

CORPORATE INTEGRITY AGREEMENT  
BETWEEN  
THE OFFICE OF INSPECTOR GENERAL OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES AND  
STATEN ISLAND UNIVERSITY HOSPITAL

**I. PREAMBLE**

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

SIUH represents that prior to the execution of this CIA, SIUH had established and implemented a voluntary Compliance Program. The Compliance Program established and implemented by SIUH provides for policies and procedures aimed at ensuring that SIUH's participation with Federal health care programs is in conformity with statutes, regulations, and other directives applicable to those programs. The SIUH Compliance Program includes, among other things, a Code of Ethical Conduct, a Compliance Committee and Compliance Officer, training and education requirements, mechanisms for individuals to report incidents of non-compliance, mechanisms for ongoing monitoring and auditing of SIUH operations to assess compliance, policies and procedures for implementing the Compliance Program, and enforcement and disciplinary measures. Pursuant to this CIA, SIUH agrees to maintain in full operation its Compliance Program for the term of this CIA. The Compliance Program may be modified as deemed appropriate by SIUH but, at a minimum, shall comply with the integrity obligations enumerated in this CIA with respect to SIUH.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by SIUH under this CIA shall be five (5) years from the effective date of this CIA, as such date is defined in Section XI, below (Effective Date), unless otherwise specified. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

Staten Island University Hospital  
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B. Sections VII, IX, X, and XI as to SIUH shall expire no later than 120 days after OIG's receipt of: (1) SIUH's final annual report; or (2) any additional materials submitted by SIUH pursuant to OIG's request, whichever is later. OIG will notify SIUH when the term of the CIA has expired.

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

1. "SIUH Covered Persons" includes:

a. all trustees, officers, employees and all non-employed medical and dental staff of SIUH (excluding housekeeping staff, maintenance workers, and dietary employees); and

b. all individuals (including individuals who are contractors, subcontractors, agents, and other persons) who: (i) are responsible for providing patient care items or services to patients on behalf of SIUH for which SIUH may bill the Federal health care programs; or (ii) perform billing or coding functions on behalf of SIUH for items or services for which SIUH may bill the Federal health care programs (excluding vendors whose sole connection with SIUH is selling or otherwise providing medical supplies or equipment to SIUH or providing construction services to SIUH and who do not bill Federal health care programs for such supplies, equipment or construction services provided to SIUH.)

Notwithstanding the above definitions, the term SIUH Covered Person does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during each Reporting Period on behalf of SIUH, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the Reporting Period.

2. "Relevant SIUH Covered Persons" includes all SIUH Covered Persons who are coders, billers, cost report preparers, compliance staff, or other persons and their direct managers involved in the preparation, submission, or review of claims for reimbursement from any Federal health care program, excluding individuals

whose duties in that regard are limited to primarily clerical functions.

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

SIUH shall maintain and, as necessary, establish a Compliance Program that includes the following elements:

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

1. *Compliance Officer.* SIUH represents that it has appointed an individual to serve as its Compliance Officer. SIUH shall continue to maintain a Compliance Officer for the term of the CIA. The Compliance 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 Compliance Officer shall be a member of senior management of SIUH, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit and Corporate Compliance Committee of the Board of Trustees of SIUH, and shall be authorized to report on such matters to the Board of Trustees at any time. The Compliance Officer is not, and shall not be, subordinate to the positions of Senior Vice President for Legal and General Counsel or Executive Vice President and Chief Financial Officer of SIUH or to any similar position created during the period this CIA is in effect. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by SIUH as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* SIUH represents that it has established an administrative Compliance Committee ("Compliance Committee"). For the duration of this CIA, SIUH shall maintain its Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance

Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

SIUH shall report to OIG, in writing, any changes in the departments or senior management positions that compose the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

**B. Written Standards.**

1. *Code of Conduct.* SIUH represents that it has developed and implemented a program to distribute a Code of Conduct to its trustees, officers, and employees. For the duration of this CIA, SIUH shall continue to maintain its Code of Conduct. To the extent necessary, SIUH shall amend its Code of Conduct to meet the requirements set forth below. The Code of Conduct shall be distributed within 90 days after the Effective Date to all SIUH Covered Persons who have not already received the current Code of Conduct. To the extent the Code of Conduct must be amended to meet the requirements set forth below, SIUH may distribute an addendum to the Code of Conduct as an alternative to republishing and redistributing the entire Code of Conduct for the purpose of complying with this Section III.B.1. SIUH shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. SIUH'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. SIUH's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with SIUH's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of SIUH's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by SIUH, suspected violations of any Federal

health care program requirements or of SIUH's own Policies and Procedures;

d. the possible consequences to both SIUH and SIUH Covered Persons of failure to comply with Federal health care program requirements and with SIUH's own Policies and Procedures and the failure to report such noncompliance; and

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

After SIUH signs the CIA, but no later than 120 days of the Effective Date, each SIUH Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by SIUH's Code of Conduct. New SIUH Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a SIUH Covered Person or within 90 days after the Effective Date or after the date SIUH has signed the CIA, whichever is later.

Notwithstanding any other provision of this CIA, the following shall constitute SIUH's obligations under this Section III.B.1 with respect to its non-employed medical and dental staff ("medical and dental staff"): (i) SIUH shall distribute the Code of Conduct to all its medical and dental staff in accordance with the time requirements for other Covered Persons as forth in this Section III.B.1; (ii) SIUH shall use its best efforts to obtain the written certifications described above; and (iii) SIUH shall keep records of the percentage of its medical and dental staff who have completed the certification requirement, such records shall be available for inspection by OIG, and SIUH shall include such percentages in the Implementation Report and each Annual Report to the OIG.

Notwithstanding any other provision of this CIA, in the event the current SIUH Board of Trustees is reorganized so that it is expanded to consist of a total of more than 100 members, SIUH shall: (i) distribute the Code of Conduct to all Trustees who are not members of the Board's Executive Committee in accordance with the time requirements for other Covered Persons as set forth in this Section III.B.1; (ii) SIUH shall use its best efforts to obtain the written certifications described above from the non-Executive Committee Trustees; (iii) SIUH shall keep records of the percentage of its non-Executive

Committee Trustees who have completed the certification requirement, such records shall be available for inspection by OIG, and SIUH shall include such percentages in the Implementation Report and each Annual Report to the OIG; and (iv) members of the Board of Trustees who are on the Executive Committee shall comply with the provisions governing the Code of Conduct applicable to Covered Persons.

SIUH shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revisions to the Code of Conduct shall be distributed within 60 days after any such revisions are finalized. The revision(s) may be distributed through an addendum to the Code of Conduct as an alternative to republishing and redistributing the entire Code of Conduct. Each SIUH Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 60 days after the distribution of the addendum or the revised Code of Conduct. In the event a revision or revisions are made to the Code of Conduct within a Reporting Period, SIUH shall distribute a revised Code of Conduct reflecting such revisions at least once prior to the end of the Reporting Period.

2. *Policies and Procedures.* Within 120 days after the Effective Date, SIUH shall review, and where appropriate, revise or develop its existing written Policies and Procedures regarding the operation of SIUH's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. compliance with all Federal health care program requirements regarding the coding of and reimbursement for radiosurgical procedures performed at SIUH;
- c. compliance with all Federal health care program requirements governing Federal health care program reimbursement for patient care provided in unlicensed beds in the Behavioral Science Units; and

- d. compliance with all Federal health care program requirements regarding the calculation of and reimbursement from Federal health care programs for graduate medical education (GME) and indirect medical education (IME) costs.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to these Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain these Policies and Procedures.

At least annually (and more frequently, if appropriate), SIUH shall assess and update, as necessary, the Policies and Procedures. Within 60 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to those individuals whose job functions relate to the updated Policies and Procedures.

### C. Training and Education.

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

- a. CIA requirements; and
- b. SIUH's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

If, pursuant to SIUH's Compliance Program, SIUH has provided General Training to SIUH Covered Persons that satisfies the requirements set forth above after SIUH has signed this CIA or within 120 days prior to the Effective Date (whichever date is earlier), the OIG shall credit that training for purposes of satisfying SIUH General Training obligations for the first year of the CIA with respect to those relevant Covered Persons who have received such General Training. Whether or not the General Training provided after SIUH has signed this CIA or within 120 days prior to the Effective Date (whichever date is earlier) satisfied the requirements set forth above shall be subject to the approval of OIG.

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

2. *SIUH Specific Training.* Within 90 days after the Effective Date, each SIUH Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. the Federal health care program requirements regarding the accurate coding and submission of claims;
- b. the policies, procedures, and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- d. the legal sanctions for violations of the Federal health care program requirements; and
- e. examples of proper and improper claims submission practices, including, but not limited to, examples regarding proper and improper coding and improper claims for uncovered services.

In addition, Specific Training for Relevant Covered Persons involved in the calculation and reimbursement of GME or IME Costs shall include training on the reimbursement statutes, regulations, and program requirements and directives and SIUH policies and procedures regarding the calculation and reimbursement of GME and IME costs. Specific Training for Relevant Covered Persons involved in the monitoring, reporting, or supervision of licensed bed capacity in SIUH's Behavioral Science Units shall include training on the reimbursement statutes, regulations, program requirements and directives and SIUH policies and procedures regarding the use of and reimbursement for the use of unlicensed beds in the Behavioral Science Units.

If, pursuant to SIUH's Compliance Program, SIUH has provided Specific Training to SIUH Relevant Covered Persons that satisfies the requirements set forth above after



SIUH has signed this CIA or within 120 days prior to the Effective Date (whichever date is earlier), the OIG shall credit that training for purposes of satisfying SIUH Specific Training obligations for the first year of the CIA with respect to those SIUH Relevant Covered Persons who have received such Specific Training. Whether or not the Specific Training provided after SIUH has signed this CIA or within 120 days prior to the Effective Date (whichever date is earlier) satisfied the requirements set forth above shall be subject to the approval of the OIG.

New SIUH Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming SIUH Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. A SIUH employee who has completed the Specific Training shall review a new SIUH Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new SIUH Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant SIUH Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend the training (or who has received General or Specific Training within 120 days prior to the Effective Date in accordance with Section III.C.) shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. SIUH's Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training described above in Section III.C. shall be knowledgeable about the subject area.

5. *Update of Training.* SIUH shall review the training provided annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, any issues discovered during the Claims Review or Unallowable Cost Reviews, and any other relevant information.

6. *Computer-based Training.* SIUH may provide the training required under this CIA through appropriate computer-based training approaches. If SIUH chooses to provide the training required under this CIA through appropriate computer-based training approaches, all applicable references to “hours” in this Section III.C. shall mean “normative hours,” meaning the number of hours usually required to complete the requirements of a training course through computer-based modules. Normative hours may vary from the actual hours of training. If SIUH 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.

7. *Other Training.* SIUH may also provide the training required under this CIA through other mediums, such as live sessions, video sessions, and independent learning modules. If other than live sessions are provided and/or accessed, SIUH shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

8. *Medical and Dental Staff.* Notwithstanding any other provision of this CIA, SIUH shall make General Training and Specific Training, where appropriate, available to its medical and dental staff and shall use its best efforts to encourage attendance and participation by its medical and dental staff in General and Specific Training. The Compliance Officer shall maintain attendance records for the training and shall maintain records of the percentage of the medical and dental staff who attend such training and SIUH shall include such percentages in the Implementation Report and each Annual Report to the OIG.

9. *Trustees.* Notwithstanding any other provision of this CIA, in the event the current SIUH Board of Trustees is reorganized so that the Board of Trustees is expanded to consist of a total of more than 100 members, SIUH shall make General Training available to all Trustees who are SIUH Covered Persons and are not members of the Board’s Executive Committee, and SIUH shall use its best efforts to encourage attendance and participation by such non-Executive Committee Trustees in General Training. The Compliance Officer shall maintain attendance records for the training and shall maintain records of the percentage of non-Executive Committee Trustees who attend such General Training and SIUH shall include such percentages in the Implementation Report and each Annual Report to the OIG. Members of the Board of Trustees who are on the Executive Committee shall comply with General Training or Specific Training requirements for SIUH Covered Persons and Relevant SIUH Covered

Persons, as may be applicable, and the certification requirements set forth in Section III.C.3 above. Non-Executive Committee Trustees who are Relevant SIUH Covered Persons shall comply with the Specific Training requirements for Relevant SIUH Covered Persons and the certifications requirements set forth in Section III.C.3 above.

D. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, SIUH shall engage, an entity, such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist SIUH, as required in this CIA, in assessing and evaluating billing and coding practices and certain other obligations pursuant to this CIA and the four Settlement Agreements. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

The IRO shall evaluate and analyze SIUH’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review), and shall analyze whether SIUH sought payment for certain unallowable costs (Unallowable Cost Review or Unallowable Cost Reviews).

- b. *Frequency of Claims Review.* The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO shall perform all components of each annual Claims Review.

- c. *Frequency of Unallowable Cost Reviews.* If applicable, the IRO shall perform the Unallowable Cost Reviews for the first Reporting Period.

- d. *Retention of Records.* The IRO and SIUH shall retain, and make available to OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports (those exchanged between the IRO and SIUH) related to the reviews.

2. *Claims Review.* The Claims Review shall include a Discovery Sample of 50 Paid Claims and, if the Error Rate for the Discovery Sample is 5% or greater, a Full Sample and Systems Review. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B.

4. *Repayment of Identified Overpayments.* In accordance with Section III.H.1, SIUH shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. SIUH shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

5. *Unallowable Cost Reviews.* The IRO shall conduct a review of SIUH's respective compliance with the unallowable cost provisions of the four Settlement Agreements. The IRO shall determine whether SIUH 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 four Settlement Agreements) 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 cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by SIUH. 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 Agreements were executed, as well as from previous years.

6. *Unallowable Cost Review Reports.* The IRO shall prepare a report based upon the Unallowable Cost Reviews performed. The Unallowable Cost Review Reports shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Reviews and whether SIUH has complied with its respective obligation not to

charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreements) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

7. *Validation Review.* In the event OIG has reason to believe that: (a) SIUH's Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results or Unallowable Cost Reviews results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Reviews complied with the requirements of the CIA and/or the findings or Claims Review results or Unallowable Cost Reviews results are inaccurate (Validation Review). SIUH 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 or prior to SIUH's final Annual Report shall be initiated no later than one year after SIUH's final submission (as described in Section II) is received by OIG.

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

8. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to SIUH a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and objective.

#### E. Disclosure Program.

SIUH shall continue to maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with SIUH'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. SIUH shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

- (1) permits a determination of the appropriateness of the alleged improper practice; and
- (2) provides an opportunity for taking corrective action, SIUH shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, 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. The disclosure log shall be made available to OIG upon request.

#### F. 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 ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

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

and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

c. "Screened Persons" includes SIUH Covered Persons, SIUH housekeeping staff, maintenance workers, and dietary employees, and contractors and agents of SIUH.

2. *Screening Requirements.* SIUH shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. SIUH shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. SIUH shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter. If, pursuant to SIUH's Compliance Program, SIUH has screened any Screened Persons against the Exclusion Lists set forth in Section III.F within 90 days prior to the Effective Date, the OIG shall credit that screening for purposes of satisfying this requirement.

c. SIUH shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) SIUH to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. SIUH understands that items or services furnished by excluded persons are not payable by Federal health care programs and that SIUH may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether SIUH meets the requirements of Section III.F.

3. *Removal Requirement.* If SIUH has actual notice that a Screened Person has become an Ineligible Person, SIUH shall remove such Screened Person from responsibility for, or involvement with, SIUH's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened 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 Screened Person is reinstated into participation in the Federal health care programs or SIUH has received permission from OIG to maintain such person in his or her position pending such reinstatement.

4. *Pending Charges and Proposed Exclusions.* If SIUH has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term or, in the case of a physician, during the term of the physician's medical staff privileges, SIUH shall take all appropriate actions to ensure that the responsibilities of that Screened 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.

G. Notification of Government Investigation or Legal Proceedings.

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

## H. Reporting.

### 1. *Overpayments.*

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

b. *Reporting of Overpayments.* If, at any time, SIUH identifies or learns of any Overpayment, SIUH shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem, if any, and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, SIUH shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, SIUH 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, and, for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. 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.

## 2. Reportable Events.

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

- i. a substantial Overpayment to SIUH;
- ii. a matter that a reasonable person would consider a probable violation by SIUH of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or
- iii. the filing of a bankruptcy petition by SIUH.

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

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

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor’s name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

- ii. A complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- iii. A description of SIUH's actions taken to correct the Reportable Event;
- iv. Any further steps SIUH plans to take to address the Reportable Event and prevent it from recurring; and
- v. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

I. Compliance Reports to the Board of Trustees.

At each quarterly Board of Trustees meeting, a report shall be made to the Board of Trustees by a member of the Audit and Corporate Compliance Committee of the Board of Trustees or by the Compliance Officer regarding compliance matters, including, but not limited to, compliance matters arising during the prior quarterly period.

J. Billing and Coding Contractors.

“Pre-Existing Contractors” includes all SIUH Covered Persons who are contractors, subcontractors, agents, or other persons who have an existing contract with SIUH on the Effective Date of this CIA to provide patient care items or services to patients or perform billing or coding functions on behalf of SIUH. To the extent such an existing contract does not require a Pre-Existing Contractor to comply with the CIA provisions applicable to SIUH Covered Persons or SIUH Relevant Covered Persons, SIUH shall use its best efforts to renegotiate such existing contracts to require Pre-Existing Contractors to meet the requirements of this CIA, as applicable. Upon the renewal or modification of an existing contract or in any contract entered into subsequent to the Effective Date for providing patient care items or services or performing billing or coding functions on behalf of SIUH, SIUH shall require its contractors, subcontractors, agents, or other persons to comply with the CIA provisions applicable to SIUH Covered Persons or SIUH Relevant Covered Persons, as applicable.

SIUH shall use its best efforts to encourage Pre-Existing Contractors' attendance and participation in General and Specific Training, as applicable. The Chief Compliance Officer shall maintain records of the names and percentage of all such pre-existing contractors who do and do not attend General and/or Specific Training, and shall include such percentages in the Implementation Report and each Annual Report to the OIG. Such records shall also be available for inspection by OIG.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, SIUH changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, SIUH 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 location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, SIUH purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, SIUH shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the name and address of the contractor that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, SIUH proposes to sell any or all of its business units or locations that are subject to this CIA, SIUH shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the 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 such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. SIUH Implementation Report. Within 120 days after the Effective Date, SIUH shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. a copy of SIUH's Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

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 available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C for SIUH:

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.

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

7. a description of the Disclosure Program required by Section III.E;

8. the following information regarding the IRO(s) engaged by SIUH: (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between SIUH and the IRO;

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

10. a description of the process by which SIUH fulfills the requirements of Section III.F regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

12. a list of all of SIUH's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which SIUH currently submits claims;

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

14. the certifications required by Section V.C.

B. SIUH Annual Report. SIUH shall submit to OIG annually a report with respect to the status of, and findings regarding, SIUH's compliance activities for each of the five (5) Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

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

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

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. the following information regarding each type of training required by Section III.C for SIUH:

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.

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

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

6. SIUH's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

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

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

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

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

11. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

12. any changes to the process by which SIUH fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by SIUH in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a description of all changes to the most recently provided list of SIUH's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which SIUH currently submits claims;

16. the certifications required by Section V.C.; and

17. a certification by a member of the Board of Trustees' Executive Committee or the Board of Trustee's Audit and Corporate Compliance Committee, or by the Secretary or Assistant Secretary of the Board, that during each quarterly Board of



Trustees meeting the report required by Section III.I above was communicated to the Board of Trustees.

C. Certifications. The SIUH Implementation Report and Annual Reports shall include a certification by the SIUH Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, SIUH is in compliance with all of the applicable 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 its knowledge, SIUH has complied with its obligations under the four Settlement Agreements: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in each of the Settlement Agreements, 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 each of the Settlement Agreements); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. SIUH shall clearly identify any portions of its respective 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. SIUH 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

SIUH:

Chief Compliance Officer  
Staten Island University Hospital  
475 Seaview Avenue  
Staten Island, New York 10305  
Telephone: 516.465.8327  
Facsimile: 516.465.8030

General Counsel  
Staten Island University Hospital  
475 Seaview Avenue  
Staten Island, New York 10305  
Telephone: 718.226.9990  
Facsimile: 718.226.8692

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

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

SIUH shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six (6) 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 SIUH prior to any release by OIG of information submitted by SIUH pursuant to its obligations under this CIA and identified upon submission by SIUH as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, SIUH shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

SIUH 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, SIUH 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 against SIUH (which shall begin to accrue on the day after the date the obligation became due) for each day SIUH fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. the training of Relevant Covered Persons;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements; and
- i. notification of Government investigations or legal proceedings.

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

3. A Stipulated Penalty of \$2,500 against SIUH (which shall begin to accrue on the day after the date the obligation became due) for each day SIUH 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 against SIUH (which shall begin to accrue on the day after the date the obligation became due) for each day SIUH fails to submit the annual Claims Review Report or Unallowable Cost Review in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of \$5,000 against SIUH for each false certification submitted by or on behalf of SIUH 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 against SIUH for each day SIUH fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to SIUH stating the specific grounds for its determination that SIUH has failed to comply fully and adequately with the CIA obligation(s) at issue and steps SIUH shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after SIUH 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. SIUH 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 SIUH 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 SIUH 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 SIUH 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 SIUH of: (a) SIUH's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, SIUH 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 SIUH elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until SIUH 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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

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 SIUH has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by SIUH to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;

- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by SIUH constitutes an independent basis for SIUH's exclusion from participation in the Federal health care programs. Upon a determination by OIG that SIUH has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify SIUH of: (a) SIUH's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* SIUH 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. SIUH 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) SIUH has begun to take action to cure the material breach; (ii) SIUH is pursuing such action with due diligence; and (iii) SIUH has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, SIUH fails to satisfy the requirements of Section X.D.3, OIG may exclude SIUH from participation in the Federal health care programs. OIG shall notify SIUH in writing of its determination to exclude SIUH (this letter shall be referred to hereinafter 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 SIUH's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, SIUH 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 SIUH 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, SIUH 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 SIUH was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. SIUH 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 SIUH to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless SIUH 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 SIUH 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) SIUH had begun to take action to cure the material breach within that period; (ii) SIUH has pursued and is pursuing such action with due diligence; and (iii) SIUH provided to OIG within that period a reasonable timetable for curing the material breach and SIUH 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 SIUH, only after a DAB decision in favor of OIG. SIUH's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude SIUH 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 SIUH 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. SIUH shall waive its right to any notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of SIUH, SIUH 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**

SIUH and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of SIUH;

B. This CIA shall become final and binding on the Effective Date, which shall be the latter of : (i) the date the final signature is obtained on the CIA; or (ii) the date all of the four Settlement Agreements have become final, binding and effective;

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

D. OIG may agree to a suspension of SIUH's obligations under the CIA in the event of SIUH's cessation of participation in Federal health care programs. If SIUH withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, SIUH shall notify OIG at least 30 days in advance of SIUH's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified;

E. The undersigned SIUH signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and

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

ON BEHALF OF SIUH

/Arthur J. Fried/

\_\_\_\_\_  
ARTHUR J. FRIED  
General Counsel  
Senior Vice President of Legal  
and Regulatory Affairs

8/5/08  
\_\_\_\_\_  
DATE

Staten Island University Hospital  
Corporate Integrity Agreement

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

/Gregory E. Demske/

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GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

9/5/08  
DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement.

SIUH shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify SIUH if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SIUH may continue to engage the IRO.

If SIUH engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, SIUH shall submit the information identified in Sections V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify SIUH if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SIUH may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review and Unallowable Cost Review engagement who have expertise in the billing, coding, reporting, and other requirements of the Claims Review or the Unallowable Cost Review and in the general requirements of the Federal health care program(s) from which SIUH seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification (e.g., CCA, CCS, CCS-P, CPC, RRA, etc.) and who have maintained this certification (e.g., completed applicable continuing education requirements); and

4. 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 Claim Review and Unallowable Cost Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare, Medicaid, and other Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review and Unallowable Cost Review;

3. if in doubt of the application of a particular Medicare, Medicaid or other Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Claims Review and Unallowable Cost Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and SIUH.

E. IRO Removal/Termination.

1. *Provider.* If SIUH terminates its IRO during the course of the engagement, SIUH must submit a notice explaining its reasons to OIG no later than 30 days after termination. SIUH must engage a new IRO in accordance with Paragraph A of this Appendix.

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/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require SIUH to engage a new IRO in accordance with Paragraph A of this Appendix.

Staten Island University Hospital  
Corporate Integrity Agreement

Prior to requiring SIUH to engage a new IRO, OIG shall notify SIUH of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, SIUH may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. SIUH shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with SIUH prior to requiring SIUH to terminate the IRO. However, the final determination as to whether or not to require SIUH to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B CLAIMS REVIEW

### A. Claims Review.

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

- a. Overpayment: The amount of money SIUH has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by SIUH and for which SIUH has received reimbursement from the Medicare or Medicaid programs.
- d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of SIUH and for which SIUH has received reimbursement from Medicare or Medicaid (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which SIUH has received reimbursement from Medicare or Medicaid (i.e., Paid Claim) during the 12-month period covered by the Claims Review.

To be included in the Population, an Item must have resulted in at least one Paid Claim.

- e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 25 Medicare Paid Claims and 25 Medicaid Paid Claims submitted by or on behalf of SIUH (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at SIUH's offices or under SIUH's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, SIUH should, as appropriate, further analyze any errors identified in the Discovery Sample. SIUH recognizes that OIG, or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at SIUH or under SIUH's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, SIUH may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (1) statistically appropriate and (2) SIUH selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from SIUH to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor

4. *Systems Review.* If SIUH's Discovery Sample identifies an Error Rate of 5% or greater, SIUH's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.



5. *Other Requirements.*

- a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which SIUH cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by SIUH for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.
- c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

- a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.
- b. Claims Review Population. A description of the Population subject to the Claims Review.
- c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

- e. Source of Data. A description of 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).
- f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.
- d. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

- i. A description of SIUH’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by SIUH (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to SIUH.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.
- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure 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. (See Attachment 1 to this Appendix.)

4. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

5. *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.



## OVERPAYMENT REFUND

### TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: \_\_\_\_\_  
 Contractor Deposit Control # \_\_\_\_\_ Date of Deposit: \_\_\_\_\_  
 Contractor Contact Name: \_\_\_\_\_ Phone # \_\_\_\_\_  
 Contractor Address: \_\_\_\_\_  
 Contractor Fax: \_\_\_\_\_

### TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

*Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.*

PROVIDER/PHYSICIAN/SUPPLIER NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 PROVIDER/PHYSICIAN/SUPPLIER # \_\_\_\_\_ CHECK NUMBER# \_\_\_\_\_  
 CONTACT PERSON: \_\_\_\_\_ PHONE # \_\_\_\_\_ AMOUNT OF CHECK \$ \_\_\_\_\_  
 CHECK DATE \_\_\_\_\_

### REFUND INFORMATION

**For each Claim, provide the following:**

Patient Name \_\_\_\_\_ HIC # \_\_\_\_\_  
 Medicare Claim Number \_\_\_\_\_ Claim Amount Refunded \$ \_\_\_\_\_  
 Reason Code for Claim Adjustment: \_\_\_\_\_ (Select reason code from list below. Use one reason per claim)

*(Please list all claim numbers involved. Attach separate sheet, if necessary)*

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: \_\_\_\_\_*

**For Institutional Facilities Only:**

Cost Report Year(s) \_\_\_\_\_  
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

**For OIG Reporting Requirements:**

Do you have a Corporate Integrity Agreement with OIG? Yes No

**Reason Codes:**

<b>Billing/Clerical Error</b> 01 - Corrected Date of Service 02 - Duplicate 03 - Corrected CPT Code 04 - Not Our Patient(s) 05 - Modifier Added/Removed 06 - Billed in Error 07 - Corrected CPT Code	<b>MSP/Other Payer Involvement</b> 08 - MSP Group Health Plan Insurance 09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including Black Lung 12 - Veterans Administration	<b>Miscellaneous</b> 13 - Insufficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 - Other (Please Specify)
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