CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ENCORE REHABILITATION SERVICES, LLC

I. PREAMBLE

Encore Rehabilitation Services, LLC (Encore) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Encore is entering into a Settlement Agreement with the United States.

Encore represents that, prior to the CIA's Effective Date, Encore voluntarily established a compliance program that addresses all seven elements of an effective compliance program and is designed to address compliance with Federal health care program requirements (Compliance Program). Encore shall continue its Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Encore may modify the Compliance Program, as appropriate, but at a minimum, Encore 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 Encore 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) Encore's final Annual Report or (2) any additional materials submitted by Encore pursuant to OIG's request, whichever is later.

C. For purposes of this CIA, the term "Covered Persons" includes: (1) all owners, officers, directors, and employees of Encore; and (2) all contractors, subcontractors, agents, and other persons who are involved in the provision or oversight of contract rehabilitation therapy services provided by Encore in third party owned and operated Skilled Nursing Facilities (SNFs), excluding vendors whose sole connection with Encore is selling or otherwise providing medical supplies or equipment to Encore.

III. CORPORATE INTEGRITY OBLIGATIONS

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

- A. <u>Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations</u>
- 1. Compliance Officer. Within 90 days after the Effective Date, Encore shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Encore, shall report directly to the Chief Executive Officer of Encore, 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 Encore. 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. making periodic (at least quarterly) reports regarding compliance matters in person to the Board of Directors of Encore (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
 - c. monitoring the day-to-day compliance activities engaged in by Encore as well as 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.

Encore 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 business days after such a change.

2. Compliance Committee. Within 90 days after the Effective Date, Encore 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 Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Encore'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.

Encore shall report to OIG, in writing, 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 business days after such a change.

3. Board Compliance Obligations. The Board of Encore shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Encore's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken,

such as the engagement of an independent advisor or other third-party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Encore's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board has made a reasonable inquiry into the operations of Encore's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Encore has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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

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

4. *Management Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Encore employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Encore department is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer; Chief Operating Officer; General Counsel; Corporate Compliance Officer; President of Business Development; Director of Patient Safety and Risk Management; Chief Financial Officer; Vice President of Recruiting; Vice President of Human Resources; Division Vice President of Operations; Regional Vice President of

Operations; and Senior Vice President of Operations. 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 Encore policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Encore 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.

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

B. Written Standards

Within 90 days after the Effective Date, Encore 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 Encore's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Encore shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Encore shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. <u>Training and Education</u>

- 1. Covered Persons Training. Within 90 days after the Effective Date, Encore shall develop a written plan (Training Plan) that outlines the steps Encore will take to ensure that all Covered Persons receive at least annual training regarding Encore's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Encore shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.
- 2. Board Training. In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

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

3. *Training Records*. Encore shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. <u>Review Procedures</u>

- 1. General Description
 - a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, Encore 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 Encore shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Encore) related to the reviews.
- c. Access to Records and Personnel. Encore shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D and that all records furnished to the IRO are accurate and complete.
- 2. Rehabilitation Therapy Services Review. For each Reporting Period, the IRO shall review Encore's provision of rehabilitation therapy services under contracts between Encore and third party owned and operated SNFs to determine Encore's adherence to Federal program requirements and conformance to generally accepted medical practices (Rehab Review), and shall prepare a Rehab Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.
- 3. Independence and Objectivity Certification. The IRO shall include in its report(s) to Encore 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. The IRO's certification shall include a summary of all current and prior engagements between Encore and the IRO.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Encore shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the provision of rehabilitation therapy, items or services furnished to Medicare and Medicaid program beneficiaries for which claims may be submitted. The Compliance Committee shall be responsible for implementation and oversight of the risk

assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require Encore 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. Encore shall maintain the risk assessment and internal review process for the term of the CIA.

F. <u>Disclosure Program</u>

Within 90 days after the Effective Date, Encore 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 Encore'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. Encore 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. The Disclosure Program also shall include a requirement that all of Encore's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Encore. 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, Encore 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 all disclosures in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received

(whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. <u>Ineligible Persons</u>

- 1. *Definitions*. For purposes of this CIA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; 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.
 - b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).
- 2. Screening Requirements. Encore shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.
 - a. Encore shall screen all prospective Covered Persons against the Exclusion List 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. Encore shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
 - c. Encore shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Encore'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. Encore understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Encore may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Encore meets the requirements of Section III.G.

- 3. Removal Requirement. If Encore has actual notice that a Covered Person has become an Ineligible Person, Encore shall remove such Covered Person from responsibility for, or involvement with, Encore's business operations related to the Federal health care program(s) from which such Covered Person has been excluded 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 any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).
- 4. Pending Charges and Proposed Exclusions. If Encore 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, Encore 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 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, Encore shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Encore conducted or brought by a governmental entity or its agents involving an allegation that Encore 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. Encore also shall provide written notice to OIG within 30 days after the resolution of the matter and a description of the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events

- 1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:
 - a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or
 - b. the filing of a bankruptcy petition by Encore.

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

- 2. Reporting of Reportable Events. If Encore determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Encore shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.
- 3. Reportable Events under Section III.1.1.a. For Reportable Events under Section III.1.1.a, 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 individuals and entities 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, if any;
 - c. the Federal health care programs affected by the Reportable Event;

- d. whether the Reportable Event may have resulted in the receipt of Federal health care program overpayments by a SNF that contracts with Encore for the provision of rehabilitation therapy services; and
- e. a description of Encore's actions taken to correct the Reportable Event and prevent it from recurring.

If Encore identifies a Reportable Event that may have resulted in the receipt of Federal health care program overpayments by a SNF that contracts with Encore for the provision of rehabilitation therapy services, Encore shall notify the SNF of any such potential overpayments.

- 4. Reportable Events under Section III.1.1.b. For Reportable Events under Section III.1.1.b, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.
- 5. 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 Encore to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Encore identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Encore is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Encore proposes to (a) 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); or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any 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 OIG. Encore shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Encore wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Encore must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>Implementation Report</u>

Within 120 days after the Effective Date, Encore 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, business address, business phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
- 2. the names and positions of the members of the Compliance Committee required by Section III.A;
- 3. the names of the Board members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;
- 4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
 - 5. a list of the Policies and Procedures required by Section III.B;
- 6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (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; and (d) a

certification from the IRO regarding its professional independence and objectivity with respect to Encore that includes a summary of all current and prior engagements between Encore and the IRO;

- 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 description of the Ineligible Persons screening and removal process required by Section III.G;
- 11. a description of Encore's corporate structure, including identification of any parent and sister companies, individual owners, subsidiaries, and their respective lines of business;
- 12. a list of all of SNFs for whom Encore is providing rehabilitation therapy services and the corresponding Encore location/business unit that is providing the services (including locations and mailing addresses); and
 - 13. the certifications required by Section V.C.

B. <u>Annual Reports</u>

Encore shall submit to OIG a written report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;
- 2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

- 3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
- 4. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
- 5. a list of any new or revised Policies and Procedures developed during the Reporting Period;
- 6. a description of any changes to Encore's Training Plan developed pursuant to Section III.C, and a summary of any Board training provided during the Reporting Period;
- 7. a complete copy of all reports prepared pursuant to Section III.D and Encore's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
- 8. a certification from the IRO regarding its professional independence and objectivity with respect to Encore, including a summary of all current and prior engagements between Encore and the IRO;
- 9. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;
- 10. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
- 11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

- 12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;
- 13. 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;
- 14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;
- 15. a summary of any audits issued to Encore during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims for rehabilitation therapy services furnished by Encore, and Encore's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;
- 16. a description of all changes to the most recently provided list of SNFs for whom Encore is providing rehabilitation therapy services or Encore's corresponding location/business units that is providing the services, as required by Section V.A.12:
- 17. a description of any changes to Encore's corporate structure, including any parent and sister companies, individual owners, subsidiaries, and their respective lines of business; and
 - 18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

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

- 2. Compliance Officer and Chief Executive Officer. The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, Encore has implemented and is in compliance with all of the requirements of this CIA;
 - 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; and
 - c. he or she understands that the certification is being provided to and relied upon by the United States
- 3. Chief Financial Officer. The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Encore 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; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. <u>Designation of Information</u>

Encore 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. Encore 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

Encore:

Corporate Compliance Officer Encore Rehabilitation Services, LLC 33533 West 12 Mile Road, Suite 290 Farmington Hills, Michigan 48331

Telephone: 414.226.5416 Facsimile: 414.918.8262

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Encore may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

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

VIII. <u>DOCUMENT AND RECORD RETENTION</u>

Encore 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 Encore prior to any release by OIG of information submitted by Encore pursuant to its obligations under this CIA and identified upon submission by Encore as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Encore shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. <u>BREACH AND DEFAULT PROVISIONS</u>

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

A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>

As a contractual remedy, Encore 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) per obligation for each day Encore fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations, as required by Section III.A.3.;
- d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings; and
- 1. reporting of Reportable Events.
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Encore fails to engage and use an IRO, as required by Section III.D, Appendix A, or 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 Encore fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.
- 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 Encore fails to submit any

Rehab Review Report in accordance with the requirements of Section III.D and Appendix B.

- 5. A Stipulated Penalty of \$1,500 for each day Encore fails to grant access as required in Section VII (This Stipulated Penalty shall begin to accrue on the date Encore fails to grant access.).
- 6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Encore as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.
- 7. A Stipulated Penalty of \$2,500 for each day Encore fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.D, and for each day Encore fails to furnish accurate and complete records to the IRO, as required by Section III.D and Appendix A.
- 8. A Stipulated Penalty of \$1,000 for each day Encore fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Encore stating the specific grounds for its determination that Encore has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Encore shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date Encore 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 1-7 of this Section.

B. <u>Timely Written Requests for Extensions</u>

Encore 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 Encore 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 Encore 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.

C. <u>Payment of Stipulated Penalties</u>

- 1. Demand Letter. Upon a finding that Encore 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 Encore of: (a) Encore'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 business days after the receipt of the Demand Letter, Encore 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 Encore elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Encore 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 Encore 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 Encore to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;
- 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, or Appendix B.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Encore constitutes an independent basis for Encore'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 Encore has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Encore of: (a) Encore'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*. Encore 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) Encore has begun to take action to cure the material breach; (ii) Encore is pursuing such action with due diligence; and (iii) Encore has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, Encore fails to satisfy the requirements of Section X.D.3, OIG may exclude Encore from participation in the Federal health care programs. OIG shall notify Encore in writing of its determination to exclude Encore. (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 Encore'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, Encore 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 Encore 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, Encore 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 Encore was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Encore 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 Encore to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Encore 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 Encore was in material breach of this CIA and, if so, whether:

- a. Encore 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 Encore's receipt of the Notice of Material Breach: (i) Encore had begun to take action to cure the material breach; (ii) Encore pursued such action with due diligence; and (iii) Encore 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 Encore, only after a DAB decision in favor of OIG. Encore's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Encore 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 Encore 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. Encore 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 Encore, Encore 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. <u>EFFECTIVE AND BINDING AGREEMENT</u>

Encore 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 Encore's obligations under this CIA based on a certification by Encore 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 Encore is relieved of its CIA obligations, Encore shall be required to notify OIG in writing at least 30 days in advance if Encore 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) Encore'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 Encore 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. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF ENCORE REHABILITATION SERVICES, LLC

/Linda Shackelford/	<u>3/11/2020</u>	
LINDA SHACKELFORD	DATE	
Chief Executive Officer		
/David Pivnick/	<u>3/11/20</u>	
DAVID PIVNICK	DATE	
Partner		
McGuireWoods, LLP		
Legal Counsel for Encore Rehabilitation Services, LLC		

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

/Lisa M. Re/	03/12/2020
LISA M. RE	DATE
Assistant Inspector General for Legal Affairs	
Office of Inspector General	
U.S. Department of Health and Human Services	
/Tomor Torrior/	2/12/2020
/Tamar Terzian/	3/13/2020
TAMAR TERZIAN	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. <u>IRO Engagement</u>

- 1. Encore 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 E. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by Encore in response to a request by OIG, whichever is later, OIG will notify Encore if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Encore may continue to engage the IRO.
- 2. If Encore 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, Encore 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 Encore at the request of OIG, whichever is later, OIG will notify Encore if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Encore may continue to engage the IRO.

B. <u>IRO Qualifications</u>

The IRO shall:

- 1. assign individuals to conduct the Rehabilitation Therapy Services Review (Rehab Review) who have expertise in the Medicare and state Medicaid program requirements relating to rehabilitation therapy in skilled nursing facilities and the general requirements of the Federal health care program(s) applicable to the rehabilitation therapy services furnished by Encore;
- 2. assign individuals to design and select the Rehab Review sample who are knowledgeable about the appropriate statistical sampling techniques;
- 3. assign individuals to conduct the Rehab Review who have expertise in the established practice guidelines and generally accepted standards of medical practice for rehabilitation therapy, including those set forth by the American Physical Therapy

Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association; and

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

C. <u>IRO Responsibilities</u>

The IRO shall:

- 1. perform each Rehab Review in accordance with the specific requirements of the CIA;
- 2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Rehab Review;
- 3. request clarification from the appropriate authority (<u>e.g.</u>, Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program 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 to the CIA.

D. <u>Encore Responsibilities</u>

Encore shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. <u>IRO Independence and Objectivity</u>

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

F. IRO Removal/Termination

- 1. Encore and IRO. If Encore terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Encore 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. Encore 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 E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Encore in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Encore 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 Encore regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Encore in writing that Encore shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Encore 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 Encore to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

REHABILITATION THERAPY SERVICES REVIEW

- A. <u>Rehabilitation Therapy Services Review</u>. Encore shall retain an IRO to perform reviews of Encore's provision of rehabilitation therapy services under contracts between Encore and third party owned and operated SNFs (Rehab Review). The IRO shall perform the Rehab Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Rehab Review.
- 1. *Definitions*. For the purposes of the Rehab Review, the following definitions shall be used:
 - a. <u>Rehab Therapy Patient</u>: A Medicare patient who is covered under Medicare Part A and who received rehabilitation therapy services reimbursed under Medicare A from Encore during the patient's stay in a third party owned or operated SNF.
 - b. <u>Rehab Therapy Patient Population</u>: The Rehab Therapy Patient Population shall be defined as all Rehab Therapy Patients at a randomly selected Service Location during the 12-month period covered by the Rehab Review.
 - c. <u>Service Location</u>: A third party owned or operated SNF at which Encore provides contract rehabilitation therapy services.
 - d. <u>Service Location Population</u>: The Service Location Population shall be defined to include all Service Locations at which Encore provided contract rehabilitation therapy services during the prior 12-month period.

Encore, or the IRO on behalf of Encore, may submit proposals identifying suggestions for the subset(s) of Service Locations to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Service Location Population, OIG may consider (1) proposals submitted by Encore or its IRO or (2) information furnished to OIG regarding the results of Encore's internal risk assessment and internal auditing. The determination of whether, and in what manner, to limit the Service Location Population shall be made at the sole discretion of OIG.

2. Sample. For the first Reporting Period, the IRO shall first randomly select 26 Service Locations from the Service Location Population. The IRO then shall select a random sample of 25 Rehab Therapy Patients from the Rehab Therapy Patient Population for each randomly-selected Service Location. For subsequent Reporting Periods, the OIG may select the 26 Service Locations subject to review, at OIG's discretion.

For each Rehab Therapy Patient selected, the IRO shall review all rehabilitation therapy services provided to the Rehab Therapy Patient by Encore reimbursed by Medicare Part A during the 12-month period covered by the Rehab Review (Rehabilitation Therapy Services). The Rehabilitation Therapy Services shall be reviewed based on all of the portions of the Encore medical record necessary to make the findings required under this Appendix for the selected Rehab Therapy Patient, which may include, but not be limited to, physicians' orders for therapy services, therapy treatment plans, daily therapy treatment notes, interim therapy progress notes, therapy CPT logs, therapy discharge summaries, therapy tests and measurement results, and applicable Medicare program requirements and practice guidelines endorsed by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association to determine whether the rehabilitation therapy furnished was (a) medically necessary and reasonable, (b) appropriate and sufficient to meet the needs of a patient in the assigned Case-Mix Groups, and (c) appropriately documented.

The IRO's review shall include a determination of whether Encore adhered to Medicare requirements related to the following:

- a. eligibility for skilled rehabilitation therapy services;
- b. physician order(s) for any therapy services;
- c. comprehensive, standardized initial therapy assessments based on thorough examination and functional tests and measurements upon admission;
- d. written evaluations describing the therapy needs of the beneficiary including diagnosis, prognosis, physical impairments and specific functional limitations;
- e. written therapy treatment plans that list interventions that would be provided to address impairments as well as well-defined goals, measurable objectives and timetables;
- f. provision of skilled therapy services that can safely and effectively performed only by, or under the supervision of, a qualified therapist

- and the service, or the condition of the beneficiary is of a nature that requires the judgment, knowledge, and skills of physical, speech, or occupational therapists, among other types of medical professionals;
- g. provision of therapy services that are reasonable and necessary for the beneficiary's condition and SNF plan of care to improve, maintain, or slow deterioration of the beneficiary's condition, or restore his or her prior levels of function;
- h. provision of services according to the frequency and duration prescribed in the therapy treatment plan; and
- i. discharge planning and drafting of post discharge therapy treatment plan.

The IRO's review also shall include a determination of whether Encore adhered to established practice guidelines and generally accepted standards of rehabilitation therapy services relating to the following:

- a. best practices in patient management including examination, evaluation, diagnosis, prognosis and intervention;
- b. use of effective tests and measures to quantify a patient's impairments and functional limitations;
- c. use of appropriate interventions targeted to a patient's specific impairments and functional limitations;
- d. setting goals consistent with a patient's diagnosis and prognosis;
- e. preferred evidence-based practice patterns;
- f. consideration of issues specific to gerontology; and
- g. ethics and professionalism standards for therapists.

3. *Other Requirements*.

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Rehabilitation Therapy Services selected as part of the Sample, and Encore shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Sample. If the IRO accepts any supplemental documentation or materials

from Encore after the IRO has completed its initial review of the Sample (Supplemental Materials), the IRO shall identify in the Rehab 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 Rehab Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

- b. <u>Use of First Samples Drawn</u>. For the purposes of the Sample discussed in this Appendix, the Service Locations or Rehab Therapy Patients selected in each first sample shall be used (<u>i.e.</u>, it is not permissible to generate more than one list of random samples and then select one for use with the Sample). Should a Service Location have less than 25 Medicare patients during the 12-month Reporting Period, Encore or the IRO shall immediately notify the OIG. OIG shall either select a new Service Location or limit the IRO's review to all Rehab Therapy Patients at that Service Location at its sole discretion.
- 4. *Reporting of IRO Findings at Service Locations*. Encore shall notify each Service Location of any Rehab Therapy Patients or Rehabilitation Therapy Services at that Service Location for which the IRO has made a determination that the Rehabilitation Therapy Services were not medically necessary and appropriate.
- B. <u>Rehab Review Report</u>. The IRO shall prepare a Rehab Review Report as described in this Appendix B for each Rehab Review performed. The following information shall be included in the Rehab Review Report for each Sample.
 - 1. Rehab Review Methodology.
 - a. Rehab Review Population. A description of the Service Location Population and the Rehab Therapy Patient Population subject to the Rehab Review.
 - b. <u>Rehab Review Objective</u>. A clear statement of the objective intended to be achieved by the Rehab Review.

- c. Source of Data. A description of the specific documentation and other information sources relied upon by the IRO when performing the Rehab Review (e.g., patient medical records, Encore policies and procedures; Medicare carrier or intermediary manual or bulletins (including issue and date); practice guidelines issued by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association; other policies, regulations, or directives; and interviews with relevant Encore representatives).
- d. <u>Review Protocol</u>. A narrative description of how the Rehab Review was conducted and what was evaluated.
- e. <u>Supplemental Materials</u>. A description of any Supplemental Materials as required by Section A.3.a above.
- 2. Statistical Sampling Documentation.
 - a. A description or identification of the statistical sampling software package used to select the Sample.
 - b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
- 3. Rehab Review Findings.
 - a. A narrative explanation of the IRO's findings and supporting rationale (including adequacy of documentation, patterns noted, etc.) regarding whether each Rehabilitation Therapy Service reviewed by the IRO was medically necessary and appropriate.
 - b. Total number and percentage of Rehabilitation Therapy Services reviewed that the IRO determined were not

- supported by the medical record and not medically necessary and appropriate.
- c. A listing Rehab Therapy Patients and Rehabilitation Therapy Services at each Service Location for which the IRO has made a determination that the Rehabilitation Therapy Services were not supported by the medical record and not medically necessary and appropriate.
- d. The IRO's report shall include any recommendations for improvements to Encore's services and processes for determining the appropriate rehabilitation services to be provided and for documenting such services, based on the findings of the Rehab Review.
- 4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Rehab Review and (2) performed the Rehab Review.