

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE SAINT BARNABAS HEALTH CARE SYSTEM**

I. PREAMBLE

The Saint Barnabas Health Care System (the “SBHCS”) 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, the SBHCS is entering into a Settlement Agreement with the United States.

Prior to the execution of this CIA, the SBHCS established a corporate compliance program (Compliance Program) that applies to all the SBHCS entities and facilities. The SBHCS’ Compliance Program includes a Code of Conduct, written policies and procedures, an education and training component, mechanisms for ongoing monitoring and auditing of the SBHCS operations to assess compliance, mechanisms for employees and agents to report incidents of noncompliance in an anonymous manner, disciplinary actions for individuals violating compliance policies and procedures, and oversight of the Compliance Program by the SBHCS’ Compliance Steering Committee. The SBHCS agrees that during the term of this CIA it shall continue to operate its Compliance Program in a manner that meets the requirements of this CIA. The SBHCS may modify the compliance program as appropriate, but at a minimum, the SBHCS shall ensure that it complies with the integrity obligations that are enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by the SBHCS under this CIA shall be 6 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA

(Effective Date). 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, VIII, IX, X, and XI shall expire no later than 120 days after the OIG's receipt of: (1) The SBHCS' final Annual Report; or (2) any additional materials submitted by the SBHCS pursuant to the 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, officers, trustees, and employees of the SBHCS (excluding housekeeping staff, maintenance workers, and dietary employees);
- 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 the SBHCS, excluding vendors whose sole connection with the SBHCS is selling or otherwise providing medical supplies or equipment to the SBHCS; and
- c. the SBHCS' employed medical staff.

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. "Relevant Covered Persons" includes all persons involved in the preparation or submission of claims for reimbursement from, or cost reports to, any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

The SBHCS shall continue to operate and maintain its Compliance Program and ensure that it includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* The SBHCS represents that it has appointed an individual to serve as its Compliance Officer. The SBHCS 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 the SBHCS, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Trustees of the SBHCS, and shall be authorized to report on such matters to the Board of Trustees at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the SBHCS as well as for any reporting obligations created under this CIA.

The SBHCS shall report to the 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 Steering Committee.* The SBHCS represents that it has established a Compliance Steering Committee. For the duration of this CIA, the SBHCS shall maintain its Compliance Steering Committee. The Compliance Steering 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 Steering Committee and the 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).

The SBHCS shall report to the OIG, in writing, any changes in the composition of the Compliance Steering Committee, or any actions or changes that would affect the Compliance Steering 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.* The SBHCS represents that it has developed, and implemented a program to distribute a Code of Conduct to its employees. For the duration of this CIA, the SBHCS shall continue to maintain the Code of Conduct. To the extent necessary, the SBHCS shall amend its Code of Conduct to meet the requirements set forth below. The Code of Conduct shall be distributed within 120 days after the Effective Date to all Covered Persons who have not already received the Code of Conduct. The SBHCS 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. The SBHCS' 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. The SBHCS' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with the SBHCS' own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of the SBHCS' Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by the SBHCS suspected violations of any Federal health care program requirements or of the SBHCS' own Policies and Procedures;
- d. the possible consequences to both the SBHCS and Covered Persons of failure to comply with Federal health care program requirements and with the SBHCS' 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.F, and the SBHCS' commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the SBHCS' Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The SBHCS shall make its best efforts to distribute the Code of Conduct to its non-employed medical staff within 120 days and to obtain the requested certification.

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

2. *Policies and Procedures.* Within 120 days after the Effective Date, the SBHCS shall review, and where appropriate, revise or develop its existing written Policies and Procedures regarding the operation of the SBHCS' 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. the need for compliance in connection with all cost report and other submissions to Federal health care programs;
- c. the establishment and maintenance of the SBHCS' Compliance Program; and
- d. The SBHCS' commitment to the honest and accurate submission of cost reports and other claims in accordance with Federal health care program requirements.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), the SBHCS shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, the SBHCS shall provide at least one hour of General Training to each Covered Person, and shall make its best efforts to provide General Training to its non-employed medical staff. This training, at a minimum, shall explain the SBHCS’:

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

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 annually.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least 4 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 preparation and submission of cost reports and other claims;

- b. policies, procedures, and other requirements applicable to the submission of cost reports and other claims to Federal health care programs;
- c. the personal obligation of each individual involved in the preparation of cost reports and/or claims submission process to ensure that such cost reports and claims are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for violations of the Federal health care program requirements; and
- f. examples of proper and improper cost report and/or claims submission practices.

If, pursuant to the SBHCS' Compliance Program, the SBHCS has provided specific training to Relevant Covered Persons that satisfies the requirements set forth above within 120 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying the SBHCS' Specific Training obligations for the first year of the CIA with respect to those Relevant Covered Persons who have received such training.

Relevant Covered Persons shall receive this 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. A SBHCS employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least 4 hours of Specific Training annually.

3. *Documentation Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is directly involved in the delivery of patient care items or services, but who is not a "Relevant Covered Person" as defined in Section II.C.2, shall

annually receive one hour of documentation training (Documentation Training) in addition to the General Training required above. This Documentation Training shall include a discussion of:

- a. policies, procedures, and other requirements applicable to the documentation of medical services; and
- b. the importance of accurate documentation in the billing and coding process.

Persons providing the training must be knowledgeable about the subject area. Covered Persons subject to this subsection shall receive the Documentation Training within 30 days of the beginning of their employment or becoming Covered Persons or within 120 days of the Effective Date of this CIA, whichever is later. An SBHCS employee who has completed the Documentation Training shall monitor a new Covered Person's work, to the extent that the work relates to the delivery of patient care items or services, until such time as the new Covered Person completes his/her applicable training.

After receiving the initial training described in this Section III.C.3, every Covered Person shall receive at least one hour of Documentation Training annually.

4. *Certification.* Each individual who is required to attend training (or who has received prior training within 120 days of the Effective Date in accordance with Section III.C.2, above) shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to the OIG, upon request.

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

6. *Update of Training.* The SBHCS shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Cost Reporting Review, Diagnosis-Related Group (DRG) Claims Review(s), Unallowable Cost Review, and any other relevant information.

7. *Computer-based Training.* The SBHCS may provide the training required under this CIA through appropriate computer-based training approaches. If the SBHCS chooses to provide the training required under this CIA through appropriate computer-based 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 the SBHCS 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.

8. *Applicability of Training Requirements.* Section III.C of this CIA shall apply only to the acute care facilities that currently exist within the SBHCS and any acute care facility subsequently acquired by the SBHCS during the term of this CIA; the SBHCS corporate offices; and the SBHCS System Billing Office (SBO). Specifically, with respect to the acute care facilities, the CIA shall apply currently to Community Medical Center, Kimball Medical Center, Saint Barnabas Medical Center, Monmouth Medical Center, Newark Beth Israel Medical Center, Union Hospital, and Clara Maass Medical Center.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, the SBHCS shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist the SBHCS in assessing and evaluating its cost reporting practices, billing and coding practices and systems, and certain other obligations pursuant to this CIA and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by the SBHCS shall have expertise in the billing, coding, cost reporting, and other requirements of hospitals and in the general requirements of the Federal health care program(s) from

which the SBHCS seeks reimbursement. Each IRO shall assess, along with the SBHCS, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

b. *Types of Engagements.* The IRO(s) review shall conduct three separate engagements. One engagement shall address the SBHCS' cost reporting to the Medicare program (Cost Reporting Engagement). The Cost Reporting Engagement shall consist of two components: a Cost Reporting Systems Engagement and a Cost Reporting Review. A second engagement shall analyze whether the SBHCS sought payment for certain unallowable costs (Unallowable Cost Review). The third engagement shall address and analyze the SBHCS' billing and coding for Diagnosis-Related Group (DRG) inpatient admissions to the Federal health care programs (DRG Claims Review Engagement).

c. *Frequency of Cost Reporting Engagement.* The Cost Reporting Systems Engagement under Section III.D.2.a. shall be performed for the CIA's first Reporting Period (as defined in Section II.A above) only. The Cost Reporting Review under Section III.D.2.b. shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of the Cost Reporting Systems Engagement and each annual Cost Reporting Review.

d. *Frequency of Unallowable Cost Review.* The IRO shall perform the Unallowable Cost Review for the first Reporting Period.

e. *Frequency of DRG Claims Review.* The IRO shall annually conduct DRG Claims Reviews at a minimum of two of the SBHCS' hospitals. The IRO shall perform the components of each annual DRG Claims Review, as described below.

f. *Retention of Records.* The IRO and the SBHCS shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and the SBHCS) related to the reviews.

2. *Cost Reporting Engagement.* The Cost Reporting Engagement shall consist of the following:

a. *Cost Reporting Systems Engagement.* The IRO shall, through observation and inquiry, gain an understanding of the SBHCS' cost report preparation process ("Cost Reporting Systems Engagement"). The engagement shall be designed to compare the SBHCS' practices with best practices among similarly situated hospitals in the industry and will be designed to produce findings and recommendations aimed at improving the SBHCS' cost report preparation process. The specific focus of the engagement shall be to document and, if applicable, recommend improvements to the steps the SBHCS takes to ensure that the proper information is being recorded on such submissions to the Medicare program and that controls are reasonably designed to ensure that allowable costs and amounts are submitted for reimbursement. The IRO shall conduct interviews and review policies and procedures to present findings and recommendations on the SBHCS' cost report preparation policies, procedures, and process ("Cost Reporting Systems Findings"). The Cost Reporting Systems Engagement shall consist of interviews with key SBHCS cost reporting personnel, as well as an analysis of cost report preparation policies and procedures. The IRO's findings and recommendations shall include an analysis of the internal controls related to the allocation of costs and the derivation of dollar amounts.

b. *Cost Reporting Review.* The IRO shall perform an analysis of all costs charged directly to those departments of the SBHCS for which payment is made based upon a hospital-specific cost as reported on Medicare cost reports during the Reporting Period (the "Cost Reporting Review"), to evaluate their compliance with Medicare requirements. Specifically, the IRO's analysis shall include, but not be limited to, the SBHCS' compliance with Medicare's requirements for diagnosis related group outlier payments, which requirements are currently set forth in the regulations codified at 42 C.F.R. §§ 412.80-412.86. The IRO shall assess whether the SBHCS' costs claimed are

supported by documentation and in compliance with applicable Medicare requirements.

c. *Cost Reporting Review Report.* The IRO shall prepare a report based upon the Cost Reporting Engagement and appropriate consulting standards. The Report shall include the IRO's findings and supporting rationale regarding (i) the weaknesses in the SBHCS' cost report, cost statement, information statement, and payment request preparation process relating to any and all costs submitted to the Medicare program covered by the Cost Reporting Systems Engagement in the period being audited; (ii) any recommendations the IRO may have to improve any of these systems, operations, and processes; and (iii) a summary of the conclusions from the Cost Reporting Review.

3. *DRG Claims Review.* The IRO shall annually conduct the DRG Claims Review to identify any Overpayments (as defined below) through an appraisal of inpatient discharges paid on the basis of DRGs by the Medicare program. The IRO shall conduct a DRG Claims Review for at least two of the SBHCS' hospitals annually, which hospitals shall be selected by the OIG. Each DRG Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this Agreement, which is incorporated by reference.

a. *Discovery Samples.* The IRO shall randomly select and review a minimum of two samples (one sample from each of the hospitals selected by the OIG) of 50 Medicare Paid Claims for inpatient discharges paid on the basis of DRGs submitted by or on behalf of the SBHCS (Discovery Samples).

The Paid Claims shall be reviewed based on the supporting documentation available at the SBHCS' office or under SBHCS' control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix B) for any of the respective Discovery Samples 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, the SBHCS should, as appropriate, further analyze any errors identified in the Discovery Samples. The SBHCS 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 Samples or any other segment of the universe.)

ii. If any of the Discovery Samples indicate that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review based upon that Discovery Sample, as described below.

b. *Full Sample.* If necessary, as determined by procedures set forth in Section III.D.3.a, the IRO shall perform an additional sample of Paid Claims based upon DRG admissions using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to: (i) 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 (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at the SBHCS' office or under the SBHCS' 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 in question may serve as the probe sample, if statistically appropriate. Additionally, the SBHCS 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: (i) statistically appropriate and (ii) the SBHCS 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 the SBHCS 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.

c. *Systems Review.* If either of the SBHCS' Discovery Samples identify an Error Rate of 5% or greater, the SBHCS' 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.

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

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

4. *Unallowable Cost Review.* The IRO shall conduct a review of the SBHCS' compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether the SBHCS 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 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 the SBHCS 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. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether the SBHCS 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 the OIG has reason to believe that: (a) The SBHCS' DRG Claims Review, Cost Reporting Review, or Unallowable Cost Review fail to conform to the requirements of this CIA; or (b) the IRO's findings or DRG Claims Review Engagement results, Cost Reporting Engagement results, or Unallowable Cost Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the DRG Claims Review, Cost Reporting Engagement, or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or DRG Claims Review Engagement results, Cost Reporting Engagement results, or Unallowable Cost Review results are inaccurate (Validation Review). The SBHCS shall pay for the reasonable cost of any such review performed by the OIG or any of its designated agents. Any Validation Review of Reports submitted as part of the SBHCS' final Annual Report must be initiated no later than one year after the SBHCS' final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify the SBHCS of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, the SBHCS may request a meeting with the OIG to: (a) discuss the results of any DRG Claims Review Engagement, Cost Reporting Engagement, or Unallowable Cost Engagement submissions or findings; (b) present any additional information to clarify the results of the DRG Claims Review Engagement, Cost Reporting Engagement, or Unallowable Cost Review or to correct the inaccuracy of the DRG Claims Review Engagement, Cost Reporting Engagement, or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. The SBHCS agrees to provide any additional information

as may be requested by the OIG under this Section in an expedited manner. The OIG will attempt in good faith to resolve any DRG Claims Review, Cost Reporting Review, or Unallowable Cost Review issues with the SBHCS 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 the OIG.

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

E. Disclosure Program.

The SBHCS shall continue to maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line such as the SBHCS' Compliance HelpLine) 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 the SBHCS' 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. The SBHCS 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, the SBHCS 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 the 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://oig.hhs.gov>); and

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

c. “Screened Persons” include prospective and current owners, officers, directors, employees, contractors, and agents of the SBHCS.

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

a. The SBHCS 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 an Ineligible Person.

b. The SBHCS shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. The SBHCS 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) The SBHCS to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If the SBHCS has actual notice that a Screened Person has become an Ineligible Person, the SBHCS shall remove such Screened Person from responsibility for, or involvement with, the SBHCS' 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.

4. *Pending Charges and Proposed Exclusions.* If the SBHCS 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 his or her employment or contract term, the SBHCS 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 the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, the SBHCS shall notify the OIG, in writing, of any ongoing investigation or legal proceeding known to the SBHCS conducted or brought by

a governmental entity or its agents involving an allegation that the SBHCS 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. The SBHCS shall also provide written notice to the OIG within 30 days after the resolution of the matter, and shall provide the 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 the SBHCS 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, the SBHCS identifies or learns of any Overpayment, The SBHCS 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 and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, the SBHCS 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, the SBHCS 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; or
- ii. 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.

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

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

i. If the Reportable Event results in an Overpayment, the report to the 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 the SBHCS' actions taken to correct the Reportable Event; and

iv. any further steps the SBHCS plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, the SBHCS changes locations or sells, closes, 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, the SBHCS shall notify the OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. 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 corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION CERTIFICATION AND ANNUAL REPORTS

A. Implementation Certification. Within 130 days after the Effective Date of this CIA, the SBHCS' Compliance Officer shall be available to the OIG to summarize the status of the SBHCS' implementation of the requirements of this CIA. The SBHCS' Compliance Officer shall also submit a written certification to the OIG that includes the certification required by Section V.C and also summarizes the status of its implementation of the requirements of this CIA. The documentation supporting this certification shall be available to OIG, upon request. The Compliance Officer shall certify that:

1. all positions and committees required by Section III.A have been filled;
2. all Covered Persons have completed the Code of Conduct certification required by Section III.B.1;

3. the Policies and Procedures required by Section III.B.2 have been developed, are being implemented, and have been made available to all appropriate Covered Persons;

4. all training required by Section III.C was held and all related certifications and documentation (including documentation regarding Relevant Covered Persons receiving credit for prior training in accordance with Section III.C.2) required in Section III.C are in the possession of the SBHCS' Compliance Officer;

5. the Disclosure Program is being conducted in accordance with the requirements of Section III.E;

6. the Ineligible Persons screening required by Section III.F has been completed;

7. the requirements regarding the IRO(s) pursuant to Section III.D have been fulfilled; and

8. a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to the SBHCS.

The Compliance Officer shall also provide the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between the SBHCS and the IRO; and (d) the proposed start and completion dates of the DRG Claims Reviews, Cost Reporting Reviews, and Unallowable Cost Review.

B. Annual Reports. The SBHCS shall submit to the OIG annually a report with respect to the status of, and findings regarding, the SBHCS' compliance activities for each of the 6 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 Steering Committee described in Section III.A;

3. the Policies and Procedures required by Section III.B.2 have been developed, are being implemented, and have been made available to all appropriate Covered Persons;

4. all training required by Section III.C was held and all related certifications and documentation (including documentation regarding Relevant Covered Persons receiving credit for prior training in accordance with Section III.C.2) required in Section III.C are in the possession of the SBHCS' Compliance Officer;

5. the Disclosure Program is being conducted in accordance with the requirements of Section III.E;

6. the Ineligible Persons screening required by Section III.F has been completed; and

7. the requirements regarding the IRO(s) pursuant to Section III.D have been fulfilled.

The Compliance Officer shall also provide the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between the SBHCS and the IRO; (d) the proposed start and completion dates of the DRG Claims Reviews, Cost Reporting Reviews, and Unallowable Cost Review; and (e) the certification from the IRO(s) regarding its professional independence and/or objectivity with respect to the SBHCS.

B. Annual Reports. The SBHCS shall submit to the OIG annually a report with respect to the status of, and findings regarding, the SBHCS' compliance activities for each of the 6 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 Steering 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) and copies of any compliance-related Policies and Procedures;

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 the OIG, upon request);

4. 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. 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 the 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;

6. the SBHCS' 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 the SBHCS and the IRO, if different from what was submitted as part of the Implementation Certification;

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

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 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 the SBHCS 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 the SBHCS 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 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 the SBHCS' locations (including addresses) as required by Section V.A.11; 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 the SBHCS currently submits claims; and

16. the certifications required by Section V.C.

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

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

1. to the best of his or her knowledge, except as otherwise described in the applicable report, the SBHCS 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. The SBHCS 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. The SBHCS 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. The SBHCS 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

The SBHCS:

Jonathan H. Barkhorn
Vice President, Compliance & Chief Compliance Officer
Saint Barnabas Health Care System
95 Old Short Hills Road
West Orange, NJ 07052
Telephone: 973-322-4046
Facsimile: 973-322-4488

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.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of the SBHCS' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of the SBHCS' locations for the purpose of verifying and evaluating: (a) The SBHCS' compliance with the terms of this CIA; and (b) the SBHCS' compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by the SBHCS to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly

authorized representative(s) may interview any of the SBHCS' 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 the OIG. The SBHCS shall assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. The SBHCS' employees may elect to be interviewed with or without a representative of the SBHCS present.

VIII. DOCUMENT AND RECORD RETENTION

The SBHCS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 7 years (or longer if otherwise required by law).

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

The SBHCS 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, the SBHCS and the 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 the SBHCS 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. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements; and
- h. Notification of Government investigations or legal proceedings.

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 the SBHCS fails to engage an IRO, as required in Section III.D and Appendix A.

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 the SBHCS fails to submit the Implementation Certification or the Annual Reports to the 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 the SBHCS fails to submit the annual Cost Reporting Engagement Report, DRG Claims Review Report, or any other required Review in accordance with the requirements of Section III.D.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of the SBHCS as part of its Implementation Certification, 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 the SBHCS fails to comply fully and adequately with any obligation of this CIA. The OIG shall provide notice to the SBHCS, stating the specific grounds for its determination that the SBHCS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the SBHCS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the SBHCS receives this notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. The SBHCS 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 the 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 the SBHCS fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the 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 the SBHCS receives the 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 the 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 the SBHCS has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, the OIG shall notify the SBHCS of: (a) The SBHCS' failure to comply; and (b) the 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, the SBHCS shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event the SBHCS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the SBHCS cures, to the 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 the 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 the OIG's decision that the SBHCS has materially breached this CIA, which decision shall be made at the 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 the SBHCS 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 the SBHCS constitutes an independent basis for the SBHCS' exclusion from participation in the Federal health care programs. Upon a determination by the OIG that the SBHCS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify the SBHCS of: (a) The SBHCS' material breach; and (b) The 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.* The SBHCS shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG’s satisfaction that:

- a. The SBHCS is in compliance with the obligations of the CIA cited by the 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) The SBHCS has begun to take action to cure the material breach; (ii) the SBHCS is pursuing such action with due diligence; and (iii) the SBHCS has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, the SBHCS fails to satisfy the requirements of Section X.D.3, the OIG may exclude the SBHCS from participation in the Federal health care programs. The OIG shall notify the SBHCS in writing of its determination to exclude the SBHCS (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 the SBHCS’ 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, the SBHCS 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 the OIG’s delivery to the SBHCS 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, the SBHCS 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, the 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 the SBHCS was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. The SBHCS shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this CIA and orders the SBHCS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the SBHCS 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 the 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 the SBHCS 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) The SBHCS had begun to take action to cure the material breach within that period; (ii) the SBHCS has pursued and is pursuing such action with due diligence; and (iii) the SBHCS provided to the OIG within that period a reasonable timetable for curing the material breach and the SBHCS has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for the SBHCS, only after a DAB decision in favor of the OIG. The SBHCS' election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude the SBHCS upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that the SBHCS may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. The SBHCS 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 the SBHCS, the SBHCS 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

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, the SBHCS and the OIG agree as follows:

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

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the Parties to this CIA;

D. The OIG may agree to a suspension of the SBHCS' obligations under the CIA in the event of the SBHCS' cessation of participation in Federal health care programs. If the SBHCS withdraws from participation in Federal health care programs and is relieved of its CIA obligations by the OIG, the SBHCS shall notify the OIG at least 30 days in advance of the SBHCS' intent to reapply as a participating provider or supplier with any

Federal health care program. Upon receipt of such notification, the OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned SBHCS 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.

JUN-14-2006 13:42 FROM:

TO: AkinGump

P.2

ON BEHALF OF THE SAINT BARNABAS HEALTH CARE SYSTEM



JONATHAN H. BARKHORN
Vice President, Compliance &
Chief Compliance Officer

6/14/06

DATE

GARY W. THOMPSON, Esq.
Counsel for SBHCS

DATE

ON BEHALF OF THE SAINT BARNABAS HEALTH CARE SYSTEM

JONATHAN H. BARKHORN
Vice President, Compliance &
Chief Compliance Officer

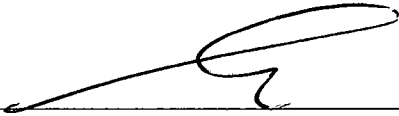
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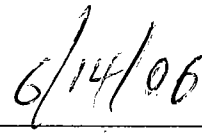
GARY W. THOMPSON, Esq.
Counsel for SBHCS

6/14/06
DATE

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



GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General



DATE

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

The SBHCS shall engage an IRO(s) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO(s) shall conduct the review in a professionally independent and/or 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 the SBHCS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the SBHCS may continue to engage the IRO.

If the SBHCS 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, the SBHCS shall submit the information pertaining to the IRO(s) identified in Section V.A 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 the SBHCS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the SBHCS may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the DRG Claims Review, Cost Reporting Review, and Unallowable Cost Review engagements who have expertise in the billing, coding, reporting, and other requirements of claims for payment based upon DRG admissions and in the general requirements of the Federal health care program(s) from which the SBHCS seeks reimbursement;
2. assign individuals to design and select the DRG Claims Review samples who are knowledgeable about the appropriate statistical sampling techniques;
3. assign individuals to conduct the coding review portions of the DRG Claims Reviews 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 DRG Claims Review, Cost Reporting Review, and Unallowable Cost Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the DRG Claims Reviews;

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

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

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

D. IRO Independence/Objectivity.

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

E. IRO Removal/Termination.

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

2. *OIG Removal of IRO.* In the event the 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 the SBHCS to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring the SBHCS to engage a new IRO, the OIG shall notify the SBHCS of its intent to do so and provide a written explanation of why the OIG believes

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

APPENDIX B DRG CLAIMS REVIEWS

A. DRG Claims Reviews.

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

- a. Overpayment: The amount of money the SBHCS has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: For purposes of each DRG Claims Review Discovery Sample, an “Item” is a hospital inpatient discharge for which an SBHCS hospital has been reimbursed by Medicare on the basis of a DRG.
- c. Paid Claim: A code or line item submitted by the SBHCS and for which the SBHCS has received reimbursement from the Medicare program.
- d. Population: All Items for which the SBHCS has submitted a code or line item and for which the SBHCS has received reimbursement from Medicare (i.e., Paid Claim) during the 12-month period covered by the DRG Claims Reviews. 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 samples. 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. *Other Requirements.*

- a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the DRG Claims Reviews, any Paid Claim for which the SBHCS cannot produce documentation sufficient to support the

Paid Claim shall be considered an error and the total reimbursement received by the SBHCS 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 Samples or Full Samples).

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

1. *DRG Claims Review Methodology*.

a. Sampling Unit. A description of the Item as that term is utilized for the DRG Claims Reviews.

b. DRG Claims Review Population. A description of the Population subject to the DRG Claims Reviews.

c. DRG Claims Review Objective. A clear statement of the objective intended to be achieved by the DRG Claims Reviews.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Samples and, if any, Full Samples have been selected and an explanation of the methodology used to identify the sampling frames. In most circumstances, the sampling frames will be identical to the Population

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the DRG Claims Reviews (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 DRG Claims Reviews were conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Items appraised in the Discovery Samples and, if applicable, in the Full Samples.

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(s), 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. *DRG Claims Review Findings.*

a. Narrative Results.

i. A description of the SBHCS’ 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 DRG Claims Reviews, including the results of the Discovery Samples, and the results of the Full Samples (if any).

b. Quantitative Results.

I. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by the SBHCS (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 the SBHCS.
- 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 each DRG 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 DRG Claims Reviews; and (2) performed the DRG Claims Reviews.

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:

- | | | |
|---|---|---|
| <p><u>Billing/Clerical Error</u></p> <ul style="list-style-type: none"> 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 | <p><u>MSP/Other Payer Involvement</u></p> <ul style="list-style-type: none"> 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 | <p><u>Miscellaneous</u></p> <ul style="list-style-type: none"> 13 - Insufficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 - Other (Please Specify) |
|---|---|---|