

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
SPECIALCARE HOSPITAL MANAGEMENT CORPORATION  
AND  
ROBERT MCNUTT**

**I. PREAMBLE**

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

Prior to the Effective Date, SpecialCare established a voluntary compliance program (Compliance Program). The Compliance Program includes, among other things, a Compliance Officer, a code of conduct, policies and procedures, a compliance hotline, and screening for Ineligible Persons. SpecialCare shall continue the Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. SpecialCare may modify the Compliance Program as appropriate, but, at a minimum, SpecialCare 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 SpecialCare 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) SpecialCare's final annual report; or (2) any additional materials submitted by SpecialCare pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction that:
  - a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between SpecialCare and any actual or potential source of health care business or referrals to SpecialCare or to a hospital with which SpecialCare has an agreement or any actual or potential recipient of health care business or referrals from SpecialCare. The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term "recipient of health care business or referrals" shall mean any individual or entity (1) to whom SpecialCare refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom SpecialCare purchases, leases, or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
  - b. is between SpecialCare and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to SpecialCare or to a hospital with which SpecialCare has an agreement for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
2. "Focus Arrangements" means every Arrangement that:
  - a. is between SpecialCare and any actual source of health care

business or referrals to SpecialCare or to a hospital with which SpecialCare has an agreement and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

- b. is between SpecialCare and any physician (or a physician's immediate family member) (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to SpecialCare or to a hospital with which SpecialCare has an agreement for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

Notwithstanding the foregoing provisions of Section II.C.2, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests); 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits); 42 C.F.R. § 411.357(o) (compliance training); 42 C.F.R. § 411.357(q) (referral services); 42 C.F.R. § 411.357(s) (professional courtesy); 42 C.F.R. § 357(u) (community-wide health information systems); or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.

- 3. "Covered Persons" includes:
  - a. all owners, officers, directors, and employees of SpecialCare; and
  - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of SpecialCare excluding vendors whose sole connection with SpecialCare is selling or otherwise providing medical supplies or equipment to SpecialCare and who do not bill the Federal health care programs for such medical supplies or equipment.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably

expected to work more than 160 hours per 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.

4. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of SpecialCare’s Arrangements.

5. “Relevant Covered Persons” includes each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation of claims for reimbursement from any Federal health care program or supporting documentation for such claims.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

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

#### **A. Compliance Officer and Committee**

1. *Compliance Officer.* SpecialCare represents that, prior to the Effective Date, SpecialCare appointed an individual 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 SpecialCare, shall report directly to the Chief Executive Officer of SpecialCare, 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 SpecialCare. 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; and
- b. monitoring the day-to-day compliance activities engaged in by SpecialCare 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.

SpecialCare 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, SpecialCare shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of SpecialCare'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.

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

3. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain SpecialCare employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable SpecialCare department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the Chief Executive Officer and any individuals with the title of Senior Executive Vice President, Executive Vice President, or Vice President. 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 SpecialCare policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of SpecialCare 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.* SpecialCare represents that, prior to the Effective Date, SpecialCare developed, implemented, and distributed a written Code of Conduct. SpecialCare shall maintain the Code of Conduct, as required herein, for the term of the CIA, and shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. SpecialCare’s commitment to full compliance with all Federal health care program requirements;
- b. SpecialCare’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with SpecialCare’s own Policies and Procedures;
- c. the requirement that all of SpecialCare’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by SpecialCare, suspected violations of any Federal health care program requirements or of SpecialCare’s own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.F, and SpecialCare’s commitment to

nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

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

2. *Policies and Procedures.* To the extent not already accomplished, within 90 days after the Effective Date, SpecialCare shall implement written Policies and Procedures regarding the operation of SpecialCare's compliance program, including the compliance program requirements outlined in this CIA and SpecialCare's compliance with Federal health care program requirements. The Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law;
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law);
- c. procedures to ensure SpecialCare is knowledgeable about and complies with state licensing requirements related to detoxification and chemical dependency services;
- d. relevant patient admissions requirements; and

- e. appropriate discharge and aftercare planning and coordination.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. Throughout the term of this CIA, SpecialCare shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), SpecialCare 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, the relevant portions of any such revised or new Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

### C. Training and Education

1. *General Training.* Within 90 days after the Effective Date, SpecialCare shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain SpecialCare's:

- a. CIA requirements; and
- b. Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Arrangements Training.* Within 90 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. SpecialCare's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;
- c. the personal obligation of each individual involved in the development, approval, management, or review of SpecialCare's Arrangements to know the applicable legal requirements and SpecialCare's policies and procedures;
- d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and
- e. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training and, if applicable, the Arrangements Training, required above. This Specific Training shall include a discussion of:

- a. applicable reimbursement statutes, regulations, and program requirements and directives;

- b. relevant patient admissions requirements;
- c. discharge and aftercare planning and coordination for appropriate chemical dependency services;
- d. the personal obligation of each individual involved in the medical documentation process to ensure that such documentation is accurate;
- e. examples of proper and improper medical documentation practices; and
- f. the legal sanctions for violations of the Federal health care program requirements.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least two hours of Specific Training, in addition to the General Training and, if applicable, the Arrangements Training, in each subsequent Reporting Period.

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, 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.

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

6. *Update of Training.* SpecialCare shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements; any issues discovered during internal audits, the Arrangements Review, or Service Review; and any other relevant information.

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

D. Compliance with the Anti-Kickback Statute and Stark Law

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, SpecialCare shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying the business need or business rationale for all

Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;

- f. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events pursuant to Section III.I when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, SpecialCare shall comply with the following requirements (Focus Arrangements Requirements):

- a. ensure that each Focus Arrangement is set forth in writing and signed by SpecialCare and the other parties to the Focus Arrangement;
- b. include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required by Section III.C.2 of this CIA. Additionally, SpecialCare shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures; and
- c. include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. *Records Retention and Access.* SpecialCare shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, SpecialCare shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. 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 SpecialCare shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and SpecialCare) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects SpecialCare’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Service Review.* The IRO shall perform a Service Review and prepare a Service Review Report as outlined in Appendix C to this CIA, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify SpecialCare of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, SpecialCare may request a meeting with OIG to: (a) discuss the results of any Arrangements Review or Service Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or Service Review or to correct the inaccuracy of the Arrangements Review or Service Review; and/or (c) propose alternatives to the proposed Validation Review. SpecialCare agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review or Service Review issues with SpecialCare prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

#### F. Disclosure Program

SpecialCare represents that, prior to the Effective Date, it established a Disclosure Program. SpecialCare shall maintain a Disclosure Program, as required herein, 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 SpecialCare'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. SpecialCare 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, SpecialCare shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

#### G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
  - a. an "Ineligible Person" shall include an individual or entity who:

- i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s System for Award Management (available through the Internet at <http://www.sam.gov>).

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

- a. SpecialCare 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. SpecialCare shall screen all 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. SpecialCare shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion,

suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If SpecialCare has actual notice that a Covered Person has become an Ineligible Person, SpecialCare shall remove such Covered Person from responsibility for, or involvement with, SpecialCare's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If SpecialCare 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, SpecialCare 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 any claims submitted to any Federal health care program.

#### H. Notification of Government Investigation or Legal Proceedings

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

OIG with a description of the findings and/or results of the investigation or proceedings, if any.

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;
- 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 SpecialCare.

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

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall 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; and
- d. a description of SpecialCare's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.b.* For Reportable Events under Section III.I.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 Person's employment or contractual relationship;
- c. a description of the Exclusions Lists screening that SpecialCare 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.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. § 1395nn (the

Stark Law) should be submitted by SpecialCare to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If SpecialCare identifies a probable violation of the Stark Law and repays the applicable overpayment directly to the CMS contractor, then SpecialCare is not required by this Section III.I.6 to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

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

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

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

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

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

In the event that, after the Effective Date, SpecialCare purchases or establishes a new business, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, SpecialCare shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit, or location. This notification shall include the address of the new business, business unit, or location; phone number; fax number; the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare

and state Medicaid program contractor to which SpecialCare currently submits claims. Each new business, business unit, or location and all Covered Persons at each new business, business unit, or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

### **A. Implementation Report**

Within 120 days after the Effective Date, SpecialCare 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.1, 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.2;
3. the names and position descriptions of the Certifying Employees required by Section III.A.3;
4. a copy of SpecialCare's Code of Conduct required by Section III.B.1;
5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);
6. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);
7. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.
8. a description of: (a) the Focus Arrangements Tracking System required by Section III.D.1.a; (b) the internal review and approval process required by Section III.D.1.e; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;
9. a description of the Disclosure Program required by Section III.F;
10. 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 SpecialCare and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to SpecialCare;
11. a certification that SpecialCare has conducted the screening required by Section III.G regarding Ineligible Persons;
12. a list of all of SpecialCare's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; if applicable, each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and, if applicable, the name and address of each Medicare and state Medicaid program contractor to which SpecialCare currently submits claims;
13. a description of SpecialCare's corporate structure, including identification of any individual owners, parent and sister companies, subsidiaries, and their respective lines of business; and
14. the certifications required by Section V.C.

## B. Annual Reports

SpecialCare shall submit to OIG annually a report with respect to the status of, and findings regarding, SpecialCare'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.2; and any changes in the group of Certifying Employees described in Section III.A.3;
2. a summary of any changes or amendments to SpecialCare's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);
4. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);
5. the following information regarding each type of training required by Section III.C:
  - a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.
6. a description of: (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and

approval process required by Section III.D.1.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

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

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

9. a summary and description of any and all current and prior engagements and agreements between SpecialCare and the IRO, if different from what was submitted as part of the Implementation Report;

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

11. 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;

12. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark Law (the complete disclosure log shall be made available to OIG upon request);

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

14. 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;

15. a description of all changes to the most recently provided list of SpecialCare's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; if applicable, each location's Medicare and state

Medicaid program provider number(s) and/or supplier number(s); and, if applicable, the name and address of each Medicare and state Medicaid program contractor to which SpecialCare currently submits claims; 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, SpecialCare shall include the certifications of Certifying Employees as required by Section III.A.3.

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

- a. to the best of his or her knowledge, except as otherwise described in the applicable report, SpecialCare is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, SpecialCare has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;
- c. to the best of his or her knowledge, SpecialCare has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA; and
- d. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful.

D. Designation of Information

SpecialCare Hospital Management Corporation & Robert McNutt  
Corporate Integrity Agreement

SpecialCare 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. SpecialCare 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, D.C. 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

SpecialCare: Thomas Millea, VP, Chief Compliance Officer  
502 Earth City Plaza, Suite 311  
Saint Louis, MO 63045  
Telephone: 314.770.2212  
Facsimile: 314.770.2224

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, SpecialCare 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**

SpecialCare Hospital Management Corporation & Robert McNutt  
Corporate Integrity Agreement

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

## **VIII. DOCUMENT AND RECORD RETENTION**

SpecialCare 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 SpecialCare prior to any release by OIG of information submitted by SpecialCare pursuant to its obligations under this CIA and identified upon submission by SpecialCare as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, SpecialCare shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

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

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, SpecialCare 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 SpecialCare 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. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons, Arrangements Covered Persons, and Relevant Covered Persons;
- f. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. reporting of Reportable Events; and
- k. disclosure of changes to business units or locations.

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SpecialCare 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 SpecialCare fails to submit the annual Arrangements Review Report or Service Report in accordance with the requirements of Section III.E, Appendix B, and Appendix C.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of SpecialCare as part of its Implementation Report, 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 SpecialCare fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to SpecialCare stating the specific grounds for its determination that SpecialCare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps SpecialCare shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after SpecialCare 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

SpecialCare 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 SpecialCare 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 SpecialCare 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 SpecialCare 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 SpecialCare of: (a) SpecialCare'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, SpecialCare 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 SpecialCare elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until SpecialCare 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 SpecialCare 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. a failure by SpecialCare to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
  - b. 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;
  - 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.E, Appendix A, Appendix B, and Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by SpecialCare constitutes an independent basis for SpecialCare'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 SpecialCare has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify SpecialCare of: (a) SpecialCare'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.* SpecialCare 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) SpecialCare has begun to take action to cure the material breach; (ii) SpecialCare is pursuing such action with due diligence; and (iii) SpecialCare has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, SpecialCare fails to satisfy the requirements of Section X.D.3, OIG may exclude SpecialCare from participation in the Federal health care programs. OIG shall notify SpecialCare in writing of its determination to exclude SpecialCare. (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 SpecialCare’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, SpecialCare 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 SpecialCare 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, SpecialCare 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 SpecialCare was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. SpecialCare 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 SpecialCare to pay Stipulated Penalties, such

Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless SpecialCare 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 SpecialCare was in material breach of this CIA and, if so, whether:

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

SpecialCare 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 SpecialCare's obligations under this CIA based on a certification by SpecialCare that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If SpecialCare is relieved of its CIA obligations, SpecialCare will be required to notify OIG in writing at least 30 days in advance if SpecialCare 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. The undersigned SpecialCare 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.

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

**ON BEHALF OF SPECIALCARE HOSPITAL MANAGEMENT CORPORATION**

/Robert McNutt/ Dec 8/2014  
\_\_\_\_\_  
ROBERT MCNUTT DATE  
Chief Executive Officer  
SpecialCare Hospital Management Corporation

/Keir N. Dougall/ 12/10/2014  
\_\_\_\_\_  
KEIR N. DOUGALL DATE  
The Law Office of Keir N. Dougall, P.C.

/Joseph V. Willey/ 12/10/2014  
\_\_\_\_\_  
JOSEPH V. WILLEY DATE  
Katten Muchin Rosenman LLP

**ON BEHALF OF ROBERT MCNUTT**

/Robert McNutt/ Dec 8/2014  
\_\_\_\_\_  
ROBERT MCNUTT DATE

/Keir N. Dougall/ 12/10/2014  
\_\_\_\_\_  
KEIR N. DOUGALL DATE  
The Law Office of Keir N. Dougall, P.C.

/Joseph V. Willey/ 12/10/2014  
\_\_\_\_\_  
JOSEPH V. WILLEY DATE  
Katten Muchin Rosenman LLP

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

/Robert K. DeConti/

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12/23/2014

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

DATE

/Kaitlyn L. Dunn/

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12/23/2014

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KAITLYN L. DUNN  
Associate Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. SpecialCare shall engage an IRO that possesses, or IROs that possess, the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO(s) shall conduct the reviews 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.10 of the CIA or any additional information submitted by SpecialCare in response to a request by OIG, whichever is later, OIG will notify SpecialCare if the IRO(s) is/are unacceptable. Absent notification from OIG that the IRO(s) is/are unacceptable, SpecialCare may continue to engage the IRO(s).

2. If SpecialCare engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, SpecialCare shall submit the information identified in Section V.A.10 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 SpecialCare at the request of OIG, whichever is later, OIG will notify SpecialCare if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SpecialCare may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes;

2. assign individuals to conduct the Service Review who are knowledgeable in the clinical and regulatory requirements of detoxification and chemical dependency services; and

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

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review and Service Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C to the CIA.

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *SpecialCare and IRO.* If SpecialCare terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, SpecialCare must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. SpecialCare 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 that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require SpecialCare to engage a new IRO in accordance with Paragraph A of this Appendix. SpecialCare must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring SpecialCare to engage a new IRO, OIG shall notify SpecialCare of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, SpecialCare may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the

IRO with SpecialCare prior to requiring SpecialCare to terminate the IRO. However, the final determination as to whether or not to require SpecialCare to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to SpecialCare's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If SpecialCare materially changes the Arrangements systems, processes, policies, and procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of SpecialCare's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. SpecialCare's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;
2. SpecialCare's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. SpecialCare's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
4. SpecialCare's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
5. SpecialCare's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with

authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

6. SpecialCare's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by SpecialCare, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

7. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, SpecialCare's internal review and approval process, and other Arrangements systems, processes, policies, and procedures;

8. SpecialCare's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

9. SpecialCare's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of SpecialCare's systems, policies, processes, and procedures relating to the items identified in Section A.1-9 above;

3. findings and supporting rationale regarding weaknesses in SpecialCare's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve SpecialCare's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-9 above.

C. Arrangements Transaction Review. The Arrangements Transaction Review shall consist of a review by the IRO of 25 randomly selected Focus Arrangements that were entered into or renewed by SpecialCare during the Reporting Period. The IRO shall assess whether SpecialCare has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in SpecialCare's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (i.e., the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.);
2. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;
3. verifying that the remuneration related to the Focus Arrangement is properly tracked;
4. verifying that the service and activity logs are properly completed and reviewed (if applicable);
5. verifying that leased space, medical supplies, medical devices and equipment, and other patient care items are properly monitored (if applicable); and
6. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transaction Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*

- a. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.
- b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and SpecialCare shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from SpecialCare after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction 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 Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The IRO's findings with respect to whether SpecialCare has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transaction Review Report shall include observations, findings, and recommendations on possible improvements to SpecialCare's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.

## APPENDIX C

### SERVICE REVIEW

A. Service Review. SpecialCare shall retain an IRO to perform reviews of SpecialCare's administrative health care management services under contracts between SpecialCare and acute care hospitals (Service Review). The IRO shall perform the Service Review annually to cover each of the five Reporting Periods. Each Reporting Period, the IRO shall randomly select one administrative health care management services contract on which to perform the Service Review. Once an administrative health care management services contract has been selected for a Service Review, it will not be considered in the pool from which the IRO randomly selects subsequent administrative health care management services contracts for review. The IRO shall perform all components of each Service Review.

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

- a. Patient Treatment Episode: Each Medicare and Medicaid in-patient admission relating to an administrative health care management services contract between SpecialCare and an acute care hospital, any SpecialCare involvement with the patient prior to admission, the hospital stay, discharge planning and coordination, and any SpecialCare follow-up interactions with the patient after discharge.
- b. Population: The Population shall be defined as all Patient Treatment Episodes during the 12-month period covered by the Service Review.

2. *IRO Review of Selected Administrative Health Care Management Services Contract*. The IRO shall review the requirements of the selected administrative health care management services contract and SpecialCare's activities under that contract during the 12-month period covered by the Service Review. The purpose of this contract review shall be to determine what services SpecialCare provided to the hospital and to the patients.

3. *IRO Review of Discovery Sample of Patient Treatment Episodes*. The IRO shall randomly select and review a sample of 25 Patient Treatment Episodes (Discovery Sample) relating to the administrative health care management services contract reviewed under Paragraph 2, above. The Patient Treatment Episodes shall be

reviewed based on interviews with relevant SpecialCare employees; supporting documentation available at SpecialCare's office(s), available at the acute care hospital, or under SpecialCare's control; the applicable Medicare and Medicaid regulations and guidance; and professionally recognized standards of care relating to detoxification and chemical dependency services. The purpose of the review shall be to determine the role SpecialCare played in each Patient Treatment Episode and whether the management services provided by SpecialCare resulted in appropriate referral, intake, and admissions; patient care; discharge planning and coordination of additional chemical dependency treatment and services; and documentation.

4. *IRO Review of Larger Sample of Patient Treatment Episodes.* For each Service Review, if 23 or more of the Patient Treatment Episodes reviewed in the Discovery Sample are found to have resulted in appropriate referral, intake, and admissions; patient care; discharge planning and coordination of additional chemical dependency treatment and services; and documentation, no additional sampling is required. If fewer than 23 of the Patient Treatment Episodes reviewed in the Discovery Sample are found to have resulted in appropriate referral, intake, and admissions; patient care; discharge planning and coordination of additional chemical dependency treatment and services; and documentation, then the IRO shall randomly select and review a sample of 50 additional Patient Treatment Episodes (Larger Sample) in a manner consistent with the methodology set forth in Section III.A.3, above.

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

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

1. *Service Review Methodology*

- a. Service Review Population. A description of the Population subject to the Service Review.
- b. Service Review Objective. A clear statement of the objective intended to be achieved by the Service Review.

- c. Source of Data. A description of the specific documentation and other information sources relied upon by the IRO when performing the Service Review (e.g., health care management services contract; SpecialCare policies and procedures; medical records; physician orders; Medicare carrier or intermediary manual or bulletins (including issue and date); State Medicaid program requirements and guidance; other policies, regulations, or directives; and interviews with relevant SpecialCare representatives).
- d. Review Protocol. A narrative description of how the Service Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A description or identification of the statistical sampling software package used to select the sample.

3. *Service Review Findings*

- a. A detailed description of the selected administrative health care management services contract subject to the Service Review and of the services SpecialCare provided to the hospital and to the patients pursuant to that contract.
- b. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Service Review, including the results of the Discovery Sample, and the results of the Larger Sample (if any). For each Patient Treatment Episode, a description of whether, and if not why, the management services provided by SpecialCare resulted in appropriate referral, intake, and admissions; patient care; discharge planning and coordination of additional chemical dependency treatment and services; and documentation.

- c. Total number of Patient Treatment Episodes reviewed in which the IRO determined that the management services provided did not result in appropriate referral, intake, and admissions; patient care; discharge planning and coordination of additional chemical dependency treatment and services; and documentation.
- d. The IRO's report shall include any recommendations for improvements to SpecialCare's management services based on the findings of the Service Review.

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