

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SUTTER HEALTH,
SUTTER BAY MEDICAL FOUNDATION,
AND SUTTER VALLEY MEDICAL FOUNDATION**

I. PREAMBLE

Sutter Health (Sutter Health), a California nonprofit public benefit corporation; Sutter Bay Medical Foundation (SBMF), a California nonprofit public benefit corporation¹; and Sutter Valley Medical Foundation (SVMF), a California nonprofit public benefit corporation², (SBMF and SVMF collectively the “Foundations”) (Sutter Health and Foundations together, “Sutter”) 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). Contemporaneously with this CIA, Sutter is entering into a Settlement Agreement with the United States. The obligations of this CIA apply to Sutter to the extent it engages in Covered Functions, as defined below in Section II.C.5, and do not apply to any Sutter-owned or operated hospitals or ambulatory surgical centers.

¹ SBMF does business as Palo Alto Medical Foundation (PAMF), Sutter East Bay Medical Foundation (SEBMF), Sutter Pacific Medical Foundation (SPMF), PAMF Research Institute, PAMF Surgery Center Mountain View, PAMF Surgery Center Fremont, PAMF Surgery Center Palo Alto, PAMF Surgery Center San Carlos, PAMF Surgery Center San Jose, PAMF Surgery Center Los Altos, and Sutter Walk-In Care. This CIA shall apply only the operations of PAMF, SEBMF and SPMF, to the extent they engage in Covered Functions.

² SVMF does business as Sutter Gould Medical Foundation (SGMF), Sutter Medical Foundation (SMF), Sutter Walk-In Care, Briggsmore Specialty Center, Sutter Medical Foundation Surgery and Endoscopy Center, Sutter Elk Grove Surgery Center, Stockton Surgery Center, and Sutter North Brownsville Family Practice Center. This CIA shall apply only the operations of SGMF and SMF to the extent they engage in Covered Functions.

Sutter represents that, prior to this CIA, Sutter voluntarily established a Compliance Program which provides for a Chief Compliance Officer, a Compliance Committee, Foundation compliance officers, a compliance training and education program, a confidential disclosure reporting hotline, auditing and monitoring activities, and various policies and procedures aimed at ensuring that Sutter's participation in the Federal health care programs conforms to all Federal and state laws and Federal health care program requirements. Sutter shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Sutter may modify its Compliance Program, as appropriate, but at a minimum, Sutter shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Sutter under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Sutter's final Annual Report or (2) any additional materials submitted by Sutter pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Arrangements" shall mean:

- a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Sutter and any actual or potential source of health care business or referrals to Sutter or any actual or potential recipient of health care business or referrals from Sutter or
- b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between Sutter 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 Sutter for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. The term “source of health care business or referrals” shall mean 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.

3. The term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom Sutter refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Sutter 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.

4. “Covered Persons” shall include: (1) all owners of Sutter who are natural persons (other than shareholders who: (a) have an ownership interest of less than 5% and (b) acquired the ownership interest through public trading), (2) officers, board members, and employees of Sutter who are engaged in, supervise, or have oversight of personnel who are engaged in Covered Functions (as defined below in Section II.C.5); and (3) all contractors, subcontractors, agents, and other persons who perform Covered Functions on behalf of Sutter or who supervise or have oversight of personnel who perform Covered Functions on behalf of Sutter.

5. The term “Covered Functions” includes functions relating to the operation and management of Foundations involving the furnishing of patient care items or services by or on behalf of Foundations; billing, coding and claims submission by the Foundations to Federal health care programs; and the development, review, maintenance and use of risk adjustment data (as defined at 42 C.F.R. § 422.310) submitted by or on behalf of the Foundations to Medicare Advantage organizations or their contractors and the development or maintenance of protocols or systems related to such data.

III. CORPORATE INTEGRITY OBLIGATIONS

Sutter shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Sutter Health shall appoint a Compliance Officer and shall maintain a Compliance Officer for

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the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Sutter Health, shall report directly to the Chief Executive Officer of Sutter Health, and shall not be or be subordinate to Sutter Health's General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Sutter Health. 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 periodic (at least quarterly) reports regarding compliance matters to the Board of Directors of Sutter Health (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Sutter Health as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and shall not interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

Sutter shall report to OIG, in writing, any changes in the identity or the duties and job responsibilities of the Compliance Officer, or any actions or other changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Sutter Health shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management of Sutter necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Sutter's risk areas and shall oversee monitoring of internal

and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Sutter shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 business days after such a change.

3. *Board Compliance Obligations.* The Sutter Health Board of Directors Audit and Compliance Committee (Board Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board Committee must include independent (i.e., non-employee and non-executive) members.

The Board Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Sutter'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 documents and other materials it reviewed, as well as 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, signed by each member of the Board Committee summarizing its review and oversight of Sutter's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Audit and Compliance Committee of the Sutter Health Board of Directors (“Board Committee”) has made a reasonable inquiry into the operations of Sutter's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its

inquiry and review, the Board Committee has concluded that, to the best of its knowledge, Sutter has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board Committee is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Sutter.

Sutter shall report to OIG, in writing, any changes in the composition of the Board Committee, or any actions or changes that would affect the Board Committee’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 business days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Sutter employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the Covered Functions within their areas of responsibility are in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Sutter Health Chief Executive Officer (CEO), the Sutter Health Chief Financial Officer (CFO), the Sutter Health Chief Compliance Officer, Sutter Health Senior Vice Presidents leading clinical, human resources, operations, and revenue cycle functions; Foundation CEOs, CFOs, and the senior leaders from each Foundation leading human resources, operations, and revenue cycle, respectively; the Comprehensive Health Assessment Program Executive Director; and each Compliance Officer or Senior Compliance Officer with oversight of a Foundation or the Comprehensive Health Assessment Program. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to the Covered Functions associated with [insert name of department], an area under my supervision. My job responsibilities include ensuring the Covered Functions under my supervisions are in compliance with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Sutter policies, and I have taken steps to promote such compliance. To the best of my knowledge, the Covered Functions associated with [insert name of department] are in compliance with all applicable Federal health

care program requirements and the obligations 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 such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, Sutter 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, Sutter shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Sutter’s compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address compliance with 42 U.S.C. §1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and shall include 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. Throughout the term of this CIA, Sutter shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Sutter shall assess and update, as necessary, the Policies and Procedures. 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. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Sutter shall develop a written plan (Training Plan) that outlines the steps Sutter will take

to ensure (a) all Covered Persons receive at least annual training regarding Sutter’s CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program requirements relating to Covered Functions and (ii) all Sutter Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Sutter shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training.* In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG’s guidance on Board member responsibilities.

New members of the Board shall receive the Board training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* Sutter 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 as required.

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Sutter shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

- b. *Retention of Records.* The IRO and Sutter shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Sutter) related to the reviews.
- c. *Access to Records and Personnel.* Sutter 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. *Chart Review.* The IRO shall review diagnosis code data submitted by Sutter to Medicare Advantage organizations and the medical records for certain Medicare beneficiaries enrolled in Medicare Advantage plans to determine whether any diagnosis code data submitted to a Medicare Advantage organization for risk adjustment payment purposes is supported by and documented in the medical record and coded correctly (Chart Review) and shall prepare a Chart 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 Sutter 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 Sutter and the IRO.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Sutter shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Sutter'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, the Anti-Kickback Statute and Stark Law risks associated with Arrangements (as defined in Section II.C.1 above), and the risks associated with obtaining risk adjustment data and submitting risk adjustment data to Medicare Advantage organizations or their contractors. 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 Sutter to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3)

implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Sutter shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 90 days after the Effective Date, Sutter shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Sutter's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Sutter shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Sutter's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Sutter. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Sutter shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and 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 the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or

department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* Sutter shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Sutter shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Sutter shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. Sutter shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Sutter’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered,

or prescribed by an excluded person. Sutter understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Sutter may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Sutter meets the requirements of Section III.G.

3. *Removal Requirement.* If Sutter has actual notice that a Covered Person has become an Ineligible Person, Sutter shall remove such Covered Person from responsibility for, or involvement with, Sutter's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and 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 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).

4. *Pending Charges and Proposed Exclusions.* If Sutter has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, Sutter shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Sutter shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Sutter conducted or brought by a governmental entity or its agents involving an allegation that Sutter has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Sutter also shall provide written notice to OIG within 30 days after the resolution of the matter and a description of the findings and/or results of the investigation or proceeding, if any.

I. Overpayments

1. *Definition of Overpayment.* An "Overpayment" means any funds that a Foundation receives or retains under any Federal health care program to which a

Foundation, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Sutter shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- 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 penalties or exclusion 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 as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Sutter.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Sutter determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Sutter shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a. and III.J.1.b.* For Reportable Events under Section III.J.1.a and b, 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, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Sutter to identify and quantify any Overpayments; and
- e. a description of Sutter'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, Sutter shall repay or otherwise report and return the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare & Medicaid Services (CMS) guidance and provide OIG with copies of the documents evidencing the repayment or report and return of the Overpayment.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, 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 List screening that Sutter 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 credentialing an Ineligible Person.

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Sutter to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Sutter identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Sutter is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Sutter 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 provision of Covered Functions; or (b) purchase or establish a new business, business unit, or location relating to the provision of Covered Functions, 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 applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Sutter shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Sutter wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Sutter must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. 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. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Sutter shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the Board Committee members who are responsible for satisfying the Board compliance obligations 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 Sutter that includes a summary of all current and prior engagements between Sutter 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;

11. a copy of Sutter's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

12. a description of Sutter's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

13. a list of all of Sutter's locations (including locations and 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

14. the certifications required by Section V.C.

B. Annual Reports

Sutter shall submit to OIG a written report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the Board Committee members who are responsible for satisfying the Board compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board Committee, and Certifying Employees;

2. 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;

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

4. the Board Committee resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board Committee, as

well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

5. a list of any new or revised Policies and Procedures developed during the Reporting Period;

6. a description of any changes to Sutter's Training Plan developed pursuant to Section III.C, and a summary of any Board training provided during the Reporting Period;

7. a complete copy of all reports prepared pursuant to Section III.D and Sutter's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

8. a certification from the IRO regarding its professional independence and objectivity with respect to Sutter, including a summary of all current and prior engagements between Sutter and the IRO;

9. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;

10. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

11. 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 (if applicable). The complete disclosure log shall be made available to OIG upon request;

12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a

description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

16. 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 Sutter's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

17. a description of all changes to the most recently provided list of Sutter's locations as required by Section V.A.13;

18. a description of any changes to Sutter's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

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. Certifications

1. *Certifying Employees.* In each Annual Report, Sutter shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Sutter 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

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Sutter has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

Sutter 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. Sutter 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

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

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
Facsimile: 202.205.0604

Sutter:

Ginger Chappell
Vice President, Ethics & Compliance Services and Chief
Compliance Officer
Sutter Health
9100 Foothills Boulevard
Roseville, CA 95747
Facsimile: 916.503.7889
Email Address: compliancehelp@sutterhealth.org

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Sutter may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

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 Sutter's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Sutter's locations, for the purpose of verifying and evaluating: (a) Sutter's compliance with the terms of this CIA and (b) Sutter's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Sutter to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Sutter's 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), employees, contractors, and directors 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. Sutter shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Sutter's

owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Sutter present.

VIII. DOCUMENT AND RECORD RETENTION

Sutter 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. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Sutter is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day Sutter fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations;
- d. the management certification obligations and the

development and implementation of a written process for Certifying Employees, as required by Section III.A.4;

- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. policies and procedures regarding the repayment of Overpayments; and
- l. reporting of Reportable Events.

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 Sutter fails to engage and use an IRO, as required by Section III.D, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Sutter fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Sutter fails to submit any Chart Review Report in accordance with the requirements of Section III.D and Appendix B or fails to notify any Medicare Advantage organization of any relevant findings, as required by Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Sutter fails to grant access as required in Section VII (This Stipulated Penalty shall begin to accrue on the date Sutter fails to grant access.).

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Sutter as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day Sutter fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.D, and for each day Sutter fails to furnish accurate and complete records to the IRO, as required by Section III.D and Appendix A.

8. A Stipulated Penalty of \$1,000 for each day Sutter fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Sutter stating the specific grounds for its determination that Sutter has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Sutter shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date Sutter receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

Sutter may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Sutter fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Sutter 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. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Sutter has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Sutter of: (a) Sutter's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, Sutter shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Sutter elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Sutter cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Sutter has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Sutter to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;

- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Sutter constitutes an independent basis for Sutter'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 per material breach. Upon a determination by OIG that Sutter has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Sutter of: (a) Sutter's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Sutter shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Sutter has begun to take action to cure the material breach; (ii) Sutter is pursuing such action with due diligence; and (iii) Sutter has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Sutter fails to satisfy the requirements of Section X.D.3, OIG may exclude Sutter from participation in the Federal health care programs. OIG shall notify Sutter in writing of its determination to exclude Sutter. (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 Sutter's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Sutter 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 delivery to Sutter of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Sutter shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. 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 Sutter was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Sutter shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Sutter to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Sutter requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or 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 Sutter was in material breach of this CIA and, if so, whether:

- a. Sutter cured such breach within 30 days of its receipt of the Notice of Material Breach; or

- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Sutter's receipt of the Notice of Material Breach:
 - (i) Sutter had begun to take action to cure the material breach;
 - (ii) Sutter pursued such action with due diligence; and (iii) Sutter provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Sutter, only after a DAB decision in favor of OIG. Sutter's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Sutter upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Sutter may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Sutter 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 Sutter, Sutter 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. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Sutter and OIG agree as follows:

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

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of Sutter's obligations under this CIA based on a certification by Sutter that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal

health care program. If Sutter is relieved of its CIA obligations, Sutter shall be required to notify OIG in writing at least 30 days in advance if Sutter plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Sutter'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.

E. The undersigned Sutter 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.

F. 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 SUTTER HEALTH

Florence L. Di Benedetto
Florence L. Di Benedetto
Senior Vice President and General Counsel, Sutter Health

8/25/2021
DATE

Joseph C. Hudzik
Joseph C. Hudzik
Latham & Watkins, LLP

08/25/2021
DATE

ON BEHALF OF SUTTER BAY MEDICAL FOUNDATION

Florence L. Di Benedetto
Florence L. Di Benedetto
Senior Vice President and General Counsel, Sutter Health
Authorized Representative of Sutter Bay Medical Foundation

8/25/2021
DATE

Joseph C. Hudzik
Joseph C. Hudzik
Latham & Watkins, LLP

08/25/2021
DATE

ON BEHALF OF SUTTER VALLEY MEDICAL FOUNDATION

Florence L. Di Benedetto
Florence L. Di Benedetto
Senior Vice President and General Counsel, Sutter Health
Authorized Representative of Sutter Valley Medical Foundation

8/25/2021
DATE

Joseph C. Hudzik
Joseph C. Hudzik
Latham & Watkins, LLP

08/25/2021
DATE

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

Lisa M. Re

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

8/26/2021

DATE

SARAH KESSLER Digitally signed by SARAH
KESSLER
Date: 2021.08.30 13:12:17 -04'00'

SARAH KESSLER
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

DATE

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. Sutter 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 Sutter in response to a request by OIG, whichever is later, OIG will notify Sutter if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Sutter may continue to engage the IRO.

2. If Sutter 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, Sutter 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 Sutter at the request of OIG, whichever is later, OIG will notify Sutter if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Sutter may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Chart Review who have expertise in the Medicare program requirements applicable to the data being reviewed;
2. assign individuals to design and select the Chart Review Sample who are knowledgeable about the appropriate statistical sampling techniques;
3. assign individuals to conduct the coding review portions of the Chart 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 any relevant determinations required by the Chart Review; and

5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Chart Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare program rules and reimbursement guidelines in making assessments in the Chart Review;

3. request clarification from the appropriate authority, if in doubt of the application of a particular Medicare 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. Sutter Responsibilities

Sutter 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 Chart 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. *Sutter and IRO.* If Sutter terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Sutter 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. Sutter 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 Sutter in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Sutter 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 Sutter regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Sutter in writing that Sutter shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Sutter 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 Sutter to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CHART REVIEW

A. Chart Review. The IRO shall perform a Chart Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Chart Review.

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

- a. Diagnosis Data: Any Risk Adjusting Diagnosis and related data submitted by Sutter to Medicare Advantage organizations for identification of and reimbursement for items and services furnished to Risk Adjusted Members during the Reporting Period.
- b. Medical Record: Documentation (electronic, hard-copy or both) of a patient's medical history, which is maintained by Sutter over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.
- c. Population: The Population(s) shall be defined as all Risk Adjusted Members.
- d. Risk Adjusted Member: A Medicare beneficiary enrolled in a Medicare Advantage plan who (1) had at least one Risk Adjusting Diagnosis during the Reporting Period; (2) had Non-End Stage Renal Disease status during the Reporting Period; and (3) had non-hospice status during the Reporting Period.
- e. Risk Adjusting Diagnosis: A Risk Adjusted Member's diagnosis code that mapped to at least one Hierarchical Condition Category (HCC) and that was submitted to a Medicare Advantage organization during the Reporting Period.

2. *Chart Review Sample*. The IRO shall randomly select a sample of 100 Risk Adjusted Members (Chart Review Sample) from the Population. The Diagnosis Data and the Medical Records associated with the Chart Review Sample and available at Sutter's office or under Sutter's control shall be reviewed to determine whether the Diagnosis Data is supported by the Medical Records and correctly documented and coded, e.g., in accordance with ICD-9/10 coding guidelines.

- a. The OIG may limit the Population to Risk Adjusted Members with specific HCCs or to Risk Adjusted Members who received care or treatment by particular Sutter physician(s), or using other factors determined by the OIG in its discretion. In the event that OIG exercises its discretion to limit the Population, OIG shall notify Sutter at least 60 days prior to the end of the Reporting Period of any information needed from Sutter in order for the OIG to identify the Population. The OIG shall notify Sutter and its IRO of the subset of the Population to be reviewed at least 30 days prior to the end of the Reporting Period.
 - b. For any Risk Adjusting Diagnosis in the Chart Review Sample that is not supported by the Medical Record or documented and coded correctly (collectively, Unsupported Diagnosis), the IRO shall identify any correction to the Diagnosis Data and the basis for the IRO's determination that the Risk Adjusting Diagnosis was not appropriately documented and coded or supported by the Medical Record, review the controls for ensuring that each Risk Adjusting Diagnosis submitted to a Medicare Advantage plan is appropriately documented and coded, review the system(s) and process(es) (e.g., improper use of an electronic problem list) that generated the Unsupported Diagnosis and identify any problems or weaknesses that may have resulted in the Unsupported Diagnosis. The IRO shall provide its observations and recommendations on suggested improvements to the system(s), process(es) and controls relating to the Unsupported Diagnosis.
3. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Chart Review Sample and Sutter shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Chart Review Sample. If the IRO accepts any supplemental documentation or materials from Sutter after the IRO has completed its initial review of the Chart Review Sample (Supplemental Materials), the IRO shall identify in the Chart Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Chart Review Report describing the process by which the Supplemental Materials were

accepted and the IRO's reasons for accepting the Supplemental Materials.

- b. Risk Adjusted Members without Supporting Documentation. Any Risk Adjusted Member for which Sutter cannot produce a Medical Record or Diagnosis Data shall be considered an error.
- c. Use of First Samples Drawn. For the purposes of the Chart Review Sample discussed in this Appendix, the first set of Risk Adjusted Members selected shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Chart Review Sample).

4. *Reporting of Findings.* Sutter shall notify the applicable Medicare Advantage organization of any Unsupported Diagnosis for a Risk Adjusted Member enrolled in that Medicare Advantage organization's plan(s). OIG, in its sole discretion, may refer the findings of the Chart Review (and any related work papers) received from Sutter to CMS, CMS's contractor, or the appropriate Medicare Advantage organization(s) for follow up.

B. Chart Review Report. The IRO shall prepare a Chart Review Report as described in this Appendix for each Chart Review performed. The following information shall be included in the Chart Review Report.

1. *Chart Review Methodology.*

- a. Chart Review Population. A description of the Population subject to the Chart Review.
- b. Chart Review Objective. A clear statement of the objective intended to be achieved by the Chart Review.
- c. Source of Data. A description of (1) the process used to identify Risk Adjusted Members in the Population and (2) the specific documentation relied upon by the IRO when performing the Chart Review (*e.g.*, Medical Records, requisition forms, CMS guidance, ICD-9/10 coding guidelines, other policies, regulations, or directives).
- d. Review Protocol. A narrative description of how the Chart Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as 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. *Chart Review Findings.*
 - a. Narrative Results.
 - i. A description of Sutter’s systems for generating and submitting Diagnosis Data, including the identification, by position description, of the personnel involved in coding and submitting Diagnosis Data to Medicare Advantage organizations.
 - ii. A description of controls in place at Sutter for (1) ensuring that each Risk Adjusting Diagnosis submitted to a Medicare Advantage organization is appropriately documented and coded and supported by the Medical Record and (2) detecting and correcting incorrect Diagnosis Data submitted to Medicare Advantage organizations and used for reimbursement.
 - iii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Chart Review, including the results of the Chart Review Sample.
 - b. Quantitative Results.
 - i. Total number and percentage of instances in which the IRO determined that a Risk Adjusting Diagnosis was an Unsupported Diagnosis.
 - ii. Error Rate in the Chart Review Sample. The Error Rate shall be calculated by dividing the number of Unsupported Diagnoses in the Chart Review Sample by the total number of Risk Adjusting Diagnoses in the Chart Review Sample.

iii. A spreadsheet of the Chart Review results that includes the following information for each Risk Adjusted Member: applicable Medicare Advantage organization, beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI), service from date, service through date, each Risk Adjusting Diagnosis, whether the Risk Adjusting Diagnosis was an Unsupported Diagnosis, type of provider (inpatient, outpatient, or physician), and any correction(s) to the Diagnosis Data (as determined by the IRO).

c. Recommendations. The IRO's report shall include any recommendations for improvements to Sutter's controls for ensuring that each Risk Adjusting Diagnosis submitted to a Medicare Advantage plan is appropriately documented and coded and supported by the Medical Record, based on the findings of the Chart Review.

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