

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
WARREN HOSPITAL**

I. PREAMBLE

Warren Hospital (Warren) 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, Warren is entering into a Settlement Agreement with the United States.

Prior to the execution of this CIA, Warren established a corporate compliance program (Compliance Program). Warren's Compliance Program includes a Code of Conduct, written policies and procedures, an education and training component, mechanisms for ongoing monitoring and auditing of Warren's operations to assess compliance, mechanisms for employees and agents to report incidents of noncompliance in an anonymous manner, disciplinary actions for individuals violating compliance policies and procedures, and oversight of the Compliance Program by Warren's Compliance Committee. Warren agrees that during the term of this CIA it shall continue to operate its Compliance Program in a manner that meets the requirements of this CIA. Warren may modify the Compliance Program as appropriate, but at a minimum, Warren shall ensure that it complies with the integrity obligations that are enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Warren 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) Warren’s final Annual Report; or (2) any additional materials submitted by Warren 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 owners, officers, directors, and employees of Warren (excluding housekeeping staff, maintenance workers, and dietary employees); 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 Warren (excluding vendors whose sole connection to Warren is selling or otherwise providing medical supplies or equipment to Warren);
- c. Warren’s employed medical staff.

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” includes all persons involved in the delivery of patient care items or services and/ or in the preparation or submission of claims for reimbursement from, or cost reports to, any Federal health care program.

3. “Arrangements” shall mean every arrangement or transaction that:

- a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Warren and any actual or potential source of health care business or referrals to Warren or any actual or potential recipient of health care business or referrals from Warren. The term “source” shall mean any physician, contractor, vendor, or agent and the term “health care

business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or

- b. is between Warren 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 Warren for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

- 4. “Arrangements Covered Persons” includes each Covered Person involved with the development, approval, management, or review of Warren’s Arrangements, as such term is defined in Section II.C.3.

III. CORPORATE INTEGRITY OBLIGATIONS

Warren shall continue to operate and maintain its Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Warren represents that it has appointed an individual to serve as its Compliance Officer. Warren shall continue to 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 Warren, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Warren, 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 Warren as well as for any reporting obligations created under this CIA.

Warren 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.* Warren certifies that it has established a Compliance Committee, and shall maintain the Compliance Committee for the duration of this CIA. 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).

Warren 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.

B. Written Standards.

1. *Code of Conduct.* Warren certifies that it has developed, implemented, and distributed, in paper or electronic form, a written Code of Conduct to its employees. For the duration of this CIA, Warren shall continue to maintain the Code of Conduct. Warren 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. Warren'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. Warren's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Warren's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Warren's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate

individual designated by Warren, suspected violations of any Federal health care program requirements or of Warren's own Policies and Procedures;

d. the possible consequences to both Warren and Covered Persons of failure to comply with Federal health care program requirements and with Warren's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and Warren's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Warren'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 120 days after the Effective Date, whichever is later.

Warren 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, 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 120 days after the Effective Date, Warren shall implement written Policies and Procedures regarding the operation of Warren'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. ensuring the proper and accurate preparation and submission of claims to Federal health care programs;

- c. ensuring the proper and accurate documentation of medical records;
- d. ensuring the proper and accurate submission of cost reports submitted to Federal health care programs;
- e. conducting periodic billing and coding reviews and audits at Warren;
- f. ensuring that Warren has an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing services (consistent with the Provider Reimbursement Manual);
- g. monitoring all changes to the chargemaster at Warren to ensure review and approval by appropriate Warren personnel;
- h. reporting and repayment of all identified Overpayments to Federal health care programs and other payors;
- i. 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 business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- j. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals 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), Warren 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 individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

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

- a. CIA requirements; and
- b. Warren's 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. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. Warren's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

c. the personal obligation of each individual involved in the development, approval, management, or review of Warren's Arrangements to know the applicable legal requirements and Warren's policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and

e. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. A Warren employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least two hours of Arrangements Training in each subsequent Reporting Period.

3. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. the Federal health care program requirements regarding the accurate coding and submission of claims and cost reports;

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

c. the personal obligation of each individual involved in the claims submission process and/or preparation of cost reports to ensure that such claims and cost reports are accurate;

d. applicable reimbursement statutes, regulations, and program requirements and directives;

- e. the legal sanctions for violations of the Federal health care program requirements;
- f. examples of proper and improper claims submission practices;
- g. policies and procedures for the reporting and repayment of Overpayments to Federal health care programs and other payors; and
- h. policies and procedures on setting or modifying charges on hospital chargemasters, including the requirement that Warren has an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing services (consistent with the Provider Reimbursement Manual).

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Warren 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 preparation or submission of claims for reimbursement from any Federal health care program, 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 two hours of Specific Training in each subsequent Reporting Period.

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.* Warren shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program

requirements, any issues discovered during audits or reviews, and any other relevant information.

7. *Computer-based Training.* Warren may provide the training required under this CIA through appropriate computer-based training approaches. If Warren 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.

D. Compliance with the Anti-Kickback Statute and the Stark Law.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, Warren shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

a. Creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);

b. Establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and/or the Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and/or the Stark Law;

c. Requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

d. Implementing effective responses when suspected violations of the Anti-Kickback Statute and/or the Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, Warren shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by Warren and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Warren's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Warren shall provide each party to the Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures;

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. *Records Retention and Access.* Warren shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *Type and Frequency of Reviews.* The following reviews shall be performed by an entity (or entities), such as an accounting, auditing, law firm, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to be engaged by Warren during the term of the CIA: (a) Outlier Payments Review; (b) Unallowable Costs Review; and (c) a review to assist Warren in assessing its compliance with the obligations pursuant to Section III.D of this CIA ("Arrangements Review"). The Outlier Payments and Arrangements Reviews shall be performed annually and shall cover each of the Reporting Periods. The IRO shall perform the Unallowable Cost Review for the first Reporting Period. The IRO(s) shall perform all components of each Outlier Payments and Arrangement Review, as well as the Unallowable Cost Review. The work plans for the Arrangements Review and IRO Reviews are attached to this CIA in Appendices A-C and are hereby incorporated by reference into this CIA.

2. *Engagement of IRO(s)*. Within 120 days after the Effective Date, Warren shall engage the IRO(s) to perform the IRO Reviews and the Arrangements Review. Warren shall notify OIG of the identity of the IRO(s) in the Implementation Report required under Section V.A of this CIA. Within 30 days after OIG receives written notice of the identity of the selected IRO(s), OIG will notify Warren if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Warren may continue to engage the IRO. If Warren engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Section. If a new IRO is engaged, Warren shall submit the information identified in Section V.A.10 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Warren if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Warren may continue to engage the IRO.

3. *IRO Qualifications*. Each IRO engaged by Warren shall have expertise in the substantive matters of the IRO Reviews, the Arrangements Review, and in the general requirements of the Federal health care program(s) from which Warren seeks reimbursement. The IRO shall:

- a. assign individuals to conduct the IRO Reviews and/or Arrangements Review who have expertise in the substantive matters of the IRO Reviews and/or Arrangements Review and in the general requirements of the Federal health care program(s) from which Warren seeks reimbursement;
- b. assign individuals to design and select the samples who are knowledgeable about the appropriate statistical sampling techniques; and
- c. have sufficient staff and resources to conduct the IRO Reviews and/or Arrangements Review required by the CIA on a timely basis.

4. *IRO Responsibilities*. The IRO shall:

- a. perform each IRO Review and/or Arrangements Review in accordance with the specific requirements of this CIA;

- b. follow all applicable Medicare, Medicaid, or other Federal health care programs rules and reimbursement guidelines in making assessments in the IRO Review and/or Arrangements Review;
- c. 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);
- d. respond to all OIG inquiries in a prompt, objective, and factual manner; and
- e. prepare timely, clear, well-written reports that include all the information required by the CIA (hereinafter "IRO Review Reports").

5. *Arrangements Review.* The IRO shall perform a review to assess whether Warren is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 10 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Warren has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Warren has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the service and activity logs are properly completed and reviewed (if applicable); (d) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (e) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (f) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and/or the Stark Law are discovered; and (g) verifying that Warren has met the requirements of Section III.D.2.

6. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to (a) whether Warren has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Warren has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include any observations, findings, and recommendations on possible improvements to Warren's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute and/or the Stark Law.

7. *IRO Independence and Objectivity.* Each IRO must perform each IRO Review and/or Arrangements 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 Warren. Warren and each IRO shall assess whether the IRO can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. Each IRO shall include in its report(s) to Warren 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 IRO Reviews and that it has concluded that it is, in fact, independent and objective.

8. *IRO Removal/Termination.* If Warren terminates any IRO during the course of the engagement, Warren must submit a notice explaining its reasons to OIG no later than 30 days after termination. Warren must engage a new IRO in accordance with Section III.D of this CIA. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Section III.D.3 of this CIA, is not independent and objective as set forth in Section III.D.5 of this CIA, or has failed to carry out its responsibilities as described in Section III.D.4 of this CIA, OIG may, at its sole discretion, require Warren to engage a new IRO in accordance with Section III.D.2 of this CIA. Prior to requiring Warren to engage a new IRO, OIG shall notify Warren 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, Warren may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence, objectivity, or performance of its responsibilities and to present additional information regarding these matters. Warren shall provide any additional information as may be requested by OIG under this paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Warren prior to requiring Warren to terminate the

IRO. However, the final determination as to whether or not to require Warren to engage a new IRO shall be made at the sole discretion of OIG.

9. *Validation Review.* In the event OIG has reason to believe that any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the IRO Reviews complied with the requirements of this CIA and/or the findings or results are inaccurate (Validation Review). Warren 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 Warren's final Annual Report must be initiated no later than one year after Warren's final submission (as described in Section II of the CIA) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Warren 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, Warren may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Reviews or to correct the inaccuracy of the IRO Reviews; and/or (c) propose alternatives to the proposed Validation Review. Warren agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Warren 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.

10. *Retention of Records.* The IRO and Warren shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Warren) related to the reviews.

F. Disclosure Program.

Within 120 days after the Effective Date, Warren 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 Warren'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. Warren 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, Warren 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>).

c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of Warren.

2. *Screening Requirements.* Warren shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Warren shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. Warren shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Warren shall implement a policy requiring all Screened 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) Warren to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Warren understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Warren may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Warren meets the requirements of Section III.G.

3. *Removal Requirement.* If Warren has actual notice that a Screened Person has become an Ineligible Person, Warren shall remove such Screened Person from responsibility for, or involvement with, Warren's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered,

or prescribed by the Screened 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 Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Warren has actual notice that a Screened 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 Screened Person's employment or contract term or, in the case of a physician, during the term of the physician's medical staff privileges, Warren shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Warren shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Warren conducted or brought by a governmental entity or its agents involving an allegation that Warren 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. Warren 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 Warren 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, Warren identifies or learns of any Overpayment, Warren shall notify the 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. Also, within 30 days after identification of the Overpayment, Warren shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Warren 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, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix D to this CIA. 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; or
- iii. the filing of a bankruptcy petition by Warren.

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

b. *Reporting of Reportable Events.* If Warren determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Warren 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 all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

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

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

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

v. 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.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Warren 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, Warren 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, Medicare Provider number, provider identification number and/or supplier number, and

the corresponding contractor's name and address that has issued each Medicare number. 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 150 days after the Effective Date, Warren 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. a copy of Warren's Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. 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);

6. 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.

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

7. a description of the Arrangements Database required by Section III.D.1.a;
8. a description of the internal review and approval process required by Section III.D.1.e;
9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;
10. a description of the Disclosure Program required by Section III.F;
11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Warren and the IRO; and (d) the proposed start and completion dates of the IRO Reviews;
12. a certification from each IRO regarding its professional independence and objectivity with respect to Warren;
13. a description of the process by which Warren fulfills the requirements of Section III.G 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 Warren'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 Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Warren currently submits claims;
16. a description of Warren'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. Warren shall submit to OIG annually a report with respect to the status of, and findings regarding, Warren'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 significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
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. 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.

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

5. a description of any changes to the Arrangements Database required by Section III.D.1.a;
6. a description of any changes to the internal review and approval process required by Section III.D.1.e;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E and Appendices A-C, along with a copy of each IRO's engagement letter (if applicable);

9. Warren's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E and Appendices A-C;

10. a summary and description of any and all current and prior engagements and agreements between Warren and each IRO, if different from what was submitted as part of the Implementation Report;

11. a certification from each IRO regarding its professional independence and objectivity with respect to Warren;

12. 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;

13. 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;

14. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark Law;

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

16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Warren 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;

17. 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;

18. a description of all changes to the most recently provided list of Warren's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Warren currently submits claims; 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. 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, Warren is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, Warren has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, Warren has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA;

4. 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

5. Warren 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. Warren 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. Warren 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

WARREN:

Marsha Faden
Chief Compliance Officer
Warren Hospital
185 Roseberry Street
Phillipsburg, NJ 08865
Telephone: 908.859.6808
Facsimile: 908.859.6817

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.

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 Warren's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Warren's locations for the purpose of verifying and evaluating: (a) Warren's compliance with the terms of this CIA; and (b) Warren's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Warren 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 Warren'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. Warren shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Warren's employees may elect to be interviewed with or without a representative of Warren present.

VIII. DOCUMENT AND RECORD RETENTION

Warren 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 Warren prior to any release by OIG of information submitted by Warren pursuant to its obligations under this CIA and identified upon submission by Warren as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Warren shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Warren 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, Warren 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 Warren 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. written Policies and Procedures;
- e. the training of Covered Persons;
- f. the Arrangements Procedures and/or Arrangements Requirements described in Section III.D.1 and III.D.2;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements; and

i. 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 Warren fails to engage an IRO, as required in Section III.E and Appendices A-C.

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 Warren fails to submit the Implementation Report or the 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 Warren fails to submit the IRO Review Reports in accordance with the requirements of Section III.D and Appendices A-C.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Warren fails to submit the annual Arrangements Review Report in accordance with the requirements of Section III.E.

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

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

8. A Stipulated Penalty of \$1,000 for each day Warren fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Warren, stating the specific grounds for its determination that Warren has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Warren shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Warren 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. Warren 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 Warren 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 Warren 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 Warren 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 Warren of: (a) Warren'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, Warren 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 Warren elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Warren 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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as 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 Warren 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 Warren to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;
- 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; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The Parties agree that a material breach of this CIA by Warren constitutes an independent basis for Warren's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Warren has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Warren of: (a) Warren'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.* Warren 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. Warren 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) Warren has begun to take action to cure the material breach; (ii) Warren is pursuing such action with due

diligence; and (iii) Warren has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Warren fails to satisfy the requirements of Section X.D.3, OIG may exclude Warren from participation in the Federal health care programs. OIG shall notify Warren in writing of its determination to exclude Warren (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 Warren’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, Warren 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 Warren 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, Warren 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 Warren was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Warren 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 Warren to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless Warren 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 Warren 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) Warren had begun to take action to cure the material breach within that period; (ii) Warren has pursued and is pursuing such action with due diligence; and (iii) Warren provided to OIG within that period a reasonable timetable for curing the material breach and Warren 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 Warren, only after a DAB decision in favor of OIG. Warren's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Warren 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 Warren 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. Warren 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 Warren, Warren 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

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, Warren and OIG agree as follows:

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

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

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

D. OIG may agree to a suspension of Warren's obligations under the CIA in the event of Warren's cessation of participation in Federal health care programs. If Warren withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Warren shall notify OIG at least 30 days in advance of Warren'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 Warren 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 WARREN HOSPITAL

Jeffrey C. Goodwin

JEFFREY C. GOODWIN
President and CEO

Stern + Kilcullen, LLC

Lisa D. Taylor

LISA D. TAYLOR, ESQ.
Counsel for Warren

12/5/07

DATE

12/4/07

DATE

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



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

12/4/07

DATE

APPENDIX A

ARRANGEMENTS DATABASE

Warren shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and the Stark Law. The Arrangements Database shall contain certain information to assist Warren in evaluating whether each Arrangement violates the Anti-Kickback Statute and the Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.D.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

APPENDIX B

OUTLIER PAYMENTS REVIEWS

The IRO shall perform reviews of Medicare inpatient operating outlier payments (as defined in 42 C.F.R. Part 412) paid to Warren (“Outlier Payments”), as well as the processes by which Warren may receive such outlier payments (collectively “Outlier Payments Reviews”), except as provided under Section 7 of this Appendix. The reviews shall be performed as follows:

1. CCR Review. If Warren’s total Outlier Payments exceed \$500,000 in a cost reporting period for a cost report filed during a Reporting Period of the CIA, the IRO shall compare Warren’s actual operating cost-to-charge ratio (CCR) based on the most recent filed cost report and the CCR(s) used by the Medicare fiscal intermediary during the corresponding time period to make Outlier Payments (hereinafter “CCR Review”). If the actual operating CCR(s) are found to be plus or minus 10 percentage points or more from the CCR(s) used by the Medicare fiscal intermediary during that time period to make Outlier Payments, the IRO shall investigate and determine the root cause(s) of the variance. Such investigation may include, but shall not be limited to, a review of Warren’s cost report, chargemaster, charge or price increases, Warren’s costs for items or services, length of stays, and any other potential causes for the variance. If applicable, the IRO shall provide its findings and recommendations to Warren for any such variance in the CCR, including a recommendation that Warren request the Centers for Medicare & Medicaid Services (CMS) to reconcile outlier payments pursuant to 42 C.F.R. Part 412. Warren shall develop and implement a corrective action plan based on the IRO’s findings and recommendations for each variance. The Compliance Officer shall certify in each Annual Report that Warren has implemented these corrective actions.
2. Outlier Payment Percentage Review. The IRO shall compare Warren’s Outlier Payment Percentage for the cost reporting period filed during each Reporting Period of the CIA to the Outlier Payment percentage for the prior cost reporting period (hereinafter “Outlier Payment Percentage Review”). “Outlier Payment Percentage” shall be defined as (a) the total Outlier Payments received by Warren divided by (b) the total Outlier Payments plus Medicare operating DRG payments. If the Outlier Payment Percentage for the cost reporting period is at least five percent (5%) and increased from the prior cost reporting period to the cost reporting period under review by more than 10%, then the IRO shall investigate and determine the root cause(s) of the variance. The IRO shall provide Warren with findings and recommendations for any

variance in the Outlier Payment Percentage. Warren shall develop and implement a corrective action plan based on the IRO's findings and recommendations for each variance. The Chief Compliance Officer shall certify in each Annual Report that Warren has implemented these corrective actions.

3. Chargemaster Review. If either (1) the CCR review reveals an actual operating CCR that is plus or minus 10 percentage points or more from the CCR(s) used by the Medicare fiscal intermediary to make Outlier payments; or (2) the Outlier Payment Percentage Review reveals an Outlier Payment Percentage in excess of five percent (5%), then the IRO shall randomly select and review 25 requests to add or increase charges to the Warren chargemaster "Chargemaster Review"). For the purposes of the Chargemaster Review, "Requests" shall include any charge additions, charge activations, charge code changes, and rate increases and adjustments, including but not limited to annual/periodic across-the-board charge increases implemented in Warren's chargemaster. For each Request selected to be reviewed, the IRO shall review (1) whether the appropriate Warren personnel, including the chief financial officer and Warren's Patient Financial Services Department, have reviewed and approved the Request; (2) whether the Request was appropriately processed in accordance with the policy and procedure described in Paragraph III.B.2.g of the CIA; and (3) whether the Request was correctly incorporated on Warren's chargemaster. If the IRO determines that there has been any variance in the process, the IRO shall investigate and determine the root cause(s) of the variance. If applicable, the IRO shall provide findings and recommendations to Warren for any variance identified during the Chargemaster Review. Warren shall develop and implement a corrective action plan based on the IRO's findings and recommendations for each variance. The Compliance Officer shall certify in each Annual Report that Warren has implemented these corrective actions.
4. Frequency of Reviews. The Outlier Payments Reviews shall be performed annually beginning with the cost reporting periods ending December 31, 2007, and shall cover each of the cost reporting periods for cost reports filed during the Reporting Periods. The IRO shall perform all components of the Outlier Payments Reviews unless performed by Warren's Internal Audit Department as permitted in Section 7 of this Appendix.
5. IRO Qualifications. The IRO engaged by Warren shall have expertise in hospital chargemasters, outlier payments, billing and reimbursement, and the general requirements of the Federal health care program(s) from which Warren seeks reimbursement.

6. Outlier Payments Review Report. The IRO shall prepare a report based upon the Outlier Payments Reviews performed for each Reporting Period (Outlier Payments Review Report). Each report shall include a narrative description of the IRO's findings, the total number of variances in the CCRs and/or Outlier Percentages identified in the Outlier Payments Reviews, a description of each identified variance, a description of the root cause(s) of the variance, and any corrective actions recommended by the IRO. The IRO shall provide Warren with a copy of the Outlier Payments Review Reports.

7. Internal Option for Outlier Payment Percentage Review. Instead of an IRO, Warren's Internal Audit Department (IAD) may conduct the CCR Review, the Outlier Payment Percentage Review and, if necessary, the Chargemaster Review, in accordance with the requirements of Sections 1, 2 and 3 of this Appendix. If Warren opts to utilize its IAD instead of an IRO, then Warren's IAD shall prepare Outlier Payments Review Reports in accordance with Section 6 of this Appendix, and Warren shall include these reports in each Annual Report.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____ AMOUNT OF CHECK
 \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

- | | | |
|---|---|---|
| <p><u>Billing/Clerical Error</u></p> <ul style="list-style-type: none"> 01 - Corrected Date of Service 02 - Duplicate 03 - Corrected CPT Code 04 - Not Our Patient(s) 05 - Modifier Added/Removed 06 - Billed in Error 07 - Corrected CPT Code | <p><u>MSP/Other Payer Involvement</u></p> <ul style="list-style-type: none"> 08 - MSP Group Health Plan Insurance 09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including Black Lung 12 - Veterans Administration | <p><u>Miscellaneous</u></p> <ul style="list-style-type: none"> 13 - Insufficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 - Other (Please Specify) |
|---|---|---|