of Extendicare's Annual Report. This report shall reflect, on a cumulative basis, all key category costs included on monthly invoices.

6. *Additional Extendicare Obligations.* Extendicare shall:

a. As a condition of retaining the Monitor, Extendicare 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 C;

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 Extendicare took in response to each recommendation

or why Extendicare 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 Extendicare;

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 or medical record number, and date of birth of the resident 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, or if appropriate, compilations and summaries of such documents or reports;

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 Extendicare 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 Extendicare 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 Extendicare;

d. if the Monitor has concerns about action plans that are not being enforced or systemic problems that could affect Extendicare'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 Extendicare'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 Extendicare;

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

Extendicare, and Extendicare 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 Extendicare from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

g. abide by the 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 Extendicare; and

h. 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.

F. Disclosure Program

Within 90 days after the Effective Date, Extendicare 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 Extendicare'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. Extendicare shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees and 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 conduct or practice; and (2) provides an opportunity for taking corrective action, Extendicare shall conduct an internal review of the allegations set forth in the disclosure and ensure that corrective action is taken and proper follow-up is conducted. If the inappropriate or improper conduct or practice places residents at risk of harm, then Extendicare will ensure that the conduct or practice ceases immediately and that appropriate action is taken.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be sent to the Monitor not less than monthly unless otherwise agreed to in writing by OIG and the Monitor.

G. Ineligible Persons

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

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

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

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

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://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.* Extendicare shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements:

a. Extendicare 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. Extendicare shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

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

3. *Removal Requirement*. If Extendicare has actual notice that a Covered Person has become an Ineligible Person, Extendicare shall remove such Covered Person from responsibility for, or involvement with the delivery of

resident care or Extendicare'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 Extendicare 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, Extendicare shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect either the quality of care rendered to any beneficiary, resident, or any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Extendicare shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Extendicare conducted or brought by a governmental entity or its agents involving an allegation that Extendicare 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. Extendicare 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, Extendicare 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.

I. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money Extendicare 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, Extendicare identifies any Overpayment, Extendicare 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, Extendicare 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.

J. 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 matter that a reasonable person would consider a probable 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.G.1.a; or

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

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

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

3. *Reportable Events under Section III.J.1.a*. For Reportable Events under Section III.J.1.a, the report to OIG shall be made at the same time as repayment to the payor required in Section III.I, and shall include:

a. a copy of the notification and repayment to the payor required in Section I.2;

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

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

d. a description of Extendicare's actions taken to correct the Reportable Event; and

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

4. *Reportable Events under Section III.J.1.b and d.* For Reportable Events under Section III.J.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 Extendicare's actions taken to correct the Reportable Event;

c. any further steps Extendicare 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 Extendicare to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.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 Extendicare's action taken to correct the Reportable Event;

c. any further steps Extendicare 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.J.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 Extendicare's action taken to ensure that the Reportable Event does not adversely impact resident care;

c. any further steps Extendicare 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 solely involves a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Extendicare 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.I.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 Extendicare identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Extendicare is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY: CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Extendicare changes locations or closes a business unit or location that is subject to this CIA (as defined in Section II.B), Extendicare 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 location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Extendicare purchases or establishes a new business unit or location that is subject to this CIA as set forth in Section II.B, Extendicare

shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new 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 Extendicare currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale or Transfer of Unit or Location. In the event that, after the Effective Date, Extendicare proposes to sell or transfer any or all of its business units or locations that are subject to this CIA (as defined in Section II.B), Extendicare shall notify OIG of the proposed sale or transfer at least 30 days prior to the sale or transfer of such business unit or location. This notification shall include a description of the business unit or location to be sold or transferred, a brief description of the terms of the transaction, and the name and contact information of the prospective purchaser or transferee. This CIA shall be binding on the purchaser or transferee of such business unit or location, unless otherwise determined and agreed to in writing by OIG. This CIA shall bind the purchaser or transferee only with respect to those business units or locations that are being sold or transferred by Extendicare to such a purchaser or transferee and not with respect to any other business unit or location owned or operated by the purchaser or transferee.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Extendicare 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 and positions of the members of the Board of Directors Committee required by Section III.A;

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

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

6. the names and positions of the members of the Staffing Committee required by Section III.A;

7. a copy of Extendicare's Code of Conduct required by Section III.B.1;

8. 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);

9. 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);

10. 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.

11. a description of the Disclosure Program required by Section III.F;

12. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Extendicare and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Extendicare;

13. a description of the process by which Extendicare fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a list of all of Extendicare'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 Extendicare currently submits claims;

15. a description of Extendicare's corporate structure, including identification of any individual owners and investors, real estate investment trusts, land ownership, parent and sister companies, subsidiaries, affiliates, and their respective lines of business;

16. the certification required by Section V.C; and

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

B. Annual Reports. Extendicare shall submit to OIG annually a report with respect to the status of, and findings regarding, Extendicare'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 non-compliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee or Board of Directors Committee; and any change in the membership of the Staffing Committee described in Section III.A;

2. a summary of activities, assessments, and recommendations under Extendicare's Quality of Care Review Program and a summary of any corrective action taken in response to any issues identified through its Quality of Care Review Program;

3. a summary of the Compliance Committee's measurement, analysis, and tracking of the performance metrics included in Extendicare's Dashboard, Extendicare's progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes;

4. the Board of Directors Committee Resolution required by Section III.A;

5. a summary of activities, assessments, and recommendations and findings of the Staffing Committee required by Section III.A, and a summary of Extendicare's responses to any recommendations made by the Staffing Committee;

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 the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

8. 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 complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

9. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

10. Extendicare's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

11. a summary and description of any and all current and prior engagements and agreements between Extendicare and the IRO (if different from what was submitted as part of the Implementation Report);

12. a certification from the IRO regarding its professional independence and objectivity with respect to Extendicare;

13. Extendicare's response and action plan(s) related to any written recommendations of the Monitor pursuant to Section III.E;

14. a copy of the disclosure log required under Section III.F (excluding any communications that relate solely to human resources issues);

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

16. any changes to the process by which Extendicare fulfills the requirements of Section III.G regarding Ineligible Persons;

17. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;

18. a description of all changes to the most recently provided list of Extendicare's locations (including addresses) as required by Section V.A.14; 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 Extendicare currently submits claims; and

19. the certification required by Section V.C; and

20. the dates of each report made by the Compliance Officer and Compliance Committee to the Board (written documentation of such reports shall be made available upon request).

The first Annual Report shall be received by OIG no later than 90 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, Extendicare shall participate in an in-person meeting with a representative of OIG to review Extendicare's performance under the CIA. OIG, in its discretion, may waive this meeting requirement.

C. Certifications

The Implementation Report and Annual Reports shall include certification by the Compliance Officer, that:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, Extendicare 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.

The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Extendicare has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or

state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. Extendicare 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. Extendicare 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

Extendicare:

Donna Thiel
Vice President and Chief Compliance Officer
111 W. Michigan Street
Milwaukee, WI 53203
Telephone: (414) 908-8119

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, Extendicare 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), either instead of or 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 Extendicare's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Extendicare's locations that are covered by this CIA for the purpose of verifying and evaluating: (a) Extendicare's compliance with the terms of this CIA; and (b) Extendicare's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Extendicare 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 Extendicare'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. Extendicare shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Extendicare's employees may elect to be interviewed with or without a representative of Extendicare present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Specific Performance of CIA Provisions. If OIG determines that Extendicare 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 Extendicare with prompt written notification of such determination. (This notification shall be referred to as the "Noncompliance Notice.") Extendicare shall have 35 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that Extendicare 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, Extendicare 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 Extendicare 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;

d. a Quality of Care Review Program;

e. a Quality of Care Dashboard;

f. a Staffing Committee;

g. a written Code of Conduct;

h. written Policies and Procedures;

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

j. retention of a Monitor;

k. a Disclosure Program;

l. Ineligible Persons screening and removal requirements;

m. notification of Government investigations or legal proceedings; and

n. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the day the obligation became due) for each day Extendicare fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Extendicare 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.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Extendicare fails to submit any MDS Review Report in accordance with the requirements of Section III.D and Appendix B.

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

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

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

8. A Stipulated Penalty of $2,500 for each day Extendicare 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.E.6. OIG shall provide notice to Extendicare stating the specific grounds for its determination that Extendicare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Extendicare shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Extendicare receives this notice from OIG of the failure to comply.)

9. A Stipulated Penalty of $1,000 for each day Extendicare fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Extendicare stating the specific grounds for its determination that Extendicare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Extendicare shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Extendicare 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 1-8 of this Section.

C. Timely Written Requests for Extensions. Extendicare 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 Extendicare 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 Extendicare 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.

D. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that Extendicare 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 Extendicare of: (a) Extendicare'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, Extendicare 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 Extendicare elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Extendicare 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 Extendicare 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. a failure by Extendicare to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Sections III.I and III.J;

b. a repeated or flagrant violation of any obligation under this CIA, including, but not limited to, the obligations addressed in Section X.B;

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 use an IRO in accordance with Section III.D, Appendix A, and Appendix B;

g. a failure to retain, pay, or use the Monitor, or failure to respond to the recommendations of the Monitor, in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Extendicare constitutes an independent basis for Extendicare's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Extendicare has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Extendicare of: (a) Extendicare'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 Extendicare's facilities, locations, or corporate entities, depending upon the facts of the breach.

3. *Opportunity to Cure*. Extendicare 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. Extendicare is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Extendicare fails to satisfy the requirements of Section X.E.3, OIG may exclude Extendicare from participation in the Federal health care programs. OIG shall notify Extendicare in writing of its determination to exclude Extendicare. (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 Extendicare's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Extendicare 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 Extendicare 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, Extendicare 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, Extendicare was in material compliance with the obligations of this CIA for which OIG seeks specific performance; and

b. whether Extendicare failed to cure to OIG's satisfaction.

Extendicare shall have the burden of proving its material 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, Extendicare shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless Extendicare 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, Extendicare 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 Extendicare was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Extendicare 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 Extendicare to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Extendicare 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:

a. whether Extendicare was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Extendicare had begun to take action to cure the material breach within that period; (ii) Extendicare pursued and is pursuing such action with due diligence; and (iii) Extendicare provided to OIG within that period a reasonable timetable for curing the material breach and Extendicare followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Extendicare, only after a DAB decision in favor of OIG. Extendicare's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Extendicare 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 Extendicare 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. Extendicare 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 Extendicare, Extendicare 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

Extendicare and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Extendicare.

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

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

D. OIG may agree to a suspension of Extendicare's obligations under this CIA based on a certification by Extendicare 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 Extendicare is relieved of its CIA obligations, Extendicare will be required to notify OIG in writing at least thirty (30) days in advance if Extendicare 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.

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

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.

G. This CIA is by and between the parties hereto. The CIA is not intended to establish any legal rights for or confer any legal rights upon any non-governmental entities or persons not a party to the CIA. The parties agree, however, that this CIA is a public document and it may be admissible in a judicial or administrative proceeding.

ON BEHALF OF EXTENDICARE

/Tim Lukenda/ 10/2/14

TIM LUKENDA DATE
President and Chief Executive Officer
Extendicare Health Service, Inc.

/Glenn P. Hendrix/ 10/2/14

GLENN P. HENDRIX DATE
Arnall Golden Gregory LLP

/J. Richard Kiefer/ 10/3/14

J. RICHARD KIEFER DATE
Bingham Greenebaum Doll LLP

ON BEHALF OF THE PROGRESSIVE STEP CORPORATION

/Tim Lukenda/ 10/2/14

TIM LUKENDA DATE
President and Chief Executive Officer
Extendicare Health Service, Inc.

/Glenn P. Hendrix/ 10/2/14

GLENN P. HENDRIX DATE
Arnall Golden Gregory LLP

/J. Richard Kiefer/ 10/3/14

J. RICHARD KIEFER DATE
Bingham Greenebaum Doll LLP

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

/Robert K. DeConti/ 10/3/14

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

/Tonya Keusseyan/ 9/30/14

TONYA KEUSSEYAN DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. Extendicare shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.12 of the CIA or any additional information submitted by Extendicare in response to a request by OIG, whichever is later, OIG will notify Extendicare if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Extendicare may continue to engage the IRO.

2. If Extendicare engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Extendicare shall submit the information identified in Section V.A.12 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Extendicare at the request of OIG, whichever is later, OIG will notify Extendicare if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Extendicare may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the MDS Review who have expertise in the billing, coding, reporting, and other requirements of the Medicare Prospective Payment System for skilled nursing facilities and in the general requirements of the Federal health care program(s) from which Extendicare seeks reimbursement;

2. assign individuals to design and select the MDS Review sample(s) who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the MDS Review who have a nationally recognized MDS or Resident Assessment Instrument certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each MDS Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the MDS Review;

3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required under Section III.D.4 of the CIA and by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the MDS Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO*. If Extendicare terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Extendicare must submit a notice explaining its reasons for termination or the reason for

withdrawal to OIG no later than 30 days after termination or withdrawal. Extendicare must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Extendicare to engage a new IRO in accordance with Paragraph A of this Appendix. Extendicare must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Extendicare to engage a new IRO, OIG shall notify Extendicare of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Extendicare may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Extendicare prior to requiring Extendicare to terminate the IRO. However, the final determination as to whether or not to require Extendicare to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

MINIMUM DATA SET REVIEW

A. MDS Review. The IRO shall perform the MDS Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each MDS Review. For each Reporting Period, the IRO shall randomly select ten facilities to review. The ten facilities shall be known as the "Subject Facilities."

1. *Definitions*. For the purposes of the MDS Review, the following definitions shall be used:

a. Overpayment: The amount of money Extendicare has received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

b. Paid Claim: A claim submitted by Extendicare and for which Extendicare has received reimbursement from the Medicare Part A program.

c. Population: The Population shall be defined as all Paid Claims for each of the Subject Facilities during the 12-month period covered by the MDS Review.

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Samples.* The IRO shall randomly select a sample of 30 Paid Claims from each of the ten Subject Facilities (Discovery Samples) and conduct the MDS Review (as defined below). The Paid Claims shall be reviewed based on the supporting documentation available at Extendicare's offices or under Extendicare's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for a Discovery Sample is less than 5%, no additional sampling is required for that Subject Facility, nor is the MDS Systems Review, required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Extendicare should, as appropriate, further analyze any errors identified in the Discovery Samples. Extendicare recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Samples or any other segment of the universe.)

3. *Full Sample*. If any Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) for that Subject Facility using commonly accepted sampling methods and conduct a MDS Review on the Full Sample. The Paid Claims shall be reviewed based on the supporting documentation available at Extendicare's office or under Extendicare's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Extendicare to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *MDS Review*.

a. The IRO shall obtain all appropriate medical records, billing records, and related supporting documentation.

b. For each Paid Claim selected in the Discovery and Full Samples, the IRO shall review the MDS and the medical record documentation supporting the MDS. The review process shall consist of an evaluation of the MDS and verification that each MDS entry that affects the RUG code outcome for the MDS is supported by the medical record for the corresponding period of time consistent with the assessment reference date specified on the MDS.

c. The IRO shall perform an evaluation of the data on the Paid Claim and determine whether the variables that affect the RUG assignment outcome for the MDS are supported by the medical record for the corresponding time period consistent with the assessment reference date specified in the MDS. This shall include the following issues:

i. The accuracy of the MDS coding based on the documentation within the medical record.

ii. Verification of medical necessity in the medical record by verifying the presence of physician orders for the services reflected as necessary in the MDS.

iii. The accuracy of the associated Paid Claims. At a minimum, these shall be reviewed for the following:

A. Coverage Period;
B. Revenue Codes;
C. HIPPS codes (RUG categories and the modifiers for assessment type); and
D. Units of service.

d. In those cases where an incorrect MDS data point(s) has been identified, the IRO shall re-enter data from that MDS into the IRO's grouper software to verify that the correct RUG code assignment was properly assigned on the Paid Claim. If an

incorrect RUG code was assigned, this shall be considered an error.

e. If there is insufficient support for an MDS data point(s) that results in a downward change in RUG assignment, the IRO shall consider the dollar difference to be an overpayment.

f. If an incorrect RUG was used, but it did not result in an overpayment, it shall be noted in the MDS Review Report.

5. *MDS Systems Review*. If any of the Subject Facilities' Discovery Sample identifies an Error Rate of 5% or greater, Extendicare's IRO shall also conduct a MDS Systems Review for that Subject Facility. The MDS Systems Review shall consist of the following:

a. a review of Extendicare's billing and coding systems and processes relating to claims submitted to Medicare Part A (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);

b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

6. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required for the MDS Review as part of the Discovery Sample or Full Sample (if applicable), and Extendicare shall furnish such documentation and materials to the IRO, prior to the IRO initiating its MDS Review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Extendicare after the IRO has completed its initial MDS Review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the MDS Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the MDS Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which Extendicare cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Extendicare for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

7. *Repayment of Identified Overpayments.* Extendicare shall repay within 30 days any Overpayment(s) identified in the Discovery Samples, regardless of the Error Rate, and (if applicable) the Full Sample(s), including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies.

Extendicare shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. MDS Review Report. The IRO shall prepare an MDS Review Report as described in this Appendix for each MDS Review performed. The following information shall be included in the MDS Review Report for each Discovery Sample and Full Sample (if applicable).

1. *MDS Review Methodology*.

   a. MDS Review Populations. A description of the Populations subject to the MDS Review.

   b. MDS Review Objective. A clear statement of the objective intended to be achieved by the MDS Review.

   c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the MDS Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

   d. Review Protocol. A narrative description of how the MDS Review was conducted and what was evaluated.

   e. Supplemental Materials. A description of any Supplemental Materials as required by A.6.a., above.

2. *Statistical Sampling Documentation.*

   a. A copy of the printouts of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

   b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample(s), if applicable.

c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *MDS Review Findings.*

a. Narrative Results.

i. A description Extendicare's billing and coding system(s) for submission of claims to Medicare Part A, including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the MDS Review, including the results of the Discovery Sample, and the results of the Full Sample(s) (if any).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Extendicare (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Extendicare.

iii. Total dollar amount(s) of all Overpayments in the Discovery Sample and the Full Sample (if applicable).

iv. Total dollar amount of Paid Claims included in the sample(s) and the net Overpayment associated with the Discovery Sample and the Full Sample (if applicable).

v. Error Rate(s) in the Discovery Sample and the Full Sample (if applicable).

vi. A spreadsheet of the MDS Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g. RUGs code), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Extendicare's billing and coding system based on the findings of the MDS Review

4. *MDS Systems Review Findings*. The IRO shall prepare a report based on the MDS Systems Review (MDS Systems Review Report) that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in Extendicare's medical record documentation, coding process, billing system, policies and procedures, internal controls, and/or reporting mechanisms; and

b. possible improvements to Extendicare's medical record documentation, coding process, billing system, policies and procedures, internal controls or reporting mechanisms to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the MDS Review and (2) performed the MDS Review.

APPENDIX C

DATA ANALYSIS SUBCONTRACT DESCRIPTION

This Appendix contains the requirements relating to the Monitor's subcontract with a data analysis expert, as required by Section III.E of the CIA.

1. Under the Monitor's subcontract the data analysis expert shall provide, at a minimum, the following reports to the Monitor and Extendicare on a quarterly basis:

   a. Facility Reports: a summary report for Extendicare, 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 Extendicare to compare the QI values among the facilities.

   c. Peer Comparison Reports: a summary report comparing Extendicare'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.