CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TOURO INFIRMARY

I. PREAMBLE

Touro Infirmary (Touro) 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, Touro is entering into a Settlement Agreement with the United States.

Prior to execution of this CIA, Touro voluntarily established a corporate compliance program (Compliance Program). Touro's Compliance Program includes a Code of Conduct, written policies and procedures, an education and training component, mechanisms for ongoing monitoring and auditing of Touro's 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 Touro's Compliance Committee. Touro agrees that it shall maintain the Compliance Program during the term of this CIA in a manner that meets the requirements of this CIA. Touro may modify the Compliance Program as appropriate, but at a minimum, Touro shall ensure that it complies with the integrity obligations that are set forth in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Touro under this CIA shall be 5 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Touro's final annual report; or (2) any additional materials submitted by Touro pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction that:

   a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Touro and any actual or potential source of health care business or referrals to Touro or any actual or potential recipient of health care business or referrals from Touro. The term "source" shall mean any physician, contractor, vendor, or agent, and the term "health care business or referrals" shall include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or

   b. is between Touro and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Touro for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Focus Arrangements" means every Arrangement that:

   a. is between Touro and any actual source of health care business or referrals to Touro and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

   b. is between Touro and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5) to Touro for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

Notwithstanding the foregoing provisions of Section II.C, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership of

investment interests), 42 C.F.R. § 411.357(g) (remuneration related to the provision of designated health services), 42 C.F.R. § 411.357(i) (payments by a physician for items and services), 42 C.F.R. § 411.357(m) (medical staff incidental benefits), 42 C.F.R. § 411.357(o) (compliance training), 42 C.F.R. § 411.357(q) (referral services), 42 C.F.R. § 411.357(s) (professional courtesy), 42 C.F.R. § 411.357(u) (community-wide health information systems), or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA. In addition, Focus Arrangements shall not include any Arrangement between Touro and any employee of Touro (i) who is not a licensed or certified health care provider; (ii) who does not provide health care items or services on behalf of Touro for which payment may be made in whole or in part by a Federal health care program; and (iii) whose employment relationship with Touro meets the safe harbor set forth at 42 C.F.R. § 1001.952(i).

3. "Covered Persons" includes:

a. all owners, officers, directors, and employees of Touro; and

b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Touro; and

c. physicians with active medical staff privileges at Touro.

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.

4. "Arrangements Covered Persons" includes each Covered Person involved with the negotiation, development, approval, management, or review of Touro's Arrangements, as such term is defined above in Section II.C.1.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* Touro certifies that it has appointed an individual to serve as its Compliance Officer who meets the requirements set forth in this Section III.A.1. Touro shall continue to maintain a Compliance Officer for the term of this CIA who meets the requirements set forth in this Section III.A.1. 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 Touro, reporting quarterly to the Audit and Compliance Committee of the Governing Board and shall also make annual reports regarding compliance matters directly to the Governing Board of Touro, and shall be authorized to report on such matters to the Governing Board 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 Touro as well as for any reporting obligations created under this CIA.

Touro 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.* Touro certifies that it has established a Compliance Committee that meets the requirements set forth in this Section III.A.2. Touro shall continue to maintain a Compliance Committee for the term of this CIA who meets the requirements set forth in this Section III.A.2. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Touro certifies that it has developed, implemented, made available for review and distributed, in paper or electronic form, a written Code of Conduct to its employees that meets the requirements set forth in this Section III.B.1. For the term of this CIA, Touro shall continue to maintain, make available, and distribute a Code of Conduct that meets the requirements set forth in this Section III.B1. Touro 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. Touro'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. Touro's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements, with Touro's own Policies and Procedures as implemented pursuant to Section III.B, and with the requirements of this CIA that apply to Covered Persons;

c. the requirement that all of Touro's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Touro, suspected violations of any Federal health care program requirements or of Touro's own Policies and Procedures;

d. the possible consequences to both Touro and Covered Persons of failure to comply with Federal health care program requirements and with Touro'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.F, and Touro's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person who has not received the Code of Conduct and provided paper or electronic certification of receipt as required by this Section III.B.1 prior to the Effective Date of this CIA shall certify, in paper or electronic form, that he or she has received, read, understood, and shall abide by Touro's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Additionally, the following shall constitute the obligations of Touro under this Section III.B.1 with respect to physicians who have active medical staff privileges but with whom Touro does not have a financial relationship ("Excepted Physicians"): (i) Touro shall make available or distribute the Code of Conduct to Excepted Physicians in accordance with the time requirements for other Covered Persons as set forth in this Section III.B.1; (ii) Touro shall also use its best efforts to obtain a written certification from each Excepted Physician indicating that he or she has received, read, understood, and shall abide by Touro's Code of Conduct; and (iii) Touro shall keep records of the percentage of Excepted Physicians who have completed the certification requirement.

Touro 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 made available or distributed to all Covered Persons, in paper or electronic form, within 30 days after any revisions are finalized. Each Covered Person shall certify, in paper or electronic form, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* To the extent not completed prior to the Effective Date of this CIA, within 120 days after the Effective Date, Touro shall implement written Policies and Procedures regarding the operation of Touro'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. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and

c. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Focus Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

To the extent not completed prior to the Effective Date of this CIA, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available or distributed, in paper or electronic form, to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Touro 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 made available for review or distributed, in paper or electronic form, to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

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

a. CIA requirements; and

b. Touro's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

If, pursuant to Touro's Compliance Program, Touro provided training to Covered Persons that satisfies the General Training requirements set forth in this section on or after August 1, 2007, then the OIG shall credit such training for purposes of satisfying the applicable General Training requirements for the first Reporting Period.

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

2. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

a. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;

b. Touro's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Focus Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

c. the personal obligation of each individual involved in the development, approval, management, or review of Touro's Arrangements to know the applicable legal requirements and the Touro's policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and

e. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. A Touro employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least one hour of Arrangements Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

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

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

6. *Computer-based Training.* Touro may provide the training required under this CIA through appropriate computer-based training approaches. If Touro 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. Excepted Physicians. Notwithstanding any other provision of this Section III.C., Touro shall: (i) make the General Training available to Excepted Physicians; (ii) use its best efforts to encourage the attendance and participation of Excepted Physicians in the General Training; and (iii) maintain records of the percentage of all Excepted Physicians who attend such training.

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

1. *Arrangements Procedures*. Within 120 days after the Effective Date, Touro shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Focus Arrangements that shall contain the information specified in Appendix A (Focus Arrangements Database);

b. tracking remuneration to and from all parties to Focus Arrangements;

c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review of Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law;

f. requiring the Compliance Officer to review the Focus Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

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

a. Ensure that each Focus Arrangement is set forth in writing and signed by Touro and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Touro's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Touro shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures;

c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Focus Arrangement.

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

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days after the Effective Date, Touro shall retain an entity (entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform Verification Reviews, as defined below in Section III.E.6, to assist Touro in assessing and evaluating its compliance with the obligations set forth in Section III.D. of this CIA. Each IRO retained by Touro shall have expertise with respect to 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law. Each IRO shall assess, along with Touro whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or engagements that may exist. The engagement of the IRO by Touro pursuant to this CIA shall not be deemed to create an attorney-client relationship between Touro and the IRO.

b. Focus Arrangements Review. Touro, through its internal audit personnel, shall conduct annual reviews to analyze Touro's compliance with the obligations set forth in Section III.D. of this CIA (Focus Arrangements Review). The Focus Arrangements Review shall be conducted in accordance with Section III.E.2 of this CIA.

c. Frequency of Focus Arrangements Review. The Focus Arrangements Review shall be performed annually and shall cover each of the Reporting Periods.

d. Unallowable Cost Review. Touro, through its internal audit personnel, shall conduct a review to analyze whether Touro sought

payment from any Federal health care program for certain unallowable costs (Unallowable Cost Review).

e. Frequency of Unallowable Cost Review. Touro shall perform the Unallowable Cost Review for the first Reporting Period.

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

g. Responsibilities and Liabilities. Nothing in this Section III.E affects Touro's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Focus Arrangements Review.* Touro's internal audit personnel shall perform an internal review to assess whether Touro is complying with the Arrangements Procedures and Focus Arrangements Requirements required by Section III.D. of this CIA. Touro shall randomly select a sample of 25 Focus Arrangements that were entered into or renewed during the Reporting Period. Touro shall assess whether it has implemented the Arrangements Procedures and, for each selected Focus Arrangement, Touro shall assess whether it has complied with the Arrangements Procedures and Focus Arrangements Requirements specifically with respect to that Focus Arrangement. Touro's assessment shall include, but is not limited to (a) verifying that the Focus Arrangement is listed in the Focus Arrangements Database; (b) verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Focus Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (f) verifying that the Compliance Officer is reviewing the Focus Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and Stark Law are discovered; and (h)

verifying that Touro has met the Focus Arrangements Requirements set forth above in Section III.D.2.

3. *Focus Arrangements Review Report.* Touro shall prepare a report based upon the Focus Arrangements Review performed (Focus Arrangements Review Report). The Focus Arrangements Review Report shall include Touro's findings with respect to (a) whether Touro has generally implemented the Arrangements Procedures described above in Section III.D.1; and (b) specific findings as to whether Touro has complied with the Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Focus Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to Touro's policies, procedures, and systems in place to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law.

4. *Unallowable Cost Review.* Touro's internal audit personnel shall conduct an internal review of its compliance with the unallowable cost provisions of the Settlement Agreement. Touro shall determine whether Touro 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 Touro 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, Touro shall determine if such adjustments were proper. In making this determination, Touro 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.* Touro shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the Touro's findings and supporting rationale regarding the Unallowable Costs Review and whether Touro 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. *IRO Verification Review.* The IRO shall conduct a review of Touro's Unallowable Cost Review and at least 20% of the sampling units reviewed by Touro in its internal Focus Arrangements Review (Verification Review). As part of Touro's Annual Report, the IRO shall submit a report that verifies that the Review Procedures outlined in Section III.E of this CIA have been satisfied and shall report the results, sampling unit by sampling unit, of the Verification Review performed.

7. *IRO Qualifications.* The IRO engaged by Touro to perform the Focus Arrangements Review shall have expertise in the Anti-kickback Statute, the Stark Law, and the general requirements of the Federal health care programs from which Touro seeks reimbursement. The IRO engaged by Touro to perform the Unallowable Cost Review shall have expertise in the cost reporting requirements applicable to Touro and in the general requirements of the Federal health care program(s) from which Touro seeks reimbursement.

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

Prior to initiating a Validation Review, OIG shall notify Touro 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, Touro may request a meeting with OIG to: (a) discuss the results of any Focus Arrangements Review and/or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Focus Arrangements Review and/or Unallowable Cost Review or to correct the inaccuracy of the Focus Arrangements Review and/or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Touro agrees to provide any additional information as may be requested by OIG under this Section III.E.9

in an expedited manner. OIG will attempt in good faith to resolve any Focus Arrangements Review and/or Unallowable Cost Review issues with Touro 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.

9. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Touro 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 Focus Arrangements Review and Unallowable Cost Review and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

Touro certifies that it has implemented a Disclosure Program that meets the requirements of this Section III.F. For the term of this CIA, Touro shall 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 Touro'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. Touro 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, Touro 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.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the 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" include prospective and current owners, officers, directors, employees, contractors, and agents of Touro.

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

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

c. Touro 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) Touro to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Touro understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Touro may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Touro meets the requirements of this Section III.G.

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

4. *Pending Charges and Proposed Exclusions.* If Touro 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," Touro 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.

5. *Physicians with Staff Privileges.* Prior to granting staff privileges to a physician after the Effective Date, Touro shall screen in the manner described in Section III.G.2 above to determine if the physician is an Ineligible Person. Furthermore, Touro shall review its list of physicians with staff privileges against the Exclusion Lists within 90 days after the Effective Date and at least annually thereafter. If a physician with staff privileges is an Ineligible Person, Touro shall ensure that the physician does not furnish, order, or prescribe any items or services payable in whole or in part by any Federal health care program. In addition to any other appropriate measures, Touro shall ensure that any physician who is an Ineligible Person is not "on call" at Touro.

H. Notification of Government Investigation or Legal Proceedings.

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

I. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Touro 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, Touro identifies or learns of any Overpayment, Touro 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, Touro 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, Touro 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 B 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 and need not be reported to the OIG.

2. *Reportable Events.*

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

i. a substantial Overpayment;

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; or

iii. the filing of a bankruptcy petition by Touro.

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

b. *Reporting of Reportable Events.* If Touro determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Touro 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.I.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 Touro's actions taken to correct the Reportable Event; and

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

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.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Touro 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, Touro shall notify 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 AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Touro 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 Touro'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:

   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 Focus Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

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

11. the following information regarding the IRO(s): (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 Touro and the IRO;

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

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

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; 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;

15. a list of all of Touro'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 Touro currently submits claims;

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

17. the certifications required by Section V.C.

B. Annual Reports. Touro shall submit to OIG annually a report with respect to the status of, and findings regarding, Touro's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer 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:

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 description of any changes to the Focus Arrangements Database required by Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.e;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

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

9. Touro's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

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

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

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

13. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: 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;

14. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law;

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

16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Touro in response to the

screening and removal obligations set forth in Section III.G; 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;

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

18. a description of all changes to the most recently provided list of Touro's locations (including addresses) as required by Section V.A.15; 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 Touro currently submits claims; and

19. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period, as defined in Section II.A. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Notwithstanding the term set forth in Section II.A. above, Touro shall have the right to submit with its third Annual Report a request in writing seeking modification or early termination of this CIA (Request). Touro shall include in its Request facts in support of modification or early termination of this CIA. OIG may, in its sole discretion, modify or terminate this CIA prior to the expiration of the 5 year term.

C. Certifications. The Implementation Report 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, Touro is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, Touro has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback

Statute and Stark Law, including the Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, Touro has fulfilled the Focus Arrangements Requirements;

4. 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

5. to the best of his or her knowledge, Touro 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. Touro 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. Touro 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

Touro Infirmary:

Norman A. Stiteler, Esq.
Director, Corporate Compliance and Internal Audit
Touro Infirmary
1401 Foucher Street
New Orleans, Louisiana 70115
Telephone: 504.897.8338
Facsimile: 504.897.7540

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Touro 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, Touro and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Touro 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 Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements; and

i. 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 Touro fails to engage an IRO, as required in Section III.E.

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 Touro fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day fails to submit the annual Focus Arrangements Review Report and/or Unallowable Cost Review in accordance with the requirements of Section III.E.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Touro as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Touro fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Touro stating the specific grounds for its determination that Touro has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Touro shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Touro 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. Touro 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 Touro 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 Touro 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 Touro 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 Touro of: (a) Touro'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, Touro 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 Touro elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Touro 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 Touro 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 Touro to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;

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.E.

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Touro fails to satisfy the requirements of Section X.D.3, OIG may exclude Touro from participation in the Federal health care programs. OIG shall notify Touro in writing of its determination to exclude Touro (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 Touro'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, Touro 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 Touro 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, Touro 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 Touro was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Touro 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 Touro to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Touro 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 Touro 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) Touro had begun to take action to cure the material breach within that period; (ii) Touro has pursued and is pursuing such action with due diligence; and (iii) Touro provided to OIG within that period a reasonable timetable for curing the material breach and Touro 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 Touro, only after a DAB decision in favor of OIG. Touro's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Touro 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 Touro 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. Touro 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 Touro, Touro 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

Touro and OIG agree as follows:

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

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

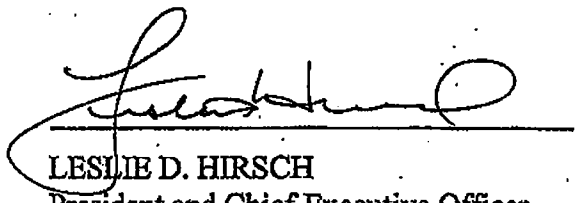
C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. OIG may agree to a suspension of Touro's obligations under the CIA in the event of Touro's cessation of participation in Federal health care programs. If Touro withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Touro shall notify OIG at least 30 days in advance of Touro'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 Touro signatory represents and warrants that he is 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.

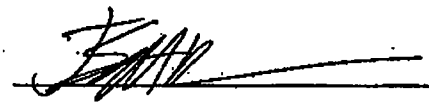
F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF TOURO INFIRMARY



LESLIE D. HIRSCH
President and Chief Executive Officer

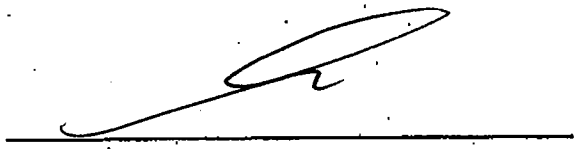
4/7/08
DATE



J. SCOTT NEWTON, ESQ.
Baker, Donelson, Bearman, Caldwell
& Berkowitz, P.C.
Counsel for Touro Infirmary

4/7/08
DATE

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



4/14/08

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

DATE

APPENDIX A

FOCUS ARRANGEMENTS DATABASE

Touro shall create and maintain a Focus Arrangements Database to track all new and existing Focus Arrangements in order to ensure that each Focus Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Focus Arrangements Database shall contain certain information to assist Touro in evaluating whether each Focus Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Focus Arrangement;

2. The type of Focus Arrangement (e.g., physician employment contract, medical directorship, lease agreement);

3. The term of the Focus Arrangement, including the effective and expiration dates and any automatic renewal provisions;

4. The amount of compensation to be paid pursuant to the Focus Arrangement and the means by which compensation is paid;

5. The methodology for determining the compensation under the Focus Arrangements, including the methodology used to determine the fair market value of such compensation;

6. Whether the amount of compensation to be paid pursuant to the Focus Arrangement is determined based on the volume or value of referrals between the parties;

7. Whether each party has fulfilled the requirements of Section III.D.2; and

8. Whether the Focus Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

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/SUPPLIERNAME_____
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:

Billing/Clerical Error
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

MSP/Other Payer Involvement
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

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____