CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

SIERRA VISTA REGIONAL MEDICAL CENTER AND TWIN CITIES COMMUNITY HOSPITAL

I. PREAMBLE

Sierra Vista Regional Medical Center (Sierra Vista) and Twin Cities Community Hospital (Twin Cities) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Sierra Vista and Twin Cities may be collectively referred to in this CIA as "SV/TC." However, Sierra Vista and Twin Cities are each required to implement all obligations in this CIA at their respective facility. Tenet Healthcare Corporation (Tenet) owns and operates Sierra Vista, Twin Cities, as well as other hospitals across the United States. Tenet undertakes certain obligations under this CIA that relate to the operation and oversight of Sierra Vista and Twin Cities. The obligations of this CIA do not apply to any other hospital owned or operated by Tenet. Contemporaneously with this CIA, SV/TC is entering into a Settlement Agreement with the United States.

SV/TC represents that SV/TC has implemented a compliance program that includes the following elements: a compliance officer, a compliance committee, training and education, policies and procedures, a hotline for reporting compliance issues, monitoring and auditing activities, screening of ineligible persons, and removal requirements for ineligible persons. SV/TC shall continue its compliance program throughout the term of this CIA and shall do so in accordance with the terms set forth below. SV/TC may modify its compliance program as appropriate, but, at a minimum, SV/TC shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

- A. <u>Effective Date</u>. The "Effective Date" of this CIA shall be the signature date of the final signatory to this CIA.
- B. <u>Term.</u> The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) SV/TC's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect

until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and SV/TC complies with the decision.

C. Definitions.

- 1. "Arrangements" means:
 - a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between SV/TC and (i) any actual or potential source of health care business or referrals to SV/TC or (ii) any actual or potential recipient of health care business or referrals from SV/TC; and
 - b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between SV/TC and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to SV/TC for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
 - i. "Source of health care business or referrals" means any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
 - ii. "Recipient of health care business or referrals" means any individual or entity (a) to whom SV/TC refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom SV/TC purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service, for which payment may be made in whole or in part by a Federal health care program.
- 2. "Certifying Employees" means the following: all members of SV/TC senior management and the leaders of all business units, divisions or departments with operations that relate to the Federal health care programs and Tenet employees with direct oversight of SV/TC, including Group Chief Executive Officer, Market Chief Financial Officer, Group Chief Financial Officer, Group Director of Revenue Analysis, Assistant Vice President Managed Care California, Director of Managed Care California, Managed Care Compliance Officer, Group Lead Compliance Officer, Vice President Hospital Compliance Operations, Senior Vice President and Chief Compliance Officer, and Senior Director of Quality Management.

- 3. "Covered Persons" means: (a) all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, board members, and employees of SV/TC; (b) all contractors who furnish patient care items or services or perform billing or coding functions on behalf of SV/TC; (c) all physicians and other non-physician practitioners who are members of SV/TC's active medical staff; and (d) any officers or employees of Tenet with oversight or management responsibilities of SV/TC specifically referenced in this CIA, including but not limited to any Certifying Employees;
- 4. "Disclosure Program" means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual's chain of command any potential violations of criminal, civil, or administrative law related to the Federal health care programs or any issues or questions associated with SV/TC's policies, conduct, practices, or procedures.
- 5. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.
- 6. "Ineligible Person" means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.
- 7. "Overpayment" means any funds that SV/TC receives or retains under any Federal health care program to which SV/TC, after applicable reconciliation, is not entitled under such Federal health care program.
- 8. "Reportable Event" means: (a) a substantial Overpayment; (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with or having as a member of the active medical staff a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by SV/TC.
- 9. "Reporting Period" means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.
- 10. "Training Plan" means a written plan that outlines the steps SV/TC will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding SV/TC's CIA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. § 1395nn (the Stark Law).

11. "Transition Plan" means a plan to address whether and how SV/TC's compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA's term.

III. COMPLIANCE PROGRAM REQUIREMENTS

SV/TC shall establish and maintain a compliance program that includes the following elements:

- A. <u>Compliance Officer, Compliance Committee, Board Oversight, and Management</u> Certifications.
- 1. Compliance Officer. Within 90 days after the Effective Date, SV/TC shall appoint a Compliance Officer for SV/TC ("Compliance Officer") who is an employee of a Tenet entity and a member of senior management of SV/TC. The Compliance Officer shall report directly to the Chief Executive Officer of SV/TC and shall not be or be subordinate to the General Counsel or Chief Financial Officer of SV/TC or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for SV/TC. The Compliance Officer shall be authorized to report to the Chief Compliance Officer for Tenet (Chief Compliance Officer), the SV/TC Boards of Directors (SV/TC Boards), and the Tenet Board regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:
 - a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
 - b. making at least quarterly reports regarding compliance matters to the SV/TC Boards;
 - c. monitoring the day-to-day compliance activities engaged in by SV/TC; and
 - d. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

The Chief Compliance Officer shall make at least quarterly reports regarding compliance matters related to SV/TC and the status of compliance with the terms of the CIA to the Tenet Board.

SV/TC shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. Compliance Committee. Within 90 days after the Effective Date, SV/TC shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.J below. The Compliance Committee shall meet at least quarterly.

SV/TC shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. Board Oversight. The SV/TC Boards shall be responsible for the review and oversight of SV/TC's compliance with Federal health care program requirements and the requirements of this CIA. The SV/TC Boards must include independent (i.e., non-employee and non-executive) members.

The SV/TC Boards shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee SV/TC's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the materials it reviewed and any additional steps taken, such as the engagement of an independent advisor or other third-party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution approved by each member of the SV/TC Boards regarding its review and oversight of SV/TC's compliance with Federal health care program requirements and the requirements of this CIA.

At minimum, the resolution shall include the following language:

"The Board has made a reasonable inquiry into the operations of [SV's or TC's] compliance program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [SV or TC] has implemented an effective compliance program to meet Federal health care program requirements and the requirements of [SV's or TC's] Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

If the SV/TC Boards are unable to adopt such a resolution, the applicable board shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps the applicable board is taking to implement an effective compliance program at SV/TC.

SV/TC shall report to OIG, in writing, any changes in the membership of the SV/TC Boards, within 15 business days after such a change.

4. *Management Certifications*. The Certifying Employees shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable SV/TC division or department is in compliance with applicable Federal health care program requirements and the requirements of this CIA. For each Reporting Period, each Certifying Employee shall certify as follows:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of division or department], an area under my supervision. My job responsibilities include ensuring [insert name of division or department]'s compliance with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and SV/TC's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide this certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, SV/TC shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards. Within 90 days after the Effective Date, SV/TC shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of SV/TC's compliance program, including the compliance program requirements outlined in this CIA; (2) SV/TC's compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law, and the regulations and other guidance documents related to these statutes; (3) a written review and approval process for Arrangements, the purpose of which is to ensure that all Arrangements do not violate the Anti-Kickback Statute and the Stark Law; and (4) the identification, quantification, and repayment of Overpayments. SV/TC shall enforce its Policies and Procedures and make compliance with its Policies and Procedures an element of evaluating

the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures as necessary. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. <u>Training and Education</u>.

- 1. Covered Persons Training. Within 90 days after the Effective Date, SV/TC shall develop a Training Plan that includes the following information: (a) training topics: (b) categories of Covered Persons required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.
- 2. Board Training. Within 90 days after the Effective Date, members of the SV/TC Boards shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of the OIG's guidance on board member responsibilities. Each member of the SV/TC Boards also shall receive the training described in Section III.C.1.

New members of the SV/TC Boards shall receive the training described in this Section III.C.2 within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the SV/TC Board training at least annually and update the training as necessary.

3. *Training Records*. SV/TC shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

- 1. *General Description*.
 - a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, SV/TC shall engage an entity (the "Independent Review Organization" or "IRO") that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.

- b. Retention of Records. The IRO and SV/TC shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and SV/TC related to the reviews described in this Section III.D.
- c. Access to Records and Personnel. SV/TC shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D and that all records furnished to the IRO are accurate and complete.
- 2. Claims Review. The IRO shall review claims submitted by SV/TC and reimbursed by the Medicare and Medicaid programs, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted, and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.
- 3. Independence and Objectivity Certification. The IRO shall include in its report(s) to SV/TC a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between SV/TC and the IRO.
- E. <u>Risk Assessment and Internal Review Process</u>. Within 90 days after the Effective Date, SV/TC shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with SV/TC's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries and the Anti-Kickback Statute and Stark Law risks associated with Arrangements. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require SV/TC to: (1) identify and prioritize risks, (2) develop work plans or audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.
- F. <u>Disclosure Program</u>. Within 90 days after the Effective Date, SV/TC shall establish a Disclosure Program. SV/TC shall appropriately publicize the existence of the Disclosure Program (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to use of the Disclosure Program and SV/TC shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each

disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. <u>Ineligible Persons</u>.

- 1. *Screening Requirements*. SV/TC shall:
 - screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process or medical staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons;
 - b. screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter; and
 - c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.
- 2. Removal Requirement. If SV/TC has actual notice that a Covered Person has become an Ineligible Person, SV/TC shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid for in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and SV/TC may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether SV/TC meets the requirements of Section III.G.
- H. <u>Notification of Government Investigation or Legal Proceeding</u>. SV/TC shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that SV/TC has committed a crime or has engaged in fraudulent activities, within 30 days of SV/TC receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding.

Within 30 days after resolution of the matter, SV/TC shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

- I. <u>Reportable Events</u>. SV/TC shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:
 - 1. Substantial Overpayment. The report to OIG shall include:
 - a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
 - b. the Federal health care programs affected by the Reportable Event;
 - c. a description of the steps taken by SV/TC to identify and quantify the Overpayment; and
 - d. a description of SV/TC's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, SV/TC shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance, and provide OIG with documentation of the repayment.

- 2. Probable Violation of Law. The report to OIG shall include:
 - a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
 - b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;
 - c. the Federal health care programs affected by the Reportable Event;
 - d. a description of the steps taken by SV/TC to identify and quantify any Overpayments; and

e. a description of SV/TC's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, SV/TC shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

- 3. *Ineligible Person*. The report to OIG shall include:
 - a. the identity of the Ineligible Person and the job duties performed by that individual;
 - b. the dates of the Ineligible Person's employment or contractual relationship or medical staff membership;
 - c. a description of the Exclusion Lists screening that SV/TC completed before and/or during the Ineligible Person's employment or contract or medical staff membership and any flaw or breakdown in the screening process that led to the hiring or contracting with or credentialing the Ineligible Person;
 - d. a description of how the Ineligible Person was identified; and
 - e. a description of any corrective action implemented to prevent future employment or contracting with or medical staff membership an Ineligible Person.
- 4. *Bankruptcy*. The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.
- 5. Reportable Events Involving the Stark Law. Any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by SV/TC to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if SV/TC identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then SV/TC is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.
- J. <u>Transition Plan</u>. Prior to the end of the fourth Reporting Period, SV/TC shall develop a Transition Plan that is reviewed and approved by the SV/TC Boards. The Transition Plan shall be implemented following the end of the CIA's term. A copy of SV/TC's approved Transition Plan shall be included in SV/TC's fourth Annual Report.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, SV/TC proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. SV/TC shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit, or location.

If SV/TC wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, SV/TC must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. <u>IMPLEMENTATION REPORT AND ANNUAL REPORTS</u>

- A. <u>Implementation Report</u>. Within 120 days after the Effective Date, SV/TC shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:
- 1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;
- 2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
- 3. the names of the SV/TC Board members who are responsible for satisfying the compliance requirements described in Section III.A.3;
- 4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
 - 5. a list of the Policies and Procedures required by Section III.B;

- 6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
- 7. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to SV/TC that includes a summary of all current and prior engagements between SV/TC and the IRO;
- 8. a description of the risk assessment and internal review process required by Section III.E;
 - 9. a description of the Disclosure Program required by Section III.F;
- 10. a description of the Ineligible Persons screening and removal process required by Section III.G;
- a description of SV/TC's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
- 12. a list of all of SV/TC's locations (including mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and
- 13. a certification by the Chief Compliance Officer, the SV/TC Compliance Officer and the SV/TC Chief Executive Officer that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, SV/TC has implemented and is in compliance with all of the requirements of this CIA;
 - b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful: and
 - c. he or she understands that the certification is being provided to and relied upon by the United States.
- B. <u>Annual Reports</u>. SV/TC shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods that includes, at a minimum, the following information:
- 1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the SV/TC Board members who are responsible for satisfying the Board

compliance requirements, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, SV/TC Boards, or Certifying Employees;

- 2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);
- 3. the dates of each report made by the Compliance Officer to the SV/TC Boards and the Tenet Board (written documentation of such reports shall be made available to OIG upon request);
- 4. the SV/TC Board resolutions required by Section III.A.3 and a description of the materials reviewed by the SV/TC Boards and any additional steps taken in their oversight of the compliance program and in support of making the resolution;
- 5. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
 - 6. the certifications of Certifying Employees required by Section III.A.4;
- 7. a list of any new or revised Policies and Procedures required by Section III.B. developed during the Reporting Period;
- 8. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons and SV/TC Board members during the Reporting Period;
- 9. a complete copy of all reports prepared pursuant to Section III.D and SV/TC's response to the reports, along with corrective action plan(s) related to any issues raised by the report, and documentation of SV/TC's refund of the Estimated Overpayment (as defined in Appendix B to this CIA);
- 10. a certification from the IRO regarding its professional independence and objectivity with respect to SV/TC, including a summary of all current and prior engagements between SV/TC and the IRO;
- 11. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;
- 12. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (c) internal audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

- 13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;
- 14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;
- 15. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 16. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;
- 17. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.J;
- 18. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and SV/TC's response and corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;
- 19. a description of all changes to the most recently provided list of SV/TC's locations (including addresses) as required by Section V.A.12;
- 20. a description of any changes to SV/TC's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and
- 21. a certification by the Chief Compliance Officer, the SV/TC Compliance Officer and by the SV/TC Chief Executive Officer that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, SV/TC has implemented and is in compliance with all of the requirements of this CIA;
 - b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
 - c. he or she understands that the certification is being provided to and relied upon by the United States.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

All notifications and reports required under this CIA shall be submitted using the following contact information:

OIG:

Administrative and Civil Remedies Branch 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, S.W. Washington, DC 20201 Telephone: 202.619.2078

Email Address: officeofcounsel@oig.hhs.gov

SV/TC:

Hospital Compliance Officer 1100 Las Tablas Road Templeton, California 93465 Telephone: 833.300.8748

Email Address: SVTCComplianceOfficer@tenethealth.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify SV/TC in writing of any changes to the OIG contact information listed above. SV/TC shall notify OIG in writing within two business days of any changes to the SV/TC contact information listed above.

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 conduct interviews, examine and/or request copies of or

copy SV/TC's books, records, and other documents and supporting materials, and conduct onsite reviews of any of SV/TC's locations, for the purpose of evaluating: (a) SV/TC's compliance with the requirements of this CIA and (b) SV/TC's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by SV/TC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of SV/TC's owners (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), employees, contractors, and Board members 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. SV/TC shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. SV/TC's owners (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), employees, contractors, and Board members may elect to be interviewed with or without a representative of SV/TC present.

VIII. DOCUMENT AND RECORD RETENTION

SV/TC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. <u>DISCLOSURES</u>

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify SV/TC prior to any release by OIG of information submitted by SV/TC pursuant to this CIA and identified upon submission by SV/TC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, SV/TC shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. <u>BREACH AND DEFAULT PROVISIONS</u>

- A. Stipulated Penalties. OIG may assess:
- 1. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.A;
- 2. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.B;
- 3. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.C;
- 4. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.D;

- 5. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.E:
- 6. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.F:
- 7. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.G:
- 8. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.H;
- 9. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.I:
- 10. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section III.J;
- 11. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section IV;
- 12. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section V;
- 13. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section VII;
- 14. A Stipulated Penalty of up to \$2,500 for each day SV/TC fails to comply with Section VIII; or
- 15. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of SV/TC under this CIA.
- B. <u>Timely Written Requests for Extensions</u>. SV/TC may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. 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 SV/TC fails to meet the revised deadline set by OIG. If OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after SV/TC receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG

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

C. <u>Payment of Stipulated Penalties</u>.

- 1. Demand Letter. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify SV/TC of: (a) SV/TC's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")
- 2. Response to Demand Letter. Within 15 business days after the date of the Demand Letter, SV/TC shall either: (a) pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.
- 3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

D. Exclusion for Material Breach.

- 1. *Definition of Material Breach*. A material breach of this CIA means:
 - a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;
 - b. failure to comply with Section III.A.1;
 - c. failure to comply with Section III.D;
 - d. failure to comply with Section III.I;
 - e. failure to comply with Section V;
 - f. failure to respond to a Demand Letter in accordance with Section X.C:
 - g. a false statement or false certification made to OIG by or on behalf of SV/TC under this CIA;
 - h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering SV/TC to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

- i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by SV/TC constitutes an independent basis for SV/TC's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that SV/TC has materially breached this CIA, OIG shall notify SV/TC of: (a) SV/TC's material breach and (b) OIG's intent to exclude SV/TC. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")
- 3. Response to Notice. SV/TC shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.
- 4. Exclusion Letter. If OIG determines that exclusion is warranted, OIG shall notify SV/TC in writing of its determination to exclude SV/TC. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by SV/TC, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, SV/TC may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

- 1. Review Rights. Upon OIG's issuing a Demand Letter or Exclusion Letter to SV/TC, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, SV/TC 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. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at
- http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether SV/TC was in full and

timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. SV/TC shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that SV/TC has breached this CIA and orders SV/TC to pay Stipulated Penalties, SV/TC must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless SV/TC properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, SV/TC must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether SV/TC was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. SV/TC shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of SV/TC, SV/TC shall be reinstated effective on the date of the original exclusion.
- 4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and SV/TC agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

SV/TC and OIG agree as follows:

- A. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) SV/TC's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.
- C. The undersigned SV/TC signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.
- D. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF SIERRA VISTA REGIONAL MEDICAL CENTER

/Mark Lisa/	12/1/2022
MARK LISA	DATE
Chief Executive Officer	
Sierra Vista Regional Medical Center	
/Bill Morrison/ BILL MORRISON Partner, Haynes and Boone, LLP	<u>12/2/22</u> DATE
Counsel for Sierra Vista Regional Medical Center	
/Stacy Brainin/	12/2/22
STACY BRAININ	DATE
Partner, Haynes and Boone, LLP Counsel for Sierra Vista Regional Medical Center	
ON BEHALF OF TWIN CITIES COM	IMUNITY HOSPITAL
/Mark Lisa/	12/1/2022
MARK LISA	DATE
Chief Executive Officer	2
Twin Cities Community Hospital	

	10/0/00
/Bill Morrison/	<u>12/2/22</u>
BILL MORRISON Portner Haynes and Bases LLB	DATE
Partner, Haynes and Boone, LLP Counsel for Twin Cities Community Hospital	
Counsel for Twin Cities Community Hospital	
/Stacy Brainin/	<u>12/2/22</u>
STACY BRAININ	DATE
Partner, Haynes and Boone, LLP Counsel for Twin Cities Community Hospital	
Counsel for 1 win Cities Community Hospital	
ON BEHALF OF THE OFFICE OF IN	ISPECTOR CENERAL
OF THE DEPARTMENT OF HEALTH	
/Lisa M. Re/	12/02/2022
LISA M. RE	DATE
Assistant Inspector General for Legal Affairs	2112
Office of Inspector General	
U.S. Department of Health and Human Services	
/Sarah Kessler/	12/05/2022
SARAH KESSLER	DATE
Senior Counsel	
Office of Inspector General	
U.S. Department of Health and Human Services	

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

- 1. SV/TC shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by SV/TC in response to a request by OIG, whichever is later, OIG will notify SV/TC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SV/TC may continue to engage the IRO.
- 2. If SV/TC engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, SV/TC shall submit the information identified in Section V.A.7 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by SV/TC at the request of OIG, whichever is later, OIG will notify SV/TC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SV/TC may continue to engage the IRO.

B. <u>IRO Qualifications</u>

The IRO shall:

- 1. assign individuals to conduct the Claims Review who have expertise in the Federal health care program requirements applicable to the claims being reviewed;
- 2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
- 3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);
- 4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and
- 5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. <u>IRO Responsibilities</u>

The IRO shall:

- 1. perform each Claims Review in accordance with the specific requirements of the CIA;
- 2. follow all applicable Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review;
- 3. request clarification from the applicable Federal health care program if in doubt of the application of a particular program policy or regulation;
 - 4. respond to all OIG inquires in a prompt, objective, and factual manner; and
- 5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. <u>SV/TC Responsibilities</u>

SV/TC shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

- 1. SV/TC and IRO. If SV/TC terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, SV/TC must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. SV/TC must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.
- 2. OIG Removal of IRO. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify SV/TC in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. SV/TC shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of

any information provided by SV/TC regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify SV/TC in writing that SV/TC shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. SV/TC must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require SV/TC to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

- A. <u>Claims Review</u>. The IRO shall perform the Claims Review at Sierra Vista and Twin Cities for each of the five Reporting Periods.
 - 1. Definitions.
 - a. "Sierra Vista Paid Claim" means a claim submitted by Sierra Vista and for which Sierra Vista has received reimbursement from the Medicare program or a Medicaid Managed Care Organization.
 - b. "Twin Cities Paid Claim" means a claim submitted by Twin Cities and for which Twin Cities has received reimbursement from the Medicare program or a Medicaid Managed Care Organization.
 - "Sierra Vista Population" means all Sierra Vista Paid Claims during the c. 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Sierra Vista Population to one or more subset(s) of Paid Claims to be reviewed and shall notify Sierra Vista and the IRO of its selection of the Sierra Vista Population at least 30 days prior to the end of each Reporting Period. Sierra Vista, or its IRO on behalf of Sierra Vista, may submit proposals identifying suggestions for the subset(s) of Sierra Vista Paid Claims to be reviewed at least 120 days prior to the end of each Reporting Period. In connection with limiting the Sierra Vista Population, OIG may consider (1) proposals submitted by Sierra Vista or its IRO, (2) information furnished to OIG regarding the results of Sierra Vista's internal risk assessment and internal auditing, or (3) other information obtained by OIG. The determination of whether, and in what manner, to limit the Sierra Vista Population shall be made at the sole discretion of OIG.
 - d. "Twin Cities Population" means all Twin Cities Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Twin Cities Population to one or more subset(s) of Paid Claims to be reviewed and shall notify Twin Cities and the IRO of its selection of the Twin Cities Population at least 30 days prior to the end of each Reporting Period. Twin Cities, or its IRO on behalf of Twin Cities, may submit proposals identifying suggestions for the subset(s) of Twin Cities Paid Claims to be reviewed at least 120 days prior to the end of each Reporting Period. In connection with limiting the Twin Cities Population, OIG may consider (1) proposals submitted by Twin Cities or its IRO, (2) information furnished to OIG regarding the results of Twin Cities' internal risk assessment and internal auditing, or (3) other information obtained by OIG. The determination of whether, and in what

- manner, to limit the Twin Cities Population shall be made at the sole discretion of OIG.
- c. "Overpayment" means the amount of money Sierra Vista or Twin Cities (as applicable) has received in excess of the amount due and payable under Medicare or Medicaid Managed Care Organization requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix.
- d. "Error Rate" means the percentage of net Overpayments identified in each Claims Review Sample. The net Overpayment for each Claims Review Sample shall be calculated by subtracting all underpayments identified in the Claims Review Sample from all Overpayments identified in the Claims Review Sample. The Error Rate is calculated by dividing the net Overpayment by the total dollar amount associated with the Paid Claims in the Claims Review Sample.
- Claims Review Samples. For the first Reporting Period of the CIA, the IRO shall select a random sample of 100 Sierra Vista Medicare Paid Claims and a random sample of 100 Twin Cities Medicare Paid Claims (Claims Review Samples). The IRO shall review the Paid Claims based on Sierra Vista's or Twin Cities' documentation (as applicable) and the applicable Medicare program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For the second Reporting Period of the CIA, the IRO shall select a random sample of 100 Sierra Vista Medicaid Managed Care Paid Claims and a random sample of 100 Twin Cities Medicaid Managed Care Paid Claims. The IRO shall review the Paid Claims based on Sierra Vista's or Twin Cities' documentation (as applicable) and the applicable Medicaid Managed Care Organization requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For the remaining three Reporting Periods, at least 30 days prior to the end of the applicable Reporting Period, the OIG shall select whether the Claims Review Samples shall consist of Medicare Paid Claims or Medicaid Managed Care Paid Claims and shall notify Sierra Visit and Twin Cities of its selection.

3. *Other Requirements.*

a. <u>Supplemental Materials</u>. The IRO shall request all documentation required for its review of the Sierra Vista Paid Claims and the Twin Cities Paid Claims in the Claims Review Samples and Sierra Vista or Twin Cities (as applicable) shall furnish such documentation to the IRO prior to the IRO initiating its review of the Claims Review Samples. If the IRO accepts any supplemental documentation from Sierra Vista or Twin Cities (as applicable) after the IRO has completed its initial review of the Claims Review Samples (Supplemental Materials), the IRO shall include the following in the Claims Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental

- Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.
- b. <u>Paid Claims without Supporting Documentation</u>. Any Paid Claim for which Sierra Vista or Twin Cities (as applicable) cannot produce documentation shall be considered an error and the total reimbursement received by Sierra Vista or Twin Cities for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims without documentation is not permitted.
- c. <u>Use of First Sample Drawn</u>. The first set of Paid Claims selected shall be used for each Claims Review Sample (<u>i.e.</u>, it is not permissible to generate more than one list of random samples and then select one for use).
- 4. Repayment of Estimated Overpayment. The findings of each Claims Review Sample shall be used by the IRO to estimate the actual Overpayment in the applicable Population with the point estimate and a two-sided 90% confidence interval. Within 60 days of receipt of the Claims Review Report, Sierra Vista and Twin Cities shall repay the lower limit of the two-sided 90% confidence interval (Estimated Overpayment) to the Centers for Medicare and Medicaid Services (CMS) or the applicable Medicaid Managed Care Organization.

 Documentation of Sierra Vista's and Twin Cities' refund of the Estimated Overpayment to CMS or a Medicaid Managed Care Organization shall be submitted to OIG with the Annual Report. OIG, in its sole discretion, may refer the findings of the Claims Review Samples to the applicable payor(s) for appropriate follow up.
- B. <u>Claims Review Report</u>. The IRO shall prepare a Claims Review Report for each Claims Review that includes the following information:
 - 1. Claims Review Methodology.
 - a. <u>Claims Review Objective</u>. A statement of the objective intended to be achieved by the Claims Review.
 - b. <u>Claims Review Population</u>. A description of the Sierra Vista Population and the Twin Cities Population subject to the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify Sierra Vista Paid Claims in the Sierra Vista Population and the Twin Cities Paid Claims in the Twin Cities Population and (2) the specific documentation and other information sources relied on by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicaid Managed Care Organization contract terms, Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

- d. <u>Review Protocol</u>. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. <u>Supplemental Materials</u>. The information regarding any Supplemental Materials required by A.3.a., above.
- 2. Statistical Sampling Documentation.
 - a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
 - b. A description or identification of the statistical sampling software package used by the IRO.
- 3. Claims Review Findings.
 - a. <u>Narrative Results</u>.
 - i. A description of Sierra Vista's and Twin Cities' billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at Sierra Vista and Twin Cities to ensure that all items and services furnished by Sierra Vista and Twin Cities are correctly coded, appropriately documented, and medically necessary.
 - iii. A narrative explanation of the results of the IRO's review of the Claims Review Samples, including an explanation of all errors identified by the IRO.

b. Quantitative Results.

- Total number and percentage of instances in which the IRO determined that the coding of the Sierra Vista Paid Claims Sierra Vista differed from what should have been the correct coding. Total number and percentage of instances in which the IRO determined that the coding of the Twin Cities Paid Claims differed from what should have been the correct coding.
- ii. Total number and percentage of instances in which the IRO determined that a Sierra Vista Paid Claim or a Twin Cities Paid Claim (as applicable) was not appropriately documented.
- iii. Total number and percentage of instances in which the IRO determined that a Sierra Vista Paid Claim or a Twin Cities Paid

- Claim (as applicable) was for items or services that were not medically necessary.
- iv. Total dollar amount of Sierra Vista Paid Claims included in the Sierra Vista Claims Review Sample and the net Overpayment associated with the Sierra Vista Claims Review Sample. Total dollar amount of Twin Cities Paid Claims included in the Twin Cities Claims Review Sample and the net Overpayment associated with the Twin Cities Claims Review Sample.
- v. Error Rate in the Sierra Vista Claims Review Sample and the Error Rate in the Twin Cities Claims Review Sample.
- vii. An estimate of the actual Overpayment in the Sierra Vista Population with the point estimate and a two-sided 90% confidence interval and an estimate of the actual Overpayment in the Twin Cities Population with the point estimate and a two-sided 90% confidence interval.
- viii. For each Claims Review Sample, a spreadsheet of the Claims Review results that includes the following information for each Paid Claim:
 - 1. Federal health care program billed;
 - 2. Beneficiary health insurance claim number;
 - 3. Date of service;
 - 4. Code submitted (<u>e.g.</u>, DRG, CPT code, etc.);
 - 5. Code reimbursed;
 - 6. Allowed amount reimbursed by payor;
 - 7. Correct code (as determined by the IRO);
 - 8. Correct allowed amount (as determined by the IRO):
 - 9. Whether the item or service was medically necessary;
 - 10. Whether the item or service was appropriately documented;
 - 11. The dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Sierra Vista's and Twin Cities' billing and coding system or to Sierra Vista's and Twin Cities' controls for ensuring that all items and services billed under the Medicare or Medicaid program by Sierra Vista and Twin Cities are correctly coded, appropriately documented, and medically necessary, based on the findings of the Claims Review.

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.