CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
OUR LADY OF LOURDES REGIONAL MEDICAL CENTER, INC.

I. PREAMBLE

Our Lady of Lourdes Regional Medical Center, Inc. (Provider) 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, Provider 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 Provider 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, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Provider's final annual report; or (2) any additional materials submitted by Provider 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 Provider; and

   b. all contractors, subcontractors, agents, and other persons who provide patient care items or patient care services or who perform billing or coding functions on behalf of Provider;

c. physicians with current medical staff privileges to perform interventional cardiac procedures at Provider.

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 involved in the provision of interventional cardiac care at Provider.

3. "Pre-existing Contractor" shall mean any Covered Person who is an independent contractor with whom Provider has an existing contract on the Effective Date of this CIA. Once Provider renegotiates, modifies, or renews a contract with a Pre-existing Contractor, such independent contractor ceases to be a Pre-existing Contractor as that term is used under the CIA and shall be treated as a Covered Person under the CIA.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Hospital Management.

1. *Compliance Officer.* Provider has appointed, and shall maintain for the term of the CIA, a full time Compliance Officer. 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 Provider, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Provider, 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 Provider as well as for any reporting obligations created under this CIA.

Provider 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.* Provider has appointed, and shall maintain for the term of the CIA, 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).

Provider 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. *Physician Executive(s).* Provider has appointed, and shall maintain for the term of the CIA, at least one but no more than three Physician Executive(s). The Physician Executive(s) shall be responsible for oversight of medical staff quality of care matters at Provider, 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 Executive(s) shall be members of senior management of Provider, shall make periodic (at least quarterly) reports regarding quality of care matters directly to the Board of Directors of Provider, and shall be authorized to report on such matters to the Board of Directors 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.

Provider shall report to OIG, in writing, any changes in the identity or position description of the Physician Executive(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 Provider is unable to fully comply with this Section III.A.3 at any point in time during the term of the CIA, Provider shall have 90 days to recruit and appoint Physician Executive(s) in order to comply with this Section III.A.3. If Provider is not in compliance with this Section III.A.3 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.

4. *Medical Director of the Cardiac Catheterization Laboratory.* Provider has appointed, and shall maintain for the term of the CIA, a cardiologist who is certificated by the American Board of Internal Medicine in interventional cardiology to serve as the Medical Director for Provider's Cardiac Catheterization Laboratory (Medical Director). The Medical Director shall be responsible for the clinical management and oversight of the Cardiac Catheterization Laboratory. 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 Board of Directors at any time.

Provider 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 Provider is unable to fully comply with this Section III.A.4 at any point in time during the term of the CIA, Provider shall have 120 days to recruit and appoint a Medical Director for the Cardiac Catheterization Laboratory in order to comply with this Section III.A.4. If Provider is not in compliance with this Section III.A.4 by the end of the 120 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.* Provider has developed, implemented, and distributed a written Code of Conduct to all Covered Persons. During the term of the CIA, Provider 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. Provider'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. Provider's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Provider's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

c. the requirement that all of Provider's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Provider suspected violations of any Federal health care program requirements or of Provider's own Policies and Procedures;

d. the possible consequences to both Provider and Covered Persons of failure to comply with Federal health care program requirements and with Provider'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.F, and Provider'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, that he or she has received, read, understood, and shall abide by Provider'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.

Provider 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, to the extent not already done so, Provider shall implement written Policies and Procedures regarding the operation of Provider'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 on a regular basis.

d. Medical staff peer review, including but not limited to: (i) appropriate screening of cases; (ii) conducting case reviews; (iii) ensuring adequate participation by members of the medical staff; (iv) review by Physician Executives and Medical Staff Executive Committee; (v) appropriate corrective action and disciplinary procedures; and (vi) reporting peer review activities to the Board of Directors on a regular basis.

e. 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 Board of Directors on a regular basis.

f. Management and oversight of Provider'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 procedures; (iii) ensuring interventional cardiac 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 physicians and by the Cardiac Catheterization Laboratory as a whole; (vii) comparing individual physician 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 interventional cardiac procedures by individual physician and by Cardiac

Catheterization Laboratory; (x) reviewing physician competence to perform interventional cardiac procedures through credentialing and privileging; (xi) implementing appropriate corrective actions for individual physicians 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 120 days after the Effective Date, to the extent not already done so, 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), Provider 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, Provider shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain the following:

a. Provider's CIA requirements; and

b. Provider's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues). In particular, the General Training shall include discussion on the Code of Conduct's requirement that all Covered Persons are expected (i) to comply with all Federal health care program requirements and with Provider's own Policies and Procedures; and (ii) to report to the Compliance Officer or other appropriate individual designated by Provider suspected violations of any Federal health care program requirements or of Provider's own Policies and Procedures.

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.

If, pursuant to Provider's Compliance Program, Provider has provided training to Covered Persons that satisfies the requirements set forth in this Section III.C.1 within 60 days prior to the Effective Date, the OIG will credit the training for purposes of satisfying Provider's General Training obligations for the first Reporting Period of the CIA.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least 4 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 Laboratory

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 Provider 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 interventional cardiac procedures at Provider, 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.

If, pursuant to Provider's Compliance Program, Provider has provided training to Relevant Covered Persons that satisfies the requirements set forth in this Section III.C.2 within 60 days prior to the Effective Date, the OIG will credit the training for purposes of satisfying Provider's Specific Training obligations for the first Reporting Period.

3. *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.

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

5. *Update of Training.* Provider shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the engagement of the Peer Review Consultant, or the Cardiac Procedures Review, Unallowable Cost Review, and any other relevant information.

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

7. *Pre-existing Contractors.* Provider shall make the Code of Conduct, General Training, and Specific Training (where appropriate) available to all Pre-existing Contractors, and shall use best efforts to encourage their attendance and participation. The Compliance Officer shall keep a record of all Pre-existing Contractors who attend such training and shall include such record in each Annual Report to the OIG.

8. *Physicians with Current Medical Staff Privileges.* Provider shall make the Code of Conduct, General Training and Specific Training (where appropriate) available to all Physicians with Current Medical Staff Privileges who are not Covered Persons, and shall use best efforts to encourage their attendance and participation. The Compliance Officer shall maintain records of all Physicians with Active Medical Staff Privileges 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, Provider shall engage an entity (hereinafter "Peer Review Consultant") to perform reviews to assist Provider in assessing and evaluating 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 Provider if the Peer Review Consultant is unacceptable. Absent notification from OIG that the Peer Review Consultant is unacceptable, Provider may continue to engage the Peer Review Consultant. The engagement of the Peer Review Consultant shall be for the term of the CIA. If Provider terminates the Peer Review Consultant during the course of the engagement, Provider must submit a notice explaining its reasons to OIG no later than 30 days after termination and Provider 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 Provider 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 Provider's policies and procedures, practices, bylaws, meeting minutes, case reviews, corrective actions, disciplinary records, medical staff participation, ongoing quality-monitoring data, and oversight by Provider's senior management and Board of Directors. Such review may include, but shall not be limited to, document review, interviews, 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 Provider'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 recommendations the Peer Review Consultant may have to improve any of these systems, operations, and processes (Peer Review Recommendations).

The Systems Review Report shall be delivered to Provider 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, Provider shall implement the recommendation or provide a written explanation of why the recommendation was not implemented. Provider 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 Provider.

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 Provider a report within 60 days of the end of each Reporting Period that evaluates Provider's implementation of the Peer Review Recommendations (Monitoring Reports). A copy of the Monitoring Report shall be provided to the OIG in the Annual Report as required by Section V.B of the CIA, beginning with the Second Annual Report.

If the Peer Review Consultant's monitoring does not reveal significant deficiencies in the implementation of the Peer Review Recommendations, Provider may request the OIG to modify the frequency of the monitoring by the Peer Review Consultant required by the CIA. The OIG shall retain sole discretion to modify the frequency of the monitoring. If the OIG so permits, the OIG shall notify Provider in writing of this decision.

6. *Retention of Records*. Provider 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 Provider and the Peer Review Consultant related to the engagements.

E. Independent Review Organizations.

1. *Engagement of Independent Review Organizations*. Within 90 days after the Effective Date, Provider shall engage an entity or entities (hereinafter "Independent Review Organization" or "IRO") to perform reviews to assist Provider in assessing and evaluating the medical necessity and appropriateness of interventional cardiac procedures and Provider's compliance with the unallowable costs provisions pursuant to this CIA and the Settlement Agreement. The IRO(s) shall perform all components of each review. Each IRO shall assess, along with Provider, whether it can perform the reviews in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix

A to this Agreement, which is incorporated by reference. The IRO(s) and Provider shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Provider) related to the reviews.

2. *Cardiac Procedures Review.* Provider shall engage an IRO to evaluate and analyze the medical necessity and appropriateness of interventional cardiac procedures performed at the Provider's Cardiac Catheterization Laboratory (Cardiac Procedures Review). The IRO shall randomly select and review a sample of 50 interventional cardiac procedures performed at Provider's Cardiac Catheterization Laboratory. The interventional cardiac 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 Provider or under Provider'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.

The Cardiac Procedures Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by Provider shall have expertise in the medical necessity and appropriateness of interventional cardiac procedures and in the general requirements of the Federal health care program(s) from which Provider seeks reimbursement.

The IRO shall prepare a report based upon the Cardiac Procedures Review performed (Cardiac Procedures Review Report). Information to be included in the Cardiac Procedures Review Report is described in Appendix B.

3. *Unallowable Cost Review.* Provider shall engage an IRO to conduct a review of Provider's compliance with the unallowable cost provisions of the Settlement Agreement (Unallowable Cost Review). The IRO shall determine whether Provider 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 Provider 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.

The IRO shall perform the Unallowable Cost Review for the first Reporting Period. The IRO engaged by Provider shall have expertise in billing and reimbursement and in the general requirements of the Federal health care program(s) from which Provider seeks reimbursement.

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 Provider 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.

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

Prior to initiating a Validation Review, OIG shall notify Provider 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, Provider may request a meeting with OIG to: (a) discuss the results of any Cardiac Procedures Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Cardiac Procedures Review or Unallowable Cost Review or to correct the inaccuracy of the Cardiac Procedures Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Provider 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 Cardiac Procedures Review or Unallowable Cost Review issues with Provider 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.

5. *Independence/Objectivity Certification.* The IRO(s) shall include in its report(s) to Provider 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 Procedures Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

F. Disclosure Program.

Provider shall maintain a Disclosure Program that includes a mechanism (e.g., a dedicated 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 Provider'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. Provider 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, Provider 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://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 Provider.

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

a. Provider 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 persons to disclose whether they are an Ineligible Person.

b. Provider shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Provider 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) Provider to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Provider has actual notice that a Screened Person has become an Ineligible Person, Provider shall remove such person from responsibility for, or involvement with, Provider's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Provider 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 his or her employment or contract term, or, in the case of a physician, during the term of the physician's medical staff privileges, Provider shall take all appropriate actions to ensure that the responsibilities of that 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, Provider shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Provider conducted or brought by a governmental entity or its agents involving an allegation that Provider 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. Provider 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 Provider 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, Provider identifies or learns of any Overpayment, Provider shall notify the Federal health care program 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, Provider 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, Provider 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 C 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; or

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. 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 Provider determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Provider 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 Provider's actions taken to correct the Reportable Event; and

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Provider 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, Provider 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, Provider 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.1, and a summary of other job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names, addresses, phone numbers, and position descriptions of the Physician Executive(s) required by Section III.A.3, and a summary of other job responsibilities that each Physician Executive may have;

4. the name, address, phone number, and position description of the Medical Director of the Cardiac Catheterization Laboratory required by Section III.A.4, and a summary of other job responsibilities that the Medical Director may have;

5. a copy of Provider'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.

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 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 Provider and the Peer Review Consultant; and (d) 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; (c) a summary and description of any and all current and prior engagements and agreements between Provider and the IRO; and (d) the proposed start and completion dates of the Cardiac Procedures Review and Unallowable Cost Review;

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Provider;

13. a description of the process by which Provider 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 Provider'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 Provider currently submits claims;

16. a description of Provider'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. Provider shall submit to OIG annually a report with respect to the status of, and findings regarding, Provider'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, Physician Executive(s), or Medical Director, 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. 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;

6. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);

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

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

9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Provider;

10. 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;

11. 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;

12. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

13. any changes to the process by which Provider 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 by Provider 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 relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. 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;

16. a description of all changes to the most recently provided list of Provider'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 Provider currently submits claims; and

17. 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, Provider 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, Provider 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. Provider 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. Provider 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

Provider: Elizabeth J. Champion
Corporate Compliance Officer
Our Lady of Lourdes Regional Medical Center
611 St. Landry Street
Lafayette, LA 70501
Telephone: (337) 289-2825
Facsimile: (337) 289-2574

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

VIII. DOCUMENT AND RECORD RETENTION

Provider shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 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 Provider prior to any release by OIG of information submitted by Provider pursuant to its obligations under this CIA and identified upon submission by Provider as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Provider shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Provider 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, Provider 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 Provider fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. Physician Executive(s);

d. a Medical Director of the Cardiac Catheterization Laboratory;

e. a written Code of Conduct;

f. written Policies and Procedures;

g. the training of 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 Provider (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 and Appendix A.

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 Provider 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 Provider (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 Procedures Review Report or the Unallowable Costs Review Report in accordance with the requirements of Section V.B.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Provider 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 Provider fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Provider, stating the specific grounds for its determination that Provider has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Provider shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Provider 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. Provider 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 Provider 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 Provider 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 Provider 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 Provider of: (a) Provider'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, Provider 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 Provider elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Provider 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 Provider 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 Provider 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.

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

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Provider fails to satisfy the requirements of Section X.D.3, OIG may exclude Provider from participation in the Federal health care programs. OIG shall notify Provider in writing of its determination to exclude Provider (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 Provider'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, Provider 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 Provider 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, Provider 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 Provider was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Provider 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 Provider to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Provider 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 Provider 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) Provider had begun to take action to cure the material breach within that period; (ii) Provider has pursued and is pursuing such action with due diligence; and (iii) Provider provided to OIG within that period a reasonable timetable for curing the material breach and Provider 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 Provider, only after a DAB decision in favor of OIG. Provider's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Provider 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 Provider 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. Provider 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 Provider, Provider 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, Provider and OIG agree as follows:

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

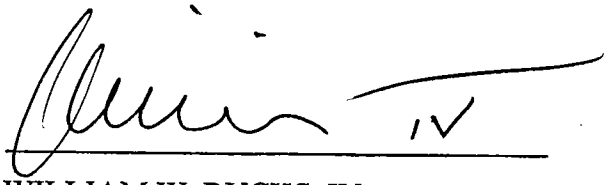
B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

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 Provider's obligations under the CIA in the event of Provider's cessation of participation in Federal health care programs. If Provider withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Provider shall notify OIG at least 30 days in advance of Provider'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 Provider 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.

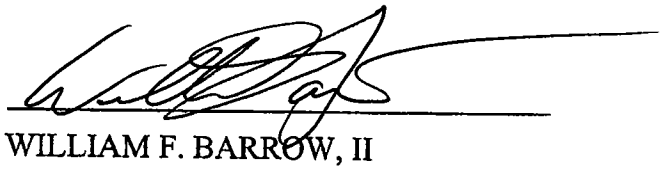
ON BEHALF OF OUR LADY OF LOURDES REGIONAL MEDICAL CENTER, INC.



8/10/06

WILLIAM W. RUCKS, IV
Chairman of the Board of Directors
Our Lady of Lourdes Regional Medical Center, Inc.

DATE

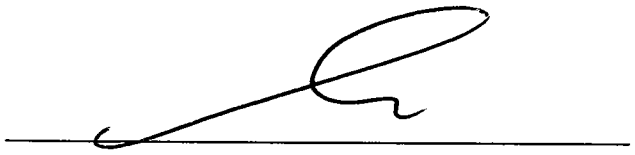


8/10/06

WILLIAM F. BARROW, II
Chief Executive Officer
Our Lady of Lourdes Regional Medical Center, Inc.

DATE

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



8/16/06

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

DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Provider 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 written notice of the identity of the selected IRO, OIG will notify Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider may continue to engage the IRO.

If Provider 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, Provider shall submit the information identified in Section V.A.11 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 Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider 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 Provider seeks reimbursement;

2. assign individuals to design and select the Cardiac Procedures Review sample who are knowledgeable about the appropriate statistical sampling techniques;

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

4. 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 and Unallowable Cost Review;

3. if in doubt of the application of a particular Medicare, Medicaid or other Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Cardiac Procedures Review and/or Unallowable Cost 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 Provider.

E. IRO Removal/Termination.

1. *Provider.* If Provider terminates its IRO during the course of the engagement, Provider must submit a notice explaining its reasons to OIG no later than 30 days after termination. Provider must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that 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 Provider to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Provider to engage a new IRO, OIG shall notify Provider 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, Provider 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. Provider 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 Provider prior to requiring Provider to terminate the IRO. However, the final determination as to whether or not to require Provider to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
CARDIAC PROCEDURES REVIEW

A. Cardiac Procedures Review.

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

a. Interventional Cardiac Procedure: Any percutanaeous coronary interventions, including but not limited to percutaneous transluminal coronary angioplasties, balloon angioplasties, and implantation of intracoronary stenting, performed at Provider's Cardiac Catheterization Laboratory.

b. Population: For each Reporting Period, the Population shall be defined as all Interventional Cardiac Procedures for which Provider has received reimbursement from Medicare, Medicaid, or other Federal health care programs during the relevant 12-month Reporting Period.

2. *Other Requirements*.

a. Interventional Cardiac Procedures without Supporting Documentation. For the purpose of reviewing Interventional Cardiac Procedures, any Interventional Cardiac Procedure for which Provider cannot produce documentation sufficient to support the medical necessity or appropriateness of the Interventional Cardiac Procedure shall be considered an error. Replacement sampling for Interventional Cardiac Procedures with missing documentation is not permitted.

b. Replacement Sampling. Considering the Population shall consist only of Interventional Cardiac Procedures and that Interventional Cardiac Procedures with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

c. Use of First Samples Drawn. For the purposes of the Sample, the Interventional Cardiac Procedures selected in each first sample (or first sample for each strata, if applicable) shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one to be used).

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

1. *Claims Review Methodology*.

a. Sampling Unit. A description of the Interventional Cardiac Procedures as that term is utilized for the Cardiac Procedure Review.

b. Cardiac Procedures Review Population. A description of the Population subject to the Cardiac Procedures Review.

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

d. Sampling Frame. A description of the sampling frame, which is the totality of Interventional Cardiac 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 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 Procedures Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Interventional Cardiac 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 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 Procedures Review, including the results of the Sample.

b. Total number of instances in which the IRO determined that the Interventional Cardiac Procedure 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 Procedures Review results that includes the following information for each Interventional Cardiac Procedures appraised: type of Interventional Cardiac Procedure performed, whether the Interventional Cardiac 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. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Cardiac Procedures Review; and (2) performed the Cardiac Procedures Review.

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/SUPPLIERNAME_____
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:

Billing/Clerical Error
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

MSP/Other Payer Involvement
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

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____