# CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER AT SHREVEPORT

## I. PREAMBLE

The Board of Supervisors of the Louisiana State University and Agricultural and Mechanical College ("Board") on behalf of its Health Sciences Center at Shreveport ("HSC") 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 ensure compliance by HSC's employees, physicians, other health care professionals, contractors or other individuals who participate in the provision, marketing, or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports, or other requests for reimbursement for such items or services (hereinafter collectively referred to as "Covered Persons") with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs.").

The parties acknowledge that only the Board is authorized to enter into a legally binding agreement but that any and all obligations, duties, remedies and/or rights set forth in this Agreement are applicable to HSC as set forth further below. HSC's compliance with the terms and conditions in this CIA shall constitute an element of HSC's present responsibility with regard to participation in the Federal health care programs. The Board hereby agrees that it will do nothing in its capacity as having legal authority over HSC that will interfere with, or diminish, HSC's ability to discharge HSC's corporate integrity obligations under this Agreement. Accordingly, the Board will take all reasonable steps to promote compliance with the terms of this Agreement by HSC. Contemporaneously with this CIA, the Board on behalf of HSC is entering into a Settlement Agreement with

the United States, and this CIA is incorporated by reference into the Settlement Agreement.

## II. TERM OF THE CIA

The period of the compliance obligations assumed by HSC under this CIA shall be 5 years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA.

## III. CORPORATE INTEGRITY OBLIGATIONS

HSC represents that in December 1998 it formally established a corporate compliance program designed to ensure, among other things, compliance with the Federal health care program requirement and that the compliance program has been in effect up to and including the time of the execution of this Agreement. HSC hereby agrees to continue to maintain in operation for the duration of this CIA its current compliance program and amend it, as necessary, to meet the elements and requirements set forth in this CIA. HSC represents that it operates a School of Medicine and a University Hospital. As further set forth below, certain requirements of section III.D shall apply only to the HSC School of Medicine. All other sections shall apply to both HSC entities and their Covered Persons.

### A. Compliance Officer and Compliance Committee.

HSC represents that under its current compliance program it has appointed an individual to serve as Compliance Officer. HSC shall ensure that within 90 days after the effective date of this CIA and for the rest of the term of this CIA that the Compliance Officer meets the following requirements. 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 the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of HSC, shall make regular (at least quarterly) reports regarding compliance matters directly to the Dean of HSC School of Medicine and/or the Administrator of HSC University Hospital and to the Board's authorized representatives and shall be authorized to report to the Board's authorized representatives at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by HSC to further its compliance objectives as well as any reporting obligations created under this CIA. In

the event a new Compliance Officer is appointed during the term of this CIA, HSC shall notify the OIG, in writing, within fifteen (15) days of such a change.

HSC represents that its current compliance program includes a Compliance Committee. HSC shall ensure that within 90 days after the effective date of this CIA and for the rest of the term of this CIA the Compliance Committee meets the following requirements. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within the provider's corporate structure (e.g., senior executives of each major department, 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.

B. Written Standards.

1. *Code of Conduct.* Within 150 days of the effective date of this CIA, HSC shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 150 days of the effective date of this CIA. HSC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

a. HSC's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;

b. HSC's requirement that all of its Covered Persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with HSC's own policies and procedures (including the requirements of this CIA);

c. the requirement that all of HSC's Covered Persons shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of HSC's own policies and procedures;

d. the possible consequences to both HSC and to any Covered Person of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with HSC's own policies and procedures or of failure to report such non-compliance; and

e. the right of all Covered Persons to use the confidential disclosure program, as well as HSC's commitment to confidentiality and non-retaliation with respect to disclosures.

Within 150 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understands, and will abide by HSC's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 2 weeks after the commencement of their employment or contract or within 150 days of the effective date of the CIA, whichever is later.

HSC will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within 30 days of initiating such a change. Covered Persons shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. *Policies and Procedures*. Within 150 days of the effective date of this CIA, HSC shall develop and initiate implementation of written Policies and Procedures regarding the operation of HSC's compliance program and its compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. The Policies and Procedures shall include the following: (a) provisions implementing the substantive requirements of this CIA, including those set forth in section III; (b) disciplinary guidelines and methods for Covered Persons to make disclosures or otherwise report on compliance issues to HSC management through the Confidential Disclosure Program set forth in section III.E; (c) specific Policies and Procedures addressing the proper documentation, coding and billing of physician services; and (d) specific Policies and Procedures regarding the credentialing and re-credentialing of its physicians (including those that are employees and those on the active medical staff) and other health care professionals in order to ensure that such providers are properly licensed and qualified under applicable State laws to perform their relevant health care services. Such Policies and Procedures shall be clear and comprehensive and articulate specific procedures that personnel should follow in the credentialing process. Within 150 days of the effective date of this CIA, HSC shall perform a complete review of its physicians and other health care professionals to

determine whether they are appropriately credentialed. The Policies and Procedures shall also address the methods that HSC uses to trigger the re-credentialing process. All such policies should be organized, indexed and easily retrievable by all Covered Persons involved in the credentialing and re-credentialing process.

HSC shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. The Policies and Procedures will be available to OIG upon request.

Within 150 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate Covered Persons. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education

1. *General Training*. Within 150 days of the effective date of this CIA, HSC shall provide at least 2 hours of training to each Covered Person. This general training shall explain HSC's:

a. Corporate Integrity Agreement requirements; and

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

These training material shall be made available to the OIG, upon request.

New Covered Persons shall receive the general training described above within 30 days of commencing work as an employee or under a contract or within 150 days after the effective date of this CIA, whichever is later. Every Covered Person shall receive such general training on an annual basis.

2. *Specific Training for Relevant Covered Persons*. Within 150 days of the effective date of this CIA, each Covered Person who is (a) a physician; or (b) any person who participates in the preparation or submission of claims, reports, or other requests for reimbursement for items or services (including, but not limited to, coding and billing) for any Federal health care programs ("Relevant Covered Persons") shall receive at least 3

hours of training in addition to the general training required above. This training shall include a discussion of:

a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;

b. policies, procedures and other requirements applicable to the documentation of medical records;

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

d. applicable reimbursement rules and statutes;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

These training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Affected new Relevant Covered Persons shall receive this training within 30 days of commencing work as an employee or under a contract or within 150 days of the effective date of this CIA, whichever is later. If a new Relevant Covered Person has any responsibility for the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a HSC Relevant Covered Person who has completed the substantive training shall review all of the untrained person's work regarding the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes or the assignment of billing codes.

Every Relevant Covered Person shall receive such specific training on an annual basis.

3. *Credentialing Training.* Within 150 days of the effective date of this CIA, each Covered Person who participates in the credentialing process shall receive at least 1 hour of training in addition to the general training required above. Such training shall include a discussion of HSC's specific credentialing guidelines. Every such Covered Person shall receive such specific credentialing training on an annual basis.

4. *Certification.* Each Covered Person shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

D. Review Procedures.

HSC shall perform review procedures to assess the adequacy of its billing and credentialing practices. This review shall be an annual requirement and shall cover a continuous 12 month period. The review procedures shall consist of an analysis of HSC School of Medicine's billing to the Federal health care programs to assist HSC and OIG in determining compliance with all Federal health care program requirements ("billing audit") and an analysis of whether HSC School of Medicine's physicians and other health care professionals are appropriately credentialed ("credentialing audit"). The audits shall be performed according to the procedures described below ("agreed-upon procedures"). HSC shall ensure that the billing audits are performed by individuals with appropriate expertise, specifically including coding expertise.

HSC shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") to review whether HSC has performed the billing and credentialing audits in conformance with the agreed-upon procedures. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which HSC seeks reimbursement. HSC shall require the IRO to produce a report on its findings, which report shall be included in HSC's Annual Report to OIG.

1. *Billing Audit.* The billing audit shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted to the Federal health care programs for items and services provided by HSC's School of Medicine. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims for that review, the projection provides a minimum 90 percent confidence level and a maximum precision of plus or minus 25 percent of the point estimate (i.e, the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the sample must be selected through random number sampling. To generate the random sample, HSC shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-

STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html".

Each annual billing audit analysis shall include the following components in its methodology:

a. Billing Audit Objective: A clear statement of the objective intended to be achieved by the billing audit and the procedure or combination of procedures that will be applied to achieve the objective;

b. Billing Audit Population: Identify the population, which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination;

c. Sources of Data: Provide a full description of the source of the information upon which the billing audit conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations;

d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest;

e. Sampling Frame: Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected;

The billing audit shall provide:

a. findings regarding HSC School of Medicine's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. findings regarding whether HSC is submitting accurate claims and/or cost reports for services billed to the Federal health care programs;

c. findings regarding HSC's procedures to correct inaccurate billings or codings to the Federal health care programs; and

d. findings regarding the steps HSC is taking to bring its operations into compliance or to correct problems identified by the audit;

2. *Credentialing Audit.* HSC shall also determine through (a) a review of HSC's credentialing system, operations, and processes; and (b) random sampling, whether HSC's physicians and other health care professionals have the appropriate credentials to perform their respective services. The random sample shall consist of a review of the credentials of 10% of the relevant personnel.

3. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement that shall provide findings regarding whether HSC's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section by section findings regarding the requirements of this CIA. Based on the results of the first Compliance Engagement and the results of the billing audit for the first year of the term of this CIA, OIG may, at its sole discretion, relieve HSC of its obligations to retain an IRO to conduct a Compliance Engagement for the subsequent years of this CIA.

A complete copy of HSC's billing and credentialing audit report and the Independent Review Organization's report of findings regarding such audits and the IRO compliance engagement report shall be included in each of HSC's Annual Reports to OIG.

4. *Verification/Validation.* In the event that the OIG has reason to believe that either HSC's billing or credentialing audit fails to conform to its obligations under the CIA or indicates improper billings or credentialing not otherwise adequately addressed in the annual review report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which HSC is complying with its obligations under this CIA, HSC agrees to reimburse the OIG for the reasonable cost of any such review by the OIG or any of its designated agents.

E. Confidential Disclosure Program.

HSC represents that its current compliance program includes a Confidential Disclosure Program. HSC shall ensure that within 90 days after the effective date of this CIA and for the rest of the term of this CIA that the Confidential Disclosure Program

meets the following requirements. The Confidential Disclosure Program must include measures (e.g., a toll-free compliance telephone line) to enable Covered Persons to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with HSC's policies, practices or procedures with respect to any Federal health care program, believed by the individual to be inappropriate. HSC shall publicize the existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. 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, HSC shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services, but has not been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements*. HSC shall not hire or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, HSC shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs

(available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 90 days of the effective date of this CIA, HSC will review its list of current employees and contractors and physicians with staff privilege against the Exclusion Lists. Thereafter, HSC will review the list once semi-annually. If HSC has notice that an employee, agent, or physician has become an Ineligible Person, HSC will remove such person from responsibility for, or involvement with, HSC's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the 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 person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If HSC has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract with HSC, HSC shall take all appropriate actions to ensure that the responsibilities of that employee or contractor do not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Proceedings.

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

H. Reporting.

1. *Overpayments*

*a. Definition of Overpayments.* For purposes of this CIA, an "overpayment" shall mean the amount of money HSC has received in excess of the amount due and payable under any Federal health care program requirements. HSC may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

*b. Reporting of Overpayments.* If, at any time, HSC identifies or learns of any overpayments, HSC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Exhibit 1 to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

(ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

*b. Reporting of Material Deficiencies.* If HSC determines that there is a Material Deficiency, HSC shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency 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) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of HSC's actions taken to correct the Material Deficiency; and

(iv) any further steps HSC plans to take to address the Material Deficiency and prevent it from recurring.

## IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, HSC changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, HSC shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare and Medicaid provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare or Medicaid provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the effective date of this CIA, HSC shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;

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

3. a copy of HSC's Code of Conduct required by section III.B.1;

4. the summary of the Policies and Procedures required by section III.B.2;

5. a description of the training programs required by section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all pertinent Covered Persons;

   b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and

   c. all Covered Persons have completed the training and executed the certification required by section III.C.

7. a description of the confidential disclosure program required by section III.E;

8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and

9. a summary of personnel actions taken pursuant to section III.F.

B. Annual Reports. HSC shall submit to OIG an Annual Report with respect to the status and findings of HSC's compliance activities. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

   a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1; and

   b. all Covered Persons have completed the training and executed the certification required by section III.C.

3. notification of any 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);

4. a complete copy of the internal audit report and the Independent Review Organization's report of findings as required by section III.D, including a copy of the methodology used along with a copy of the IRO's engagement letter;

5. HSC's response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to section III.H;

7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal health care programs;

8. a copy of the confidential disclosure log required by section III.E;

9. a description of any personnel action (other than hiring) taken by HSC as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that HSC has committed a crime or has engaged in fraudulent activities, which is required to have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a corrective action plan to address all material deficiencies (as defined in section III.H) identified over the previous twelve months; and

12. a listing of all of the HSC'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 Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and 60 days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of law, that: (1) except as otherwise described in the report, HSC is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

## VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted in writing to the entities listed below. 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.

OIG:

Civil Recoveries Branch - Compliance Unit
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, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

HSC:

Assistant Vice President for Medical Fiscal Policy
LSU System, 3810 West Lakeshore Drive
Baton Rouge, LA 70808
Phone 504.388.6118
Fax 504.388.8835

## 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 HSC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) HSC's compliance with the terms of this CIA; and (b) HSC's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by HSC 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, after providing HSC with adequate notice, interview any of HSC's employees or contractors who consent to be interviewed at their place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee or contractor and OIG. HSC agrees to assist OIG in contacting and arranging interviews with such persons upon OIG's request. HSC's employees may elect to be interviewed with or without a representative of HSC present. The arrangement and conduct of such interviews shall be accomplished in a manner consistent with the employee's obligations to deliver health care services.

## VIII. DOCUMENT AND RECORD RETENTION

HSC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA for 6 years (or longer if otherwise required by law).

## IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify HSC prior to any release by OIG of information submitted by HSC pursuant to its obligations under this CIA and identified upon submission by HSC as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. HSC shall refrain from designating any information as trade secrets, commercial or financial information and privileged and confidential if it does not meet the criteria for exemption from disclosure under FOIA.

## X. BREACH AND DEFAULT PROVISIONS

HSC 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, HSC and OIG hereby agree that failure to comply with certain obligations 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, beginning 150 days after the

effective date of this CIA and concluding at the end of the term of this CIA, HSC fails to have in place any of the following:

a. a Compliance Officer;

b. a Compliance Committee;

c. written Code of Conduct;

d. written Policies and Procedures;

e. a training program; and

f. a Confidential Disclosure Program;

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 HSC fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day HSC:

a. hires or enters into a contract with or grants staff privileges to an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which HSC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);

b. employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, HSC's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which HSC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

4. A Stipulated Penalty of $1,500 (which shall begin to accrue on the date the HSC fails to grant access) for each day HSC fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that HSC receives notice of the failure to comply) for each day HSC fails to comply fully and adequately with any obligation of this CIA not already covered in subparagraphs 1- 4. In its notice to HSC, the OIG shall state the specific grounds for its determination that the HSC has failed to comply fully and adequately with the CIA obligation(s) at issue. With respect to the Stipulated Penalty provision described in this subparagraph 5 only, the OIG shall not seek a Stipulated Penalty if HSC demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that (i) HSC has begun to take action to cure the failure to comply; (ii) HSC is pursuing such action with due diligence, and (iii) HSC has provided to OIG a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that HSC has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify HSC by personal service or certified mail of (a) HSC's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within 10 days of receipt of the Demand Letter, HSC 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.D. In the event HSC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HSC 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.C.

2. *Timely Written Requests for Extensions.* HSC may 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 HSC fails to meet the revised OIG-approved deadline. 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 two (2) business days after HSC receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

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 otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that HSC has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by HSC constitutes an independent basis for HSC's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that HSC has materially breached this CIA and that exclusion should be imposed, the OIG shall notify HSC by certified mail of (a) HSC'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").

2. *Opportunity to cure.* HSC shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. HSC is in full compliance with this CIA;

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) HSC has begun to take action to cure the

material breach, (ii) HSC is pursuing such action with due diligence, and (iii) HSC has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the 30-day period, HSC fails to satisfy the requirements of section X.C.2, OIG may exclude HSC from participation in the Federal health care programs. OIG will notify HSC in writing of its determination to exclude HSC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If HSC is excluded under the provisions of this CIA, HSC may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

a. a failure by HSC to report a matter it has determined to be a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;

b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to HSC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, HSC 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 ALJ and, in the event of an

appeal, the 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of the receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be (a) whether HSC was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. HSC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders HSC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless HSC requests a 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 Chapter 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 HSC was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach could not have been cured within the 30 day period, but that (i) HSC has begun to take action to cure the material breach, (ii) HSC is pursuing such action with due diligence, and (iii) HSC has provided to OIG a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. HSC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude HSC upon the issuance of an ALJ's decision. 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 HSC may request review of the ALJ decision by the DAB.

## XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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; and

D. The undersigned Board and HSC 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.

**ON BEHALF OF BOARD OF SUPERVISORS OF LOUISIANA STATE UNIVERSITY AND AGRICULTURAL AND MECHANICAL COLLEGE**
**& ON BEHALF OF LSU HEALTH SCIENCES CENTER IN SHREVEPORT**

William L. Jenkins
President, LSU System

3/24/00
DATE

**ON BEHALF OF BOARD OF SUPERVISORS OF LOUISIANA STATE UNIVERSITY AND AGRICULTURAL AND MECHANICAL COLLEGE & ON BEHALF OF LSU HEALTH SCIENCES CENTER IN SHREVEPORT**

| | |
|---|---|
| Mervin L. Trail<br>Chancellor, LSU Health Sciences Center | 3-24-00<br>DATE |

**ON BEHALF OF BOARD OF SUPERVISORS OF LOUISIANA STATE UNIVERSITY AND AGRICULTURAL AND MECHANICAL COLLEGE & ON BEHALF OF LSU HEALTH SCIENCES CENTER IN SHREVEPORT**

Ike Muslow
Dean, Health Sciences Center
LSU Medical School in Shreveport

3/23/00
DATE

Roy G. Clay
Associate Dean for Clinical Affairs
Health Sciences Center
LSU Medical School in Shreveport

3/23/00
DATE

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

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

3/24/00
DATE