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

I. PREAMBLE

Ventura County hereby enters into this Integrity Agreement ("IA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by the Ventura County Medical Center ("VCMC") and all departments and entities within its control, including but not limited to the Department of Mental Health Services, the Department of Ambulatory Clinic Services, and the Department of Inpatient Medical Care Programs, its physicians, employees, and other agents, as well as all third parties with whom VCMC may choose to engage to act as billing or coding agents or consultants for VCMC, 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"). In the event that Ventura County provides mental health services (other than those provided exclusively through the Alcohol and Drug Program at the time of execution of this IA), in addition to those provided through VCMC, that are reimbursable by any Federal health care program, the terms and obligations of this IA shall also apply to such mental health services and the department(s) or operating unit(s) through which such services are provided. In such a case, the term "VCMC" shall include such department(s) and operating unit(s) for the purposes of this IA. Ventura County's compliance with the terms and conditions in this IA shall constitute an element of the present responsibility of VCMC with regard to participation in the Federal health care programs. Contemporaneously with this IA, Ventura County is entering into a Settlement

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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 the compliance obligations assumed by Ventura County under this IA shall be 5 years from the effective date 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 (the "effective date").

B. Definitions

1. *Covered Individuals.* Except as otherwise provided within this IA, the term "covered individuals" shall refer to all employees, and all 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 VCMC premises or for which VCMC 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 VCMC (or who are employed by or sub-contract with a person or entity who contracts with VCMC) to provide services not on VCMC's premises. This term does not include covered individuals with responsibilities for coding or billing of services for which VCMC seeks reimbursement from the Federal health care programs.

3. *Pre-Existing Contractors.* The term "Pre-Existing Contractors" shall refer to covered individuals who are independent contractors with whom VCMC 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 VCMC 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 VCMC will have full responsibility for the certification and training compliance obligations as pertain to that contractor.

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III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Compliance Committee

Within 150 days after the effective date of this IA, VCMC 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 VCMC, shall make regular (at least quarterly) reports regarding compliance matters directly to the Board of Supervisors of Ventura County and shall be authorized to report to the Board of Supervisors of Ventura County at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by VCMC 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, VCMC shall notify the OIG, in writing, within fifteen (15) days of such a change.

VCMC shall also appoint a Compliance Committee within 150 days after the effective date of this IA. 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 VCMC'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 150 days of the effective date of this IA, VCMC shall establish a Code of Conduct. Except as further provided below, the Code of Conduct shall be distributed to all covered individuals within 150 days of the effective date of this IA. VCMC shall make the promotion of and adherence to the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

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

b. the responsibility of all covered individuals to comply with all statues, regulations, and guidelines applicable to Federal health care programs and with VCMC's own Policies and Procedures (including the requirements of this IA);

c. the responsibility of all covered individuals to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or with VCMC's own Policies and Procedures;

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

e. information about the Confidential Disclosure Program, including the toll-free hotline telephone number, and the right of all covered individuals to use the Confidential Disclosure Program and VCMC's commitment to confidentiality and non-retaliation with respect to disclosures.

Except as otherwise provided in section III.B.1, within 150 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 VCMC's Code of Conduct.

For Off-Site Contractor Providers, VCMC shall require in its contracts with the contracting individuals or entities through which the Off-Site Contractor Providers are associated with VCMC that (1) the contractors acknowledge VCMC's Compliance

Program and Code of Conduct; (2) the Code of Conduct (including the toll-free telephone number) will be provided (either by VCMC or the contracting entity) to all covered individuals who are employees of VCMC contractors; and (3) the contractors obtain and retain (subject to review by VCMC 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 VCMC's Compliance Program. VCMC shall make a good faith effort to ensure that the above obligations are met by the VCMC contractor. If VCMC meets its obligations set forth above, then the failure of the VCMC contractor to meet the above obligations (set forth in its contract with VCMC) shall not constitute a breach of this IA by VCMC. If a VCMC 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 VCMC 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 VCMC or within 150 days of the effective date of the IA, whichever is later. VCMC will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within 30 days of initiating such change. Covered individuals shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

VCMC shall distribute the Code of Conduct to all physicians with privileges at VCMC and all Pre-Existing Contractors (as defined in section II.B.3, above). Within 150 days of the effective date of the IA, VCMC shall use its best efforts to obtain written certification from each physician with privileges and Pre-Existing Contractor that he, she, or it has received, has read, understands, and will abide by VCMC's Code of Conduct. New physicians with privileges shall receive the Code of Conduct, and VCMC shall use its best efforts to obtain the written certification within two weeks after the granting of staff privileges at VCMC or within 150 days of the effective date of the IA, whichever is later. Any revisions to the Code of Conduct shall be distributed to each physician with privileges and Pre-Existing Contractor within 30 days of initiating the changes. VCMC shall use its best efforts to obtain on an annual basis written certification from each physician with privileges and Pre-Existing Contractor that he, she, or it has received, read, understands, and will abide by VCMC's Code of Conduct. VCMC shall maintain records of the percentage of physicians with privileges and Pre-Existing Contractors who provide such certifications.

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2. *Policies and Procedures.*

a. Phase One: Within 150 days of the effective date of this IA, VCMC shall develop and initiate implementation of written Policies and Procedures regarding the operation of VCMC's compliance program and, at a minimum, the following:

(1) compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs, regarding mental health services, and specifically including:

(a) the development, documentation, and operation of medically necessary individualized treatment plans as a requirement for Medicare reimbursement for mental health services and treatment; and

(b) the use of proper physician identifiers in all claims to Federal health care programs, identifying the physician who provided or supervised the provision of mental health treatments or services;

(2) the Medicare requirements regarding submission of claims as "provider-based"; and

(3) disciplinary guidelines and methods for employees and other individuals to make disclosures or otherwise report on compliance issues to VCMC management through the Confidential Disclosure Program required by section III.E.

Within 150 days of the effective date of the IA, the relevant portions of the Policies and Procedures developed pursuant to Phase One shall be distributed to all appropriate covered individuals, except Off-Site Contractor Providers. Compliance staff or supervisors should be available to explain any and all policies and procedures.

b. Phase Two: Within 240 days of the effective date of this IA, VCMC shall develop and initiate implementation of written Policies and Procedures regarding

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VCMC's compliance with all federal and state health care statutes, regulations, and guidelines, other than those addressed in Phase One, above, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address the following:

(1) the proper use of site of service codes, CPT and National Revenue Codes, and ICD-9-CM codes;

(2) the proper reporting on cost reports of all revenue received;

(3) the proper reporting, in accordance with Medicare requirements, of charges incurred within the Ventura County Medical Center; and

(4) the necessity of revenue and usage reports for all units of the Ventura County Medical Center and of VCMC.

Within 240 days of the effective date of the IA, the relevant portions of the Policies and Procedures developed pursuant to Phase Two shall be distributed to all appropriate covered individuals, except Off-Site Contractor Providers. Compliance staff or supervisors should be available to explain any and all policies and procedures.

c. Amendments and Reporting. VCMC 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.

C. Training and Education

1. *General Training*. Within 150 days of the effective date of this IA, VCMC shall provide at least two (2) hours of training to each covered individual. This General Training shall explain VCMC'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.

The General Training materials shall be made available to the OIG, upon request.

New covered individuals shall receive the General Training described above within thirty (30) days of the beginning of their employment or contract, or within 150 days after the effective date of this IA, whichever is later. Every covered individual shall receive such General Training on an annual basis.

2. *Reimbursement Training.* Within 150 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 VCMC premises or for which VCMC 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.

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

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Affected new covered individuals shall receive the Reimbursement Training within thirty (30) days of the beginning of their employment or contract, or within 150 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 four (4) 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, or provision of patient care or medical items or services at VCMC or for which VCMC seeks reimbursement shall receive at least four (4) hours of Provider Training in addition to the General Training required above. At least sixty percent of the covered individuals required to receive the Provider Training shall receive this training within 150 days after the effective date of this IA. The remainder of the covered individuals required to receive the Provider Training shall receive this training within 180 days after the effective date of this IA. The Provider Training shall include a discussion of:

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

b. VCMC'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.

The Provider 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 150 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, or provision 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 person's work regarding delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes.

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 four (4) hours of such Provider Training.

4. *Physicians with Privileges.* Notwithstanding any other provision of this IA, VCMC shall make the General Training and the Reimbursement Training and Provider Training, where appropriate, available to all physicians with privileges at VCMC, and shall use its best efforts to encourage their attendance and participation. VCMC shall maintain records of the percentage of all physicians with privileges who attend such training.

5. *Exception for Off-Site Contractor Providers.* Notwithstanding any other provision of this IA, the following are VCMC's only obligations with respect to training

and certification of Off-Site Contractor Providers. VCMC 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. VCMC shall maintain records of the Off-Site Contractor Providers who attend such training. Such records shall be available for inspection by OIG.

6. *Exception for Pre-Existing Contractors.* Notwithstanding any other provision of this IA, the following are VCMC's only obligations hereunder with respect to training and certification for Pre-Existing Contractors. VCMC 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. VCMC 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 attend such training.

7. *Certification.* Each covered person who 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. Review Procedures

VCMC shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist VCMC in assessing the adequacy of its billing and compliance practices pursuant to this IA. Each review shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which VCMC seeks reimbursement. The Independent Review Organization must be retained to conduct the audits for the first year within 150 days of the effective date of this IA.

Each year the Independent Review Organization will conduct three separate engagements. Two will be analyses of VCMC's billing to the Federal health care programs to assist VCMC and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("Billing Engagements"). The third

engagement will determine whether VCMC is in compliance with this IA ("compliance engagement").

1. *Billing Engagements.*

a. *Mental Health Services Billing Engagement.* Each year, the Independent Review Organization shall conduct a review of the claims for mental health services submitted by VCMC to any Federal health care program. Such review shall utilize the guidelines and statistical parameters provided in Section III.D.1.c, below. In addition to determining compliance with all applicable statutes, regulations, and directives/guidance, the Mental Health Services Billing Engagements shall specifically include: (a) findings regarding VCMC's treatment plans for mental health services provided to Medicare beneficiaries; (b) findings regarding VCMC's use of physician identifiers; (c) findings regarding VCMC's submission of claims as "provider based" services or treatments and such claims' compliance with the requirements of the Federal health care program(s) to which such claims were submitted; and (d) findings regarding whether VCMC has complied with its obligation under the Settlement Agreement 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 denial of claims.

b. *Rotating Billing Engagement.* For the first year following the execution of this IA, the Independent Review Organization shall conduct a review of claims submitted to any Federal health care program by VCMC for all outpatient hospital services. For the second year following the execution of this IA, the Independent Review Organization shall conduct a review of claims submitted to any Federal health care program by VCMC for all inpatient hospital services. For the third year following the execution of this IA, the Independent Review Organization shall conduct a review of claims submitted to any Federal health care program by VCMC for all laboratory services. For the fourth year following the execution of this IA, the Independent Review Organization shall conduct a review of claims submitted to any Federal health care program by VCMC for all outpatient hospital services. For the fifth year following the execution of this IA, the Independent Review Organization shall conduct a review of claims submitted to any Federal health care program by VCMC for all inpatient hospital services. Each of these Rotational Billing Engagements shall utilize the guidelines nad statistical parameters provided in Section III.D.1.c, below.

c. *Statistical Parameters and Guidelines for Billing Engagements.* Each Billing Engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted by VCMC to the Federal health care programs for the 12-month period covered by the engagement. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling. To generate the random sample, VCMC shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html."

Each Billing Engagement and its corresponding report shall include the following components:

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

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

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

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

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

The Billing Engagement report shall provide:

a. findings regarding VCMC'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 VCMC is submitting accurate claims for services billed to the Federal health care programs;

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

d. findings regarding the steps VCMC is taking to bring its operations into compliance or to correct problems identified by the audit.

A complete copy of the Independent Review Organization's Billing Engagements shall be included in each of VCMC's Annual Reports to OIG.

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a Compliance Engagement, that shall provide findings regarding whether VCMC'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 Independent Review Organization's Compliance Engagement shall be included in each of VCMC's Annual Reports to OIG.

3. *Verification/Validation.* In the event OIG has reason to believe that VCMC's Billing Engagement Review(s) fails to conform to its obligations under this IA or indicates improper billings not otherwise adequately addressed in the Billing Engagement report(s), and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which VCMC is complying with its

obligations under this IA, VCMC agrees to pay for the reasonable cost of any such review or engagement by OIG or any of its designated agents.

E. Confidential Disclosure Program

Within 150 days after the effective date of this IA, VCMC shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with VCMC's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. VCMC 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 complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, VCMC shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

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

3. *Review and Removal Requirement.* Within 150 days of the effective date of this IA, VCMC will review its list of current employees and contractors and physicians with staff privilege against the Exclusion Lists. Thereafter, VCMC will review the list once annually. If VCMC has notice that an employee, agent, or physician has become an Ineligible Person, VCMC will remove such person from responsibility for, or involvement with, VCMC'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 VCMC has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with VCMC, within 10 days of receiving such notice VCMC will remove such individual from responsibility for, or involvement with, VCMC's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

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G. Notification of Proceedings

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

H. Reporting.

1. *Reporting of Overpayments.* If, at any time, VCMC identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, VCMC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) 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. If the overpayment is discovered as the result of any of the activities required by this IA, the notice to the payor shall include:

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

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

c. the methodology by which the overpayment was determined;

d. the amount of the overpayment;

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

f. the provider identification number under which the repayment is being made;

g. the cost reporting period (if applicable); and

h. any applicable Overpayment Refund Form provided and required by the payor.

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

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

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

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

This section III.H.2 does not require VCMC to report to OIG private medical malpractice actions where VCMC has not determined that a material deficiency exists. Furthermore, this section III.H.2 shall not require VCMC to report the proceedings or records of organized committees or of a peer review body, where such proceedings and records are protected from discovery and testimony under California Evidence Code section 1157. A material deficiency must be reported under this section regardless of whether the acts underlying the material deficiency are the subject of a medical malpractice action or a peer review proceeding described above. The finding of a material deficiency triggers the reporting requirement as set forth in this Section III.H.2, and does not in and of itself constitute a breach of the IA.

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 program directives, including carrier and intermediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this IA, a "material deficiency" means anything that involves: (i) a substantial overpayment relating to any Federal health care program; (ii) 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 (iii) 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 a beneficiary unnecessarily in high-risk situations. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. NEW LOCATIONS

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 185 days after the effective date of this IA, VCMC 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 VCMC's Code of Conduct required by section III.B.1;

4. the summary of the Policies and Procedures developed pursuant to Phase One and required by section III.B.2.a;

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.a have been developed, are being implemented, and have been distributed to all pertinent covered individuals;

   b. all appropriate 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, Provider Training, and the Reimbursement Training, and executed the certifications required by section III.C,

7. A description of the efforts made to provide training to physicians with privileges and encourage their attendance and a report of the percentage physicians with privileges who have: (a) completed the Code of Conduct certification; and (b) attended the training describing described in section III.C.

8. 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.

9. a description of the Confidential Disclosure Program required by section III.E;

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

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

C. Annual Reports

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

The Annual Reports 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 individuals have completed the annual Code of Conduct certification required by section III.B.1; and

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

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

4. a description of the efforts made to provide training to physicians with privileges and encourage their attendance and a report of the percentage physicians with privileges who have: (a) completed the annual Code of Conduct certification; and (b) attended the training described in section III.C.

5. 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

Exhibit A

Contractors who have: (a) completed the annual Code of Conduct certification; and (b) attended the training described in section III.C.

6. a complete copy of the report prepared pursuant to the Independent Review Organization's Billing Engagements and Compliance Engagement, including a copy of the methodology used;

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

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

9. 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 (each applicable state separately), and other Federal health care programs;

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

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

12. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that VCMC has committed a crime or has engaged in fraudulent activities, which is required to 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;

13. a corrective action plan to address the probable violations of law identified in section III.H; and

14. a listing of all of VCMC'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 90 days after the effective date of this IA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

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

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
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Exhibit A

VCMC:

Michael B. Powers
Deputy Director
Ventura County Health Care Agency
2323 Knoll Drive, Room 410
Ventura, CA 93003
Telephone: (805) 677-5165
Facsimile: (805) 677-5118

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 VCMC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) VCMC's compliance with the terms of this IA; and (b) VCMC's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by VCMC 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 VCMC's employees, contractors, and agents who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, contractor, or agent and OIG. VCMC agrees to assist OIG in contacting and arranging interviews with such employees, contractors, and agents upon OIG's request. VCMC's employees may elect to be interviewed with or without a representative of VCMC present.

VIII. DOCUMENT AND RECORD RETENTION

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

Exhibit A

IX. DISCLOSURES

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

Ventura County 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, Ventura County 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 150 days after the effective date of this IA and concluding at the end of the term of this IA, VCMC 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 VCMC 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 VCMC:

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

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

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

4. A Stipulated Penalty of $1,500 (which shall begin to accrue on the date the VCMC fails to grant access) for each day VCMC 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) business days after the date that OIG provides notice to VCMC of the failure to comply) for each day VCMC fails to comply fully and adequately with any obligation of this IA. In its notice to VCMC, OIG shall state the specific grounds for its determination that the VCMC has failed to comply fully and adequately with the IA obligation(s) at issue. With respect to the Stipulated Penalty provision described in this section X.A.5 only, the OIG shall not seek a Stipulated Penalty if VCMC demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-business-day period, but that: (i) VCMC has begun to take action to cure the failure to comply, (ii) VCMC is pursuing such action with due diligence, and (iii) VCMC has provided to OIG a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties

1. *Demand Letter.* Upon finding that VCMC has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify VCMC by personal service or certified mail of (a) VCMC'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 ten (10) days of VCMC's receipt of the Demand Letter, VCMC 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 VCMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until VCMC 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.* VCMC 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 VCMC 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 VCMC 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 Ventura County 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. Exclusion for Material Breach of this IA

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 VCMC constitutes an independent basis for VCMC'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 VCMC has materially breached this IA and that exclusion should be imposed, the OIG shall notify VCMC by certified mail of (a) VCMC'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.* VCMC 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. VCMC 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) VCMC has begun to take action to cure the material breach, (ii) VCMC is pursuing such action with due diligence, and (iii) VCMC 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, VCMC fails to satisfy the requirements of section X.C.2, OIG may exclude VCMC from participation in the Federal health care programs. OIG will notify VCMC in writing of its determination to exclude VCMC (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 VCMC is excluded under the provisions of this IA, VCMC 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 VCMC 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 VCMC 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, VCMC 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 VCMC'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. VCMC 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 VCMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that VCMC 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 VCMC 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) VCMC had begun to take action to cure the material breach within the 35 day period, (ii) VCMC is pursuing such action with due diligence, and (iii) VCMC provided to OIG within the 35 day period a reasonable timetable for curing the material breach.

Exhibit A

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. VCMC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude VCMC 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 VCMC 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, Ventura County and OIG agree as follows:

A. This IA shall be binding on the successors, assigns and transferees of Ventura County or VCMC;

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 Ventura County 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.

Exhibit A

ON BEHALF OF VENTURA COUNTY

Susan K. Lacey — 11/3/99

SUSAN K. LACEY — DATE
Chair, Ventura County Board of Supervisors

[signature] — 11/3/99

PIERRE DURRAND — DATE
Director, Ventura County Health Care Agency

[signature] — 11/3/99

PIERRE DURRAND — DATE
Administrator, Ventura County Medical Center

[signature] — 11/4/99

DARON TOOCH — DATE
HOOPER, LUNDY & BOOKMAN
Counsel for Ventura County, Ventura County Medical Center, and Ventura County Health Care Agency

Exhibit A

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

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

11/4/99
DATE

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

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Ventura County ("Ventura") entered into an Integrity Agreement ("IA") on November 4, 1999.

A. Pursuant to section XI.C. of Ventura's IA, modifications to the IA may be made with the prior written consent of both the OIG and Ventura. Therefore, the OIG and Ventura hereby agree that Ventura'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.

The attached Appendix A and Attachment 1 are hereby added to Ventura's IA.

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

C. The undersigned Ventura 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.

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

ON BEHALF OF VENTURA COUNTY

Frank Schillo
Chair, Board of Supervisors
County of Ventura

1/15/02
DATE

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

Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

1/23/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. VCMC 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 VCMC in assessing and evaluating its billing and coding practices and systems. Each IRO retained by VCMC 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 VCMC seeks reimbursement. Each IRO shall assess, along with VCMC, 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 VCMC's billing and coding to the Federal health care programs ("Claims Review").

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

c. Retention of Records. The IRO and VCMC 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 VCMC related to the reviews).

2. *Claims Review.* The Claims Review shall include two Discovery Samples and, if necessary, one or more Full Samples. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this IA, which is incorporated by reference.

a. Mental Health Services Discovery Sample. Each year, the IRO shall randomly select and review a sample of 50 mental health services Paid Claims submitted by or on behalf of VCMC to any Federal health care program. The Paid Claims shall be reviewed based on the supporting documentation available at VCMC or under VCMC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

b. Rotating Discovery Sample. For the first year following the execution of this IA, the IRO shall conduct a review of claims for outpatient hospital services

submitted by or on behalf of VCMC to any Federal health care program. For the second year following the execution of this IA, the IRO shall randomly select and review a sample of 50 inpatient hospital services Paid Claims submitted by or on behalf of VCMC to any Federal health care program. For the third year following the execution of this IA, the IRO shall randomly select and review a sample of 50 laboratory services Paid Claims submitted by or on behalf of VCMC to any Federal health care program. For the fourth year following the execution of this IA, the IRO shall randomly select and review a sample of 50 outpatient hospital services Paid Claims submitted by or on behalf of VCMC to any Federal health care program. For the fifth year following the execution of this IA, the IRO shall randomly select and review a sample of 50 inpatient hospital services Paid Claims submitted by or on behalf of VCMC to any Federal health care program. In each year, the Paid Claims shall be reviewed based on the supporting documentation available at VCMC or under VCMC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

c. Results of Discovery Samples. If the Error Rate (as defined in Appendix A) for either the Mental Health Services Discovery Sample or the Rotating Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, VCMC should, as appropriate, further analyze any errors identified in the applicable Discovery Sample. VCMC 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 Samples.). If the Error Rate for the Mental Health Services Discovery Sample or the Rotating Discovery Sample is 5% or greater, the IRO shall perform a Full Sample and a Systems Review relating to that Discovery Sample, as described below.

d. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.c, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at VCMC or under VCMC'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 applicable Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, VCMC may use the Items sampled as part of the applicable 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 VCMC 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.

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

f. Repayment of Identified Overpayments. In accordance with section III.H.1 of the IA, VCMC agrees to repay within 30 days any Overpayment(s) identified in the Discovery Samples or the Full Samples (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. VCMC 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"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) VCMC's Claims 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 complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). VCMC 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 VCMC's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify VCMC 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, VCMC may request a meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the

proposed Validation Review. VCMC 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 with VCMC 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.* The IRO shall include in its report(s) to VCMC a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims 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 VCMC 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 VCMC and for which VCMC has received reimbursement from any Federal health care program.

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

e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The 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 VCMC cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by VCMC for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for

each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

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

1. **Claims Review Methodology.**

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

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

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

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Discovery Samples and, if any, Full Samples 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. **Claims Review Findings.**

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

b. The IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review, including the results of the Discovery Samples, and the results of the Full Samples (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. In addition, the report for the Mental Health Services Discovery Sample specifically shall include the IRO's findings regarding (i) VCMC's treatment plans for mental health services provided to Medicare beneficiaries, (ii) VCMC's use of physician identifiers, (iii) VCMC's submission of claims as "provider based" services or treatments and such claims' compliance with the requirements of the Federal health care program(s) to which such claims were submitted; and (iv) whether VCMC has complied with its obligation under the Settlement Agreement 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 denial of claims. Note: for the purpose of this reporting, 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 Samples or Full Samples (as applicable) shall be included as part of the net Overpayment calculation.

c. The IRO's findings and recommendations concerning the Systems Review (if any).

3. **Statistical Sampling Documentation.**

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

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 Samples, if applicable.

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

4. **Claims Review Results.**

a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by VCMC ("Claims 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 VCMC.

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

d. Error Rate in the sample.

e. 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.)

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

6. **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.

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt