

**CERTIFICATION OF COMPLIANCE AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
HARRIS METHODIST H-E-B HOSPITAL**

**I. PREAMBLE**

Harris Methodist H-E-B Hospital (HMHEB) hereby enters into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). Contemporaneously with this CCA, HMHEB is entering into a Settlement Agreement with the United States.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

**II. INTEGRITY REQUIREMENTS**

HMHEB shall, for a period of three years from the Effective Date of this CCA:

A. Continued Implementation of Compliance Program. HMHEB shall continue to operate in accordance with the HMHEB Program, as described in the attached Declaration (which is incorporated by reference as Appendix A), and continue to provide, at a minimum, the same level of resources currently provided, throughout this time period. HMHEB may amend the HMHEB Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

B. Reporting of Overpayments. HMHEB shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money HMHEB has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, HMHEB identifies or learns of any Overpayment, HMHEB 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 actions to prevent the underlying problem and the Overpayment from

recurring. Also, within 30 days after identification of the Overpayment, HMHEB 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, HMHEB 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 CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

C. Reportable Events. HMHEB shall report to OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, (2) 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 (3) the filing of a bankruptcy petition by HMHEB. In such report, HMHEB shall include the following information:

1. 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 II.B, 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;
2. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
3. a description of HMHEB's actions taken to correct the Reportable Event; and
4. any further steps HMHEB plans to take to address the Reportable Event

and prevent it from recurring.

5. 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.

D. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery, HMHEB shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to HMHEB conducted or brought by a governmental entity or its agents involving an allegation that HMHEB 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. HMHEB 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.

E. Annual Reporting Requirements. HMHEB shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):

1. A description of any material amendments to the HMHEB Program and the reasons for such changes;
2. Any changes to the level of resources dedicated to the HMHEB Program and the reasons for such changes;
3. A summary of all internal or external reviews, audits, or analyses of the HMHEB Program (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;
4. A summary of all internal or external reviews, audits, or analyses related to compliance with Federal health care program requirements, including compliance issues related to any financial arrangements between HMHEB and physicians, or other potential referral sources (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

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

6. A certification by the Compliance Officer that: (a) to the best of his or her knowledge, except as otherwise described in the Annual Report, HMHEB is in compliance with the requirements of this Section II; and (b) he or she has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

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

F. Notifications and Submission of Annual Reports. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

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

Harris Methodist H-E-B Hospital:

David Hall, Compliance and Privacy Officer  
Harris Methodist HEB  
1600 Hospital Parkway Bedford, TX 76022  
Phone: 817-685-4457  
Fax: 817-469-4469

With a copy to:

Kenneth Kramer  
Associate General Counsel  
Texas Health Resources  
611 Ryan Plaza Drive, 14th Floor  
Arlington, TX 76011-4018  
United States of America  
Telephone: 817-462-7144  
Facsimile: 817-462-6150

Unless otherwise specified, all notifications and reports required by this CCA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such report or notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

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

representative of HMHEB present.

H. Document and Record Retention. HMHEB shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law) from the Effective Date.

### **III. BREACH AND DEFAULT PROVISIONS**

HMHEB is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, HMHEB and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA 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 HMHEB fails to establish and implement any of the following compliance program elements as described in Section II and the Declaration attached to this CCA as Appendix A:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the annual training of owners, officers, directors, employees (including employed physicians), contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of HMHEB and the availability of annual training for medical staff;
- f. an auditing program that requires periodic performance of internal and external reviews to monitor HMHEB's compliance with Federal health care program requirements;

- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements; and
- i. notification of government investigations and 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 HMHEB fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.E by the stated deadlines for submission.

3. A Stipulated Penalty of \$1,500 for each day HMHEB fails to grant access to the information or documentation as required in Section II.G of this CCA. (This Stipulated Penalty shall begin to accrue on the date HMHEB fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of HMHEB as part of its Annual Reports or otherwise required by this CCA.

5. A Stipulated Penalty of \$1,000 for each day HMHEB fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to HMHEB, stating the specific grounds for its determination that HMHEB has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps HMHEB shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 days after HMHEB receives 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 1-4 of this Section III.A.

B. Timely Written Requests for Extensions. HMHEB 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 CCA. 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 HMHEB 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 HMHEB 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 HMHEB has failed to comply with any of the obligations described in Section III.A and after determining that Stipulated Penalties are appropriate, OIG shall notify HMHEB of: (a) HMHEB'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, HMHEB 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 III.E. In the event HMHEB elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HMHEB 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 CCA and shall be grounds for exclusion under Section III.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 II.F.

4. *Independence from Material Breach Determination.* Except as set forth in Section III.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that HMHEB has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section III.D, below.

**D. Exclusion for Material Breach of this CCA.**

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

- a. a failure by HMHEB to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section II.C;
- b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section



III.A; or

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section III.C.

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

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, HMHEB fails to satisfy the requirements of Section III.D.3, OIG may exclude HMHEB from participation in the Federal health care programs. OIG shall notify HMHEB in writing of its determination to exclude HMHEB (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 days after the date of HMHEB'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, HMHEB 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 HMHEB of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, HMHEB 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 CCA. 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 CCA shall be: (a) whether HMHEB was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. HMHEB 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 CCA and orders HMHEB to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless HMHEB 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 CCA shall be:

- a. whether HMHEB was in material breach of this CCA;
- 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) HMHEB had begun to take action to cure the material breach within that period; (ii) HMHEB has pursued and is pursuing such action with due diligence; and (iii) HMHEB provided to OIG within that period a reasonable timetable for curing the material breach and HMHEB 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 HMHEB, only after a DAB decision in favor of OIG. HMHEB's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude HMHEB 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 HMHEB 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. HMHEB 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 HMHEB, HMHEB 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 CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

#### **IV. EFFECTIVE AND BINDING AGREEMENT**

HMHEB and OIG agree as follows:

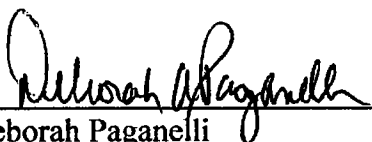
- A. This CCA shall be binding on the successors, assigns, and transferees of HMHEB;
- B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;
- C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;
- D. OIG may agree to a suspension of HMHEB's obligations under this CCA in

the event of HMHEB's cessation of participation in Federal health care programs. If HMHEB withdraws from participation in Federal health care programs and is relieved of its CCA obligations by OIG, HMHEB shall notify OIG at least 30 days in advance of HMHEB'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 CCA should be reactivated or modified.

E. The undersigned HMHEB signatory represents and warrants that he or she is authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.


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

**ON BEHALF OF HARRIS METHODIST H-E-B HOSPITAL**

  
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Deborah Paganelli  
President  
Harris Methodist H-E-B Hospital

11/05/2007  
DATE

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

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

12/5/07  
DATE

**DECLARATION**

The declarant is currently the President of Harris Methodist H-E-B Hospital ("HMHEB") and has personal knowledge of the facts stated herein. The following describes the compliance program currently in place at HMHEB (HMHEB Program). The HMHEB Program is jointly administered by HMHEB and Texas Health Resources (THR), the sole corporate member of HMHEB.

1. The annual budget for the HMHEB Program is attached hereto as Exhibit 1, and HMHEB shall sustain, at a minimum, the levels of funding reflected therein for three years subsequent to the Effective Date.

2. The HMHEB Program includes a Compliance Officer who is responsible for implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. The Compliance Officer also is responsible for monitoring the day-to-day compliance activities of HMHEB. The Compliance Officer is a member of senior management of HMHEB, is not subordinate to the General Counsel, and reports directly to THR's Chief Compliance Officer (THR's CCO). THR's CCO is a member of senior management and reports directly to THR's Chief Executive Officer and to its Board of Directors. The Compliance Officer makes quarterly reports regarding compliance matters directly to the Board of Trustees of HMHEB and is authorized to report on such matters to the Board of Trustees of HMHEB at any time.

3. The HMHEB Program includes a Compliance Committee that is chaired by the Compliance Officer and that is made up of other members of senior management necessary to support the Compliance Officer in fulfilling his/her responsibilities under the HMHEB Program (e.g., senior executives of relevant departments, such as billing, clinical, medical records, human resources, audit, and operations).

4. HMHEB has in place a Code of Conduct (presently known as the "THR Code of Business Ethics") that includes: (a) HMHEB'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) HMHEB's requirement that all of its personnel are expected to comply with all Federal health care program requirements and with the Policies and Procedures described in Paragraph 5 below; (c) the requirement that all of HMHEB's personnel are expected to report to the Compliance Officer or other appropriate individuals designated by HMHEB suspected violations of

any Federal health care program requirements or of Policies and Procedures applicable to HMHEB; (d) the possible consequences to both HMHEB and its personnel of failure to comply with Federal health care program requirements and with Policies and Procedures applicable to HMHEB and the failure to report such noncompliance; and (e) the right of HMHEB's personnel to use the Disclosure Program described in Paragraph 8 below and HMHEB's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures. Each (i) owner, officer, director, and employee; and (ii) contractor, subcontractor, or other agent who provides patient care (other than medical staff members) or who performs billing or coding functions on behalf of HMHEB is required to certify receipt of the Code of Conduct, and each employee must re-certify, at each performance evaluation date, that he or she is familiar with and will adhere to the Code of Conduct standards.<sup>1</sup> In addition, HMHEB distributes its Code of Conduct to all of its active medical staff and requests each of them to certify in writing that he or she has reviewed, read, and will abide by the Code of Conduct.

5. HMHEB has in place Policies and Procedures regarding the operation of the HMHEB Program and HMHEB's compliance with Federal health care program requirements, including Policies and Procedures regarding lease arrangements with physicians and other referral resources, physician recruitment, physician services agreements, and business courtesies provided to physicians. The Policies and Procedures are made available to all relevant HMHEB personnel. At least annually (and more frequently, if appropriate), HMHEB's policies and procedures are reviewed and updated as necessary by HMHEB and/or THR, and, if revisions are made, HMHEB makes available the relevant portions of any revised Policies and Procedures to all HMHEB personnel whose job functions relate to the revised Policies and Procedures.

6. HMHEB has in place an annual training program that requires all (i) owners, officers, directors, and employees; and (ii) contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of HMHEB to attend or participate in at least one hour of annual compliance training that addresses HMHEB's Code of Conduct and the operation of the HMHEB Program.<sup>2</sup> HMHEB will use its best efforts to encourage all of its medical staff

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<sup>1</sup> The Certification related to the Code of Conduct is not required for 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. Such individuals shall be required to make the appropriate certification at the point when they work more than 160 hours during the calendar year.

<sup>2</sup> Compliance training is not required for 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. Such individuals shall be required to receive the compliance training, however, at the point when they work more than 160 hours during the

to attend or participate in at least one hour of the annual compliance training described above. HMHEB's training program also requires additional hours of training for all employees, contractors, subcontractors, agents, and other persons who provide patient care items or services (other than medical staff members) or who perform billing, coding, or claims submission functions on behalf of HMHEB. Such additional training addresses, according to job function,: (a) the Federal health care program requirements regarding the accurate coding and submission of claims; (b) policies, procedures, and other requirements applicable to the documentation of medical records; (c) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (d) applicable reimbursement statutes, regulations, and program requirements and directives; (e) the legal sanctions for violations of Federal health care program requirements; (f) examples of proper and improper claims submission practices; and (g) compliance with the Stark Law and the Anti-Kickback Statute and related regulations. HMHEB maintains written or electronic records that identify the type of training provided, the date(s) of the training, and the attendees or participants. Persons providing or developing the training are knowledgeable about the subject area. HMHEB and/or THR reviews the training content on an annual basis and, as appropriate, updates the training to reflect changes in Federal health care program requirements and/or any issues discovered during the compliance audits described in Paragraph 7 below.

7. The HMHEB Program includes an audit program that requires periodic performance of internal and external audits and reviews to monitor HMHEB's compliance with Federal health care program requirements, including focused reviews relating to specific risk areas identified by the OIG and/or through the HMHEB Program. HMHEB utilizes the services of 5.5 full-time qualified THR employees who are assigned to review compliance with Federal health care program requirements. Compliance policies and procedures applicable to HMHEB require that any financial arrangement between HMHEB and any physician, including each physician lease arrangement, be set forth in writing, reviewed by THR's legal counsel for compliance with Federal health care program requirements prior to execution or renewal, and submitted to THR's System Compliance Department for posting into a physician contract database maintained by THR. A written support memorandum must be prepared for contracts with remuneration in excess of \$25,000. The support memorandum must clearly document the business purpose of the arrangement, the reasons for selection of a particular physician or group to provide the contracted service and the basis for determining that fair market value is being paid under the contract terms. Unless an exception is made by an authorized individual, a Services Agreement Certification must also be signed by the HMHEB official responsible for administering the agreement and provided to THR's System

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calendar year.

Compliance Department to certify that (a) the services to be provided under the contract do not exceed those reasonable and necessary to accomplish the contract's business purpose; (b) compensation is consistent with fair market value; (c) there are no unwritten arrangements relating to the agreement; and (d) procedures have been established to ensure that the required services are rendered prior to making any payment. In addition, a THR Check Request policy applicable to HMHEB requires HMHEB and the THR Corporate Accounts Payable Department to verify the existence of a current, written agreement before a disbursement is made to a physician.

HMHEB also utilizes a centralized real estate leasing and management system for real estate leasing arrangements involving physicians. All HMHEB real estate leasing and management activities for properties involving physicians are centralized under the control of the THR Real Estate Services Department. HMHEB's real estate leasing and management activities are subject to an annual compliance review process and are conducted pursuant to detailed leasing policies and procedures that are compliant with all applicable regulatory requirements, including requirements set forth in the Stark Law and the Anti-Kickback Statute and related regulations. HMHEB's president must certify on an annual basis that HMHEB is not a party to any real estate leasing arrangements that fall outside of this centralized process. Individuals responsible for real estate leasing and management of HMHEB properties receive periodic mandatory regulatory compliance training, which includes training concerning the Stark Law and the Anti-Kickback Statute and related regulations.

8. HMHEB maintains a Disclosure Program that includes a mechanism 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 HMHEB'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. HMHEB publicizes the existence of the disclosure mechanism to all personnel.

The Disclosure Program emphasizes a nonretribution, nonretaliation policy and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Each disclosure is reviewed by the Compliance Officer, who either investigates the disclosure or refers the disclosure to the relevant department or manager for follow up and any appropriate corrective action.

The Compliance Officer (or designee) maintains a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status



of the internal review of the question or allegation, and any corrective action taken in response to the internal review.

9. HMHEB has in place a policy and procedure for screening all prospective owners, officers, directors, employees, contractors, agents, and medical staff members to ensure that they are not Ineligible Persons<sup>3</sup> by: (a) requiring such persons to disclose whether they are an Ineligible Person; and (b) appropriately querying 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://oig.hhs.gov>) (these lists shall hereinafter be referred to as the "Exclusion Lists"). HMHEB also performs at least quarterly screening of its current owners, officers, employees, contractors, agents, and medical staff members against the Exclusion Lists and requires all owners, officers, directors, employees, contractors, agents, and medical staff members to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person. Directors are screened at least annually.

HMHEB also has a policy in place that, if HMHEB has actual notice that an owner, officer, director, employee, contractor, agent, or medical staff member has become an Ineligible Person, HMHEB will remove such person from responsibility for, or involvement with, HMHEB's business operations related to the Federal health care programs and will remove such person from any position for which the person's compensation or items or services furnished, ordered, or prescribed by the person are paid in whole or in 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. (Nothing in this Declaration affects the responsibility of HMHEB to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded individuals or HMHEB's liability for overpayments received by HMHEB as a result of billing any Federal health care program

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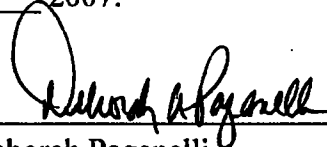
<sup>3</sup> An "Ineligible Person" is an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

for such items or services.).

The undersigned signatory represents and warrants that he/she is authorized to execute this declaration on behalf of HMHEB.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 05 day of November 2007.



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Deborah Paganelli  
President  
Harris Methodist H-E-B Hospital