

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
COMMUNITY HEALTH SYSTEMS, INC.,
AMENDED**

I. PREAMBLE

Effective July 28, 2014, Community Health Systems, Inc. (CHSI) entered into a 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). That CIA is hereby amended and extended for an additional period. Specifically, this amended CIA (hereafter "CIA") will be in effect for three years commencing on its Effective Date. Contemporaneously with this CIA, CHSI is entering into a Settlement Agreement with the United States.

CHSI represents that, prior to this CIA, CHSI voluntarily established a Compliance Program which provides for a Corporate Compliance and Privacy Officer, various compliance committees, a compliance training and education program, a confidential disclosure reporting hotline, and auditing and monitoring activities, and which includes various policies and procedures aimed at ensuring that CHSI's participation in the federal health care programs conforms to all federal and state laws and federal health care program requirements. CHSI shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. CHSI may modify its Compliance Program, as appropriate, but at a minimum, CHSI shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

For purposes of this CIA, "CHSI" shall mean the following: (1) Community Health Systems, Inc. and its directly or indirectly wholly-owned subsidiaries and affiliates that provide hospital services; and (2) any other corporation, limited liability company, partnership, or any other legal entity or organization in which CHSI, or a directly or indirectly wholly-owned subsidiary or affiliate of CHSI, owns a direct or indirect equity interest of 50% or more and that provides hospital services.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by CHSI under this amended CIA shall be three 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) CHSI’s final annual report; or (2) any additional materials submitted by CHSI 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% and (2) acquired the ownership interest through public trading), officers, directors, and employees of CHSI;
- 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 CHSI, excluding vendors whose sole connection with CHSI is selling or otherwise providing medical supplies or equipment and who do not bill the Federal health care programs for such medical supplies or equipment to CHSI; and
- c. all physicians and other non-physician practitioners who are members of the active medical staff at CHSI.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become

“Covered Persons” at the point when they work more than 160 hours

during the calendar year.

2. “Covered Facility” or “Covered Facilities” includes all CHSI hospitals, but shall not include any CHSI hospital that has been designated as a Critical Access Hospital pursuant to 42 U.S.C. § 1395i-4(c)(2).
3. “Relevant Billing Covered Persons” includes Covered Persons involved in the preparation or submission of claims or cost reports for reimbursement from any Federal health care program on behalf of CHSI’s Covered Facilities.
4. “Relevant Clinical Covered Persons” includes Covered Persons involved in the delivery of patient care items or services at or on behalf of CHSI’s Covered Facilities.
5. “Relevant Case Management Covered Persons” includes Covered Persons who work in or for a Case Management Department and who are involved in case management or utilization review functions relating to inpatient admissions or discharge decisions.
6. “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 CHSI and any actual or potential source of health care business or referrals to CHSI or any actual or potential recipient of health care business or referrals from CHSI. 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 CHSI refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2)

from whom CHSI 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 CHSI 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 CHSI for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

7. "Focus Arrangements" means every Arrangement that:

- a. is between CHSI and any actual source of health care business or referrals to CHSI and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
- b. is between CHSI 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 CHSI for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

Notwithstanding the foregoing provisions of Section II.C.7, 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), any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement or that does not constitute a "financial relationship" as

defined by 42 C.F.R. § 411.354 shall not be considered a Focus Arrangement for purposes of this CIA.

8. “Relevant Arrangements Covered Persons” includes all Covered Persons involved in the negotiation, preparation, review, maintenance, and approval for payment of all Arrangements, as defined above, involving CHSI.

III. CORPORATE INTEGRITY OBLIGATIONS

CHSI shall maintain a Compliance Program that includes the following elements:

A. Compliance Management and Oversight

1. *Corporate Compliance and Privacy Officer.* CHSI has appointed a Corporate Compliance and Privacy Officer and shall maintain a Corporate Compliance and Privacy Officer for the term of the CIA. The Corporate Compliance and Privacy Officer shall be responsible for 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. The Corporate Compliance and Privacy Officer shall be a member of senior management of CHSI, shall report directly to the Chief Executive Officer of CHSI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit and Compliance Committee of the Board of Directors of CHSI (“Board of Directors”), and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Corporate Compliance and Privacy Officer’s reports to the Board of Directors shall be made available to OIG upon request. The Corporate Compliance and Privacy Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Corporate Compliance and Privacy Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by CHSI as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Corporate Compliance and Privacy Officer shall be limited and must not interfere with the Corporate Compliance and Privacy Officer’s ability to perform the duties outlined in this CIA.

CHSI shall report to OIG, in writing, any change in the identity of the Corporate Compliance and Privacy Officer, or any actions or changes that would affect the

Corporate Compliance and Privacy Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Regional and Facility Compliance Officers.* CHSI has appointed individuals to serve as Regional Compliance Officers known as Corporate Compliance Directors. CHSI also has appointed a Facility Compliance Officer for each CHSI Covered Facility. CHSI shall maintain the Corporate Compliance Directors and Facility Compliance Officers for the duration of the CIA. The Corporate Compliance Directors shall be responsible for implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements for the applicable regions, and shall monitor the day-to-day compliance activities for the applicable regions. The Facility Compliance Officers shall be responsible for implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements for the Covered Facilities, and shall monitor the day-to-day compliance activities of the Covered Facilities. The Corporate Compliance Directors shall report to the Corporate Compliance and Privacy Officer (through Senior Compliance Directors), and shall be members of the Corporate Compliance Work Group. The Facility Compliance Officers shall report to their assigned Corporate Compliance Directors for ethics and compliance purposes and shall be independent from CHSI's Legal Department. The Facility Compliance Officers shall make periodic (at least quarterly) written reports regarding compliance matters directly to the Corporate Compliance Directors, and shall be authorized to report on such matters directly to the Corporate Compliance Work Group, the Corporate Compliance and Privacy Officer, and the Board of Directors at any time. CHSI shall report to OIG, in writing any actions or changes that would affect any Facility Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change.

3. *Corporate Compliance Committee.* CHSI has an existing Corporate Compliance Committee known as the Corporate Compliance Work Group. CHSI shall maintain this Corporate Compliance Work Group for the duration of the CIA. The Corporate Compliance Work Group shall, at a minimum, include the Corporate Compliance and Privacy Officer, Senior Compliance Directors, Corporate Compliance Directors, 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 Corporate Compliance and Privacy Officer shall chair the Corporate Compliance Work Group, and the Corporate Compliance Work Group shall support the Corporate Compliance and Privacy Officer in fulfilling his/her

responsibilities (e.g., shall assist in the analysis of the CHSI's risk areas and shall oversee monitoring of internal and external audits and investigations). The Corporate Compliance Work Group shall meet at least quarterly. The minutes of the Corporate Compliance Work Group meetings shall be made available to OIG upon request.

CHSI shall report to OIG, in writing, any changes in the composition of the Corporate Compliance Work Group, or any actions or changes that would affect the Corporate Compliance Work Group's ability to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change.

4. *Facility Compliance Committees.* CHSI has established a Facility Compliance Committee at each CHSI Covered Facility. The Facility Compliance Committees shall be maintained for the duration of the CIA and shall include appropriate personnel and other members of senior management at each of CHSI's Covered Facilities 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 Facility Compliance Committees shall support the Corporate Compliance Directors and Facility Compliance Officers in fulfilling their responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations). CHSI shall report to OIG, in writing, any actions or changes that would affect any Facility Compliance Committee's ability to perform the duties necessary to meet the obligations of the CIA, within 30 days after such a change.

5. *Board of Directors Compliance Obligations.* The Board of Directors of CHSI 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 of Directors must include independent (i.e., non-executive) members.

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

- a. meeting at least quarterly to review and oversee CHSI's Compliance Program, including but not limited to the performance of the Corporate Compliance and Privacy Officer and Corporate Compliance Work Group; and
- b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board of Directors summarizing its review and oversight of CHSI'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 of the Board of Directors has made a reasonable inquiry into the operations of CHSI’s Compliance Program including the performance of the Corporate Compliance and Privacy Officer and the Corporate Compliance Work Group. Based on its inquiry and review, the Board of Directors has concluded that, to the best of its knowledge, CHSI has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

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

CHSI shall report to OIG, in writing, any changes in the composition of the Board of Directors, or any actions or changes that would affect the Board of Directors’ ability to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change.

B. Written Standards

1. *Code of Conduct.* CHSI has developed, implemented and distributed a written Code of Conduct to all Covered Persons and shall maintain this Code of Conduct for the duration of the CIA. CHSI shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall, at a minimum, set forth:

- a. CHSI’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

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

CHSI currently requires all newly employed Covered Persons to certify in writing or electronic form that he or she has received, read, understood, and shall abide by CHSI's Code of Conduct. CHSI shall maintain this practice for the duration of the CIA and shall ensure that New Covered Persons receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person. CHSI shall distribute the Code of Conduct to all active medical staff members as described above and shall use its best efforts to encourage such active medical staff members to submit the required certification. The Corporate Compliance and Privacy Officer shall maintain records indicating that the Code of Conduct was distributed to all active medical staff members and whether the certification was completed.

CHSI shall periodically review the Code of Conduct 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.* CHSI has developed, implemented, and distributed written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and in compliance with Federal health care program requirements, and shall maintain these Policies and Procedures for the duration of the CIA.

Within 120 days after the Effective Date, the Policies and Procedures shall address, at a minimum:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the compliance program requirements outlined in this CIA;
- c. CHSI's compliance with Federal health care program requirements, including Federal health care program rules governing medical necessity determinations for inpatient admission; and
- d. billing and reimbursement, including:
 - i. ensuring proper and accurate submission of claims and cost reports to Federal health care programs;
 - ii. ensuring the proper and accurate documentation of medical records;
 - iii. ensuring the proper and accurate assignment and designation of patients into inpatient, outpatient, or observation status; and
 - iv. ensuring the necessary and appropriate length of stays and timely discharges for all patients.
- e. documentation of medical records, including:
 - i. ensuring proper and accurate documentation in the pre-admission, admission, case management, billing, coding and reimbursement process;
 - ii. ensuring that physicians are aware of relevant Federal health care program requirements governing admission, and any relevant Medicare regulations regarding treatment of a patient as an inpatient;

- iii. the personal obligation of each individual involved in the medical documentation process to ensure that such documentation is accurate;
 - iv. ensuring proper order authentication practices to ensure: (1) physician orders are not implemented without physician knowledge and consent; and (2) unauthorized markings are not added to physician orders without physician knowledge or consent;
 - v. ensuring that employees do not disregard physician orders relating to the admission of a patient;
 - vi. the legal sanctions for violations of the Federal health care program requirements; and
 - vii. examples of proper and improper medical documentation practices.
- f. requirements for Case Management employees, including:
- i. the Policies and Procedures for determining the medical necessity and appropriateness of inpatient admissions, including applicable Medicare rules and regulations; and
 - ii. the policies and procedures for proper order authentication and modification.

Within 120 days after the Effective Date, the Policies and Procedures shall be made available 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), CHSI shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

Within 120 days after the Effective Date, CHSI shall implement written Policies and Procedures addressing the following: (1) 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; and (2) the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law). Within 120 days after the Effective Date, these Policies and Procedures shall be made available to all Relevant Arrangements Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. At least annually (and more frequently, if appropriate), CHSI shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Relevant Arrangements Covered Persons and any revised Policies and Procedures shall be made available to all Relevant Arrangements Covered Persons.

C. Training and Education

CHSI represents that it provides training to its employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and distinct from the regular training provided by CHSI, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, CHSI shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain CHSI'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 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive Specific Training in addition to the General Training required above. This Specific Training shall include the following:

a. Billing and Reimbursement Specific Training. Each Relevant Billing and Reimbursement Covered Person shall receive at least two hours of Billing and Reimbursement Specific Training, which shall include a discussion of:

- i. the Federal health care program requirements regarding the accurate coding and submission of claims;
- ii. policies, procedures, and other requirements applicable to the documentation of medical records;
- ii. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- iv. applicable reimbursement statutes, regulations, and program requirements and directives;
- v. the legal sanctions for violations of the Federal health care program requirements; and
- vi. examples of proper and improper claims submission practices.

b. Clinical Documentation and Decision-Making Specific Training. Each Relevant Clinical Covered Person shall receive at least two hours of Clinical Documentation and Decision-Making Specific Training, which shall include a discussion of:

- i. policies, procedures, and other Federal health care program requirements applicable to the documentation of medical records;

- ii. the role of individual medical necessity determinations in the admission decision;
- iii. the importance of accurate documentation in the billing, coding, and reimbursement process;
- iv. the personal obligation of each individual involved in the medical documentation process to ensure that such documentation is accurate;
- v. the legal sanctions for violations of the Federal health care program requirements; and
- vi. examples of proper and improper medical documentation practices.

c. Case Management Specific Training. Each Relevant Case Management Covered Person shall receive at least two hours of Case Management Specific Training, which shall include a discussion of:

- i. policies, procedures, and applicable Federal health care program requirements for determining the medical necessity and the appropriateness of inpatient admissions; and
- ii. the role and function of any bodies or groups, including contractors, at CHSI that review admission decisions.

d. Arrangements Specific Training. Each Relevant Arrangements Covered Person shall receive at least three hours of Arrangements Specific Training, which shall include a discussion of:

- i. 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;
- ii. CHSI'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;

- iii. the personal obligation of each individual involved in the development, approval, management, or review of CHSI's Arrangements to know the applicable legal requirements and the CHSI's policies and procedures;
- iv. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and
- v. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Relevant Covered Persons shall receive Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Relevant Billing Covered Person shall receive at least two hours of Billing and Reimbursement Specific Training, in addition to the General Training, in each subsequent Reporting Period. Each Relevant Clinical Covered Person shall receive at least two hours of Clinical Documentation and Decision-Making Specific Training, in addition to the General Training, in each subsequent Reporting Period. Each Relevant Case Management Covered Person shall receive at least two hours of Case Management Specific Training, in addition to the General Training, in each subsequent Reporting Period. Each Relevant Arrangements Covered Person shall receive at least two hours of Arrangements Specific Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, CHSI shall provide at least one hour of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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

4. *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 Corporate Compliance and Privacy 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.* CHSI shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Inpatient Medical Necessity and Appropriateness Review , and any other relevant information.

7. *Computer-based Training.* CHSI may provide the training required under this CIA through appropriate computer-based training approaches. If CHSI 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. In addition, if CHSI chooses to provide computer based General or Specific Training, all applicable requirements to provide a number of “hours” of training in this Section may be met with respect to computer-based training by providing the required number of “normative” hours as that term is used in the computer-based training industry.

8. *Exception for Active Medical Staff Members.* CHSI shall make the General Training and Specific Training (as appropriate) described in this section available to all of CHSI’s active medical staff members and shall use its best efforts to encourage such active medical staff members to complete the training. The Corporate Compliance and Privacy Officer shall maintain records of all active medical staff members who receive training, including the type of training and the date received.

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

1. *Focus Arrangements Procedures.* Within 120 days after the Effective Date, CHSI 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 Corporate Compliance and Privacy 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 Board of Directors; and

- g. 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 pursuant to Sections III.I and III.J 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, CHSI shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by CHSI 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 Relevant Arrangements Covered Person shall complete at least one hour of training regarding the Anti-Kickback Statute and the Stark Law and examples of arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law. Additionally, CHSI 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;
- 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.* CHSI 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 120 days after the Effective Date, CHSI 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.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 CHSI shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and CHSI) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects CHSI’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. *Claims Review.* The IRO shall review claims submitted by CHSI Covered Facilities and reimbursed by Medicare, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined

in Appendix C to this CIA, which is incorporated by reference. CHSI may engage an IRO to perform the Arrangements Review that is different from the IRO engaged to perform the Claims Review.

4. *Unallowable Cost Review.* For the first Reporting Period, the IRO shall conduct a review of CHSI's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether CHSI has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable costs analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by CHSI or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed (Unallowable Cost Review Report). The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether CHSI has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

6. *Validation Review.* In the event OIG has reason to believe that: (a) CHSI's Claims Review, Arrangements Review, or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review, Arrangements Review, or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Arrangements Review, or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review, Arrangements Review, or Unallowable

Cost Review results are inaccurate (Validation Review). CHSI 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 CHSI's final Annual Report shall be initiated no later than one year after CHSI's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify CHSI 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, CHSI may request a meeting with OIG to: (a) discuss the results of any Claims Review, Arrangements Review, or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review, Arrangements Review, or Unallowable Cost Review or to correct the inaccuracy of the Claims Review, Arrangements Review, or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. CHSI agrees to provide any additional information as may be requested by OIG under this Section III.E.6 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review, Arrangements Review, or Unallowable Cost Review issues with CHSI 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.

7. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to CHSI 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

CHSI has an established Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Corporate Compliance and Privacy Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CHSI'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. CHSI shall continue to maintain this Disclosure Program for the duration of the CIA. CHSI shall continue to publicize appropriately 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 continue to 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 Corporate Compliance and Privacy Officer (or designee) shall gather all relevant information from the disclosing individual. The Corporate Compliance and Privacy 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, CHSI shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

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” shall include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s System for Award Management (available through the Internet at <http://www.sam.gov>).

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

- a. CHSI 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. CHSI shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on a monthly basis thereafter.
- c. CHSI 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 CHSI’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. CHSI understands that items or services furnished, ordered or prescribed by excluded persons are not payable by Federal health care programs and that CHSI may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether CHSI meets the requirements of Section III.G.

3. *Removal Requirement.* If CHSI has actual notice that a Covered Person has become an Ineligible Person, CHSI shall remove such Covered Person from

responsibility for, or involvement with, CHSI'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. If a physician or other non-physician practitioner with staff privileges at CHSI is determined to be an Ineligible Person, CHSI shall ensure that (i) the medical staff member does not furnish, order, or prescribe any items or services payable in whole or in part by any Federal health care program; and (ii) the medical staff member is not "on call" at CHSI.

4. *Pending Charges and Proposed Exclusions.* If CHSI has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, CHSI 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, CHSI shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to CHSI conducted or brought by a governmental entity or its agents involving an allegation that CHSI 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. CHSI 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. Repayment of Overpayments

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

2. *Repayment of Overpayments*

- a. If, at any time, CHSI identifies or learns of any Overpayment, CHSI shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, CHSI shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies.
- b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by CHSI.

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

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

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

- a. a description of the steps taken by CHSI to identify and quantify the Overpayment;
- b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- c. a description of CHSI's actions taken to correct the Reportable Event; and
- d. any further steps CHSI plans to take to address the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, CHSI shall provide OIG with a copy of the notification and repayment to the payor required in Section III.I.2.

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of CHSI's actions taken to correct the Reportable Event;

- c. any further steps CHSI plans to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by CHSI to identify and quantify the Overpayment.

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

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 CHSI to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If CHSI identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then CHSI is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit or Location.

In the event that, after the Effective Date, CHSI proposes to sell any or all of its business, business units or hospitals (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, CHSI 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, CHSI changes locations or closes a business, business unit or hospital related to the furnishing of items or services that may be reimbursed by Federal health care programs, CHSI 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 hospital.

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

In the event that, after the Effective Date, CHSI purchases or establishes a new business, business unit or hospital related to the furnishing of items or services that may be reimbursed by Federal health care programs, CHSI shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or hospital. This notification shall include the address of the new business, business unit or hospital, phone number, fax number, the hospital'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 CHSI currently submits claims. Each new business, business unit or hospital and all Covered Persons at each new business, business unit or hospital 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 150 days after the Effective Date, CHSI 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 Corporate Compliance and Privacy Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Corporate Compliance and Privacy Officer may have;

2. the name, address, phone number, and position description of each Senior Compliance Director, Corporate Compliance Director, and Facility Compliance Officers required by Section III.A.2, and a summary of other noncompliance job responsibilities each Senior Compliance Director, Corporate Compliance Director, and Facility Compliance officers may have;
3. the names and positions of the members of the Corporate Compliance Work Group required by Section III.A.3;
4. the names and positions of the members of each Facility Compliance Committee required by Section III.A.4;
5. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.5;
6. a copy of CHSI's Code of Conduct required by Section III.B.1;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);
8. 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);
9. 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;
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions; and
 - c. with respect to active medical staff members, the number and percentage who completed the training, the type of training

and the date received, and a description of CHSI's efforts to encourage medical staff members to complete the training.

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

10. 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;

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

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

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

14. a list of all of CHSI's Covered Facilities (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which CHSI currently submits claims;

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

16. the certifications required by Section V.C.

B. Annual Reports

CHSI shall submit to OIG annually a report with respect to the status of, and findings regarding, CHSI's compliance activities for each of the three 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 Corporate Compliance and Privacy Officer, Senior Compliance Directors, Corporate Compliance Directors, and Facility Compliance Officers, and any change in the membership of the Corporate Compliance Work Group described in Section III.A;
2. the dates of each report made by the Corporate Compliance and Privacy Officer to the Board (written documentation of such reports shall be made available upon request);
3. the Board of Directors resolution required by Section III.A.5;
4. a summary of any changes or amendments to CHSI'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;
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 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);
7. 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;

- 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; and
- c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of CHSI's efforts to encourage medical staff members to complete the training.

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

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

9. CHSI'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;

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

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

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

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

14. 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);

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

16. 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;

17. a description of all changes to the most recently provided list of CHSI's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which CHSI currently submits claims; and

18. the certifications required by Section V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Corporate Compliance and Privacy Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, CHSI is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

3. to the best of his or her knowledge, CHSI has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

CHSI 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. CHSI 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

CHSI:

Andi Bosshart

Senior Vice President, Corporate Compliance and Privacy
Officer

Community Health Systems, Inc.

4000 Meridian Boulevard

Franklin, TN 37067

Telephone: 615.465.7150

Facsimile: 615.465.3004

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, CHSI 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 or request copies of CHSI's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of CHSI's locations for the purpose of verifying and evaluating: (a) CHSI's compliance with the terms of this CIA; and (b) CHSI's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by CHSI to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of CHSI's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. CHSI shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. CHSI's employees may elect to be interviewed with or without a representative of CHSI present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

CHSI 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, CHSI 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 CHSI fails to establish and implement any of the following obligations as described in Section III:
 - a. a Corporate Compliance and Privacy Officer, Corporate Compliance Directors, and/or Facility Compliance Officers;
 - b. a Corporate Compliance Work Group; and/or Facility Compliance Committees;
 - c. the Board of Directors compliance obligations;

- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings; and
- j. reporting of Reportable Events.

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CHSI 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 CHSI fails to submit any Claims Review Report, Unallowable Cost Review Report, or Arrangements Review 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 CHSI fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date CHSI fails to grant access.)

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

CHSI 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 CHSI fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after CHSI receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that CHSI 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 CHSI of: (a) CHSI'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, CHSI 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 CHSI elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CHSI 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 CHSI 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 repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A.
- b. a failure by CHSI to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.J;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by CHSI constitutes an independent basis for CHSI's

exclusion from participation in the Federal health care programs. Upon a determination by OIG that CHSI has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify CHSI of: (a) CHSI'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.* CHSI shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. CHSI is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) CHSI has begun to take action to cure the material breach; (ii) CHSI is pursuing such action with due diligence; and (iii) CHSI has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, CHSI fails to satisfy the requirements of Section X.D.3, OIG may exclude CHSI from participation in the Federal health care programs. OIG shall notify CHSI in writing of its determination to exclude CHSI. (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 CHSI'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, CHSI 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 CHSI 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, CHSI 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.

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

- a. whether CHSI was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) CHSI had begun to take action to cure the material breach within that period; (ii) CHSI has pursued and is pursuing such action with due diligence; and (iii) CHSI provided to OIG within that period a

reasonable timetable for curing the material breach and CHSI has followed the timetable.

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

CHSI 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 CHSI's obligations under this CIA based on a certification by CHSI 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 CHSI is relieved of its CIA obligations, CHSI will be required to notify OIG in writing at least 30 days in advance if CHSI 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 CHSI 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 CHSI

/Andi Bosshart/

9/20/2018

Andi Bosshart
CHSI
Senior Vice President, Corporate Compliance and Privacy Officer

DATE

/Richard A. Sauber/

9/21/18

Richard A. Sauber
Counsel for CHSI
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP

DATE

/Michael L. Waldman/

9/21/18

Michael L. Waldman
Counsel for CHSI
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP

DATE

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

/Lisa M. Re/

LISA RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

9/21/2018

DATE

/Sandra Jean Sands/

SANDRA JEAN SANDS
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

9/21/2018

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. CHSI shall engage an IRO to perform the Unallowable Cost Review and the Claims Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the reviews in a professionally independent and objective fashion, as set forth in Paragraph E.

2. CHSI shall also engage an IRO to perform the Arrangements Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to CHSI as set forth in Paragraph F.

3. Within 30 days after OIG receives the information identified in Section V.A.12 of the CIA or any additional information submitted by CHSI in response to a request by OIG, whichever is later, OIG will notify CHSI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CHSI may continue to engage the IRO.

4. If CHSI 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, CHSI shall submit the information identified in Section V.A.12 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by CHSI at the request of OIG, whichever is later, OIG will notify CHSI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CHSI 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. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review;
3. assign individuals to conduct the Claims Review who have expertise in the Medicare program requirements applicable to the claims being reviewed;
4. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
5. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);
6. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and
7. 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, Unallowable Cost Review, and Claims Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare program rules and reimbursement guidelines in making assessments in the Claims Review;
3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare program policy or regulation;
4. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C (as applicable) to the CIA.

D. CHSI Responsibilities

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

E. IRO Independence and Objectivity

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

F. IRO Relationship to CHSI

The IRO engaged to perform the Arrangements Review shall not (1) currently represent or currently be employed or engaged by CHSI or (2) have a current or prior relationship to CHSI or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the Arrangements Review.

G. Assertions of Privilege

CHSI shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement to perform the Arrangements Review. CHSI's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

H. IRO Removal/Termination

1. *CHSI and IRO.* If CHSI terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, CHSI 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. CHSI 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 E or has a prohibited relationship as set forth in paragraph F (as applicable), or has failed to carry out its responsibilities as described in

Paragraph C, OIG shall notify CHSI in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. CHSI shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence, relationship to CHSI or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by CHSI regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify CHSI in writing that CHSI shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. CHSI 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 CHSI to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the three Reporting Periods. The IRO shall perform all components of each Claims Review. The Claims Review shall be conducted at four of CHSI's Covered Facilities for each Reporting Period.

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

- a. Overpayment: The amount of money CHSI has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. Paid Claim: A claim submitted by CHSI and for which CHSI has received reimbursement from the Medicare program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify CHSI and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may also select the CHSI facilities that will be subject to the Claims Review in each Reporting Period. In order to facilitate OIG's selection, at least 90 days prior to the end of the Reporting Period, CHSI shall furnish to OIG the following information for each CHSI facility for the prior reporting year: (1) Federal health care program revenues, (2) Federal health care program patient census, and (3) Federal health care program payor mix.

CHSI, or its IRO on behalf of CHSI, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed and the CHSI facilities to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by CHSI or its IRO or (2) information furnished to OIG regarding the results of CHSI's internal risk assessment and internal auditing.

The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

2. *Claims Review Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample) at each CHSI facility selected for review. The Paid Claims shall be reviewed based on the supporting documentation available at CHSI's office or under CHSI's control and applicable Medicare program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim.

3. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and CHSI shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from CHSI after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims 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 Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which CHSI cannot produce documentation shall be considered an error and the total reimbursement received by CHSI for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected 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 Claims Review Sample).

4. *Repayment of Identified Overpayments.* CHSI shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations or Centers for Medicare and Medicaid Services (CMS) guidance (the “CMS overpayment rule”). If CHSI determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, CHSI shall repay that amount at the mean point estimate as calculated by the IRO. CHSI shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from CHSI to the appropriate Medicare program contractor for appropriate follow up by the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*

- a. Claims Review Population. A description of the Population subject to the Claims Review.
- b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.

2. *Statistical Sampling Documentation.*
 - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
 - b. A description or identification of the statistical sampling software package used by the IRO.
3. *Claims Review Findings.*
 - a. Narrative Results.
 - i. A description of CHSI’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at CHSI to ensure that all items and services billed to Medicare are medically necessary and appropriately documented.
 - iii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.
 - b. Quantitative Results.
 - i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by CHSI differed from what should have been the correct coding and in which such difference resulted in an Overpayment to CHSI.
 - ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to CHSI.
 - iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to CHSI.

- iv. Total dollar amount of all Overpayments in the Claims Review Sample.
 - v. Total dollar amount of Paid Claims included in the Claims Review Sample.
 - vi. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.
 - vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
 - viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to CHSI's billing and coding system or to CHSI's controls for ensuring that all items and services billed to Medicare are medically necessary and appropriately documented, based on the findings of the Claims Review.

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

APPENDIX C

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 CHSI's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first Reporting Period only. If CHSI 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 Reporting Period. The Arrangements Transactions Review shall be performed annually and shall cover each of the three Reporting Periods.

A. Selection of CHSI Covered Facilities To Be Reviewed. OIG may select four CHSI Covered Facilities that will be subject to the Arrangements Review in each Reporting Period. In order to facilitate OIG's selection, at least 90 days prior to the end of the Reporting Period, CHSI shall furnish to OIG the following information for each CHSI Covered Facility for the prior Reporting Period: the number of arrangements entered into for each Covered Facility.

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

1. CHSI's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all current 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. CHSI's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. CHSI'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. CHSI'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. CHSI'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. CHSI'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 CHSI, 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, CHSI's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

8. CHSI'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. CHSI'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.

C. 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 CHSI's systems, policies, processes, and procedures relating to the items identified in Section B.1-9 above;

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

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

D. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 25 randomly selected Focus Arrangements that were entered into or renewed by CHSI during the Reporting Period. The IRO shall assess whether CHSI 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 CHSI'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.

E. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions 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 CHSI 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 CHSI 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 CHSI 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 Transactions Review Report shall include observations, findings and recommendations on possible improvements to CHSI's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.