CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES,

AND

CATHOLIC HEALTHCARE WEST;

MERCY HEALTHCARE SACRAMENTO; MERCY SAN JUAN HOSPITAL; MERCY GENERAL HOSPITAL; MERCY AMERICAN RIVER HOSPITAL; WOODLAND MEMORIAL HOSPITAL; METHODIST HOSPITAL OF SACRAMENTO; MERCY HOSPITAL OF FOLSOM; WOODLAND HEALTHCARE; WOODLAND CLINIC MEDICAL GROUP; AND MEDCLINIC

I. <u>Introduction</u>

A. Preamble.

Catholic Healthcare West ("CHW"), Mercy Healthcare Sacramento ("MHS"), Mercy San Juan Hospital, Mercy General Hospital, Mercy American River Hospital and Mercy Hospital of Folsom (MHS and these four hospitals are collectively referred to as the "Kimball Affiliates") and Woodland Memorial Hospital, Methodist Hospital of Sacramento, Woodland Healthcare, Woodland Clinic Medical Group, and "MedClinic", a term used to characterize the combined operations of the Medical Clinic of Sacramento, Inc. and Catholic Healthcare West Medical Foundation (these six entities are collectively referred to as "Non-Kimball Affiliates") hereby enter into this Corporate Integrity Agreement ("CIA"), including the corresponding Attachments A and B, with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements") by its officers, directors, employees, contractors and agents. The Kimball Affiliates and the Non-Kimball Affiliates are collectively referred to hereinafter as "Affiliates."

Contemporaneously with this CIA, the Kimball Affiliates are entering into a Settlement Agreement with the United States to resolve the allegations asserted in the qui tam action United States ex rel. Joseph A. Kimball v. Catholic Healthcare West et al., (the

"Kimball Settlement Agreement") and this CIA is incorporated by reference into the Kimball Settlement Agreement.

This CIA and its corresponding Attachments A and B supercede the CIA dated August 1, 2001 along with its corresponding Attachments A and B. The terms and conditions of Appendix 1 to this CIA dated August 1, 2001 remain in effect for Non-Kimball Affiliates.

B. Release.

In consideration of the obligations of CHW and the Affiliates with the exception of Mercy American River Hospital in the CIA dated August 1, 2001 and the obligations in the United States ex rel. Arlan Boyd v. Mercy Health Care Systems and United States ex rel. George Baca v. Catholic Healthcare West et al. Settlement Agreements (the "Baca and Boyd Agreements", respectively, and collectively with the Kimball Settlement Agreement, are hereinafter referred to as the "Agreements"), conditioned upon the payment in full of the Settlement Amounts required by the Baca and Boyd Agreements, and subject to the provisions of the Baca and Boyd Agreements concerning bankruptcy proceedings commenced within 91 days of any payment under the Baca and Boyd Agreements, the OIG-HHS agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion) against CHW or the Hospitals for the Covered Conduct as defined in the Boyd Agreement and against CHW or Clinics for the Covered Conduct as defined in the Baca Agreement (except as reserved in Paragraph 3 of the Boyd Agreement and Paragraph 5 of the Baca Agreement respectively, and as reserved in this Paragraph). Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 of the Boyd Agreement and Paragraph 5 of the Baca Agreement, respectively.

II. TERM OF THE CIA AND DEFINITIONS

A. <u>Term</u>. The CIA and Attachments shall be effective, and the compliance obligations assumed by CHW and each of the Affiliates shall begin, as of the date specified in each respective Attachment.

- B. <u>Definitions</u>. For purposes of this CIA, the following terms have the following meanings.
- 1. Covered Person shall mean (a) any CHW officer or director; (b) any officer, director, or employee of the Affiliates; or (c) any agent or other individual who furnishes, markets or documents health care items or services to any Federal health care program beneficiary at a facility owned or operated by an Affiliate for which any of the Affiliates claim reimbursement from any Federal health care program. Notwithstanding the above, this term does not include part-time or per diem employees, agents or other individuals who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point in which they have worked more than 160 hours during the calendar year.
- 2. Covered Contractor shall mean any agent or other individual (who is not a Covered Person) who participates in the process of preparing claims, cost reports or other requests for reimbursement from any Federal health care program on behalf of an Affiliate on a regular basis of more than 160 hours per calendar year.
- 3. *CHW* shall mean a California non-profit public benefit corporation in the business of operating health care service organizations. The term does not include any hospitals, divisions or other entities that are a part of or are affiliated with CHW unless otherwise specified.

III. CORE INTEGRITY OBLIGATIONS

CHW has represented to OIG that prior to entering into this CIA, CHW and the Affiliates have instituted a compliance program that substantially conforms to the terms of the CIA as set forth below. CHW and Affiliates hereby agree to maintain a Compliance Program that includes the following elements:

A. Compliance Officers and Committee.

1. Corporate Compliance Officer. CHW has represented to OIG that it has appointed an individual to serve as its Corporate Compliance Officer. The Compliance Officer is responsible for overseeing compliance with the requirements set forth in this CIA and with Federal health care program requirements and ensuring adherence to any reporting obligations created under this CIA. The Compliance Officer is a member of

senior management of CHW, will make periodic (at least quarterly) reports regarding compliance matters directly to the Audit and Compliance Oversight Committee of the CHW Board of Directors, and is authorized to report on such matters to the CHW Board of Directors at any time.

Any changes in the identity of the Corporate Compliance Officer, or any actions or changes that would materially affect the Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

- 2. Assistants to the Corporate Compliance Officer. CHW has represented to OIG that in addition to the appointment of a Corporate Compliance Officer, it will appoint other senior level management and Compliance Department personnel ("Assistants") to assist the Corporate Compliance Officer with monitoring Affiliates to ensure that Affiliates implement policies, procedures and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. These Assistants to the Corporate Compliance Officer shall participate in the CHW Compliance Oversight Committee meetings.
- 3. CHW Compliance Oversight Committee. CHW has represented to OIG that it has established a CHW Compliance Oversight Committee. The CHW Compliance Oversight Committee includes, at a minimum, the Corporate Compliance Officer, the Assistants, and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major and pertinent department, such as cost reporting, billing, clinical, human resources, audit, and operations). The Corporate Compliance Officer chairs the CHW Compliance Oversight Committee and the Committee supports the Corporate Compliance Officer, Assistants, and Compliance Department in fulfilling their responsibilities (e.g., assists in the analysis of the organization's risk areas and oversees monitoring of the Integrity Program).

Any changes in the composition of the CHW Compliance Oversight Committee, or any other actions or changes that would materially affect the CHW Compliance Oversight Committee's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

B. Standards of Conduct.

1. Written Standards. To the extent not already accomplished within 90 days after the Non-Kimball Affiliates Effective Date of this CIA, CHW and the Affiliates will distribute the revised Standards of Conduct to (i) all existing Covered Persons within 90 days of the Kimball Affiliates Effective Date, and (ii) to all new Covered Persons within 30 days after such person becomes a Covered Person. Additionally, to the extent not already accomplished within 90 days after the Non-Kimball Affiliates Effective Date of this CIA, within 90 days of the Kimball Affiliates Effective Date, each Covered Person shall certify, in writing, that he or she has received CHW's Standards of Conduct and understands that they represent mandatory policies of CHW. New Covered Persons shall receive the Standards of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Kimball Affiliates Effective Date, whichever is later.

CHW and Affiliates shall make the promotion of, and adherence to, the Standards of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Standards of Conduct shall at all times set forth, at a minimum:

- a. CHW's commitment to full compliance with all Federal health care program requirements;
- b. CHW's requirement that all Covered Persons are expected to comply with all Federal health care program requirements and with CHW's own Policies and Procedures as implemented pursuant to Section III.B and Attachments A and B as applicable (including the requirements of this CIA);
- c. the requirement that all Covered Persons shall be expected to report to appropriate personnel in CHW or the Affiliates suspected violations of any Federal health care program requirements or of CHW's own Policies and Procedures;
- d. the possible consequences to CHW, Affiliates and Covered Persons of failure to comply with all Federal health care program requirements and with CHW's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.C, and CHW's and Affiliates' commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

CHW shall annually review the Standards of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Standards of Conduct shall be distributed within 90 days of finalizing such changes. Covered Persons shall certify that they have received and understand the revised Standards of Conduct within 30 days of the distribution of such revisions.

2. Covered Contractor Requirements. CHW shall use its best efforts to include in all new and renewing contracts language requiring that a Covered Contractor: (a) agree to abide by CHW's Standards of Conduct or adopt its own Standards of Conduct substantially similar to CHW's Standards of Conduct; (b) distribute either (i) CHW's Standards of Conduct or (ii) its Standards of Conduct and information about CHW's Disclosure Program (including the Hotline number); and (c) certify to CHW that employees working on CHW matters have received a copy of (i) CHW's Standards of Conduct or (ii) its Standards of Conduct and information about CHW's Disclosure Program (including the Hotline number).

CHW shall use reasonable efforts to obtain the written documentation requested in this Section III.B.2 from each new Covered Contractor within 30 days after commencing work for CHW or within 120 days after the Kimball Affiliates Effective Date, whichever is later.

The Compliance Officer (or his or her designee) shall retain: (1) the written documentation from each Covered Contractor and (2) a list of Covered Contractors who satisfy the requirements of III.B.2. This documentation shall be made available to OIG, upon request.

C. Disclosure Program.

CHW has represented to the OIG that it has established and shall maintain a Disclosure Program, which includes a toll-free CHW Hotline to enable individuals to disclose, to a person who is not in the disclosing individual's chain of command, any potential or suspected violations associated with CHW's Standards of Conduct, practices,

or procedures. CHW shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program emphasizes a non-retribution, non-retaliation policy, and includes a reporting mechanism for anonymous communications. Upon receipt of a disclosure, the designated personnel shall gather all relevant information from the disclosing individual. The designated personnel 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, CHW shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

A designated person or persons shall maintain a disclosure log for all disclosures received by the designated person or persons that relate to: (i) Federal health care programs; or (ii) allegations of abuse or neglect of patients. The disclosure log shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. CHW shall include with the Annual report a copy of the disclosure log entries for Affiliates that relate to (i) Federal health care programs or (ii) allegations of abuse or neglect of patients.

D. Ineligible Persons.

- 1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred or otherwise declared ineligible.
- 2. Screening Requirements. CHW and Affiliates shall not hire as employees or engage as Covered Contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, CHW and Affiliates shall screen all prospective

employees and prospective Covered Contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) CHW and Affiliates to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Review and Removal Requirement. To the extent not already accomplished within 90 days after the Non-Kimball Affiliates Effective Date, within 90 days of the Kimball Affiliates Effective Date of this CIA and corresponding Attachment, CHW and Affiliates shall review their lists of current employees and Covered Contractors against the Exclusion Lists. Thereafter, CHW and Affiliates shall review their lists of current employees and Covered Contractors against the Exclusion Lists on an annual basis. In addition, CHW and Affiliates shall require employees and contractors (both Covered Contractors and all other contractors) in contracts negotiated after the Kimball Affiliates Effective Date to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If CHW and Affiliates receive notice that an employee or contractor has become an Ineligible Person, Affiliates shall remove such person from responsibility for, or involvement with, Affiliates' business operations related to 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 Affiliates receive notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Affiliates shall take all appropriate actions to ensure that the responsibilities of that employee or contractor shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

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

E. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, CHW and Affiliates 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 CHW and Affiliates have committed a crime or have engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. CHW and Affiliates 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.

F. Reporting.

Unless the subject of an ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that CHW or Affiliates have committed a crime or have engaged in fraudulent activities and that was reported in accordance with Section III.E., the following matters shall be reported to the party or parties identified below.

1. Overpayments

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Affiliates have received in excess of the amount due and payable under any Federal health care program requirements. Affiliates may not subtract any

underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, Affiliates identify or learn of any overpayments, Affiliates shall (i) notify the payor (e.g., Medicare fiscal intermediary or carrier), and (2) repay the overpayment to the appropriate payor to the extent such overpayment has been quantified, within 30 days of identification of the overpayment. If, however, the overpayment is not yet quantified within 30 days of the identification, Affiliates shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. In addition, within 60 days of identification of the overpayment (or such additional time as may be agreed to by the payor), Affiliates shall take remedial steps to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the CMS policies.

Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Material Deficiencies.

- a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:
 - (i) a substantial overpayment; or
 - (ii) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

- b. Reporting of Material Deficiencies. If Affiliates determine through any means that there is a Material Deficiency, Affiliates shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:
 - (i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.F.1, and shall include all of the information on the CMS Voluntary Refund Form, as well as:
 - (A) the payor's name, address, and contact person to whom the overpayment was sent; and
 - (B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;
 - (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - (iii) a description of Affiliates' actions taken to correct the Material Deficiency; and
 - (iv) any further steps Affiliates plan to take to address the Material Deficiency and prevent it from recurring.

IV. SPECIFIC INTEGRITY OBLIGATIONS

Attachments A and B to this CIA address the following Specific Integrity Obligations: Policies and Procedures; Training and Education; and Review Procedures. In addition to the Core Integrity Obligations described above, Affiliates also agree to

comply with the Specific Integrity Obligations described in Attachments A and B that apply to them as follows:

Attachment A applies to: Mercy Healthcare Sacramento, Mercy San Juan Hospital, Mercy General Hospital, Mercy Hospital of Folsom, Mercy American River Hospital, Woodland Memorial Hospital and Methodist Hospital of Sacramento.

Attachment B applies to: Mercy Healthcare Sacramento; Woodland Healthcare; Woodland Clinic Medical Group; and MedClinic.

V. <u>New Business Units or Locations</u>

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

VI. ANNUAL REPORTS

Affiliates shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Affiliates' compliance activities for each of the periods covered by this CIA. Affiliates may submit a joint Annual Report. The first period shall run from August 1, 2001 through June 30, 2002. (The period covered by each Annual Report shall be referred to as "the Reporting Period"). The second period shall run from July 1, 2002 through June 30, 2003. The third period for the Non-Kimball Affiliates shall run from July 1, 2003 through three years from the Effective Date of this CIA and the third period for the Kimball Affiliates shall run from July 1, 2003 through June 30, 2004. The fourth period shall run from July 1, 2004 through June 30, 2005. The fifth period shall run from July 1, 2005 through June 30, 2006. The Non-Kimball Affiliates are not obligated under the terms of this CIA to submit an Annual Report for the fourth or fifth periods.

Each Annual Report shall include:

- 1. the name, address, phone number, position description, and summary of other non-compliance job responsibilities of the Corporate Compliance Officer and his/her Assistants required by Section III.A;
- 2. the names and positions of the members of the CHW Compliance Committee required by Section III.A;
- 3. a copy of CHW's Standards of Conduct required by Section III.B.1;
- 4. a copy of all compliance-related Policies and Procedures and all other Policies and Procedures required by Section IV.A of Attachments A and B that have not been previously provided to OIG;
- 5. a copy of all training materials used for the training required by Section IV.B of Attachments A and B, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
- 6. a certification by the Corporate Compliance Officer or applicable Assistants that:
 - a. all Covered Persons have completed any Standards of Conduct certifications required by Section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed their respective certification(s) required by Section IV.B of Attachment A and B; and
 - c. CHW and Affiliates have complied with their respective obligations under the Agreements: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Agreements, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Agreements); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

- 7. a certification from the IRO regarding its professional independence from CHW and Affiliates;
- 8. a summary/description of all engagements between CHW, Affiliates and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;
- 9. a complete copy of all reports prepared pursuant to the IRO's billing engagement, cost report review, systems review and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
- 10. Affiliates' response and corrective action plan(s) related to any issues raised by the IRO(s);
- 11. a summary of Material Deficiencies (as defined in III.F) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 12. a report of the aggregate overpayments that have been returned to the Federal health care programs by Affiliates. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
- 13. a summary of the disclosures in the disclosure log required by Section III.C that relate to Affiliates and that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 14. a description of any personnel actions (other than hiring) taken by Affiliates as a result of the obligations in Section III.D, and the name, title, and responsibilities of any person that falls within the ambit of Section III.D.4, and the actions taken in response to the obligations set forth in that section;

- 15. a summary describing any ongoing investigation or legal proceeding required to have been reported by Affiliates pursuant to Section III.E. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 16. a list of all of Affiliates' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number;
- 17. to the extent not already furnished to OIG, or if modified, a description of CHW's and Affiliates' organization structures, including identification of any parent and sister companies, Affiliates, divisions and their respective lines of business; and
- 18. a certification by the Corporate Compliance Officer that: (a) except as otherwise described in the applicable report, CHW and Affiliates are in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (b) the Corporate Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

The first Annual Report shall be received by the OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than 90 days following the end of such subsequent Reporting Period.

C. <u>Designation of Information</u>: CHW and Affiliates shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. CHW and Affiliates shall attempt to refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

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

Fax: (415) 591-2324

CHW:

Daniel R. Roach Vice President & Corporate Compliance Officer Catholic Healthcare West 1700 Montgomery Street, Suite 300 San Francisco, CA 94111 Phone: (415) 438-5579

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

VIII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Affiliates' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Affiliates' locations for the purpose of verifying and evaluating: (a)

CHW's or Affiliates' compliance with the terms of this CIA; and (b) Affiliates' compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by CHW or Affiliates 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 employees, contractors, or agents of the Affiliates 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. CHW and the Affiliates agree to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Notwithstanding such agreement, OIG recognizes that employees have the right to refuse to submit to interviews, and CHW and the Affiliates shall not be · obligated to require their employees to submit to interviews. In those instances where CHW or one of the Affiliates is involved in ongoing litigation with the United States, or is under a government investigation manifested by the issuance of a subpoena, Civil Investigative Demand, Authorized Investigative Demand, or other formal civil or criminal request from HHS or any other Government agency for records at the Affiliates, CHW retains the discretion (in accordance with the law) to prevent interviews sought pursuant to this paragraph of officer or employees of those Affiliates. Subject to the above, employees of the Affiliates may elect to be interviewed with or without a representative of CHW or the Affiliates present.

IX. DOCUMENT AND RECORD RETENTION

In addition to any other requirements for record retention, CHW and Affiliates shall maintain for inspection all documents and records: (1) related to reimbursement from the Federal health care programs for at least 5 years after the submission of the request for reimbursement (or longer if otherwise required by law); and (2) necessary to establishing CHW and Affiliates' compliance with this CIA for at least 3 years following the submission of the Annual Report for that particular year.

X. <u>DISCLOSURES</u>

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify CHW or Affiliates prior to any release by OIG of information submitted by CHW or Affiliates pursuant to its obligations under this CIA and identified upon submission by CHW or Affiliates as trade secrets, or information that

is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, CHW and Affiliates shall have the rights set forth at 45 C.F.R. § 5.65(d). CHW and Affiliates shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

XI. BREACH AND DEFAULT PROVISIONS

CHW and Affiliates are expected to fully and timely comply with all of their respective CIA obligations.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, CHW, Affiliates 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 CHW or Affiliates, as applicable, fail to have in place any of their respective obligations described in Section III and Attachments A and B:
 - a. a Corporate Compliance Officer;
 - b. a CHW Compliance Committee;
 - c. written Standards of Conduct;
 - d. written Policies and Procedures;
 - e. a requirement that Covered Persons be trained; and
 - f. a 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 Affiliates fail to meet any of the deadlines for the submission of the Annual Reports to OIG.

- 3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Affiliates employ or contract with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Affiliates' 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 (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Affiliates can demonstrate that they did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.D) as to the status of the person).
- 4. A Stipulated Penalty of \$1,500 for each day CHW or Affiliates fail to grant access to the information or documentation as required in Section VIII of this CIA. (This Stipulated Penalty shall begin to accrue on the date CHW or Affiliates fail to grant access.)
- 5. A Stipulated Penalty of \$1,000 for each day CHW or Affiliates, as applicable, fail to comply fully and adequately with any of their respective obligations of this CIA. In its notice to CHW or Affiliates, OIG shall state the specific grounds for its determination that CHW or Affiliates have failed to comply fully and adequately with the CIA obligation(s) at issue and steps CHW or Affiliates must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to CHW or Affiliates of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-4 of this section.
- B. <u>Timely Written Requests for Extensions</u>. CHW or Affiliates may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after CHW or Affiliates fail to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after CHW or Affiliates receive OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in

writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

- 1. Demand Letter. Upon a finding that CHW or Affiliates have failed to comply with any of the obligations described in Section XI.A and after determining that Stipulated Penalties are appropriate, OIG shall notify CHW or Affiliates of: (a) CHW or Affiliates'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").
- 2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, CHW or Affiliates 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 XI.E. In the event CHW or Affiliates elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CHW or Affiliates cure, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section XI.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VII.
- 4. Independence from Material Breach Determination. Except as set forth in Section XI.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that CHW or Affiliates have materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section XI.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. a failure by Affiliates to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.F;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section XI.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section XI.C; or
- d. a failure to retain and use an Independent Review Organization in accordance with Section IV.D of Attachment A and Section IV.C of Attachment B.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by CHW or Affiliates constitutes an independent basis for CHW or Affiliates's exclusion from participation in the Federal health care programs of the party in breach, whether CHW or one or more Affiliates. Upon a determination by OIG that CHW or an Affiliate has materially breached this CIA and that exclusion should be imposed, OIG shall notify CHW or the Affiliate of: (a) CHW or the Affiliates's Material Breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").
- 3. Opportunity to Cure. CHW or Affiliates shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
 - a. CHW or Affiliates are in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) CHW or Affiliates have begun to take action to cure the material breach; (ii) CHW or Affiliates are pursuing such

action with due diligence; and (iii) CHW or Affiliates have provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, CHW or Affiliates fail to satisfy the requirements of Section XI.D.3, OIG may exclude the entity in breach from participation in the Federal health care programs. OIG will notify CHW or Affiliates in writing of its determination to exclude the party in breach (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, CHW or Affiliates wish to apply for reinstatement, CHW or Affiliates must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

- 1. Review Rights. Upon OIG's delivery to CHW or Affiliates of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, CHW or Affiliates shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether CHW or Affiliates were in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. CHW or Affiliates shall have the burden of proving their full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a

finding of a breach of this CIA and orders CHW or Affiliates to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless CHW or Affiliates request review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:
 - a. whether CHW or Affiliates were in material breach of this CIA;
 - b. whether such breach was continuing on the date of the Exclusion Letter; and
 - c. whether the alleged material breach could not have been cured within the 30 day period, but that:
 - (i) CHW or Affiliates had begun to take action to cure the material breach within that period;
 - (ii) CHW or Affiliates have pursued and are pursuing such action with due diligence; and
 - (iii) CHW or Affiliates provided to OIG within that period a reasonable timetable for curing the material breach and CHW or Affiliates have followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the CHW or Affiliates, only after a DAB decision in favor of OIG. CHW's or Affiliates' election of their contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude CHW or Affiliates upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that CHW or Affiliates may request review of the ALJ decision by the DAB. If the DAB finds in

favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. CHW or Affiliates agree to waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

XII. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Agreements pursuant to which this CIA is entered, and into which this CIA is incorporated, CHW, Affiliates and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of CHW and Affiliates;
- B. This CIA and its corresponding Attachment shall become final and binding on the date the final signature is obtained on the relevant Attachment;
- C. Any modifications to this CIA or Attachments shall be made with the prior written consent of the parties to this CIA and Attachments;
- D. OIG may agree to a suspension of CHW's or Affiliates' obligations under the CIA and Attachments in the event of CHW's or Affiliates' cessation of participation in Federal health care programs. If CHW or Affiliates withdraw from participation in Federal health care programs and are relieved from its CIA obligations by the OIG, CHW or Affiliates agree to notify OIG 30 days in advance of CHW's or Affiliates' intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA and corresponding Attachment should be reactivated or modified.
- E. The undersigned CHW and Affiliates signatories represent and warrant that they are authorized to execute this CIA and relevant Attachments. The undersigned OIG signatory represents that he is signing this CIA and the relevant Attachments in his official capacity and that he is authorized to execute this CIA and Attachments.

ON BEHALF OF CATHOLIC HEALTRCARE WEST;

MERCY HEALTHCARE SACRAMENTO; MERCY SAN JUAN HOSPITAL; MERCY GENERAL HOSPITAL; MERCY AMERICAN RIVER HOSPITAL; WOODLAND MEMORIAL HOSPITAL; METHODIST HOSPITAL OF SACRAMENTO; MERCY HOSPITAL OF FOLSOM; WOODLAND HEALTHCARE; WOODLAND CLINIC MEDICAL GROUP; AND MEDICLINIC

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Woodland Healthcare			

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On Behalf of Catholic Healthcare West;

Mercy Healthcare Sacradento; Mercy San Juan Hospital; Mercy General Hospital; Mercy American River Hospital; Woodland Memorial Hospital; Methodist Hospital of Sacramento; Mercy Hospital of Folsom; Woodland Healthcare; Woodland Clinic Medical Group; and Medclinic

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THOMAS W. ORMISTON, M.D. Woodland Clinic Medical Group

JOHN W. YOUNG, M.D.

President

The Medical Group of Secremento, Inc.

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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

Catholic Healthcare West Corporate Integrity Agreement June 2002

ATTACHMENT A TO THE

CATHOLIC HEALTHCARE WEST CORPORATE INTEGRITY AGREEMENT

IV. SPECIFIC INTEGRITY OBLIGATIONS

Mercy Healthcare Sacramento, Mercy San Juan Hospital, Mercy General Hospital, Mercy Hospital of Folsom, Mercy American River Hospital, Woodland Memorial Hospital and Methodist Hospital of Sacramento (collectively referred to as "Hospitals") agree to the Specific Integrity Obligations contained in this Attachment A to the CIA:

The period of the compliance obligations assumed by (i) CHW and Woodland Memorial Hospital and Methodist Hospital of Sacramento under this Attachment and the corresponding CIA shall be 3 years from August 1, 2001 (the "Non-Kimball Affiliates Effective Date"), and (ii) CHW, Mercy Healthcare Sacramento, Mercy San Juan Hospital, Mercy General Hospital, Mercy American River Hospital and Mercy Hospital of Folsom shall be 4 years and 2 months from June 1, 2002 (the "Kimball Affiliates Effective Date", collectively, with the Non-Kimball Affiliates Effective Date, are referred to as the "Effective Date").

Sections VIII, IX, X, XI and XII of the CIA shall remain in effect until OIG has completed its review of the final Annual Report and any additional materials submitted by CHW pursuant to OIG's request.

A. Policies and Procedures.

To the extent not already accomplished within 90 days after the Non-Kimball Affiliates Effective Date of the CIA, within 90 days after the Kimball Affiliates Effective Date of the CIA Hospitals shall implement written Policies and Procedures regarding the operation of Hospitals' compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the procedures for the proper and accurate preparation of cost reports, including the proper reporting of contingent liabilities, reserves, and adjustments to such reports submitted to any Federal health care program by or on behalf of Hospitals;
- b. the procedures for proper and timely refunding of any

overpayments (as defined in Section III.F.1.a.) received from a Federal health care program by Hospitals;

- c. the commitment of CHW and Hospitals to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, bulletins, newsletters, or other correspondence from the Fiscal Intermediary related to Federal health care program requirements;
- d. the Disclosure Program as described in Section III.C; and
- e. the review and removal of Ineligible Persons as described in Section III.D.

To the extent not already accomplished within 90 days after the Non-Kimball Affiliates Effective Date, within 90 days after the Kimball Affiliates Effective Date of this CIA and Attachment, the Hospitals shall distribute the relevant portions of the Policies and Procedures to all Covered Persons whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), the Hospitals shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures.

B. Training and Education.

- 1. General Training. To the extent not already accomplished within 90 days after the Non-Kimball Affiliates Effective Date of the CIA, within 90 days after the Kimball Affiliates Effective Date of this CIA and Attachment, Hospitals shall provide appropriate general training to each Covered Person. This training, at a minimum, shall explain the CHW and Hospitals':
 - a. CIA and Attachment requirements; and
 - b. Compliance Program (including the Standards of Conduct and the Policies and Procedures as they pertain to general compliance

issues).

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the Kimball Affiliates Effective Date of this CIA and Attachment, whichever is later. After receiving the initial training described above, each Covered Person shall receive general training on the minimum required topics annually.

- 2. Specific Training. To the extent not already accomplished 90 days after the Non-Kimball Affiliates Effective Date, within 90 days after the Kimball Affiliates Effective Date of this CIA and Attachment, each Covered Person who is involved in the preparation or submission of cost reports or claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive specific training in addition to the general training required above. This specific training shall include a discussion of:
 - a. the submission of proper and accurate cost reports to Federal health care programs;
 - b. the proper and accurate characterization of contingent liabilities, reserves and adjustments to Federal health care program cost reports;
 - c. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
 - d. the proper and timely refunding of overpayments received from Federal health care programs;
 - e. the personal obligation of each individual involved in the cost reporting, billing, or refunding/reconciliation process to ensure that such cost reports, billings, or refunds are accurate;
 - f. applicable reimbursement statutes, regulations, and program requirements and directives;
 - g. the legal sanctions for submission of improper cost reports or billings, or the failure to appropriately and timely refund overpayments received from Federal health care programs; and

h. examples of proper and improper cost reporting and billing practices.

Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days after the Kimball Affiliates Effective Date of this CIA and Attachment, whichever is later. An employee at any of the Hospitals who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of cost reports or claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive specific training on the minimum required topics annually.

- 3. Certification. Each Covered Person who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Department personnel (or their designee) shall retain the certifications, along with all course materials. The certifications shall be made available to OIG, upon request. The course materials shall be provided to OIG with the Annual Report.
- 4. Covered Contractor Requirements. CHW and Hospitals shall require a Covered Contractor to: (a) agree to provide Specific Training on the topics outlined in Section B.2 of this Attachment to employees working on CHW or Hospital matters; and (b) certify to CHW and Hospitals that all relevant employees have received such training.

C. Review Procedures.

- 1. General Description.
 - a. Retention of Independent Review Organization. Within 90 days after the Effective Date of this CIA, CHW and the Hospitals 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 the Hospitals in assessing and evaluating its billing, cost reporting practices and certain compliance

obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by CHW and the Hospitals shall have expertise in the billing, cost 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 CHW and the Hospitals seek reimbursement. Each IRO shall assess, along with CHW and the Hospitals, 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 Hospitals' cost reporting practices that involve the Federal health care programs ("Systems Review") and shall analyze whether Hospitals sought payment for certain unallowable costs ("Unallowable Cost Review").

- b. <u>Frequency of Systems Review</u>. The Systems Review shall be performed for the reporting period of the CIA covering July 1, 2002 through June 30, 2003. The IRO(s) shall perform all components of the Systems Review.
- c. Frequency of Unallowable Cost Review. The Unallowable Cost Review shall be performed by the IRO for the reporting period of the CIA covering July 1, 2002 through June 30, 2003; provided, however, if an IRO previously completed an Unallowable Cost Review of the Boyd Settlement Agreement, the IRO is only obligated to perform an Unallowable Cost Review that relates to compliance with the Unallowable Cost provisions of the Kimball Agreement.
- d. <u>Retention of Records</u>. The IRO and CHW 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 CHW and the Hospitals related to the reviews).
- 2. Systems Review. The IRO shall review the Hospitals' cost report preparation process (the "Systems Review"). The Systems Review shall consist of a thorough review of (i) Hospitals' cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs, and (ii) CHW's home office cost statement, information statement

and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps CHW and the Hospitals take to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

- 3. Systems Review Report. The IRO shall prepare a report based upon the Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:
 - a. the strengths and weaknesses in (i) Hospitals' cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs, and (ii) CHW's home office cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs; and
 - b. any recommendations the IRO may have to improve any of these systems, operations, and processes.
- 4. Pre-Submission Cost Report Review. CHW and Hospitals have represented to OIG that the Medicare and Medicaid cost reports prepared by the Covered Contractors or by Hospitals are reviewed by an Independent Review Organization ("IRO") prior to submission to the Federal health care programs. CHW and Hospitals agree that they will continue to have the Hospitals' Medicare and Medicaid cost reports reviewed by an IRO prior to submission to the Federal health care programs for the duration of this CIA.
- 5. IRO Certification. The Hospitals shall include with each Annual Report submission a certification or sworn affidavit from the IRO stating that it reviewed Hospitals Medicare and Medicaid cost reports prior to submission to the respective programs and that the cost reports appeared to meet the Medicare and Medicaid cost reporting requirements.
- 6. Unallowable Cost Review. Subject to the limitations specified under Section IV.C.1.c. herein, the IRO shall conduct a review of the Hospitals' compliance with the unallowable cost provisions of the <u>Boyd</u> and <u>Kimball</u> Agreements. The IRO shall determine whether CHW and the Hospitals have complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs

(as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the Hospitals or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the <u>Boyd</u> and <u>Kimball</u> Settlement Agreements were executed, as well as from previous years.

- 5. Unallowable Cost Review Report. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include: the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether the Hospitals' have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Agreements) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.
- 6. Validation Review. In the event the OIG has reason to believe that: (a) the Systems Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Systems Review or Unallowable Cost Review complied with the requirements of the CIA ("Validation Review"). The Hospitals agree 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 the Hospitals' final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify CHW and the Hospitals 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, CHW and/or the Hospitals may request a meeting with the OIG to discuss the results of the Systems Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Systems Review or Unallowable Cost Review to correct the inaccuracy of the Systems Review; and/or propose alternatives to the proposed Validation Review. CHW and the Hospitals agree 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 Systems Review or

Unallowable Cost Review with CHW and the Hospitals 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 CHW and the Hospitals a certification or sworn affidavit that it has evaluated its professional independence with regard to the Systems Review or Unallowable Cost Review and that it has concluded that it was, in fact, independent.

ROM. LATHAM & WATKINS 519-696-7419

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MERCY HEALTHCASE SACRAMENTO; MERCY SAN JUAN HOSPITAL; MERCY GENERAL HOSPITAL; MERCY AMERICAN RIVER HOSPITAL; WOODLAND MEMORIAL HOSPITAL; METHODIST HOSPITAL OF SACRAMENTO; AND MERCY HOSPITAL OF FOLSOM

DATE: JUNE 3. Chref Brecutive Officer/President Catholic Healthcare West WILLIAM HUNT Chief Executive Officer Mercy Healthcare Sacramento, on behalf of itself and Mercy San Juan Hospital, Mercy General Hospital, Mercy American River Hospital and Mercy Hospital of Folsom DENNY POWELL Vice President & Chief Operating Officer Methodist Hospital of Sacramento DATE MARGARET CLEARY Chief Operating Officer Woodland Memorial Hospital

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Latham & Waikins
Counsel for CHW and Hospitals

DATE: 6/3/02

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

ATTACHMENT B TO THE

CATHOLIC HEALTHCARE WEST CORPORATE INTEGRITY AGREEMENT

IV. SPECIFIC INTEGRITY OBLIGATIONS

The following Affiliates agree to institute the Specific Integrity Obligations contained in this Attachment B to the CIA: Mercy Healthcare Sacramento, Woodland Healthcare, Woodland Clinic Medical Group and MedClinic (hereinafter collectively referred to as "Clinics").

The period of the compliance obligations assumed by Clinics under this Attachment and corresponding CIA shall be 3 years from August 1, 2001.

Sections VIII, IX, X, XI and XII of the CIA shall remain in effect until OIG has completed its review of the final Annual Report and any additional materials submitted by CHW or Clinics pursuant to OIG's request.

A. Policies and Procedures.

If Clinics have not already done so, within 90 days of the Effective Date of this CIA and Attachment B, Clinics shall implement written Policies and Procedures regarding the operation of Clinics' compliance programs and their compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the procedures for the proper and accurate coding, preparation and submission of claims in accordance with Federal health care program requirements;
- b. the proper documentation of services and billing information and the retention of such information in a readily retrievable form;
- c. the procedures for proper and timely refunding of any overpayments (as defined in Section III.F.1.a.) received from a Federal health care program by Clinics;
- d. the commitment of Clinics to remain current with all Federal

health care program requirements by obtaining and reviewing program memoranda, bulletins, newsletters, or other correspondence from the Fiscal Intermediary related to Federal health care program requirements;

- e. the Disclosure Program as described in Section III.C; and
- f. the review and removal of Ineligible Persons as described in Section III.D.

If Clinics have not already done so, within 90 days of the Effective Date of the CIA and Attachment, Clinics shall distribute the relevant portions of the Policies and Procedures to all Covered Persons whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Clinics shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures.

B. Training and Education.

- 1. General Training. If Clinics have not already done so, within 90 days of the Effective Date of this CIA and Attachment, Clinics shall provide general training to each Covered Person. This training, at a minimum, shall explain Clinics':
 - a. CIA and Attachment requirements; and
 - b. Compliance Program (including the Standards of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the Effective Date of this CIA and Attachment, whichever is later. After receiving the initial training described above, each Covered Person shall receive general training on the minimum required topics annually.

- 2. Specific Training. Within 90 days of the Effective Date of this CIA and Attachment, each Covered Person who is involved in the documentation, coding, preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive specific training in addition to the general training required above. This specific training shall include a discussion of:
 - a. the submission of proper and accurate claims to Federal health care programs;
 - b. the proper and accurate documentation of services rendered to Federal health care program beneficiaries;
 - c. the proper and accurate coding of services billed to Federal health care programs;
 - d. the proper and timely refunding of overpayments received from Federal health care programs;
 - e. the personal obligation of each individual involved in the billing, claims or refunding/reconciliation process to ensure that such billings, claims or refunds are accurate;
 - f. applicable reimbursement statutes, regulations, and program requirements and directives;
 - g. the legal sanctions for submission of improper billings, or the failure to appropriately and timely refund overpayments received from Federal health care programs; and
 - h. examples of proper and improper billing practices.

Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the Effective Date of this CIA and Attachment, whichever is later. An employee of any of the Clinics who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or

submission of cost reports or claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive specific training on the minimum required topics annually.

- 3. Certification. Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Department personnel (or their designee) shall retain the certifications, along with all course materials. The certifications shall be made available to OIG, upon request. The course materials shall be provided to OIG with the Annual Report.
- 4. Covered Contractor Requirements. CHW and Clinics shall require a Covered Contractor to: (a) agree to provide Specific Training on the topics outlined in Section A.2 of this Attachment to employees working on CHW or Clinic matters; and (b) certify to CHW and Clinics that all relevant employees have received such training.

C. Review Procedures.

1. General Description.

a. Retention of Independent Review Organization. Clinics shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Clinics in assessing and evaluating their billing and coding practices and their compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by Clinics shall have expertise in the billing, coding 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 Clinics seek reimbursement. Each IRO shall assess, along with Clinics, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

- b. Types of Engagements. The Billing Engagement shall be conducted by the CHW Internal Audit Department ("CHW IAD"), or an outside vendor, and verified by the IRO. Alternatively, the Billing Engagement may be performed by the IRO. The Billing Engagement shall address Clinics' billing and coding to Medicare and Medicaid. The Compliance Engagement shall be conducted by the IRO and shall address Clinics' compliance with the obligations assumed under this CIA, Attachment B and the Settlement Agreement.
- c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the Reporting Periods. The Compliance Engagement shall be performed by the IRO for the first Reporting Period.
- d. Retention of Records. The CHW IAD, the IRO and Clinics shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the CHW IAD, IRO and/or Clinics) related to the engagements.
- 2. Billing Engagement. The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review."
 - a. Claims Review. The CHW IAD (or an IRO or outside vendor) shall perform a Claims Review to identify any overpayments through a variable appraisal of Paid Claims submitted by Clinics to the Medicare and Medicaid programs. The Claims Review shall be performed in accordance with the procedures set forth in Appendix 1 to this CIA.
 - b. Claims Review Report. CHW IAD and the IRO (or if performed by the outside vendor, the outside vendor) shall each prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix 1 to this CIA.
 - c. Systems Review. CHW IAD (or an outside vendor) shall review

Clinics' billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

- i. Clinics' billing systems and/or operations relating to claims submitted to Medicare and Medicaid (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and
- ii. Clinics' coding systems and/or operations relating to claims submitted to Medicare and Medicaid (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding); and
- d. Systems Review Report. CHW IAD (or the outside vendor) shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include CHW IAD's (or the outside vendor's) findings and supporting rationale regarding:
 - i. the strengths and weaknesses in Clinics' billing systems and/or operations;
 - ii. the strengths and weaknesses in Clinics' coding systems and/or operations; and
 - iii. any recommendations CHW IAD (or the outside vendor) may have to improve any of these systems, operations, and processes.

3. Compliance Engagement.

a. Compliance Review. The IRO shall conduct a review of Clinics' compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Clinics' adherence to the obligations set forth in Sections I through VIII of this CIA and Attachment B, and a review of Clinics' compliance with certain

provisions of the Settlement Agreement

- i. CIA Obligations Review. The IRO shall assess and evaluate Clinics' compliance with the obligations set forth in Sections I through VIII of this CIA and Attachment B.
- ii. Unallowable Costs Review. The IRO shall determine whether Clinics have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Clinics or any of their subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which of the Settlement Agreement was executed, as well as from previous years.
- b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:
 - i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Clinics' compliance with the terms of Sections I through VIII of the CIA and Attachment B, as applicable; and
 - ii. the IRO's findings and supporting rationale regarding whether Clinics have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement

Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

4. Validation Review. In the event the OIG has reason to believe that: (a) Clinics' Billing or Compliance Engagement fails to conform to the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Clinics agree 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 the final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Clinics of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Clinics may request a meeting with the OIG to discuss the results of any Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Clinics agree 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 Billing or Compliance Engagement and/or Claims Review issues with Clinics 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.

5. Independence Certification. Within 90 days from the Effective Date of this CIA, the IRO shall provide to Clinics a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in Clinics' Annual Report submission.

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Woodland Clinic Medical Group

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

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APPENDIX 1

A. Claims Review.

- 1. **Definitions**. For the purposes of the Claims Review, the following definitions shall be used:
 - a. <u>Claims Review Sample</u>: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, practitioner, code, line item, beneficiary, patient encounter, etc.).
 - c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.F.1.a of the CIA, the amount of money Clinics have received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, Clinics shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.
 - d. <u>Paid Claim</u>: A code or line item submitted by Clinics and for which Clinics have received reimbursement from the Medicare and Medicaid programs.
 - e. <u>Population</u>: All Items for which Clinics have submitted a code or line item and for which Clinics have received reimbursement from the Medicare and Medicaid programs (<u>i.e.</u>, 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.
 - f. <u>RAT-STATS</u>: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".
- 2. Description of CHW IAD Claims Review.
 - a. Size of Claims Review Sample. CHW IAD shall randomly select 35%

of the practitioners per Clinic, per year for review. CHW IAD shall review no less than 30 randomly selected Items for each practitioner selected (the Claims Review Sample). The random samples of practitioners and random samples of Items shall be drawn using RAT-STATS.

- b. <u>Item Appraisal</u>. For each of the 30 or more randomly selected Items appraised per practitioner, only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by CHW IAD to determine whether the Paid Claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.
- c. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Clinics cannot produce documentation to support the Paid Claim shall be considered an error and the total reimbursement received by Clinics for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- d. <u>Use of First Samples Drawn</u>. For the purposes of all samples discussed in this Appendix, the first sample (or first sample for each strata, if applicable) generated shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Claims Review Sample.

3. Description of IRO Claims Review Verification

- a. <u>Size of Claims Review Sample</u>. The IRO shall randomly select 20% of the Items previously reviewed by CHW IAD in its Claims Review Sample. The random sample of Items shall be drawn using RAT-STATS.
- b. <u>Item Appraisal</u>. For each Item appraised, only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Verification Report.

- c. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Clinics cannot produce documentation to support the Paid Claim shall be considered an error and the total reimbursement received by Clinics for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- d. <u>Use of First Samples Drawn</u>. For the purposes of all samples discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Claims Review Sample.
- **B.** <u>CHW IAD Claims Review Report</u>. CHW IAD may, at its option, produce a separate Claims Review Report for each facility or CHW IAD may produce one report with findings for each facility separately identifiable, providing that the same claims review methodology is employed for each review. The following information shall be included in each Claims Review Report generated by CHW IAD:

1. Claims Review Methodology

- a. <u>Claims Review Objective</u>: A clear statement of the objective intended to be achieved by the Claims Review.
- b. <u>Sampling Unit</u>: As required by this Appendix, the primary sampling unit for this Billing Review is the practitioner. The secondary sampling unit is referred to as "Item" in this Appendix.
- c. <u>Claims Review Population</u>: A description of the Population subject to the Claims Review.
- d. <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of practitioners from which the Claims Review 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. Sources of Data: A description of the documentation relied upon by

CHW IAD when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated.

2. Statistical Sampling Documentation

- a. The number of practitioners, by Clinic, selected for review in the Claims Review Sample.
- b. The number of Items appraised, by practitioner and Clinic, in the Claims Review Sample.
- c. A copy of all RAT-STATS printouts of the random numbers generated by the "Random Numbers" function.
- d. The Sampling Frame used in the Claims Review Sample will be available to the OIG upon request.

3. Claims Review Results

- a. Total number and percentage of instances in which CHW IAD determined that the Paid Claims submitted by Clinics ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- b. 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 Clinics.
- c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) CHW IAD may, in their reports to Clinics, identify underpayments, but any underpayments

identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

- d. 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 CHW IAD), correct allowed amount (as determined by CHW IAD), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- 4. *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.
- C. <u>IRO Claims Review Verification Report</u>. The IRO may, at its option produce a separate Claims Review Verification Report for each facility or the IRO may produce one report with findings for each facility separately identifiable, providing that the same claims review methodology is employed for each review. The following information shall be included in the Claims Review Verification Report generated by the IRO:

1. Claims Review Verification Methodology

- a. <u>Claims Review Objective</u>: A clear statement of the objective intended to be achieved by the IRO's Claims Review.
- b. <u>Sampling Unit</u>: As required by this Appendix, the primary sampling unit for this Billing Review is the practitioner. The secondary sampling unit is referred to as "Item" in this Appendix.
- c. <u>Claims Review Population</u>: A description of the Population subject to the IRO's Claims Review.
- d. <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of practitioners from which the IRO's Claims Review 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. <u>Sources of Data</u>: A description of the documentation relied upon by the IRO when performing the Claims Review (<u>e.g.</u>, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted by the IRO and what was evaluated.

2. Statistical Sampling Documentation

- a. The number of Items appraised in the IRO's Claims Review Sample.
- b. A copy of all RAT-STATS printouts of the random numbers generated by the "Random Numbers" function.
- c. The Sampling Frame used in the IRO's Claims Review Sample will be available to the OIG upon request

3. Claims Review Results

- a. Total number and percentage of instances in which the IRO determined that CHW IAD's Paid Claim determinations differed from the IRO's Paid Claim determinations.
- b. Total number and percentage of instances in which CHW IAD's Paid Claim determinations differed from the IRO's Paid Claim determinations and in which CHW IAD determined the Paid Claim to be reimbursed at a higher amount than the IRO.
- c. Total number and percentage of instances in which CHW IAD's Paid Claim determinations differed from the IRO's Paid Claim determinations and in which CHW IAD determined the Paid Claim to be reimbursed at a lesser amount than the IRO.

- d. The dollar difference amounts, by paid claim, in which, CHW IAD's and the IRO's reimbursement determination differed.
- e. A spreadsheet of the IRO Verification 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 to payor; procedure code reimbursed by payor; allowed amount reimbursed by payor; correct procedure code as determined by CHW IAD; correct procedure code as determined by the IRO; correct allowed amount as determined by the IRO; dollar difference between correct allowed amount as determined by CHW IAD; and correct allowed amount as determined by the IRO.
- 4. *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.