CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ESSEX GROUP MANAGEMENT CORP.
AND
CLAFLIN HILL CORPORATION
AND
DARTMOUTH HOUSE NURSING HOME, INC.,
AND
ST. JOHN'S NURSING HOME, INC.,
AND
ERLIN MANOR NURSING HOME, INC.,
AND
WESTSIDE CORPORATION,
AND
HOUGHTON CORPORATION

I. PREAMBLE

Essex Group Management Corp., Claflin Hill Corporation d/b/a Blair House of Milford, and Dartmouth House Nursing Home, Incorporated d/b/a Brandon Woods of Dartmouth, St. John's Nursing Home, Inc., d/b/a/ Brandon Woods of New Bedford, and Erlin Manor Nursing Home, Inc., d/b/a Blaire House of Tewksbury, Westside Corporation, d/b/a Westside House, and Houghton Corporation, d/b/a Blaire House of Worcester (hereinafter referred to collectively as "Essex") 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). This CIA shall cover all skilled nursing facilities owned, operated, affiliated with or managed by Essex Group Management Corp. Contemporaneously with this CIA, Essex is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Essex 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. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Covered Persons" includes:

   a. all owners, officers, directors, and employees of Essex; and

   b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Essex, excluding vendors whose sole connection with Essex is selling or otherwise providing medical supplies or equipment to Essex.

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 during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during a Reporting Period.

2. "Relevant Covered Persons" includes all Covered Persons who (1) are involved directly or in a supervisory role in the delivery of rehabilitation therapy (2) perform assessments of residents that affect treatment decisions regarding rehabilitation therapy services or affect reimbursement for rehabilitation therapy from Federal health care programs, including but not limited to Resource Utilization Groups (RUGs) under Medicare Part A, or (3) are involved in the preparation or submission of the Minimum Data Set (MDS) or claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee

1. *Compliance Officer.* Within 90 days after the Effective Date, Essex shall appoint an employee to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be a member of senior management of Essex, shall report directly to the Chief Executive Officer of Essex, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Essex. The Compliance Officer shall be responsible for, without limitation:

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

b. monitoring the day-to-day compliance activities engaged in by Essex as well as for any reporting obligations created under this CIA.

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.

Essex shall report to OIG, in writing, any changes in the identity or position description 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, Essex shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The

Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Essex's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Essex shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or 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 such a change.

3. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Essex employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Essex department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer (or the functional equivalent), Chief Operating Officer, Corporate Director of Clinical Services, and Director of Nursing. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

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

B. Written Standards

1. *Code of Conduct.* Within 120 days after the Effective Date, Essex shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Essex shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Essex'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. Essex's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Essex's own Policies and Procedures;

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

d. the right of all individuals to use the Disclosure Program described in Section III.F, and Essex's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

2. *Policies and Procedures.* Within 120 days after the Effective Date, Essex shall develop and implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Essex's compliance with Federal health care program requirements. Throughout the term of this CIA, Essex shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees. The Policies and Procedures shall address, at a minimum:

a. the compliance program requirements outlined in this CIA; and

b. management and oversight of rehabilitation therapy services provided to residents at Essex facilities, including, but not limited to, the requirements that skilled rehabilitation therapy: (1) be pursuant to an individualized plan of care; (2) be consistent with the nature and severity of the resident's individual illness or injury; (3) comply with accepted standards of medical practice; (4) be reasonable in terms of duration and quantity; (5) be reasonable and necessary given the resident's condition, and plan of care to improve, maintain, or slow deterioration of the resident's condition; and (6) only include services that are inherently complex and require the skills of physical, speech, or occupational therapists, among other types of professionals.

Within 120 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education

1. *Training Plan.* Within 120 days after the Effective Date, Essex shall develop a written plan (Training Plan) that outlines the steps Essex will take to ensure that: (a) all Covered Persons (with the exception of cafeteria, maintenance, and housekeeping staff) receive adequate training regarding Essex's CIA requirements and Compliance Program, including the Code of Conduct and (b) all Relevant Covered Persons receive adequate training regarding: (i) the Federal health care program requirements regarding the accurate coding and submission of claims, 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, and ensuring appropriate and accurate use of the current Resource Utilization Groups (RUG) classification system; (ii) policies, procedures, and other requirements applicable to the documentation of medical records; (iii) the coordinated interdisciplinary approach to providing care and the related communications between disciplines; (iv) the personal obligation of each individual involved in resident and/or patient care to ensure that care is appropriate and meets professionally recognized standards of care; (v) examples of

proper and improper care (vi) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (vii) applicable reimbursement statutes, regulations, and program requirements and directives; (viii) the legal sanctions for violations of the Federal health care program requirements; and (ix) examples of proper and improper claims submission practices.

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

2. *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.

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

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

5. *Computer-based Training.* Essex may provide the training required under this CIA through appropriate computer-based training approaches. If Essex 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 120 days after the Effective Date, Essex 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 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 Essex shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Essex) related to the reviews.

c. *Selection of Facilities.* For each Reporting Period, the IRO shall randomly select a facility to assess and review. The facility selected for the Reporting Period shall be known as the "Subject Facility."

2. *Minimum Data Set Review.* For each Reporting Period, the IRO shall review Essex's coding, billing, and claims submission to Medicare Part A and the reimbursement received (MDS Review) at the Subject Facility and shall prepare a MDS Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Therapy Systems Assessment.* For each Reporting Period, the IRO shall assess the effectiveness, reliability, and thoroughness of Essex's oversight of its therapy services at the Subject Facility, as outlined in Appendix C to this CIA, which is incorporated by reference.

4. *Validation Review.* In the event OIG has reason to believe that: (a) any MDS Review or Therapy Systems Assessment fails to conform to the requirements of this CIA; or (b) the IRO's findings or MDS Review or Therapy Systems Assessment results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the MDS Review or Therapy Systems Assessment complied with the

requirements of the CIA and/or the findings or MDS Review or Therapy Systems Assessment results are inaccurate (Validation Review). Essex shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of an MDS Review or Therapy Systems Assessment submitted as part of Essex's final Annual Report shall be initiated no later than one year after Essex's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Essex in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. Essex shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the MDS Review or Therapy Systems Assessment or to correct the inaccuracy of the MDS Review or Therapy Systems Assessment and/or propose alternatives to the proposed Validation Review. The final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Essex a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required 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. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Essex shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process should require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Essex shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 120 days after the Effective Date, Essex 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 Essex's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Essex shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Essex shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

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, or suspended from participation in the Federal health care programs or in Federal procurement or nonprocurement programs; or

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

b. "Exclusion Lists" include:

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

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

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

a. Essex 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. Essex shall screen all current Covered Persons against the Exclusion Lists within 120 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

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

Nothing in this Section III.G affects Essex's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered,

or prescribed by an excluded person. Essex understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Essex may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Essex meets the requirements of Section III.G.

3. *Removal Requirement.* If Essex has actual notice that a Covered Person has become an Ineligible Person, Essex shall remove such Covered Person from responsibility for, or involvement with, Essex'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 Essex 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 or during the term of a physician's or other practitioner's medical staff privileges, Essex shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

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

I. Overpayments

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

2. *Overpayment Policies and Procedures.* Within 120 days after the Effective Date, Essex shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

a. If, at any time, Essex identifies any Overpayment, Essex 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, Essex 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. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Essex.

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

2. *Reporting of Reportable Events.* If Essex determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Essex 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 within 30 days after making a determination that a substantial Overpayment exists and shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. the Federal health care programs affected by the Reportable Event;

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

d. a description of Essex's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Essex shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;

c. the Federal health care programs affected by the Reportable Event;

d. a description of Essex's actions taken to correct the Reportable Event and prevent it from recurring; and

e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Essex 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. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Persons employment or contractual relationship;

c. a description of the Exclusion Lists screening that Essex completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Reportable Event was discovered; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Essex 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.3 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 solely the Stark Law that is disclosed to CMS pursuant to the SRDP. If Essex identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Essex 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. Sale of Business, Business Unit or Location

In the event that, after the Effective Date, Essex proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, Essex shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, business unit or location to

be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

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

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

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

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, Essex 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 Certifying Employees required by Section III.A.3;

4. a copy of Essex's Code of Conduct required by Section III.B.1;

5. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);

6. the Training Plan required by Section III.C.1 (including a summary of the topics covered, the length of the training; and when the training was provided);

7. 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 Essex and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Essex;

8. a description of the risk assessment and internal review process required by Section III.E;

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

10. a certification that Essex has implemented the screening requirements described in Section III.G regarding Ineligible Persons, or a description of why Essex cannot provide such a certification;

11. a copy of Essex's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

12. a list of all of Essex'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 Essex currently submits claims;

13. a description of Essex's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

14. the certifications required by Section V.C.

B. Annual Reports

Essex shall submit to OIG annually a report with respect to the status of, and findings regarding, Essex's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee described in Section III.A, and any change in the group of Certifying Employees described in Section III.A.3;

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

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

4. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter, and Essex's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

5. a summary and description of any and all current and prior engagements and agreements between Essex and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to Essex;

6. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;

7. a summary of all internal audits performed pursuant to Section III.E during the Reporting Period and any corrective action plans developed in response to those internal audits. Copies of the internal audit reports and corrective action plans shall be made available to OIG upon request;

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

9. a certification that Essex has completed the screening required by Section III.G regarding Ineligible Persons;

10. 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;

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

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

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

14. a summary describing any audits conducted during the applicable Reporting Period by a Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and

Essex's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

15. a description of all changes to the most recently provided list of Essex's locations (including addresses) as required by Section V.A.12; and

16. the certifications required by Section V.C.

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.

C. Certifications

1. *Certifying Employees.* In each Annual Report, Essex shall include the certifications of Certifying Employees as required by Section III.A.3;

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

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

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer (or the functional equivalent) that, to the best of his or her knowledge, Essex 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

Essex 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. Essex 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

Essex:

Compliance Officer
Essex Group Skilled Nursing Facilities
51 Summer Street
Rowley, MA 01969
T: 978-948-7383
F: 978-948-2718

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, Essex may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

Essex shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and 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 Essex prior to any release by OIG of information submitted by Essex pursuant to its obligations under this CIA and identified upon submission by Essex as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Essex shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Essex 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 Essex fails to establish and implement any of the following obligations as described in Sections III and IV:

a. a Compliance Officer;

b. a Compliance Committee;

c. the management certification obligations;

d. a written Code of Conduct;

e. written Policies and Procedures;

f. the development and/or implementation of a Training Plan for the training of Covered Persons, and Relevant Covered Persons;

g. a risk assessment and internal review process as required by Section III.E;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. policies and procedures regarding the repayment of Overpayments;

l. the repayment of Overpayments as required by Section III.I and Appendix B;

m. reporting of Reportable Events; and

n. disclosure of changes to business units or locations.

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

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 Essex 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 Essex fails to submit any MDS Review or Therapy Systems Assessment Report in accordance with the requirements of Section III.D, Appendix B, and Appendix C.

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

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

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

described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

Essex 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 Essex 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 days after Essex 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 days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Essex has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Essex of: (a) Essex'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, Essex shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Essex elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Essex 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.D.

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.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Essex has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

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

b. a failure by Essex to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;

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

d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, Appendix B, or Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Essex constitutes an independent basis for Essex's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Essex has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Essex of: (a) Essex'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.")

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

a. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Essex fails to satisfy the requirements of Section X.D.3, OIG may exclude Essex from participation in the Federal health care programs. OIG shall notify Essex in writing of its determination to exclude Essex. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Essex's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Essex may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Essex of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Essex 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 Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to 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 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. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *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 Essex was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Essex 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 Essex to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Essex 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.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Essex was in material breach of this CIA and, if so, whether:

a. Essex cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Essex's receipt of the Notice of Material Breach: (i) Essex had begun to take action to cure the material breach; (ii) Essex pursued such action with due diligence; and (iii) Essex provided to OIG a reasonable timetable for curing the material breach.

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

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Essex and OIG agree as follows:

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

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

C. OIG may agree to a suspension of Essex's obligations under this CIA based on a certification by Essex that it is no longer providing health care items or services that will be billed to any Federal health care program and 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 Essex is relieved of its CIA obligations, Essex shall be required to notify OIG in writing at least 30 days in advance if Essex plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

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

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

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

ON BEHALF OF ESSEX

/Frank C. Romano/

FRANK C. ROMANO
President
Essex Group Management, Corp.

31/11/2016
DATE

/Damien C. Powell/

DAMIEN C. POWELL, Esq.
Donoghue Barrett & Singal

1/11/16
DATE

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

/Robert K. DeConti/

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

1/11/16
DATE

/Tonya Keusseyan/

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

1/11/16
DATE

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. Essex 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.7 of the CIA or any additional information submitted by Essex in response to a request by OIG, whichever is later, OIG will notify Essex if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Essex may continue to engage the IRO.

2. If Essex engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Essex shall submit the information identified in Section V.A.7 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 Essex at the request of OIG, whichever is later, OIG will notify Essex if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Essex 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 MDS requirements, Resource Utilization Group determination, claims submission, 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 Essex seeks reimbursement;

2. assign individuals to design and select the MDS Review sample 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);

4. assign individuals to conduct the Therapy Systems Assessment who have expertise in the Medicare requirements relating to rehabilitation therapy in skilled nursing facilities and in the general requirements of the Federal health care program(s) from which Ensign Group seeks reimbursement; and

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

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 by Appendix B and Appendix C to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the MDS Review and Therapy Systems Assessment in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Essex and IRO.* If Essex terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Essex must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Essex 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 shall notify Essex in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Essex shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Essex regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Essex in writing that Essex shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Essex must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Essex 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.

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

a. Overpayment: The amount of money Essex has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, including any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

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

c. Population: The Population shall be defined as all Paid Claims for the Subject Facility 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 Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims from the Subject Facility (Discovery Sample) and conduct the MDS Review (as defined below). The Paid Claims shall be reviewed based on the supporting documentation available at Essex's office or under Essex's control and applicable regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample for the Subject Facility is less than 5%, no additional sampling is required, nor is the MDS Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Essex should, as appropriate, further analyze any errors identified in the Discovery Sample. Essex 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 Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample at the Subject Facility indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims from the Subject Facility (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Essex or under Essex'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 Essex 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 Sample, 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 Audit Report.

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

a. a review of Essex'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.

5. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required the MDS Review as part of the Discovery Sample or Full Sample (if applicable), and Essex 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 Essex 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 Essex cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Essex 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).

6. *Repayment of Identified Overpayments.* Essex shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, 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. Essex shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

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

1. *MDS Review Methodology.*

   a. MDS Audit Population. A description of the Population 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.5.a., above.

2. *Statistical Sampling Documentation.*

   a. A copy of the printout 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, 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 of Essex'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 (if any).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Essex (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 Essex.

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

iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.

v. Error Rate in the Discovery Sample and the Full Sample.

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., DRG, CPT code, etc.), 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 Essex's billing and coding system based on the findings of the MDS Review.

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

a. the strengths and weaknesses in Essex's medical record documentation, billing and coding systems and processes relevant policies and procedures, internal controls, and/or reporting mechanisms;

b. the strengths and weaknesses in Essex's coding systems and processes; and

c. possible improvements to Essex's medical record documentation, coding process, billing and coding systems and processes 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

THERAPY SYSTEMS ASSESSMENT

A. Therapy Systems Assessment.

1. For each Reporting Period, the IRO shall assess the effectiveness, reliability, and thoroughness of Essex's rehabilitative therapy systems and Essex's oversight of its rehabilitation therapy contractor at the randomly selected Subject Facility. The systems assessment shall include, but is not limited to, ensuring that the rehabilitation therapy contractor:

a. provides only skilled rehabilitation therapy that is:

i. delivered pursuant to an individualized plan of care;

ii. consistent with the nature and severity of the resident's and/or patient's individual illness or injury;

iii. in compliance with accepted standards of medical practice;

iv. reasonable and necessary given the resident's and/or patient's condition and plan of care to improve, maintain, or slow deterioration of his or her condition, or restore the his or her prior levels of function; and

v. limited to services that are inherently complex and require the skills of physical, speech, or occupational therapists, among other types of professionals;

b. complies with Medicare program requirements relating to the tracking of therapy minutes (e.g., only includes services that are inherently complex and require the skills of physical, speech, or occupational therapists, among other types of professionals; appropriately accounts for group and concurrent therapy);

c. complies with all Medicare and Essex requirements relating to the documentation of medical records;

d. obtains an assessment, by a physician, of the resident's and/or patient's need for skilled therapy and that the skilled services will improve, maintain, or slow deterioration of his or her condition, or restore his or her prior levels of function;

e. receives appropriate and effective training that, at a minimum, includes the subject matters set forth in Section III.C.1 of the CIA; and

f. communicates and interacts effectively among the corporate, regional, and facility level employees who provide, manage, or oversee the delivery of skilled rehabilitative therapy services to Essex's residents and/or patients.

2. If, at any time during the term of the CIA, Essex no longer contracts for the provision of therapy services to its residents and, instead, provides therapy services through its own employees or other arrangement, the IRO shall assess the effectiveness, reliability, and thoroughness of Essex's oversight of those therapy services, including, but not limited to, the areas described in Section A.1.

3. In conducting the Therapy Systems Assessments, the IRO shall, at a minimum, review policies and procedures, medical records, and other therapy-related documentation, observe the provision of therapy services at Essex, observe therapy-related care planning meetings, and interview key employees and contractors. Essex shall take all necessary steps to ensure the IRO has access to Essex's facilities, documents, employees, and contractors to perform the activities set forth in this Section A.3 in a legally and clinically appropriate manner.

B. Therapy Systems Assessment Report.

1. The IRO shall submit a written report to Essex and OIG (hereinafter the "Therapy Systems Assessment Report") that sets forth, at a minimum:

a. A summary of the IRO's activities in conducting the Therapy Systems Assessment;

b. The IRO's findings regarding the effectiveness, reliability, and thoroughness of the oversight described in Section A.1 of this Appendix C;

c. The IRO's recommendations to Essex as to how to improve the effectiveness, reliability, and thoroughness of the oversight described in Section A.1 of this Appendix C;

d. The IRO's assessment of Essex's response to the IRO's recommendations in the prior Therapy Systems Assessment Reports (this does not need to be included in the Therapy Systems Assessment Report for the first Reporting Period); and

e. The names and credentials of the individuals who performed the Therapy Systems Assessment.

2. The IRO shall submit each Therapy Systems Assessment Report to Essex and OIG no later than 30 days after the end of each Reporting Period.

C. Essex's Response to the IRO's Therapy System Assessment Report.

Within 30 days after receipt of each IRO Therapy Systems Assessment Report, Essex shall submit to OIG and the IRO a written response to each recommendation contained in the Therapy Systems Assessment Report stating what action Essex took in response to each recommendation or why Essex has not elected to take action based on the recommendation.