CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ASHLAND HOSPITAL CORPORATION D/B/A
KINGS DAUGHTERS' MEDICAL CENTER

I. PREAMBLE.

Ashland Hospital Corporation d/b/a Kings Daughters' Medical Center ("Hospital") hereby agrees to enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") and to implement any reasonable and necessary policies, procedures, and practices to seek to ensure compliance 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") by Hospital, its employees, contractors, physicians with privileges, and other health care professionals, as well as all third parties which Hospital engages to act as billing or coding agents or consultants for Hospital. Hospital's compliance with the terms and conditions in this CIA shall constitute an element of Hospital's present responsibility with regard to participation in Federal health care programs. On or about this date, Hospital is entering into a settlement agreement with the United States and this CIA is incorporated by reference into that settlement agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Hospital under this CIA shall be three years and 30 days from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signature is obtained on the CIA.

III. CORPORATE INTEGRITY OBLIGATIONS

Hospital has established a compliance program. Hospital's compliance program either currently contains, or will contain within 90 days of the effective date of this CIA (unless otherwise specified), the following elements:

A. Compliance Officer and Compliance Committee

1. Compliance Officer. Hospital's Compliance Officer is and shall be responsible for developing and implementing policies, procedures, and practices designed to seek to ensure compliance with the requirements set forth in this CIA and with the requirements of all Federal health care programs. The Compliance Officer is and shall be a member of senior management of Hospital. The

Compliance Officer shall make regular (at least quarterly) reports regarding compliance matters directly to the Hospital's CEO and/or to the Board of Directors of Hospital and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Hospital 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, Hospital shall notify OIG, in writing within 15 days of such a change.

2. Compliance Committee. Hospital has appointed a Compliance Committee. 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 Hospital's corporate structure (e g., senior executives of each major department, such as billing, clinical, human resources, audit, 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. Hospital has established a Code of Conduct. The Code of Conduct shall be distributed to all employees, all contractors who provide services related to the delivery of health care or the preparation or submission of claims, reports, or requests for reimbursement to Federal health care programs, and all other individuals affected by them, including but not limited all physicians with privileges (hereinafter collectively referred to as the "covered individuals") within 90 days of the effective date of this CIA. Hospital 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. Hospital'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) or its agents;

b. the responsibility of all covered individuals to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Hospital's own policies and procedures (including the requirements of this CIA);

c. the responsibility of all covered individuals to report suspected violations of any statute, regulation, or guideline appli-

cable to Federal health care programs or with Hospital's own policies and procedures;

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

e. the right of all covered individuals to use the confidential disclosure program and Hospital's commitment to confidentiality and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, Hospital shall require all covered individuals to certify, in writing, that he or she has received, read, understands, and will abide by Hospital's Code of Conduct. New covered individuals shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or other relationship with Hospital or within 90 days of the effective date of the CIA, whichever is later. Hospital will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within 30 days of initiating such change. Covered individuals 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 90 days of the effective date of this CIA, Hospital shall develop and initiate implementation of written Policies and Procedures regarding the operation of Hospital'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. At a minimum, the Policies and Procedures shall specifically require that all diagnosis codes submitted for claims purposes to any Federal health care program be properly supported by documentation of the diagnosis by the treating physician in the patient's medical record. The Policies and Procedures shall require that all inpatient claims with a principal diagnosis codes of 482.83 or 482.89 (or any successors to these codes) intended for submission to Medicare shall first be subject to pre-billing review to ensure that the diagnosis code was properly assigned. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to Hospital management through the Confidential Disclosure Program required by section III.E. Hospital shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate employees,

contractors and physicians with responsibilities for assignment of codes for submission of claims to any Federal health care program. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education.

1. General Training. Within 120 days of the effective date of this CIA, Hospital shall provide at least two hours of training to each covered individual other than physicians. This requirement may be met by compliance plan training provided to covered individuals by Hospital during the 6 month period prior to the effective date of this CIA. Furthermore, this general training requirement shall not apply to third party contractors who:

a. are not members of Hospitals' Medical Staff;

b. are not engaged to provide reimbursement advice or services;

c. contractually agree to require their employees to certify that they have read, understand and will abide by the Hospital's Code of Conduct ; and

d. contractually agree to comply with the requirements of the Federal health care programs.

This general training shall explain Hospital's:

a. Corporate Integrity Agreement requirements;

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

c. Code of Conduct.

These training material shall be made available to OIG, upon request. New covered individuals shall receive the general training described above within 30 days of the beginning of their employment or relationship with Hospital or within 120 days after the effective date of this CIA, whichever is later. Each individual required to be trained under this provision shall receive such general training on an annual basis.

2. Specific Training. Within 120 days of the effective date of this CIA, each covered individual, other than members of Hospital's Medical Staff, who is involved directly or indirectly in the assignment of diagnosis or procedure codes for billing any Federal health care program shall receive at least five 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. New covered individuals with any responsibility for the preparation or submission of claims and/or the assignment of procedure codes shall receive this training within 30 days of the beginning of their employment or relationship with Hospital or within 120 days of the effective date of this CIA, whichever is later. Annually thereafter, Hospital shall require and provide three hours of the above described coding training to such individuals. If a new covered individual has any responsibility for the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Hospital employee who has completed this specific training shall review all of the untrained person's work regarding the preparation or submission of claims and/or the assignment of procedure codes.

3. Medical Staff Training. Within 120 days of the effective date of this CIA, each member of Hospital's Medical Staff (which includes all physicians with staff privileges at Hospital) shall be provided with two hours of training regarding the Compliance Program, the Corporate Integrity Agreement, the Code of Conduct, the necessity for submission of accurate bills for services rendered to Federal health care program patients and the policies, procedures and other requirements applicable thereto. This requirement may be met by compliance plan training provided by Hospital to members of the Hospital's Medical Staff during the 6 month period prior to the effective date of this CIA. Thereafter, Hospital shall provide such training on an annual basis.

4. Certification. Hospital shall require each employee, contractor, and physician with privileges who is required to attend training to 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. Hospital shall retain an entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review procedures to assist Hospital in assessing the adequacy of its billing and compliance practices pursuant to this CIA. The reviews will be done annually and cover each of the one-year periods beginning on the effective date of this CIA or the anniversary of that date. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Hospital seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within 90 days of the effective date of this CIA. The Independent Review Organization will conduct two separate engagements annually and will prepare a report of each of these engagements. One will be an analysis of Hospital's billing to the Federal health care programs to assist the Hospital and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether Hospital is in compliance with this CIA ("compliance engagement").

1. Billing Engagement. The billing engagement 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 the 12-month period covered by the engagement. 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, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% 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 full sample must be selected through random number sampling. To generate the random sample, Hospital 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 engagement and its corresponding report shall include the following components:

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

b. Billing Engagement Population: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.

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

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

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

The billing engagement report shall provide:

a. findings regarding Hospital'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 Hospital is submitting accurate claims and cost reports for services billed to the Federal health care programs.

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

d. findings regarding the accuracy of the coding hospital admissions involving a principal diagnosis of pneumonia; and

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

2. Compliance Engagement. An Independent Review Organization shall also conduct a compliance engagement that shall provide findings regarding whether Hospital's program, policies, procedures, and operations comply with the terms of this CIA. This report of the engagement shall provide section by section findings regarding the requirements of this CIA.

A complete copy of the Independent Review Organization's billing and compliance engagement reports shall be included in each of Hospital's Annual Reports to OIG.

3. Disclosure of Overpayments and Material Deficiencies. If, as a result of these engagements, Hospital or the Independent Review Organization

identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment, Hospital shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency or overpayment 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 deficiency from recurring. The notice to the payor shall include:

a. a statement that the refund is being made pursuant to this CIA;

b. a description of the complete circumstances surrounding the overpayment;

c. the methodology by which the overpayment was determined;

d. the amount of the overpayment;

e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);

f. the cost reporting period; and

g. the Hospital identification number under which the repayment is being made.

If Hospital determines an overpayment represents a material deficiency, contemporaneous with Hospital's notification to the payor as provided above, Hospital shall also notify OIG of:

a. a complete description of the material deficiency;

b. the amount of overpayment due to the material deficiency;

c. Hospital's action(s) to correct and prevent such material deficiency from recurring;

d. the payor's name, address, and contact person where the overpayment was sent;

e. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this CIA, an "overpayment" shall mean the amount of money the Hospital has received in excess of the amount due and payable under the

Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to a Federal health care program; or (ii) conduct or policies that clearly violate Federal health care program statutes, regulations, or program directives (e.g., for Medicare issuances by HCFA, fiscal intermediaries, and carriers). A material deficiency may be the result of an isolated event or a series of occurrences.

4. Verification/Validation. If Hospital's Billing Engagement Review or Compliance Engagement Review fails to conform to its obligations under the CIA or indicates improper billings not otherwise adequately addressed in the audit report, then the OIG (or a designated agent of the OIG) may conduct an independent review to determine whether or the extent to which Hospital is in compliance with its obligations under this CIA, and, in such event, Hospital agrees to pay the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program. Within 90 days after the effective date of this CIA, Hospital shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals 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 Hospital's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. Hospital shall publicize the existence of the Confidential Disclosure Program (e.g., for a hotline, email to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retributio n, nonretaliation 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, Hospital 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. Hospital shall retain all documents related to the review of disclosures and make such documents available to OIG upon request.

F. Ineligible Persons.

1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, 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 and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. Screening Requirements. Hospital shall not hire or engage as contractors or grant staff privilege to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Hospital 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://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/progorg/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. Review and Removal Requirement. Within ninety (90) days of the effective date of this CIA, Hospital will review its list of current employees, contractors, and physicians with staff privilege against the Exclusion Lists. Thereafter, Hospital will review the list once semi-annually. If Hospital has notice that an employee, agent, or physician has become an Ineligible Person, Hospital will remove such person from responsibility for, or involvement with, Hospital'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 Hospital has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with Hospital, within 10 days of receiving such notice Hospital will remove such individual from responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

G. Notification of Proceedings. Within 30 days of discovery, Hospital 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 Hospital has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. Hospital 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. Credible evidence of misconduct. If Hospital discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning Hospital's practices relating to the Federal health care programs, then Hospital shall promptly report the probable violation of law to OIG. Hospital shall make this disclosure as soon as practicable, but, not later than 30 days after becoming aware of the existence of the probable violation. The Hospital report to OIG shall include:

a. the findings concerning the probable violation, including the nature and extent of the probable violation;

b. Hospital's actions to correct such probable violation; and

c. any further steps it plans to take to address such probable violation and prevent it from recurring.

To the extent the misconduct involves an overpayment, the report shall include the information listed in section III.D.3 regarding material deficiencies.

2. Inappropriate Billing. If Hospital discovers inappropriate or incorrect billing through means other than the Independent Review Organization's engagement, the Hospital shall follow procedures in section III.D.3 regarding overpayments and material deficiencies.

IV. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the effective date of this CIA, Hospital 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 Hospital'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 employees, contractors, and physicians with privileges;

b. all employees, contractors, and physicians with privileges have completed the Code of Conduct certification required by section III.B.1 or a listing of those who have failed or refused to do so; and

c. all employees, contractors, and physicians with privileges have completed the training and executed the certification required by section III.C or a listing of those who have failed or refused to do so.

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. Hospital shall submit to OIG Annual Reports with respect to the status and findings of Hospital's compliance activities.

Each Annual Report 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 employees, contractors, and physicians with privileges have completed the annual Code of Conduct certification required by section III.B.1 or a listing of those who have failed or refused to do so; and

b. all employees, contractors, and physicians with privileges have completed the training and executed the certification required by section III.C or a listing of those who have failed or refused to do so.

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 Independent Review Organization's billing and compliance engagement reports, including a copy of the methodology used;

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

6. a summary of material deficiencies and reported throughout the course of the previous 12 months pursuant to III.D.3 and 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 Hospital as a result of the obligations in section III.F;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Hospital has committed a crime or has engaged in fraudulent activities, which 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 the probable violations of law identified in section III.H; and

12. a listing of all of Hospital'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 Hospital identification number(s) and the payor (specific contractor) that issued each Hospital identification number.

The first Annual Report shall be received by 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 that: (1) Hospital 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.

V. 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 to the entities listed below:

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

Hospital:

King's Daughters' Medical
Attn: Rick Lewis
2201 Lexington Avenue
P.O. Box 151

Ashland, Kentucky 41105-0151
Phone 606.327.4583
Fax 606.327.7532

VI. 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 Hospital's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Hospital's compliance with the terms of this CIA; and (b) Hospital's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Hospital 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 Hospital's employees, contractors, or physicians with privileges 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. Hospital agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. Hospital's employees may elect to be interviewed with or without a representative of Hospital present.

VII. DOCUMENT AND RECORD RETENTION

Hospital shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, for four years and 30 days (or longer if otherwise required by law).

VIII. DISCLOSURES

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

IX. BREACH AND DEFAULT PROVISIONS

Hospital is expected to comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to. Nothing in this CIA affects the rights of the OIG or the United States to exercise any criminal, civil, or administrative authority with respect to conduct of Hospital or others.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Hospital 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 $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days after the effective date of this CIA and concluding at the end of the term of this CIA, Hospital 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 $1,500 (which shall begin to accrue on the date after the date the obligation became due) for each day Hospital fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to OIG.

3. A Stipulated Penalty of $1,500 (which shall begin to accrue on the date the failure to comply began) for each day Hospital:

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 Hospital 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, contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Hospital'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 Hospital 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); or

c. employs or contracts with a person who (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after Hospital received notice of the relevant matter or after the resolution of the matter).

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

5. A Stipulated Penalty of $1,000 (which shall begin to accrue 10 days after the date that OIG provides notice to Hospital of the failure to comply) for each day Hospital fails to comply with any obligation of this CIA, and for which a Stipulated Penalty is not assessed pursuant to Section IX.A.1 though 4. In its notice to Hospital, OIG shall state the specific grounds for its determination that the Hospital has failed to comply with the CIA obligation(s) at issue. With respect to the Stipulated Penalty provision described in this section IX.A.5 only, the OIG shall not seek a Stipulated Penalty if Hospital demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) Hospital has begun to take action to cure the failure to comply, (ii) Hospital is pursuing such action with due diligence, and (iii) Hospital 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 Hospital has failed to comply with any of the obligations described in section IX.A and determining that Stipulated Penalties are appropriate, OIG shall notify Hospital by personal service or certified mail of (a) Hospital's failure to comply; and (b) 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 fifteen (15) days of the date of the Demand Letter, Hospital 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 IX.D. In the event Hospital elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Hospital cures, to OIG's satisfaction, the alleged breach in dispute. Hospital may cure the alleged

breach after requesting an ALJ hearing and continue to prosecute its appeal to the ALJ.. 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 IX.C.

2. Timely Written Requests for Extensions. Hospital 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 Hospital 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 two business days after Hospital 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 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 V.

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 OIG's determination that Hospital has materially breached this CIA, which decision shall be made at OIG's discretion and governed by the provisions in section IX.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 Hospital constitutes an independent basis for Hospital'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 Hospital has materially breached this CIA and that exclusion should be imposed, OIG shall notify Hospital by personal service or certified mail of (a) Hospital'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 Letter").

2. Opportunity to Cure. Hospital shall have 35 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to OIG's satisfaction that:

a. Hospital is in full compliance with this CIA;

b. the alleged material breach has been cured; or

c. the alleged material breach could not be cured within the 35 day period, but that: (i) Hospital has begun to take action to cure the material breach, (ii) Hospital is pursuing such action with due diligence, and (iii) Hospital has provided to OIG a reasonable timetable for curing the material breach.

3. Exclusion Letter. If at the conclusion of the 35-day period, Hospital fails to satisfy the requirements of section IX.C.2, OIG may exclude Hospital from participation in the Federal health care programs. OIG will notify Hospital in writing of its determination to exclude Hospital (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.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 Hospital is excluded under the provisions of this CIA, Hospital 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 Hospital to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D;

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

c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section IX.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 OIG's delivery to Hospital 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, Hospital shall be afforded the review rights hereinafter set forth. Specifically, 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 15 days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 30 days of the date 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 Hospital was in compliance with the obligations of this CIA for which OIG demands payment; (b) the period of noncompliance and (c) with respect to a stipulated penalty authorized under section IX.A.5 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) Hospital had begun to take action to cure the failure to comply, (ii) Hospital was and is pursuing such action with due diligence, and (iii) Hospital had provided to OIG a reasonable timetable for curing the material breach which is being followed. Hospital shall have the burden of proving its compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for OIG with regard to a finding of a breach of this CIA and orders Hospital to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision notwithstanding that Hospital may request review of the ALJ decision by the DAB.

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 ~~35~~ proceeding for exclusion based on a material breach of this CIA shall be (a) whether Hospital was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not be cured within the 35-day period, but that by the end of that period (i) Hospital had begun to take action to cure the material breach, (ii) Hospital was and is pursuing such action with due diligence, and (iii) Hospital had provided to OIG a reasonable timetable for curing the material breach which is being followed. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to OIG. Hospital's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Hospital upon the issuance of the ALJ's decision. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 30 days after the ALJ issues such a decision, notwithstanding that Hospital may request review of the ALJ decision by the DAB.

X. 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, Hospital and OIG agree as follows:

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

B. This CIA shall become final and binding on the execution date, which is 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 Hospital 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 ASHLAND HOSPITAL CORPORATION
D/B/A KINGS DAUGHTERS' MEDICAL CENTER

Fred Jackson
Chief Executive Officer
Ashland Hospital Corporation
d/b/a Kings Daughters' Medical Center

11/99
DATE

Larry Casher, Esq.
Wyatt, Tarrant and Combs
Counsel to Ashland Hospital Corporation
d/b/a Kings Daughters' Medical Center

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

11/26/99
DATE

ON BEHALF OF ASHLAND HOSPITAL CORPORATION
D/B/A KINGS DAUGHTERS' MEDICAL CENTER

Fred Jackson
Chief Executive Officer
Ashland Hospital Corporation
d/b/a Kings Daughters' Medical Center

11/16/99
DATE

Larry Casher, Esq.
Wyatt, Tarrant and Combs
Counsel to Ashland Hospital Corporation
d/b/a Kings Daughters' Medical Center

11/29/99
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

11/26/99
DATE