# CORPORATE INTEGRITY AGREEMENT
## BETWEEN THE
## OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
## AND
## KAPI'OLANI HEALTH

## I. PREAMBLE

Kapi'olani Health ("KH") hereby agrees to enter into this Corporate Integrity Agreement (the "CIA") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to ensure compliance by its subsidiaries which either participate as providers of services or who administrates benefits to the Federal health care programs, physicians with staff privileges, employees, contractors and third parties with whom KH may choose to engage to act as billing or coding agents or consultants for KH (hereinafter collectively referred to as "covered individuals"), 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"). KH's compliance with the terms and conditions in this CIA shall constitute an element of KH's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, KH is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Home Care Hawaii, ("HCH"), one of KH's subsidiaries that participates in the Federal health care programs, shall not be subject to this CIA since KH has represented to OIG that it is in the process of divesting itself of its interest in HCH. However, HCH shall become subject to this CIA if KH fails to divest itself of its interest in HCH by December 20, 1999.

Prior to the execution of this CIA, KH voluntarily established a compliance program ("Compliance Program"), which provides for corporate integrity policies and procedures and which, as represented by KH, is aimed at ensuring that its participation in the Federal health care programs is in conformity with the statutes, regulations, and other directives applicable to the Federal health care programs. Therefore, pursuant to this CIA, KH hereby agrees to maintain in full operation the Compliance Program for the term of this CIA. The Compliance Program may be modified by KH as appropriate, but



EXHIBIT A

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at a minimum, shall always comply with the integrity obligations enumerated in this CIA.

## II. TERM OF THE CIA

Except as otherwise provided, the period of compliance obligations assumed by KH under this CIA shall be five (5) years from the date of execution of this CIA. The date of execution will be the date of the final signature on the CIA.

## III. CORPORATE INTEGRITY OBLIGATIONS

Pursuant to this CIA, and for the term of this CIA, KH will make the following integrity obligations permanent features of its Compliance Program, which shall be established in accordance with the provisions below:

### A. Corporate Compliance Officer and Committee

1. *Compliance Officer.* KH has represented to OIG that, pursuant to its Compliance Program, it has created a Compliance Officer position, a Compliance Manager position, a Compliance Specialist position and Compliance Network Representatives. Accordingly, KH shall formally maintain the appointment of individuals to serve as the Compliance Officer, Compliance Manager, Compliance Specialist and Compliance Network Representatives. At a minimum, the Compliance Officer must continuously be charged with the responsibility for the day-to-day compliance activities in furtherance of the integrity obligations assumed herein, as well as for any reporting obligations established under this CIA. The Compliance Officer must report directly to the Chief Executive Officer ("CEO") of KH and shall have unrestricted access to the Board of Directors of KH. The Compliance Officer shall be a member of the management and shall make regular (at least quarterly) reports regarding compliance matters directly to KH's CEO and/or to the Board of Directors of KH. When the identity of the Compliance Officer changes, KH shall notify the OIG, in writing, within 15 days of such change.

2. *Compliance Committee.* KH has represented to OIG that, pursuant to its Compliance Program, it has created a Compliance Committee. Accordingly, KH shall formally maintain a Compliance Committee, which shall be responsible for, at a minimum, compliance with the integrity obligations in this CIA. KH shall ensure that the Compliance Committee is continuously composed of representatives of multiple disciplines and segments of KH's operations. At a



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minimum, the Compliance Committee shall include the following KH employees: Compliance Officer, Chief Financial Officer, Vice President of Human Resources, Director of Risk Management, Vice President of Compliance and Revenue Management, Compliance Manager, Director of Internal Audits, Chief Medical Officer of Kapi'olani Medical Specialists, and Vice-President of Hospital Operations for Kapi'olani Medical Center for Women and Children ("KMCWC") and Kapi'olani Medical Center at Pali Momi ("KMCPM"). The Compliance Officer shall report directly to the CEO at least on a monthly basis. The Compliance Committee will support the Compliance Officer in fulfilling his/her responsibilities. The names and positions of the Compliance Committee members shall be included in the Implementation Report.

## B. Written Standards

KH has represented to OIG that, pursuant to its Compliance Program, it has created a written Code of Conduct as well as written Policies and Procedures regarding the operations of KH's Compliance Program in a booklet titled "Standards of Business Conduct, A Guide for Kapi'olani Health Employees." Accordingly, KH shall formally maintain the written Code of Conduct and Policies and Procedures regarding the operation of KH's Compliance Program with the following minimum requirements.

1. *Code of Conduct.* The Code of Conduct shall be distributed to all covered individuals within ninety (90) days of the effective date of this CIA. KH shall make the promotion of, and adherence to, the Code of Conduct an element in the performance of managers, supervisors, and all other covered individuals. The Code of Conduct shall, at a minimum, set forth:

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

b. KH's requirement that all covered individuals shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with KH's own policies and



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procedures (including the requirements of this CIA);

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

d. the possible consequences to both KH and to any covered individual of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with KH'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, as well as KH's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, each covered individual shall certify, in writing, that he or she has received, read, understands, and will abide by KH'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 contract or within ninety (90) days of the effective date of the CIA, whichever is later.

KH will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a 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.* At a minimum, the Polices and Procedures shall address compliance with all Federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. In addition to other requirements as determined by the Board of Directors, the Policies and Procedures shall specifically address what types of services and items can be reimbursed by the Federal health care programs. Also, KH shall formally maintain its written Policies and Procedures that include disciplinary guidelines and methods for covered individuals to make disclosures or otherwise report on compliance issues to KH's management through the Confidential Disclosure Program required by section III.E. KH shall assess and



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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 ninety (90) days of the effective date of the CIA, KH shall distribute any changes to its Policies and Procedures to all appropriate covered individuals whose positions are impacted by the changes. Compliance staff or supervisors should be available to explain any and all Policies and Procedures.

C. **Training and Education**

KH has represented to OIG that, pursuant to its Compliance Program, it has conducted a systems-wide training program for its employees. KH shall formally maintain the annual compliance training and education of its employees. Pursuant to this CIA, general training and education must meet the provisions of section III.C.1 for all covered individuals of KH. However, specific training and education, subject to the provisions of section III.C.2, shall be required only at the following KH subsidiaries: (i) KMCWC; (ii) KMCPM; and (iii) Kapi'olani Medical Specialists ("KMS").

1. *General Training*. Within ninety (90) days of the effective date of this CIA, KH shall provide at least one (1) hour of training annually to each covered individual (excluding any physician who is not an employee of KH). General training shall still be made available to physicians who are not employees of KH and attendance logs of training by such physicians shall be maintained by KH and made available to the OIG upon request. This general training shall explain:

a. CIA requirements;

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

c. Code of Conduct.

These training materials (including attendance logs) shall be maintained by KH and made available to the OIG upon request.

New covered individuals shall receive the general training described above within



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30 days of the beginning of their employment or within 90 days after the execution of this CIA, whichever is later.

2. *Specific Training.* Within ninety (90) days of the effective date of this CIA, each covered individual (excluding any physician who is not an employee of KH) of KMCWC, KMCPM, and KMS who is involved directly or indirectly in the delivery of patient care and/or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care program shall receive at least four (4) hours of training in addition to the general training required above. Specific training shall still be made available to physicians who are not employees of KH and attendance logs of training by such physicians shall be maintained by KH and made available to the OIG upon request. Specific training shall include a discussion of:

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

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

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

d. applicable reimbursement rules and statutes;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

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

Affected new covered individuals shall receive this training within thirty (30) days of the beginning of their employment or within ninety (90) days of the effective date of this CIA, whichever is later. If a new covered individual has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a KH covered individual who has completed the substantive training shall review all of the untrained person's work regarding the assignment of billing



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codes.

Each year, every pertinent covered individual shall receive such specific training on an annual basis.

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

**D. Review Procedures**

KH has represented to OIG that, pursuant to its Compliance Program, it has retained an independent review organization (the "Independent Review Organization"), such as an accounting firm or consulting firm, with expertise in the reimbursement and billing requirements of the Federal health care programs, to review and audit on an annual basis the billing policies, procedures and practices of KH to verify that KH's submissions for reimbursement comply with all applicable Federal health care program statutes, regulations, program and carrier directives and to identify any and all instances where claims fail to meet these standards. Pursuant to this CIA, the review and audit shall be an annual requirement covering a twelve (12) month period for the following subsidiaries of KH: (i) KMCWC; (ii) KMCPM; and (iii) KMS. During the duration of this CIA if there are substantial modifications to the Federal health care programs reimbursement system, the OIG may require KH to incorporate new criteria into the Review Procedures described hereinafter.

The Independent Review Organization will conduct two separate engagements annually. One will be an analysis of KH's billing to the Federal health care programs to assist KH and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether KH 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 for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample shall generate an estimate with a ninety (90) percent confidence level and a precision of twenty-five (25)



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percent (i.e., the upper and lower bounds of the confidence interval shall not exceed 125% and shall not be lower than 75% of the median of the confidence interval, respectively). The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the full sample must be selected through random numbers. The Independent Review Organization 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 analysis shall include the following components in its methodology:

a. Billing Engagement Objective: A statement stating clearly 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 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 audits shall provide at a minimum:

a. findings regarding KH'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 KH is submitting accurate claims and cost reports for services billed to Medicare, Medicaid, and other Federal health



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care programs;

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

d. findings regarding the steps KH 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 KH's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section by section findings regarding the requirements of this CIA.

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

*3. Verification/Validation.* In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which KH is complying with its obligations under this CIA, KH agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

**E. Confidential Disclosure Program**

KH has represented to OIG that, pursuant to its Compliance Program, it has created a Confidential Disclosure Program ("CDP"), which includes a toll-free compliance telephone line whereby each call is reported in a confidential disclosure log. Accordingly, KH shall maintain its CDP which must include measures to enable covered individuals to disclose, to the Compliance Committee and/or Compliance Officer, or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with KH's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. KH shall also publicize the existence of its hotline (e.g., e-mail to covered individuals or post hotline number in prominent common areas).

KH's CDP shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, KH's Compliance Officer shall gather information in



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such a way as to elicit all relevant information from individuals reporting alleged misconduct. The Compliance Officer and/or Compliance Committee shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that it has obtained all of the information necessary to determine whether a further review should be conducted. Moreover, KH shall, as part of its CDP, require the internal review of any disclosure that is sufficiently specific so that it reasonably: (i) permits a determination of the appropriateness of the alleged improper practice; and (ii) permits corrective action to be taken and ensures that proper follow-up is conducted.

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

**F. Ineligible Persons**

KH has represented to OIG that, pursuant to its Compliance Program, it has implemented a practice whereby KH shall not employ or contract with, with or without pay, any individual or entity that is listed by a federal agency as excluded, suspended, or otherwise ineligible for participation in federal programs (hereinafter "Ineligible Person Policy"). KH shall formally maintain this policy. At a minimum, KH's Ineligible Person Policy shall include the following requirements:

*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.* KH shall not hire or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, KH 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 OIG List of Excluded Individuals/Entities



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(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, KH will review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, KH will review the list once semi-annually. If KH has notice that an employee, agent, or physician has become an Ineligible Person, KH will remove such person from responsibility for, or involvement with, KH'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 KH 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 KH, within 10 days of receiving such notice KH will remove such individual from responsibility for, or involvement with KH'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 thirty (30) days of discovery, KH 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 KH has committed a crime or has engaged in fraudulent activities or any other knowing misconduct related to a Federal or non-Federal health care program. The 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. KH shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings.

## H. Reporting

1. *Reporting of Overpayments.* If, at any time, KH identifies or learns of



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any billing, coding or other policies, procedures and/or practices that result in an overpayment, KH shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within thirty (30) days of discovering the overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. If the overpayment is discovered as the result of any of the activities required by this CIA, 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 provider identification number under which the repayment is being made; and

g. the cost reporting period.

2. *Reporting of Material Deficiencies*. If KH determines that there is a material deficiency, KH shall notify the OIG within 30 days of discovering the material deficiency. If the material deficiency results in an overpayment, the report to the OIG shall be made at the same time as the report to the payor and shall include all of the information required by section III.H.1 plus: (i) the payor's name, address, and contact person where the overpayment was sent; and (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid. Regardless of whether the material deficiency resulted in an overpayment, the report to the OIG shall include:

a. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;



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b. KH's actions to correct the material deficiency; and

c. any further steps KH plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money the provider 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.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" means anything that involves: (i) a substantial overpayment or improper payment relating to any Federal health care program; (ii) a material violation of any Federal health care program statutes, regulations, or directives issued by relevant regulatory agencies, e.g., HCFA, or their agents (for example, such a violation would be established by credible evidence of misconduct from any source that KH, after reasonable inquiry, has reason to believe may violate criminal, civil, or administrative law related to any Federal health care program); or (iii) the provision of items or services of a quality that materially fails to meet professionally recognized standards of health care. A material deficiency may be the result of an isolated event or a series of occurrences.

## IV. NEW LOCATIONS

In the event that KH purchases or establishes new business units after the effective date of this CIA, KH shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation, phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor-specific) that has issued each provider number. All covered individuals at such locations shall be subject to the requirements in this CIA that apply to new covered individuals (e.g., completing certifications).

## V. IMPLEMENTATION AND ANNUAL REPORTS

### A. Implementation Report

Within one hundred and twenty (120) days after the effective date of this CIA, KH shall submit a written report to the OIG summarizing the status of implementation of the requirements of this CIA. This report, known as the



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"Implementation Report," shall be sent to the address set forth in section VI of this CIA. The Implementation Report shall include:

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

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

3. a copy of KH'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.2 have been developed, are being implemented, and have been distributed to all pertinent covered individuals;

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

   c. all covered individuals have completed the training and executed the certification required by section III.C.

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

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

9. a description of any personnel action (other than hiring) taken by KH as a result of the obligations in section III.F; and

10. a listing of the number of physicians who are not employees of KH and



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the percentage of these physicians who completed the general and specific training requirements described in section III.C (please list a separate ratio for both general and specific training).

**B. Annual Report**

Thereafter, KH shall submit to the OIG an Annual Report, with respect to the status and findings of KH's compliance activities.

The Annual Reports shall include:

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

2. a certification by the Compliance Officer that:

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

   b. all pertinent covered individuals have completed the training and executed the certification required by section III.C.

3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagement, including a copy of the methodology used.

5. KH'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 twelve (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



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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 KH 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 KH 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;

12. a listing of all of KH's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number; and

13. a listing of the number of physicians who are not employees of KH and the percentage of these physicians who completed the general and specific training requirements described in section III.C (please list a separate ratio for both general and specific training).

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

**C. Certifications**

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) KH is in compliance



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with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

## VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under the terms of 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
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

All correspondence to Kapi'olani Health shall be sent to:

Kapi'olani Health
Attention: General Counsel (Legal Department)
55 Merchant St.
Honolulu, Hawaii 96813
Phone 808.535.7400
Fax 808.535.7433

## VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this CIA, OIG or its duly authorized representative(s) or agents may examine KH's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) KH's compliance with the terms of this CIA; and (ii) KH's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by KH to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or



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reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any covered individual who consents to be interviewed at the covered individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the covered individual and OIG. KH agrees to assist OIG in contacting and arranging interviews with such covered individuals upon OIG's request. Covered individuals may elect to be interviewed with or without a representative of KH or counsel present.

## VIII. DOCUMENT AND RECORD RETENTION

KH shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if required by law).

## IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify KH prior to any release by OIG of information submitted by KH pursuant to its obligations under this CIA and identified upon submission by KH as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. KH 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.

## X. BREACH AND DEFAULT PROVISIONS

KH is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

### A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days after the effective date of this CIA and concluding at the end of the term of this CIA, KH fails to have in place any of the following:



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a. a Compliance Officer;

b. a Compliance Committee;

c. written Code of Conduct;

d. written Policies and Procedures;

d. an education and training program; and

e. a Confidential Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day KH fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

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

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 KH can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);

b. employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, KH'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 KH can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in



MR

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, KH'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 KH 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 that KH fails to grant reasonable access) for each day KH fails to grant reasonable access to the information or documentation necessary to exercise OIG's inspection, audit and review rights set forth in section VII of this CIA.

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to KH of the failure to comply) for each day KH fails to comply fully and adequately with any obligation of this CIA other than those specifically mentioned in paragraphs (1) through (4) of this section X.A. In its notice to KH, the OIG shall state the specific grounds for its determination that KH has failed to comply fully and adequately with the CIA obligation(s) at issue.

**B. Payment of Stipulated Penalties**

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

Within fifteen (15) days of the date of the Demand Letter, KH shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event KH elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until KH cures, to

the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions.* KH 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 KH fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after KH receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that KH has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

## C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by KH constitutes an independent basis for KH'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 KH has materially breached this CIA and that exclusion should be imposed, the OIG shall notify KH by certified mail of (a) KH'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").



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2. *Opportunity to cure.* KH shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. KH is in full compliance with this CIA;

b. the alleged material breach has been cured; or

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

3. *Exclusion Letter.* If at the conclusion of the thirty-five (35) day period, KH fails to satisfy the requirements of section X.C.2, OIG may exclude KH from participation in the Federal health care programs. OIG will notify KH in writing of its determination to exclude KH (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (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 KH is excluded under the provisions of this CIA, KH 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 KH 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 X.A of this CIA;

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

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



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## D. DISPUTE RESOLUTION

1. *Review Rights.* Upon the OIG's delivery to KH 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, KH shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (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 KH was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. KH shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders KH to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that KH 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 proceeding for exclusion based on a material breach of this CIA shall be (a) whether KH was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the thirty-five (35) day period, but that (i) KH has begun to take action to cure the material breach, (ii) KH is pursuing such action with due diligence, and (iii) KH has provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. KH's election of its contractual right



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to appeal to the DAB shall not abrogate the OIG's authority to exclude KH upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that KH may request review of the ALJ decision by the DAB.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and KH agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

## XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

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

D. The undersigned KH 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.



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IN WITNESS WHEREOF, the parties hereto affix their signatures:

**KAPI'OLANI HEALTH**

8/18/99
Date

Roger Drue
President and Chief Executive Officer
Kapi'olani Health

8.18.99
Date

Dennis M. Warren, Esquire
Counsel for Kapi'olani Health
(916) 447-9999

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

8/13/99
Date

Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services



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# AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND KAPI'OLANI HEALTH

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Kapi'olani Health ("KH") entered into a Corporate Integrity Agreement ("CIA") on August 18, 1999.

A. Pursuant to section XI.C. of KH's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and KH. Therefore, the OIG and KH hereby agree that KH's CIA will be amended as follows:

Section III.D., Review Procedures of the CIA is hereby superceded by the attached new section III.D., Review Procedures.

The attached Appendix A is hereby added to KH's CIA.

B. The OIG and KH agree that all other sections of KH's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and KH.

C. The undersigned KH signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

**ON BEHALF OF KAPI'OLANI HEALTH**

Roger Drue
President and Chief Executive Officer
Hawaii Pacific Health[1]

9/18/02
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

9/1/02
DATE

[1] Kapi'olani Health, Straub Clinic and Hospital and Wilcox Health System merged on December 23, 2001, and are under a parent corporation named Hawaii Pacific Health.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, KH shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist KH in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by KH shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which KH seeks reimbursement. Each IRO shall assess, along with KH, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze KH's billing and coding to the Federal health care programs ("Claims Review"), and shall analyze KH's compliance with the obligations assumed under the this CIA and the Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first three years of the CIA shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA.

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

2. *Claims Review*. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 150 Federal health care program Paid Claims behalf of KH. The 150 claims shall include a review of 50 claims each for the following KH subsidiaries: (i) KMCWC, (ii) KMCPM, and (iii) KMS. The Paid Claims shall be reviewed based on the supporting documentation available at KH or under KH's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, KH should, as appropriate, further analyze any errors identified in the Discovery Sample. KH recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at KH or under KH's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the

Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, KH may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from KH to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If KH's Discovery Sample identifies an Error Rate of 5% or greater, KH's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to KH the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, KH agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. KH agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Compliance Review.* The IRO shall conduct a review of KH's compliance activities. The Compliance Review shall consist of a review of KH's compliance with the obligations set forth in each section of this CIA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding KH's compliance with the terms of each section of the CIA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) KH's Claims Review or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). KH agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after KH's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify KH of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, KH may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. KH agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with KH prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to KH a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and Compliance Review and that it has concluded that it is, in fact, independent.

# APPENDIX A

## A. Claims Review.

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

a. Overpayment: The amount of money KH has received in excess of the amount due and payable under any Federal health care program requirements.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by KH and for which KH has received reimbursement from the a Federal health care program.

d. Population: All Items for which KH has submitted a code or line item and for which KH has received reimbursement from the a Federal health care program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which KH cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by KH for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

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

1. **Claims Review Methodology.**

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

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

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

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

e. Source of Data. A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Statistical Sampling Documentation.**

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

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

a. Narrative Results.

i. A description of KH's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by KH ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to KH.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Systems Review**. Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

5. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.