

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PENINSULA REGIONAL MEDICAL CENTER**

I. PREAMBLE

Peninsula Regional Medical Center, Salisbury, Maryland (PRMC) hereby enters 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, PRMC is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by PRMC under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). 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, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) PRMC’s final annual report; or (2) any additional materials submitted by PRMC pursuant to OIG’s request, whichever is later.

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

1. “Covered Persons” includes:

- a. all officers, directors, and employees of PRMC; and
- b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of PRMC, excluding vendors whose sole connection with PRMC is selling or otherwise providing medical

supplies or equipment to PRMC and who do not bill the Federal health care programs for medical supplies or equipment; and

c. physicians with active medical staff membership at PRMC and other non-physician practitioners who work in the PRMC Cardiac Catheterization Laboratory.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” shall mean any Covered Person who performs intervention procedures in the PRMC Cardiac Catheterization Laboratory or any other location affiliated with PRMC in which such procedures are performed.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 90 days after the Effective Date, PRMC shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for 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. The Compliance Officer shall be a member of senior management of PRMC, shall report directly to the Chief Executive Officer of PRMC, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of PRMC, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by PRMC as well as for any reporting obligations created under this CIA.

PRMC shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the

Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, PRMC shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management 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 Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

PRMC shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or 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 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (Board) 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 shall, at a minimum, be responsible for the following:

- a. Meeting at least quarterly to review and oversee PRMC's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. ensuring that PRMC adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and Federal health care program requirements; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of PRMC's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of PRMC'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, PRMC has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board 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 PRMC.

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

4. *Physician Executive(s)*. Within 60 days of the Effective Date, PRMC shall appoint, and maintain for the term of the CIA, at least one but no more than three Physician Executives(s). The Physician Executive(s) shall be responsible for oversight of medical staff quality of care matters at PRMC, including but not limited to performance improvement, quality assessment, patient safety, utilization review, medical staff peer review, medical staff credentialing and privileging, and medical staff training and discipline. The Physician Executives(s) shall be members of senior management of PRMC, shall make periodic (at least quarterly) reports regarding quality of care matters directly to the Board of Directors of PRMC, and shall be authorized to report on such matters to the Board of Directors of PRMC at any time. The total amount of time devoted by the Physician Executive(s) to these tasks shall be, at a minimum, the equivalent of one full-time employee.

PRMC shall report to OIG, in writing, any changes in the identity or position description of the Physician Executives(s), or any actions or changes that would affect the ability of the Physician Executive(s) to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change. Notwithstanding any other provision under this CIA, if PRMC is unable to fully comply with this Section III.A.4 at any point in time during the term of the CIA, PRMC shall have 90 days to recruit and appoint Physician Executives(s) in order to comply with this Section III.A.4. If PRMC is not in compliance with this Section III.A.4 by the end of the 90 day time period, the OIG may, at its sole discretion, grant additional extensions pursuant to timely requests for extensions under Section X.B of the CIA or seek stipulated penalties in accordance with Section X.A.1 of the CIA.

5. *Medical Director of Cardiac Catheterization Laboratory*. PRMC shall appoint, and shall maintain for the term of the CIA, a cardiologist who is certified by the American Board of Internal Medicine in cardiology to serve as the Medical Director for

PRMC's Cardiac Catheterization Laboratory (Medical Director). The Medical Director shall be responsible for the clinical management and oversight of the Cardiac Catheterization Laboratory and any other locations affiliated with PRMC where catheterization procedures are performed. The Medical Director shall make periodic (at least quarterly) reports to the Physician Executives and Compliance Officer regarding the management and oversight of the Cardiac Catheterization Laboratory, and shall be authorized to report on such matters to the Physician Executives, Compliance Officer, Compliance Committee, or Governing Board of PRMC at any time.

PRMC shall report to OIG, in writing, any changes in the identity or position description of the Medical Director, or any actions or changes that would affect the ability of the Medical Director to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change. Notwithstanding any other provision under this CIA, if PRMC is unable to fully comply with this Section III.A.5 at any point in time during the term of the CIA, PRMC shall have 90 days to recruit and appoint a Medical Director for the Cardiac Catheterization Laboratory in order to comply with this Section III.A.4. If PRMC is not in compliance with this Section III.A.5 at the end of the 90 day time period, the OIG may, at its sole discretion, grant additional extensions pursuant to timely requests for extensions under Section X.B of the CIA or seek stipulated penalties in accordance with Section X.A.1. of the CIA.

B. Written Standards.

1. *Code of Conduct.* PRMC has developed, implemented, and distributed a written Code of Conduct to all Covered Persons. During the term of the CIA, PRMC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

The Code of Conduct shall, at a minimum, set forth:

- a. PRMC's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. PRMC's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements, with PRMC's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

- c. the requirement that all of PRMC's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by PRMC, suspected violations of any Federal health care program requirements or of PRMC's own Policies and Procedures;
- d. the right of all individuals to use the Disclosure Program described in Section III.F, and PRMC's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by PRMC's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

PRMC shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 90 days after the Effective Date, PRMC shall implement written Policies and Procedures regarding the operation of PRMC's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. Appropriate documentation of medical records;
- c. Quality assessment and performance improvement program, including but not limited to: (i) measuring, analyzing, and tracking quality indicators; (ii) setting priorities for performance improvement activities; (iii) tracking medical errors and adverse patient events; (iv) conducting quality assessment and performance improvement projects; and (v) reporting data to the Board of Directors of PRMC on a regular basis.

- d. Medical staff credentialing and privileging procedures, including but not limited to: (i) collecting, verifying, and assessing current licensure, education, relevant training, experience, ability, and competence to perform requested privileges; (ii) monitoring practitioners with current privileges; (iii) review by Physician Executives and Medical Staff Executive Committee; and (iv) reporting credentialing and privileging activities to the Governing Board of PRMC on a regular basis.
- e. Management and oversight of PRMC's Cardiac Catheterization Laboratory, including but not limited to: (i) ensuring the Cardiac Catheterization Laboratory is properly equipped, staffed, and managed; (ii) ensuring appropriate recordkeeping of interventional cardiac catheterization procedures; (iii) ensuring interventional cardiac catheterization procedures are peer reviewed for quality and outcomes; (iv) developing criteria for assessment of clinical appropriateness of procedures; (v) assessing procedural outcomes with appropriate risk adjustment; (vi) tabulating results achieved by individual cardiac catheterization interventionists and by the Cardiac Catheterization Laboratory as a whole; (vii) comparing individual interventionalists and Cardiac Catheterization Laboratory results with national benchmark standards with appropriate risk adjustment; (viii) reporting results to relevant registries for benchmarking purposes; (ix) tracking volume of cardiac catheterization interventionalists by individual interventionist and by Cardiac Catheterization Laboratory; (x) reviewing interventionalist competence to perform cardiac catheterization interventional procedures through credentialing and privileging; (xi) implementing appropriate corrective actions for individual interventionalists who substantially deviate from national benchmark standards or otherwise are found to provide substandard care; and (xii) monitoring relevant industry practice guidelines for changes, updates, and improvements.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available or distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, PRMC shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain PRMC's:

- a. CIA requirements; and
- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above in a manner relevant to the individual's job responsibilities. This Specific Training shall include a discussion of the policies and procedures set forth in Section III.B, including but not limited to:

- a. Appropriate documentation of medical records;
- b. Medical staff peer review procedures;
- c. Medical staff credentialing and privileging;
- d. Quality assessment and performance improvement activities;
- e. Management and oversight of cardiac catheterization interventionalist procedures (including carotid artery stents).

New Relevant Covered Persons shall receive this training within 30 days after the

beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. A PRMC employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the provision of cardiac catheterization procedures at PRMC, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least one hour of Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 90 days after the Effective Date, PRMC shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

6. *Update of Training.* PRMC shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the reviews required by Section III., and any other relevant information.

7. *Computer-based Training.* PRMC may provide the training required under this CIA through appropriate computer-based training approaches. If PRMC chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

8. *Physicians with Active Medical Staff Membership.* PRMC shall make the Code of Conduct, General Training and Specific Training (where appropriate)

available to all Physicians with Active Medical Staff Membership who are not Covered Persons, and shall use best efforts to encourage their attendance and participation. The Compliance Office shall maintain records of all Physicians with Active Medical Staff Membership who attend such training and shall include such record in each Annual Report to the OIG.

D. Peer Review Consultant.

1. *Engagement of Peer Review Consultant.* Within 90 days after the Effective Date, PRMC shall engage an individual or entity (hereinafter “Peer Review Consultant”) to perform reviews to assist PRMC in the assessment and evaluation its peer review, credentialing, and privileging practices. The Peer Review Consultant shall have expertise in peer review, credentialing, and privileging. Within 30 days after OIG receives written notice of the identity of the selected Peer Review Consultant, OIG will notify PRMC if the Peer Review Consultant is unacceptable. Absent notification from OIG that the Peer Review Consultant is unacceptable, PRMC may continue to engage the Peer Review Consultant. The engagement of the Peer Review Consultant shall be for the term of the CIA. If PRMC terminates the Peer Review Consultant during the course of the engagement, PRMC must submit a notice explaining its reasons to OIG no later than 30 days after termination and PRMC must engage a new Peer Review Consultant in accordance with this Paragraph III.D.1

2. *Systems Review.* The Peer Review Consultant shall conduct a review of the current processes undertaken by PRMC with respect to medical staff peer review, medical staff credentialing and privileging, and medical staff training and discipline (Systems Review). The Systems Review shall consist of a thorough review of PRMC’s Policies and Procedures, practices, bylaws, meeting minutes, case review, corrective actions, disciplinary records, medical staff participation, ongoing quality-monitoring data, and oversight by PRMC’s senior management and the Governing Board of PRMC. Such review may include, but shall not be limited to, document review, interview, observation of meetings, trainings, data review, benchmarking, analysis of utilization data, and presentations. The Peer Review Consultant shall perform all components of the Systems Review. The Systems Review shall be performed in the first Reporting Period of the CIA, and shall be completed within 60 days of the end of the first Reporting Period.

3. *Systems Review Report.* The Peer Review Consultant shall prepare a report based on the Systems Review. The Systems Review Report shall include the Peer Review Consultant’s findings and supporting rationale regarding:

- a. the strengths and weaknesses in PRMC’s peer review

policies and procedures, medical staff credentialing and privileging , and medical staff training and discipline based on the Systems Review;

b. the Peer Review Consultant's conclusions based on the Systems Review; and

c. any recommendation the Peer Review Consultant may have to improve any of these systems, operation, and processes (Peer Review Recommendations).

The Systems Review Report shall be delivered to PRMC within 60 days of the end of the first Reporting Period. A copy of the Systems Review Report shall be provided to the OIG in the First Annual Report as required by Section V.B. of the CIA.

4. *Peer Review Recommendations.* For all Peer Review Recommendations, PRMC shall implement the recommendation or provide a written explanation of why the recommendation was not implemented. PRMC shall engage the Peer Review Consultant to assist in the implementation of the Peer Review Recommendations, which assistance may include, but shall not be limited to, participating in meetings, trainings, and presentations, reviewing peer review files and other supporting documentation, and furnishing personnel to assist in peer review or otherwise serving as a resource to PRMC.

5. *Monitoring of Peer Review Implementation.* The Peer Review Consultant shall monitor the implementation of the Peer Review Recommendations, which monitoring shall cover each of the Reporting Periods beginning with the Second Reporting Period. The Peer Review Consultant shall prepare and deliver to PRMC a report within 60 days of the end of each Reporting Period that evaluates PRMC's implementation of the Peer Review Recommendations (Monitoring Reports). A copy of the Monitoring Reports shall be provided to the OIG in the Annual Report as required by Section V of the CIA, beginning with the Second Annual Report.

6. *Retention of Records.* PRMC and the Peer Review Consultant shall retain, and make available to the OIG upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between PRMC and the Peer Review Consultant related to the engagements.

E. Review Procedures.

1. *General Description.*

- a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, PRMC shall retain an individual or entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the Unallowable Cost Review and Cardiac Catheterization Procedures Review. 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 PRMC shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and PRMC) related to the reviews.

2. *Cardiac Catheterization Procedures Review.* PRMC shall engage an IRO to evaluate and analyze the medical necessity and appropriateness of interventional procedures performed in the PRMC Cardiac Catheterization Lab (Cardiac Catheterization Procedures Review). The IRO shall randomly select and review a sample of 50 cardiac catheterization procedures performed at the PRMC Cardiac Catheterization Lab. The procedures shall be reviewed for appropriateness of case selection, quality of procedure execution, proper response to intra-procedural problems, accurate assessment of procedure outcome, and appropriateness of procedure management. The procedures shall be reviewed based on the supporting documentation available at PRMC or under PRMC’s control and applicable regulations and guidance to determine whether the procedure was medically necessary and appropriate, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American College of Cardiology.

- a. The Cardiac Catheterization Procedures Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by PRMC shall have expertise in the medical necessity and appropriateness of cardiac catheterization interventionalist procedures and in the general requirements of the Federal health care program(s) from which PRMC seeks reimbursement.
- b. The IRO shall prepare a report based upon the Cardiac Catheterization Procedures Review performed (Cardiac Catheterization Procedures Review Report). Information to be included in the Cardiac Catheterization Procedures Review Report is described in Appendix B.

3. *Unallowable Cost Review.* For the first Reporting Period, the IRO shall conduct a review of PRMC's compliance with the unallowable cost provision of the Settlement Agreement. The IRO shall determine whether PRMC has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for Unallowable Costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any Unallowable Costs included in payments previously sought from the United States, or any state Medicaid program. This Unallowable Cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by PRMC or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the Unallowable Costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

4. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether PRMC has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

5. *Validation Review.* In the event OIG has reason to believe that: (a) the IRO's Unallowable Cost Review, or the IRO's Cardiac Catheterization Procedures Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, Cardiac Catheterization Procedures Review and/or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Cardiac Catheterization Procedures Review and/or Unallowable Cost Review complied with the requirements of the CIA and/or the findings of the Cardiac Catheterization Procedures Review and/or Unallowable Cost Review results are inaccurate (Validation Review). PRMC shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of PRMC's final Annual Report shall be initiated no later than one year after PRMC's final submission (as described above in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify PRMC of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, PRMC may request a meeting with

OIG to: (a) discuss the results of any Cardiac Catheterization Procedures Review and/or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Cardiac Catheterization Procedures Review and/or Unallowable Cost Review or to correct the inaccuracy of the Cardiac Procedures Review and/or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. PRMC agrees to provide any additional information as may be requested by OIG under this Section III.E.5 in an expedited manner. OIG will attempt in good faith to resolve any Cardiac Catheterization Procedures Review and/or Unallowable Cost Review issues with PRMC prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to PRMC a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Cardiac Catheterization Procedures Review and Unallowable Cost Review and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

Within 90 days after the Effective Date, PRMC 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 PRMC'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. PRMC 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. 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, PRMC 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, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

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, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

- a. PRMC shall screen all prospective Covered Persons against the Exclusion Lists 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. PRMC shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. PRMC shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) PRMC to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. PRMC understands that items or services furnished by excluded persons are not payable by Federal health care programs and that PRMC may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether PRMC meets the requirements of this Section III.G.

3. *Removal Requirement.* If PRMC has actual notice that a Covered Person has become an Ineligible Person, PRMC shall remove such Covered Person from responsibility for, or involvement with, PRMC's business operations related to the Federal health care programs 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 Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If PRMC has actual notice that a Covered Person is charged with a criminal offense that falls within the ambit 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, in the case of a physician, during the term of the physician's or other practitioners' medical staff privileges," PRMC 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, patient, or resident, or any claims submitted to any Federal health care program.

5. *Physicians with Staff Privileges.* Prior to granting staff privileges to a physician after the Effective Date, PRMC shall screen in the manner described in Section III.H.2 above to determine if the physician is an Ineligible Person. Furthermore, PRMC shall review its list of physicians with staff privileges against the Exclusion Lists within 90 days after the Effective Date and at least annually thereafter. If a physician with staff privileges is an Ineligible Person, PRMC shall ensure that the physician does not furnish, order, or prescribe any items or services payable in whole or in part by any Federal health

care program. In addition to any other appropriate measures, PRMC shall ensure that any physician who is an Ineligible Person is not “on call” at PRMC.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, PRMC shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to PRMC conducted or brought by a governmental entity or its agents involving an allegation that PRMC 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. PRMC shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” shall mean the amount of money PRMC has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, PRMC identifies or learns of any Overpayment, PRMC shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 30 days after identification, PRMC shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies.

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

2. *Reportable Events.*

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

- i. a substantial Overpayment;
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- iii. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a;
- iv. the filing of a bankruptcy petition by PRMC; or
- v. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

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

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

- i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include:

- (A) a copy of the notification and repayment to the payor; and

(B) a description of the steps taken by PRMC to identify and quantify the Overpayment;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, the impact or potential impact on Federal health care program beneficiaries, and legal and Federal health care program authorities implicated;

iii. a description of PRMC's actions taken to correct the Reportable Event;

iv. any further steps PRMC plans to take to address the Reportable Event and prevent it from recurring;

v. a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies; and

vi. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

3. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by PRMC to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 30 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, PRMC changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, PRMC shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of

change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, the unit or location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which PRMC currently submits claims. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, PRMC 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, address, 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 and positions of the Physician Executives required by Section III.A;
4. the name and position description of the Medical Director of the Cardiac Catheterization Laboratory required by Section III.A;
5. a copy of PRMC's Code of Conduct required by Section III.B.1;
6. a copy of all Policies and Procedures required by Section III.B.2;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.
- c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of PRMC's efforts to encourage medical staff members to complete the training.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 9. a description of the Disclosure Program required by Section III.F;
- 10. the following information regarding the IRO(s) and the Peer Review Consultant: (a) identify, address, and phone number; (b) a copy of the engagement letter; (c) summary and description of any and all current and prior engagements and agreements between PRMC and the IRO(s) Peer Review Consultant; and (d), if applicable, the proposed start and completion dates of the Systems Review;
- 11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between PRMC and the IRO;
- 12. a certification from the IRO(s) regarding its professional independence and objectivity with respect to PRMC;
- 13. a description of the process by which PRMC fulfills the requirements of Section III.H regarding Ineligible Persons;
- 14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 15. a list of all of PRMC's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the

corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program Provider number(s), and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which PRMC currently submits claims;

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

17. the certifications required by Section V.C.

B. Annual Reports. PRMC shall submit to OIG annually a report with respect to the status of, and findings regarding, PRMC's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a summary of any changes or amendments to PRMC's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions; and

c. with respect to active medical staff members,, the number and percentage who completed the training, the type of training and the date received, and a description of PRMC's efforts to encourage medical staff members to complete the training.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. for the first Reporting Period, a complete copy of the Systems Review Report prepared by the Peer Review Consultant pursuant to Section III.D; and for each subsequent Reporting Period, a complete copy of the Monitoring Report prepared by the Peer Review Consultant pursuant to Section III.D;

7. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter;

8. PRMC's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D and E;

9. a summary and description of any and all current and prior engagements and agreements between PRMC and the IRO and Peer Review Consultant, if different from what was submitted as part of the Implementation Report;

10. a certification from the IRO and Peer Review Consultant regarding its professional independence and objectivity with respect to PRMC;

11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

14. any changes to the process by which PRMC fulfills the requirements of Section III.G regarding Ineligible Persons;

15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by PRMC in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

16. 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;

17. a description of all changes to the most recently provided list of PRMC's locations (including addresses) as required by Section IV; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program Provider number(s), and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which PRMC currently submits claims;

18. the certifications required by Section V.C; and

19. the Board resolution required by Section III.A.3

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. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, PRMC is in compliance with all of the requirements of this CIA;

2. 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

3. to the best of his or her knowledge, PRMC 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;

D. Designation of Information. PRMC 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. PRMC 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

PRMC:

William H. Wojcik
Compliance Officer
Peninsula Regional Medical Center
100 East Carroll Street
Salisbury, Maryland 21801
Telephone: 410.543.7152
Facsimile: 410.543.7718

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, PRMC may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

PRMC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or 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 PRMC prior to any release by OIG of information submitted by PRMC pursuant to its obligations under this CIA and identified upon submission by PRMC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, PRMC shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

PRMC 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, PRMC 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) for each day PRMC fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. Physician Executive(s);
- e. a Medical Director of the Cardiac Catheterization Laboratory;
- f. written Policies and Procedures;
- g. the training of Covered Persons and Relevant Covered Persons;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements; and
- j. notification of Government investigations or legal proceedings.

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 PRMC (a) fails to engage a Peer Review Consultant, as required in Section III.D; or (b) fails to engage an IRO, as required in Section III.E, Appendix A and 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 PRMC (a) fails to submit a Systems Review Report prepared by the Peer Review Consultant in accordance with the

requirements of Section V.B; or (b) fails to submit the annual Cardiac Catheterization Procedures Review Report in accordance with the requirements of Section V.B., or (c) fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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 fails to submit the annual Cardiac Catheterization Procedures Review Report, the Systems Review Report, and/or Unallowable Cost Review in accordance with the requirements of Section III.D and E.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of PRMC as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day PRMC fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to PRMC stating the specific grounds for its determination that PRMC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps PRMC shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after PRMC 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- 6 of this Section.

B. Timely Written Requests for Extensions. PRMC 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 PRMC 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 PRMC 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 PRMC 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 PRMC of: (a) PRMC's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, PRMC 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 PRMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until PRMC 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.e, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that PRMC 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. a failure by PRMC to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
 - b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
 - d. a failure to engage and use a Peer Review Consultant in

accordance with Section III.D; or

e. a failure to engage and use an IRO in accordance with Section III.E., Appendix A, and Appendix B.

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

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

a. PRMC is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, PRMC fails to satisfy the requirements of Section X.D.3, OIG may exclude PRMC from participation in the Federal health care programs. OIG shall notify PRMC in writing of its determination to exclude PRMC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of PRMC's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, PRMC 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 PRMC 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, PRMC 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.

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 PRMC was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. PRMC 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 PRMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless PRMC 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:

- a. whether PRMC was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) PRMC had begun to take action to cure the material breach within that period; (ii) PRMC has pursued and is pursuing such action with due diligence; and (iii) PRMC provided to OIG within that period a reasonable timetable for

curing the material breach and PRMC has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for PRMC, only after a DAB decision in favor of OIG. PRMC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude PRMC 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 PRMC 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. PRMC 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 PRMC, PRMC 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

PRMC and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of PRMC;

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

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

D. OIG may agree to a suspension of PRMC's obligations under the CIA in the event of PRMC's cessation of participation in Federal health care programs. If PRMC withdraws from participating in Federal health care programs and is relieved of its CIA obligations by OIG, PRMC shall notify OIG at least 30 days in advance of PRMC's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned PRMC signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is 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. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF PENINSULA REGIONAL MEDICAL CENTER

/Margaret M. Naleppa/

Margaret (Peggy) M. Naleppa, DR.M
President/CEO

August 2, 2011

Date

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

/Gregory E. Demske/

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

8/9/11

Date

/Ellen E. Slavin/

Ellen E. Slavin
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

8/8/11

Date

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. PRMC 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 D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by PRMC in response to a request by OIG, whichever is later, OIG will notify PRMC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, PRMC may continue to engage the IRO.

2. If PRMC engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, PRMC shall submit the information identified in Section V.A.8 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 PRMC at the request of OIG, whichever is later, OIG will notify PRMC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, PRMC may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Cardiac Procedures Review engagement who have expertise in the medical necessity and appropriateness of interventional cardiac procedures, the established practice guidelines and generally accepted standards of medical practice described by the American College of Cardiology, and the general requirements of the Federal health care program(s) from which PRMC seeks reimbursement;

2. assign individuals to conduct the Unallowable Cost Review engagement who have expertise in the billing, coding, reporting, and other requirements of the Federal health care program(s) from which PRMC seeks reimbursement; and

3. 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 Cardiac Procedures Review and Unallowable Cost review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare, Medicaid, or other Federal health care programs rules and reimbursement guidelines in making assessments in the Cardiac Procedures Review;
3. if in doubt of the application of a particular Medicare, Medicaid, or other Federal health care programs policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
4. respond to all OIG inquiries 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. IRO Independence and Objectivity

The IRO must perform the Cardiac Procedures Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and PRMC.

E. IRO Removal/Termination

1. *Provider and IRO.* If PRMC terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, PRMC must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. PRMC must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

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 D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require PRMC to engage a new

IRO in accordance with Paragraph A of this Appendix. PRMC must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

Prior to requiring PRMC to engage a new IRO, OIG shall notify PRMC of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, PRMC may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with PRMC prior to requiring PRMC to terminate the IRO. However, the final determination as to whether or not to require PRMC to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CARDIAC CATHETERIZATION PROCEDURES REVIEW

A. Cardiac Catheterization Procedures Review.

1. *Definitions.* For the purposes of the Cardiac Catheterization Procedures Review, the following definitions shall be used.

- a. Cardiac Catheterization Procedure. Interventional procedures performed in the cardiac catheterization laboratory (or any other designated area for such procedures) by Medical Staff of Peninsula Regional Medical Center.
- b. Population. For each Reporting Period, the Population shall be defined as all Cardiac Catheterization Procedures for which Provider has received reimbursement from Medicare, Medicaid, or other Federal health care programs during the relevant 12-month Reporting Period.

B. Cardiac Catheterization Procedures Review Report. The following information shall be included in the Cardiac Catheterization Procedures Review for each Sample.

1. *Procedures Review Methodology.*

- a. Sampling Unit. A description of the Cardiac Catheterization Procedures as that term is defined above.
- b. Cardiac Catheterization Procedures Review Population. A description of the Population subject to the Cardiac Catheterization Procedures Review.
- c. Cardiac Catheterization Review Objective. A clear statement of the objective intended to be achieved by the Cardiac Catheterization Procedures Review.
- d. Sampling Frame. A description of the sampling frame, which is the totality of Cardiac Catheterization Procedures from which the Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances the

sampling frame will be identical to the Population.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Cardiac Catheterization Procedures 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), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Cardiac Catheterization Procedures Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Cardiac Catheterization Procedures appraised in the Sample.

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

c. A description or identification of the statistical sampling software package used to select the Sample.

3. *Cardiac Catheterization Procedures Review Findings.*

a. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Cardiac Catheterization Procedures Review, including the results of the Sample.

b. Total number of instances in which the IRO determined that the Cardiac Catheterization Procedures was not medically necessary or appropriate, based on established practice guidelines and generally accepted standards of medical practice as described by the American College of Cardiology.

c. A spreadsheet of the Cardiac Catheterization Procedures Review results that includes the following information for each Cardiac Catheterization Procedure appraised: type of Cardiac

Catheterization Procedure performed, whether the Procedure was medically necessary and appropriate, beneficiary name, beneficiary health insurance claim number, date of service, procedure code submitted, Federal health care program billed, and amount reimbursed.

4. *Systems Review*. Observations, findings, and recommendations on possible improvements to the system(s) and process(es).

5. *Credential*. The names and credential of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Cardiac Catheterization Procedures Review.