EXHIBIT A

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
NAPA COUNTY

I. PREAMBLE

Napa County ("Napa") hereby agrees to enter into this Integrity Agreement (the "IA") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to ensure compliance by its Health and Human Services Agency ("HHSA") and all departments and entities within its control, including but not limited to, Behavioral Health Adult and Comprehensive Services to Older Adults, its physicians, employees, and other agents, as well as all third parties with whom HHSA may choose to engage to act as billing or coding agents or consultants for HHSA, with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs").

Napa's compliance with the terms and conditions in this IA shall constitute an element of HHSA's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this IA, Napa is entering into a Settlement Agreement with the United States, and this IA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE IA AND DEFINITIONS

A. Term of the IA

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

B. Definitions

1. *Covered Individuals.* Except as otherwise provided within this IA, the term "covered individuals" shall refer to all of HHSA's employees, and all of HHSA's

contractors and individuals with responsibilities pertaining to the ordering, provision, documentation, coding or billing of services payable by a Federal health care program and either provided on HHSA's premises or for which HHSA seeks reimbursement from the Federal health care programs.

2. *Off-Site Contractor Providers.* The term "Off-Site Contractor Providers" refers to covered individuals who contract with HHSA (or who are employed by or sub-contract with a person or entity who contracts with HHSA) to provide services not on HHSA's premises. This term does not include covered individuals with responsibilities for coding or billing of services for which HHSA seeks reimbursement from the Federal health care programs.

3. *Pre-Existing Contractors.* The term "Pre-Existing Contractors" refers to covered individuals who are independent contractors with whom HHSA has an existing contract on the effective date of this IA that has not been renewed or modified after the effective date of this IA. Once HHSA renegotiates, modifies, or renews a contract with an existing contractor, that contractor ceases to be a Pre-Existing Contractor as that term is used for the purposes of this IA, and HHSA will have full responsibility for the certification and training compliance obligations as pertain to that contractor.

III. INTEGRITY OBLIGATIONS

HHSA shall establish a Compliance Program that includes the following elements.

A. Corporate Compliance Officer and Committee

1. *Compliance Officer.* Within 90 days after the effective date of this IA, HHSA shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this IA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of HHSA, shall make regular (at least quarterly) reports regarding compliance matters directly to the County Administrator and the Board of Supervisors of Napa and shall be authorized to report to the County Administrator and the Board of Supervisors of Napa at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by HHSA to further its compliance objectives as well as any reporting obligations created under this IA. In the event a new Compliance Officer is appointed during the term of this IA, HHSA shall notify the OIG, in writing, within fifteen (15) days of such a change.

2. *Compliance Committee.* Within 90 days of the effective date of this IA, HHSA shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this IA within HHSA's organizational structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards

1. *Code of Conduct.* Within 90 days of the effective date of this IA, HHSA shall establish a Code of Conduct. Except as further provided below, the Code of Conduct shall be distributed to all covered individuals within 90 days of the effective date of this IA. The Code of Conduct shall, at a minimum, set forth:

a. HHSA's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with such requirements;

b. HHSA's requirement that all covered individuals shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with HHSA's own policies and procedures (including the requirements of this IA);

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

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

e. the right of all covered individuals to use the Confidential Disclosure Program, as well as HHSA's commitment to confidentiality and non-retaliation with respect to disclosures.

Except as otherwise provided in section III.B.1, within 90 days of the effective

date of the IA, each covered individual shall certify, in writing, that he or she has received, read, understands, and will abide by HHSA's Code of Conduct. HHSA will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within 30 days of initiating such change.

For Off-Site Contractor Providers, HHSA shall require in its contracts with the contracting individuals or entities through which the Off-Site Contractor Providers are associated with HHSA that (1) the contractors acknowledge HHSA's Compliance Program and Code of Conduct; (2) the Code of Conduct (including the toll-free telephone number) will be provided (either by HHSA or the contracting entity) to all covered individuals who are employees of HHSA contractors; and (3) the contractors obtain and retain (subject to review by HHSA and/or OIG) signed certifications that each such individual has received, has read, and understands the Code of Conduct and agrees to abide by the requirements of HHSA's Compliance Program. HHSA shall make a good faith effort to ensure that the above obligations are met by the HHSA contractor. If a HHSA contractor is also a Pre-Existing Contractor, then the exceptions for Pre-Existing Contractors, as set forth in section III.C.6, below, may be applied to that HHSA contractor.

New covered individuals shall receive the Code of Conduct and shall complete the required certification within two weeks after the commencement of their employment or other relationship with HHSA or within 90 days of the effective date of the IA, whichever is later.

HHSA shall distribute the Code of Conduct to all Pre-Existing Contractors (as defined in section II.B.3, above). Within 90 days of the effective date of the IA, HHSA shall use its best efforts to obtain written certification from each Pre-Existing Contractor that he, she, or it has received, has read, understands, and will abide by HHSA's Code of Conduct. Any revisions to the Code of Conduct shall be distributed to each Pre-Existing Contractor within 30 days of initiating the changes. HHSA shall use its best efforts to obtain on an annual basis written certification from each Pre-Existing Contractor that he, she, or it has received, read, understands, and will abide by HHSA's Code of Conduct. HHSA shall maintain records of the percentage of Pre-Existing Contractors who provide such certifications.

Within 30 days of the effective date of this IA, HHSA shall commence the process to meet and discuss with the appropriate Administrative governing body to make the promotion of and adherence to the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees.

2. *Policies and Procedures*. Within 90 days of the effective date of this IA, HHSA shall develop and initiate implementation of written Policies and Procedures regarding the operation of HHSA's compliance program and its compliance with all Federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address: (1) the development, documentation, and operation of medically necessary individualized treatment plans as a requirement for Medicare reimbursement for mental health services and treatments; (2) the use of proper physician identifiers in claims submitted to Medicare, identifying the physician who provided or supervised the provision of mental health treatments or services; (3) the requirement that HHSA staff review mental health services and treatments to be billed to Federal health care programs to determine they are properly documented as being medically necessary under the relevant program requirements; (4) the requisite qualifications required by a health care professional to render mental health services and treatments under the Medicare program; and (5) the requirement that HHSA staff review mental health services and treatments to be billed to the Federal health care programs to ensure that as coded they accurately reflect the level of service provided to its patients. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to HHSA management through the Confidential Disclosure Program required by section III.E. HHSA shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within 90 days of the effective date of the IA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate covered individuals. Appropriate staff should be available to explain any and all Policies and Procedures.

C. Training and Education

1. *General Training*. Within 90 days of the effective date of this IA, HHSA shall provide at least two (2) hours of training to each covered individual. This General Training shall explain HHSA's:

a. Integrity Agreement requirements;

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

c. Code of Conduct.

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

New covered individuals shall receive the General Training described above within 90 days of the beginning of their employment or contract, or within 90 days after the effective date of this IA, whichever is later. Each covered individual shall receive such General Training on an annual basis.

2. *Reimbursement Training.* Within 90 days of the effective date of this IA, each covered individual who has responsibility for, or who supervises any person who has responsibility for, the preparation or submission (including, but not limited to, coding and billing) of claims (other than cost reports) for reimbursement for patient care, either provided on HHSA premises or for which HHSA seeks reimbursement from the Federal health care programs, shall receive at least eight (8) hours of Reimbursement Training in addition to the General Training required above. This Reimbursement Training shall include a discussion of:

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

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

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

d. applicable reimbursement rules and statutes;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

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

Affected new covered individuals shall receive the Reimbursement Training within thirty (30) days of the beginning of their employment or contract, or within 90 days of the effective date of this IA, whichever is later. If a new covered individual has responsibility for, or supervises any person who has responsibility for, the preparation or submission of claims for reimbursement for patient care (including, but not limited to, coding and billing) for any Federal health care programs prior to completing this Reimbursement Training, a covered individual who has completed the Reimbursement

Training shall review all of the untrained person's work regarding the preparation or submission of claims.

Each year, each covered individual who has responsibility for, or who supervises any person who has responsibility for, the preparation or submission of claims for reimbursement for patient care (including, but not limited to, coding and billing) for any Federal health care programs shall receive an additional eight (8) hours of such Reimbursement Training.

3. *Provider Training.* Each covered individual who has responsibility for, or who supervises any person who has responsibility for, the ordering, prescribing, provision or documentation of patient care or medical items or services at HHSA or for which HHSA seeks reimbursement shall receive at least eight (8) hours of Provider Training in addition to the General Training required above. The Provider Training shall include a discussion of:

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

b. HHSA's billing process and an explanation of the role provider documentation plays in this process;

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

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

e. applicable reimbursement rules and statutes, including any regulations related to medical necessity;

f. the legal sanctions for improper documentation and billings; and

g. examples of proper and improper patient file documentation.

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

Affected new covered individuals shall receive this Provider Training within thirty (30) days of the beginning of their employment or contract, or within 90 days of the

effective date of this IA, whichever is later. If a new covered individual has responsibility for, or supervises any person who has responsibility for, the ordering, prescribing, provision or documentation of patient care or medical items or services prior to completing this Provider Training, a covered individual who has completed the Provider Training shall review all of the untrained persons related to those responsibilities.

Each year, each covered individual who has responsibility for, or supervises any person who has responsibility for, the ordering, prescribing, or provision of patient care or medical items or services shall receive an additional eight (8) hours of such Provider Training.

4. *Exception for Off-Site Contractor Providers.* Notwithstanding any other provision of this IA, the following are HHSA's only obligations with respect to training and certification of Off-Site Contractor Providers. HHSA shall make the General Training and the Provider Training, where appropriate, available to all Off-Site Contractor Providers, and shall use its best efforts to encourage their attendance and participation. HHSA shall maintain records of the Off-Site Contractor Providers who attend such training. Such records shall be available for inspection by OIG.

5. *Exception for Pre-Existing Contractors.* Notwithstanding any other provision of this IA, the following are HHSA's only obligations hereunder with respect to training and certification for Pre-Existing Contractors. HHSA shall attempt to renegotiate contracts with Pre-Existing Contractors to require such contractors to meet all of the certification and training requirements of this IA. HHSA shall make the General Training, the Reimbursement Training, and the Provider Training, where appropriate, available to all Pre-Existing Contractors, and shall use its best efforts to encourage their attendance and participation. The Compliance Officer shall keep a record of all Pre-Existing Contractors who do and do not attend such training.

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

D. <u>Audit and Review Procedures</u>

HHSA shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review procedures to assist HHSA in assessing the adequacy of its billing and compliance

practices pursuant to this IA. The reviews will be performed annually and cover each of the one-year periods beginning on the effective date of this IA or the anniversary of that date. The IRO must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which HHSA seeks reimbursement. The IRO must be retained to conduct the review of the first year within 90 days of the effective date of this IA.

The IRO will conduct two separate engagements. One will be an analysis of HHSA's billing to the Federal health care programs to assist the HHSA and OIG in determining compliance with all applicable statutes, regulations, and guidelines ("billing engagement"). The second engagement will determine whether HHSA is in compliance with this IA ("compliance engagement").

Pursuant to this IA, the review and audit provisions of paragraph III.D shall not apply to the following HHSA programs: Women's, Infants, and Children program, Maternal Child Health program, California Children's Services program, Child Health Disability Program, Family Planning, AIDs surveillance, AIDS Drug Assistance Program, HIV Testing, Ryan White, HOPWA (Housing Opportunities for Persons with Aids), HPCP (HIV Prevention and Community Planning), Health Medi-Cal Administrative Activities program and Health Targeted Case Management program.

1. *Billing Engagement.* The billing engagement shall include a review of a statistically valid sample of claims for mental health services that can be projected to the population of claims submitted to the Medi-Cal program during the relevant year covered by the engagement. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling. To generate the random sample, HHSA shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/oig/oas/ratstat.html."

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

a. Billing Engagement Objective: a clear statement of the objective intended to be achieved by the billing engagement and the

procedure or combination of procedures that will be applied to achieve the objective.

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

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

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

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

The billing engagement shall provide:

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

b. findings regarding whether HHSA is submitting accurate claims for services billed to the Federal health care programs.

c. findings regarding HHSA's procedures to correct inaccurate billings or codings for claims submitted to the Federal health care programs;

d. findings regarding whether HHSA submitted claims for mental health services and treatments to the Federal health care programs that were not medical necessary;

e. findings regarding whether HHSA submitted claims for mental health services and treatments to the Federal health care programs that did not accurately reflect the level of service provided to its patients;

f. findings regarding whether HHSA has complied with its obligation under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims, and (b) 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 and adjust any past charges of unallowable costs; and

g. findings regarding the steps HHSA is taking to bring its operations into compliance or to correct problems identified by the review.

2. *Compliance Engagement.* An IRO shall also conduct an annual compliance engagement that shall provide findings regarding whether HHSA's program, policies, procedures, and operations comply with the terms of this IA. This engagement shall include section by section findings regarding the requirements of this IA.

A complete copy of the IRO's billing and compliance engagement shall be included in each of HHSA's Annual Reports to OIG.

3. *Verification/Validation.* In the event that the OIG has reason to believe that HHSA's Billing Engagement Review fails to conform to its obligations under the IA or indicates improper billings not otherwise adequately addressed in the IRO's report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which HHSA is complying with its obligations under this IA, HHSA agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program

Within 90 days after the effective date of this IA, HHSA shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with HHSA's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be inappropriate. HHSA shall publicize the existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, HHSA shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons

1. *Definition.* For purposes of this IA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* HHSA shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, HHSA shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 90 days of the effective date of this IA, HHSA will review its list of current employees and contractors against the Exclusion Lists. Thereafter, HHSA will review the list semi-annually. If HHSA has notice that an employee or contractor has become an Ineligible Person, HHSA will remove such person from responsibility for, or involvement with, HHSA's business operations related to the

Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

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

G. Notification of Proceedings

Within 30 days of discovery, HHSA 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 HHSA has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. HHSA shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting

1. *Reporting of Overpayments.* If, at any time, HHSA identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, HHSA shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any overpayment within 30 days of discovering the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification to the contractor should be done in accordance with the contractor policies.

2. *Reporting of Material Deficiencies.* If HHSA determines that there is a material deficiency, HHSA shall notify the OIG within 30 days of making the determination that the material deficiency exists. The report to the OIG shall include the following information:

(a) 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 H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(i) the payor's name, address, and contact person where the overpayment was sent; and

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

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

(c) HHSA's actions to correct the material deficiency; and

(d) any further steps HHSA plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this IA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or guidelines, including carrier and intermediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this IA, a "material deficiency" means anything that involves:

(a) a substantial overpayment relating to any Federal health care program;

(b) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program; or

(c) a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

A material deficiency may be the result of an isolated event or a series of occurrences.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that HHSA purchases or establishes new business units after the effective date of this IA, HHSA shall notify OIG of this fact within 30 days of the date of 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 requirements in this IA that apply to new covered persons (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this IA, HHSA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA. This Implementation Report shall include:

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

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

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

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

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

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been distributed to all pertinent covered persons;

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

c. all appropriate covered individuals have completed the General Training, Reimbursement Training, and Provider Training, and executed the certification required by section III.C;

7. a description of the efforts made to amend contracts with Pre-Existing Contractors and to provide training to Pre-Existing Contractors and encourage their attendance, and a report of the percentage of Pre-Existing Contractors who have: (a) completed the Code of Conduct certification; and (b) attended the training described in section III.C.

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

9. the identity of the IRO and the proposed start and completion dates of the first review; and

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

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

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

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

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

c. HHSA has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims, and (ii) 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 and adjust any past charges of unallowable costs;

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

4. a description of the efforts made to amend contracts with Pre-Existing Contractors and to provide training to Pre-Existing Contractors and encourage their attendance, and a report of the percentage of Pre-Existing Contractors who have: (a) completed the Code of Conduct certification; and (b) attended the training described in section III.C;

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

6. HHSA's response/corrective action plan to any issues raised by the IRO;

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

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

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

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

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

information;

12. a summary of corrective action plans to address all material deficiencies (as defined in section III.H) identified over the previous 12 months; and

13. a description of all changes to the most recently provided list (as updated) of HHSA's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the payor (specific contractor) that issued each provider identification number.

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

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

D. Designation of Information: HHSA shall clearly identify any portions of its submissions that it believes are trade secrets, commercial or financial information or otherwise exempt from disclosure under the Freedom of Information Act ("FOIA").

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527

330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

HHSA:

Eric Zimny - Compliance Officer
Napa County
Health and Human Services Agency
2261 Elm Street
Napa, CA 94559-3721
Phone 707.253.4715
Fax 707.253.4155

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine HHSA's books, records, and other documents and supporting materials and/or conduct an on-site review of any of HHSA's locations for the purpose of verifying and evaluating: (a) HHSA's compliance with the terms of this IA; and (b) HHSA's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by HHSA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of HHSA's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. HHSA agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. HHSA's employees may elect to be interviewed with or without a representative of HHSA present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 90 days after the effective date of this IA and concluding at the end of the term of this IA, HHSA fails to have in place any of the following:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a training program; and

f. a Confidential Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day HHSA fails meet any of the

deadlines to submit the Implementation Report or the Annual Reports to the OIG.

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

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

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

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

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to HHSA of the failure to comply) for each day HHSA fails to comply fully and adequately with any obligation of this IA. In its notice to HHSA, OIG shall state the specific grounds for its determination that the HHSA has failed to comply fully and adequately with the IA obligation(s) at issue.

B. Payment of Stipulated Penalties

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

Within fifteen (15) days of the date of the Demand Letter. HHSA shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event HHSA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HHSA cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under section X.C.

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

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

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

C. <u>Exclusion for Material Breach of this IA</u>

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

OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

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

a. HHSA is in full compliance with this IA;

b. the alleged material breach has been cured; or

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

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, HHSA fails to satisfy the requirements of section X.C.2, OIG may exclude HHSA from participation in the Federal health care programs. OIG will notify HHSA in writing of its determination to exclude HHSA (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If HHSA is excluded under the provisions of this IA, HHSA may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

a. a failure by HHSA to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;

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

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

d. a failure to retain and use an Independent Review Organization

for review purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to HHSA of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this IA, HHSA 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 IA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within ten (10) days of HHSA's receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this IA shall be (a) whether Hospital was in full and timely compliance with the obligations of this IA for which OIG demands payment; (b) the period of noncompliance; and (c) with respect to a stipulated penalty authorized under section X.A.5 only, whether the failure to comply could not be cured within the 10-business-day period, but that by the end of that period (i) Hospital had begun to take action to cure the failure to comply, (ii) Hospital was and is pursuing such action with due diligence, and (iii) Hospital had provided to OIG a reasonable timetable for curing the breach which is being followed. HHSA shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this IA and orders HHSA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that HHSA may request review of the ALJ decision by the DAB.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be (a) whether HHSA was in material breach of this IA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that (i) HHSA had begun to take action to cure the material breach within the 35 day period, (ii) HHSA is pursuing such action with due diligence, and (iii) HHSA provided to OIG within the 35 day period a reasonable timetable for curing the material

breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. HHSA's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude HHSA upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that HHSA may request review of the ALJ decision by the DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This IA shall be binding on the successors, assigns, and transferees of Napa or HHSA;

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

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

D. The undersigned Napa signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatory represents that he is signing this IA in his official capacity and that he is authorized to execute this IA.

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

4/17/03
DATE

ON BEHALF OF NAPA COUNTY

Robert Westmeyer
County Counsel
(707) 259-8245

3/28/00
DATE

Jay Hull
County Administrator
(707) 253-4421

3/28/00
DATE

Terry Longoria
HHSA Director
(707) 253-4279

3/28/00
DATE

Judith A. Waltz, Esquire
Counsel for Napa County
(415) 438-6412

4/4/00
DATE

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND NAPA COUNTY

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Napa County ("Napa") entered into an Integrity Agreement ("IA") on April 17, 2000.

1. Pursuant to Section XI.C. Napa's IA, modifications to the IA may be made with the prior written consent of both the OIG and Napa. Therefore, the OIG and Napa hereby agree that Napa's IA will be amended as follows:

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

   Appendix A of Napa's IA is hereby added by the attached new Appendix A.

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

3. The undersigned Napa signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

4. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF NAPA COUNTY

Robert Westmeyer
County Counsel

11/21/2002
DATE

Nancy Watt
Acting County Executive Officer

11/26/02
DATE

Bruce Heid
HHSA Director

11/20/02
DATE

Jackie Gong
Counsel for Napa County

11/26/02
DATE

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

Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

12/4/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this IA, HHSA 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 HHSA in assessing and evaluating its billing and coding practices and systems for mental health services, and its compliance obligations pursuant to this IA and the Settlement Agreement. Each IRO retained by HHSA shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this IA and in the general requirements of the Federal health care program(s) from which HHSA seeks reimbursement. Each IRO shall assess, along with HHSA, 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 HHSA's billing and coding to the Federal health care programs ("Claims Review") and shall analyze HHSA's compliance with the obligations assumed under this IA and Settlement Agreement ("Compliance Review").

Pursuant to this IA, the review provisions of paragraph III.D. shall not apply to the following HHSA programs: Women's, Infants, and Children program, Maternal Child Health program, California Children's Services program, Child Health Disability Program, Family Planning, AIDs surveillance, AIDs Drug Assistance Program, HIV Testing, Ryan White, HOPWA (Housing Opportunities for Persons with Aids), HPCP (HIV Prevention and Community Planning), Health Medi-Cal Administrative Activities program and Health Targeted Case Management program.

2. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover the following time period:

Annual Report #3 July 1, 2000 - June 30, 2001[1]

[1] This time period will only include claims that were not previously included in the population of HHSA's year two

July 1, 2001 - June 30, 2002

Annual Report #4 July 1, 2002 - June 30, 2003

Annual Report #5 July 1, 2003 - June 30, 2004.

The IRO(s) shall perform all components of each annual Claims Review. However, if a Systems Review is required HHSA and the IRO will follow the procedures described in Section III.D.2.c below.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of this IA.

d. Retention of Records. The IRO and HHSA 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 HHSA related to the reviews).

2. *Claims Review*.

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

a. Discovery Sample. At the discretion of HHSA, it may elect to have the IRO randomly select and review either a single or multiple Discovery Sample(s) of 50 Paid Claims from the Medicare or Medi-Cal programs submitted by or on behalf of HHSA. For the claims review of annual report year three, the IRO will conduct three Discovery Samples: the first Discovery Sample will include Paid Claims from the Alcohol and Drug program, the second Discovery Sample will include Paid Claims from the Mental Health program that were not part of year two's claims review but were submitted for claims arising during the period of July 1, 2000 – June

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Claims Review. A majority of the claims will be from May and June 2001.

30, 2001, and the third Discovery Sample will include Paid Claims from the Mental Health program submitted for the period of July 1, 2001 – June 30, 2002. The Paid Claims shall be reviewed based on the supporting documentation available at HHSA or under HHSA's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

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

ii. If a Discovery Sample indicates that an Error Rate of 5% or greater, then the IRO shall perform a Full Sample and certify HHSA's Systems Review for that Discovery Sample, as described below.

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

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

c. Systems Review. If HHSA's Discovery Sample identifies an Error Rate of 5% or greater, HHSA shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, HHSA should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. HHSA shall provide to IRO observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim. The IRO shall certify that HHSA has complied with the requirements of this section. If the IRO disagrees with HHSA's findings then the IRO should report to the OIG in the annual report its concerns with the HHSA's system review. If the IRO has additional recommendations or suggestions for improvements, then it shall provide those to HHSA. If the OIG is not satisfied with HHSA's Systems Review, then the OIG may require that the IRO perform a Systems Review.

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

3. *Claims Review Report*. The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"), which shall include HHSA's report on its Systems Review if required pursuant to Section III.D.2.c. Information to be included in the Claims Review Report is detailed in Appendix A.

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

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

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

   Prior to initiating a Validation Review, the OIG shall notify HHSA 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, HHSA may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. HHSA agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with HHSA 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 HHSA a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and Compliance Review and that it has concluded that it was, in fact, independent.

APPENDIX A

A. Claims Review.

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

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

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

c. Paid Claim: A code or line item submitted by HHSA and for which HHSA has received reimbursement from the Medicare or Medi-Cal programs.

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

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

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

2. **Other Requirements.**

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

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

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

1. **Claims Review Methodology.**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

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

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

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

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

2. **Statistical Sampling Documentation.**

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

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

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

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

3. **Claims Review Findings.**

a. Narrative Results.

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

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Such explanation should include any findings regarding whether HHSA submitted claims for mental health services and treatments to Medicare or Medi-Cal programs that were not medically necessary or that did not accurately reflect the level of service provided to its patients.

b. Quantitative Results.

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

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

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

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct

procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

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

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