# CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND REHABCARE GROUP, INC. AND KINDRED HEALTHCARE, INC.

#### I. PREAMBLE

RehabCare Group Inc., (RehabCare) and Kindred Healthcare, Inc., (Kindred) 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).

RehabCare provides contract rehabilitation therapy services to patients in skilled nursing facilities (SNFs), hospitals, and outpatient clinics, and is a wholly-owned subsidiary of Kindred, a healthcare services company that provides a continuum of post-acute care services in a variety of care settings. Except as otherwise provided herein, this CIA shall apply only to RehabCare and the provision of contract rehabilitation therapy services. Although Kindred undertakes certain obligations under this CIA, all obligations relate to the operation of RehabCare and shall specifically exclude Kindred subsidiaries or operating divisions that are not involved in providing contract rehabilitation therapy services. Contemporaneously with this CIA, Kindred and RehabCare are entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), Kindred established a voluntary corporate compliance program (the Compliance Program) which includes a Chief Compliance Officer, Code of Conduct, written policies and procedures, a disclosure program, screening measures, regular compliance training for employees, and various compliance auditing programs. Kindred shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Kindred may modify its Compliance Program as appropriate, but, at a minimum, Kindred 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 Kindred 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) Kindred's final annual report; or (2) any additional materials submitted by Kindred 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 who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% in Kindred's stock, and (2) acquired the ownership interest through public trading);
      - b. all officers, directors, and employees of RehabCare;
      - c. officers, directors, and employees of Kindred who provide operational oversight of services provided by RehabCare;
      - b. all contractors, subcontractors, agents, and other persons who are involved in the provision, oversight, or support of contract rehabilitation therapy services provided by RehabCare;

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 directly provide contract rehabilitation therapy services, or provide oversight of or

support for contract therapy services, provided by RehabCare in third party owned and operated SNFs.

#### III. CORPORATE INTEGRITY OBLIGATIONS

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

# A. <u>Compliance Officer and Committee</u>

- 1. Compliance Officer. Within 90 days after the Effective Date, Kindred 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 Kindred, shall report directly to the Chief Executive Officer of Kindred, 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 Kindred. 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 directly to the Board of Directors of Kindred, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request;
  - c. monitoring the day-to-day compliance activities engaged in by Kindred and RehabCare 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.

Kindred 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, Kindred 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 Kindred and RehabCare 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 RehabCare'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.

Kindred 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. Board of Directors Compliance Obligations. The Board of Directors (or a committee of the Board) of Kindred (Board) 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-executive) members.

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

- a. meeting at least quarterly to review and oversee Kindred's compliance program for RehabCare, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of 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 RehabCare'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 of Directors has made a reasonable inquiry into the operations of Kindred's Compliance Program for RehabCare 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, Kindred has implemented an effective Compliance Program for RehabCare 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 for RehabCare.

Kindred 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 days after such a change.

4. *Management Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Kindred and RehabCare employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable RehabCare division 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 employees (or their functional equivalents): RehabCare - President, Senior Vice President of Finance, Senior Vice President of Quality, Division Vice President of Clinical Operations, Division Vice President of Clinical Services, Division Senior Vice President of Skilled Rehabilitation Services (SRS),

Senior Vice Presidents of SRS, Regional Vice Presidents of SRS, and Vice President of Sales & Business Development of SRS, Regional Vice Presidents of SRS; and, Kindred - any Kindred executives who have direct oversight responsibilities for RehabCare including but not limited to the Chief Executive Officer, and Chief Financial Officer.

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 Kindred's policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of RehabCare 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 90 days after the Effective Date, Kindred shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Kindred 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 covered by this CIA. The Code of Conduct shall, at a minimum, set forth:
  - a. Kindred's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate rehabilitation therapy data to its customers, for the purpose of enabling

- those customers to submit claims that are consistent with all Federal health care program requirements;
- b. Kindred's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Kindred's own Policies and Procedures;
- c. the requirement that all of Kindred's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Kindred, suspected violations of any Federal health care program requirements or of Kindred's Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.F, and Kindred's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

- 2. Policies and Procedures. Within 90 days after the Effective Date, Kindred 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 Kindred's compliance with Federal health care program requirements. Throughout the term of this CIA, Kindred shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees covered by this CIA. The Policies and Procedures shall address, at a minimum:
  - a. the compliance program requirements outlined in this CIA; and
  - b. delivery, management and oversight of rehabilitation therapy services by RehabCare to patients in SNFs, including, but not limited to, the requirements that skilled rehabilitation therapy: (1)

be pursuant to a comprehensive assessment and individualized therapy treatment plan; (2) be consistent with the nature and severity of the patient'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 patient's condition, and therapy treatment plan to improve, maintain, slow deterioration of the patient's condition; and (6) only include services that are so inherently complex that they can be safely and effectively performed only by, or under the supervision of a qualified therapist.

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), Kindred 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 90 days after the Effective Date, Kindred shall develop a written plan (Training Plan) that outlines the steps Kindred will take to ensure that: (a) all Covered Persons receive adequate training regarding Kindred'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 accuracy of the 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 therapy services; (iii) the coordinated interdisciplinary approach to providing care and the related communications between rehabilitation therapy disciplines and between skilled nursing and skilled rehabilitation therapy; (iv) the personal obligation of each individual involved in the provision of therapy services to ensure that a service provided is medically necessary and reasonable given the patient's condition and treatment plan and meets professionally recognized standards of care; (v) examples of proper and improper rehabilitation

therapy services, including evaluations and treatment plans; (vi) the personal obligation of each individual involved in the generation and provision of therapy-related information to RehabCare's external customers to ensure that such information is accurate and that such skilled therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of the rehabilitation services; (vii) applicable reimbursement statutes, regulations, and program requirements and directives; and (viii) reporting obligations and legal sanctions for violations of the Federal health care program requirements.

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 Kindred's Training Plan, OIG will notify Kindred of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, Kindred may implement its Training Plan. Kindred shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

If Kindred provided training within 90 days prior to the Effective Date that fully satisfies the all the requirements set forth in Section III.C.1 above, except for the requirement of prior approval by OIG, then OIG will credit that training for purposes of satisfying the applicable part of either Kindred's training and education obligations for the first Reporting Period of the CIA.

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

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

- 3. *Certification*. Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.
- 4. *Qualifications of Trainer*. Persons providing the training shall be knowledgeable about the subject area.
- 5. Update of Training Plan. Kindred 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 audits required under this CIA, and any other relevant information. Any material 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 Kindred's Training Plan, OIG will notify Kindred of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, Kindred may implement the revised Training Plan.
- 6. Computer-based Training. Kindred may provide the training required under this CIA through appropriate computer-based training approaches. If Kindred chooses to provide computer-based training, they shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

#### D. Review Procedures

#### 1. General Description

a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, Kindred 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 Kindred shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Kindred) related to the reviews.
- 2. Rehabilitation Therapy Services Medical Necessity and Appropriateness Review. For each Reporting Period, the IRO shall review RehabCare's provision of rehabilitation therapy services under contracts between RehabCare and third party owned and operated SNFs to determine RehabCare's adherence to federal program requirements and conformance to generally accepted medical practices (Rehab Medical Review), and shall prepare a Rehab Medical Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.
- 3. Validation Review. In the event OIG has reason to believe that:
  (a) any Rehab Medical Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Rehab Medical Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Rehab Medical Review complied with the requirements of the CIA and/or the findings or Rehab Medical Review results are inaccurate (Validation Review). Kindred shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of a Rehab Medical Review submitted as part of Kindred's final Annual Report shall be initiated no later than one year after Kindred's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Kindred in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. Kindred shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional information to clarify the results of the Rehab Medical Review or to correct the inaccuracy of the Rehab Medical Review; 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.

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4. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Kindred 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 90 days after the Effective Date, Kindred 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 information, items or services furnished to Medicare and Medicaid program beneficiaries for which claims may be submitted. 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. Kindred shall maintain the risk assessment and internal review process for the term of the CIA.

#### F. Disclosure Program

Within 90 days after the Effective Date, Kindred 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 Kindred'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. Kindred 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, Kindred 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 for all disclosures directly or indirectly related to the provision of contract rehabilitation therapy services 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. <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, 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:
    - 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*. Kindred shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.
  - a. Kindred 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. Kindred shall screen all current Covered Persons against the Exclusion Lists within 90 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. Kindred shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

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

3. Removal Requirement. If Kindred has actual notice that a Covered Person has become an Ineligible Person, Kindred shall remove such Covered Person from responsibility for, or involvement with, Kindred's provision of services or other 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 Kindred 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, Kindred 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 information provided for the preparation of claims submitted to any Federal health care program.

# H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Kindred shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Kindred conducted or brought by a governmental entity or its agents involving an allegation that any operational division or operating unit within Kindred Healthcare, Inc. 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. Kindred 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. Reportable Events

- 1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:
  - 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;
  - b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
  - c. the filing of a bankruptcy petition by any operating division of Kindred.

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

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- 2. Reporting of Reportable Events. If Kindred determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Kindred 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 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 Kindred's actions taken to correct the Reportable Event and prevent it from recurring.
- 4. Reportable Events under Section III.1.1.b. For Reportable Events under Section III.1.1.b, 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 Kindred 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.
- 5. Reportable Events under Section III.I.1.c. For Reportable Events under Section III.I.1.c, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.
- 6. Reportable Events Involving the Stark Law. If applicable, 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 Kindred to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Kindred identifies a probable violation of the Stark Law and repays the applicable overpayment directly to the CMS contractor, then Kindred is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

# IV. <u>SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS</u>

#### A. Sale of Business, Business Unit or Location

In the event that, after the Effective Date, Kindred proposes to sell any or all of its contract rehabilitation therapy 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, Kindred shall notify OIG of the proposed sale at least 30 days prior to the sale of its contract rehabilitation therapy business, business unit or location. For purposes of this CIA, a business unit or location shall not include sites of services in which Kindred has no ownership interest. This notification shall include a description of the contract rehabilitation therapy 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 contract rehabilitation therapy 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, Kindred changes locations or closes a contract rehabilitation therapy business, business unit or location Kindred 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, Kindred purchases or establishes a new contract rehabilitation therapy business, business unit or location Kindred shall notify OIG at least 30 days prior to such purchase or the operation of the new contract rehabilitation therapy business, business unit or location. This notification shall include the address of the new contract rehabilitation therapy business, business unit or location, phone number, fax number, and, if applicable, the Medicare and state Medicaid program provider number and/or supplier number(s). Each new contract rehabilitation therapy 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, Kindred 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;

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- 3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
- 4. the names and positions of the Certifying Employees required by Section III.A.4;
  - 5. a copy of Kindred's Code of Conduct required by Section III.B.1;
- 6. 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);
- 7. the Training Plan required by Section III.C.1 and a description of the Board of Directors 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);
- 8. 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 Kindred and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Kindred;
- 9. a description of the risk assessment and internal review process required by Section III.E;
  - 10. a description of the Disclosure Program required by Section III.F;
- 11. a certification that Kindred has implemented the screening requirements described in Section III.G regarding Ineligible Persons, or a description of why Kindred cannot provide such a certification;
- 12. a description of Kindred's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
- 13. a list of all of Kindred's contract therapy business units or locations as defined by Section IV (including mailing addresses), the corresponding name under which each location is doing business; the corresponding phone numbers

and fax numbers, and if applicable, each location's Medicare and state Medicaid program provider number(s) and/or National Provider Identifier number(s); and

14. the certifications required by Section V.C.

#### B. Annual Reports

Kindred shall submit to OIG annually a report with respect to the status of, and findings regarding, Kindred'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, any change in the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3, and any change in the group of Certifying Employees described in Section III.A.4;
- 2. 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);
- 3. 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:
- 4. a summary of any significant changes or amendments to Kindred'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);
- 5. a copy of Kindred'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 Kindred 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.

- 6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter, and Kindred's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
- 7. a summary and description of any and all current and prior engagements and agreements between Kindred 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 Kindred;
- 8. a description of the risk assessment and internal review process required by Section III.E, a summary of any material changes to the process, and a description of the reasons for such changes;
- 9. 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;
- 10. 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);
- 11. a certification that Kindred has completed the screening required by Section III.G regarding Ineligible Persons;
- 12. 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;
- 13. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;
- 14. if applicable, 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 for rehabilitation therapy by RehabCare, and Kindred'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 Kindred's contract therapy business units or locations (including addresses) as required by Section V.A.13; and
  - 16. 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, Kindred shall include the certifications of Certifying Employees as required by Section III.A.4;
- 2. Compliance Officer and Chief Executive Officer. The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:
  - a. to the best of his or her knowledge, except as otherwise described in the report, Kindred and RehabCare are 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 Kindred's Chief Financial Officer that, to the best of his or her knowledge, Kindred has complied with its obligations under the Settlement Agreement: (a) if applicable, 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. <u>Designation of Information</u>

Kindred 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. Kindred 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

#### Kindred and RehabCare:

Kelly Priegnitz Senior Vice President and Chief Compliance Officer 680 South Fourth Street Louisville, KY 40202

Telephone: (502) 596-7320

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, Kindred 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 Kindred's books, records, and other documents and supporting materials that relate to contract rehabilitation therapy services and/or conduct on-site reviews of any of Kindred's contract rehabilitation therapy business unit locations, for the purpose of verifying and evaluating: (a) Kindred's and RehabCare's compliance with the terms of this CIA and (b) Kindred's and RehabCare's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Kindred 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 Kindred's or RehabCare'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. Kindred shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Kindred's and RehabCare's Covered Persons may elect to be interviewed with or without a representative of Kindred or RehabCare present.

# VIII. DOCUMENT AND RECORD RETENTION

Kindred and RehabCare 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. <u>DISCLOSURES</u>

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

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# X. BREACH AND DEFAULT PROVISIONS

Kindred and RehabCare are expected to fully and timely comply with all of their CIA obligations.

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

As a contractual remedy, Kindred, RehabCare 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 Kindred and/or RehabCare, as applicable, 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 Board of Directors compliance obligations;
  - d. the management certification obligations;
  - e. a written Code of Conduct;
  - f. written Policies and Procedures;
  - g. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Board Members;
  - h. a risk assessment and internal review process as required by Section III.E;
  - i. a Disclosure Program;
  - j. Ineligible Persons screening and removal requirements;

- k. notification of Government investigations or legal proceedings;
- 1. reporting of Reportable Events; and
- m. disclosure of changes to Kindred's contract therapy 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 Kindred and/or RehabCare, as applicable, 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 Kindred and/or RehabCare, as applicable, 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 Kindred and/or RehabCare, as applicable, fails to submit any report in accordance with the requirements of Section III.D and Appendix B.
- 5. A Stipulated Penalty of \$1,500 for each day Kindred and/or RehabCare, as applicable, fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Kindred fails to grant access.)
- 6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Kindred and/or RehabCare, as applicable, 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 Kindred and/or RehabCare, as applicable, fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Kindred stating the specific grounds for its determination that Kindred and/or RehabCare, as applicable, has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Kindred shall take to

comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Kindred 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

Kindred 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 Kindred 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 Kindred 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 Kindred and/or RehabCare, as applicable, 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 Kindred of: (a) Kindred's or RehabCare'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, Kindred and/or RehabCare, as applicable, 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 Kindred and/or RehabCare, as applicable, elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Kindred and/or RehabCare, as applicable, 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 of RehabCare 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 Kindred and/or RehabCare 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. <u>Exclusion for Material Breach of this CIA</u>

- 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 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, Appendix B.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Kindred or RehabCare constitutes an independent basis for RehabCare'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 Kindred or RehabCare has materially breached this CIA and that exclusion is the appropriate

remedy, OIG shall notify Kindred of: (a) the 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*. Kindred 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) Kindred and/or RehabCare, as applicable, has begun to take action to cure the material breach; (ii) Kindred and/or RehabCare, as applicable, is pursuing such action with due diligence; and (iii) Kindred and/or RehabCare, as applicable, has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30 day period, Kindred fails to satisfy the requirements of Section X.D.3, OIG may exclude RehabCare from participation in the Federal health care programs. OIG shall notify Kindred in writing of its determination to exclude RehabCare. (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 Kindred'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, RehabCare 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. <u>Dispute Resolution</u>

1. Review Rights. Upon OIG's delivery to Kindred of its Demand Letter or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Kindred and RehabCare 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 Kindred and/or RehabCare, as applicable, were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Kindred and RehabCare 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 Kindred and/or RehabCare, as applicable, to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after 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 Kindred or RehabCare were in material breach of this CIA and, if so, whether:

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- a. Kindred or RehabCare 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 Kindred's receipt of the Notice of Material Breach: (i) Kindred or RehabCare had begun to take action to cure the material breach; (ii) Kindred or RehabCare pursued such action with due diligence; and (iii) Kindred or RehabCare 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 Kindred and/or RehabCare, as applicable, only after a DAB decision in favor of OIG. Kindred's and/or RehabCare's, election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude RehabCare 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 Kindred or RehabCare 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. Kindred and RehabCare 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 Kindred and RehabCare, RehabCare 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

RehabCare, Kindred 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 Kindred's and/or RehabCare's, obligations under this CIA based on a certification by Kindred and/or RehabCare, as applicable, that it is no longer providing health care items or services that will be billed by any entity 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 Kindred and/or RehabCare, as applicable, is relieved of its CIA obligations, Kindred and/or RehabCare, as applicable, shall be required to notify OIG in writing at least 30 days in advance if Kindred and/or RehabCare, as applicable,

plans to resume providing health care items or services that are billed by any entity 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) Kindred's and RehabCare'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 RehabCare and Kindred 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.
- G. This CIA is by and between the parties hereto. The CIA is not intended to establish any legal rights for or confer any legal rights upon any non-governmental entities or persons not a party to the CIA. The parties agree, however, that this CIA is a public document and it may be admissible in a judicial or administrative proceeding.

# ON BEHALF OF KINDRED HEALTHCARE DBA REHABCAREGROUP INC. AND KINDRED HEALTHCARE INC.

/Jon Rousseau/	1/7/16	
JON B. ROUSSEAU President RehabCare Group, Inc.	DATE	
/Ben Brier/	1/8/16	
BEN BREIER President and Chief Executive Officer, Kindred Healthcare, Inc.	DATE	
/Glenn Hendrix/	1/8/16	
GLENN P. HENDRIX Arnall Golden Gregory LLP	DATE	

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

/Robert K. DeConti/	1/11/16
ROBERT K. DECONTI Assistant Inspector General for Legal Affairs Office of Inspector General U. S. Department of Health and Human Services	DATE
/Tonya Keusseyan/	1/11/16
TONYA KEUSSEYAN	DATE
Senior Counsel	
Office of Inspector General	
U. S. Department of Health and Human Services	

#### APPENDIX A

#### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

- 1. Kindred 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.8 of the CIA or any additional information submitted by Kindred in response to a request by OIG, whichever is later, OIG will notify Kindred if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Kindred may continue to engage the IRO.
- 2. If Kindred 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, Kindred shall submit the information identified in Section V.A.8 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 Kindred at the request of OIG, whichever is later, OIG will notify Kindred if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Kindred may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

- 1. assign individuals to conduct the Rehabilitation Therapy Services Medical Necessity and Appropriateness Review (Rehab Medical Review) 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 RehabCare's customers seeks reimbursement
- 2. assign individuals to design and select the Rehab Medical Review sample who are knowledgeable about the appropriate statistical sampling techniques;
- 3. assign individuals to conduct the Rehab Medical 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 review required by the CIA on a timely basis.

# C. IRO Responsibilities

The IRO shall:

- 1. perform each Rehab Medical Review in accordance with the specific requirements of the CIA;
- 2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the Rehab Medical 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 to the CIA.

# D. <u>IRO Independence and Objectivity</u>

The IRO must perform the Rehab Medical 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.

# E. <u>IRO Removal/Termination</u>

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

#### APPENDIX B

# REHABILITATION THERAPY SERVICES MEDICAL NECESSITY AND APPROPRIATENESS REVIEW

- A. Rehabilitation Therapy Medical Necessity and Appropriateness Review. Kindred shall retain an IRO to perform reviews of RehabCare's provision of rehabilitation therapy services under contracts between RehabCare and third party owned and operated SNFs (Rehab Medical Review). The purpose of the Rehab Medical Review is to determine RehabCare's: 1) adherence to Federal healthcare program requirements applicable to rehabilitation therapy services furnished to SNF patients under Medicare Part A and 2) conformance with practice guidelines and generally accepted medical practices applicable to rehabilitation therapy services. The IRO shall perform the Rehab Medical Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Rehab Medical Review.
- 1. *Definitions*. For the purposes of the Rehab Medical Review, the following definitions shall be used:
  - a. Rehab Therapy Patient: A Medicare patient who is covered under Medicare Part A and who received rehabilitation therapy services from RehabCare 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 Medical Review.
  - c. <u>Service Location</u>: A third party owned or operated SNF at which RehabCare 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 RehabCare provided contract rehabilitation therapy services during the prior 12-month period.
- 2. Sample. For the first Reporting Period, the IRO shall first randomly select 25 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 limit the Rehab Therapy Patient Population or the Service Location Population or both to a subset of Rehab Therapy Patients or Service Locations based on Resource Utilization Group (RUG), length of stay, revenue, patient volume, geographical location or other factors determined by the OIG in its discretion. In the event that OIG exercises its discretion to limit the Rehab Therapy Patient Population or the Service Location Population, OIG shall notify RehabCare at least 60 days prior to the end of the Reporting Period of any information needed from RehabCare in order for the OIG to identify the Rehab Therapy Patient Population (e.g., RUG level, length of stay, etc.) or the Service Location Population (e.g., revenue, patient volume information, etc.). The OIG shall notify RehabCare and its IRO of the subset of Rehab Therapy Patients or Service Locations to be reviewed at least 30 days prior to the end of the Reporting Period.

For each Rehab Therapy Patient selected, the IRO shall review all rehabilitation therapy services provided to the Rehab Therapy Patient by RehabCare during the 12-month period covered by the Rehab Medical Review (Rehabilitation Therapy Services). The Rehabilitation Therapy Services shall be reviewed based on all of the portions of the 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, nursing records, plans of care, therapy treatment plans, daily therapy treatment notes, interim therapy progress notes, CPT logs, discharge summaries, therapy tests and measurement results. The Rehabilitation Therapy Services shall be reviewed by the IRO to determine if the services provided were medically necessary and appropriate under the applicable regulations, manuals and guidance, including but not limited to: 1) Federal healthcare program rules and regulations governing the provision of skilled rehabilitation therapy in SNFs; 2) the established practice guidelines and generally accepted standards of medical practice including those set forth by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

The IRO's review shall include a determination of whether RehabCare 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 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 only therapy services that are reasonable and necessary given 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. tracking of rehabilitation therapy minutes;
- i. provision of services according to the frequency and duration prescribed in the therapy treatment plan; and
- j. discharge planning and drafting of post discharge therapy treatment plan.

The IRO's review also shall include a determination of whether RehabCare 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*.
  - Supplemental Materials. The IRO shall request all a. documentation and materials required for its review of the Rehabilitation Therapy Services selected as part of the Sample, and RehabCare 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 RehabCare after the IRO has completed its initial review of the Sample (Supplemental Materials), the IRO shall identify in the Rehab Medical 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 Medical 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).
- 4. Reporting of IRO Findings at Service Locations. RehabCare 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 was not medically necessary and appropriate.
- B. <u>Rehab Medical Review Report</u>. The IRO shall prepare a Rehab Medical Review Report as described in this Appendix B for each Rehab Medical Review performed. The following information shall be included in the Rehab Medical Review Report for each Sample.
  - 1. Rehab Medical Review Methodology.
    - a. <u>Rehab Medical Review Population</u>. A description of the Service Location Population and the Rehab Therapy Patient Population subject to the Rehab Medical Review.

- b. <u>Rehab Medical Review Objective</u>. A clear statement of the objective intended to be achieved by the Rehab Medical Review.
- c. Source of Data. A description of the specific documentation and other information sources relied upon by the IRO when performing the Rehab Medical Review (e.g., patient medical records, RehabCare 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 RehabCare representatives).
- d. <u>Review Protocol</u>. A narrative description of how the Rehab Medical 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 Medical 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 RehabCare'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 Medical 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 Medical Review and (2) performed the Rehab Medical Review.