CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SAINT JOSEPH HEALTH SYSTEM, INC. D/B/A SAINT JOSEPH LONDON

I. PREAMBLE

Saint Joseph Health System, Inc. d/b/a Saint Joseph London located at 1001 Saint Joseph Drive, London, Kentucky (SJL) 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). Saint Joseph Health System, Inc. is a not for profit corporation that is a part of KentuckyOne Health, Inc., which in turn is part of Catholic Health Initiatives. Saint Joseph Health System, Inc. operates six hospitals in Central and Eastern Kentucky. The obligations of this CIA do not apply to any other hospital within Saint Joseph Health System, Inc. other than Saint Joseph Health System, Inc. d/b/a Saint Joseph London and all related services provided under the Medicare Provider Number 180011. Contemporaneously with this CIA, SJL 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 SJL under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) SJL's final annual report; or (2) any additional materials submitted by SJL 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 SJL; 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 SJL excluding vendors whose sole connection with SJL is selling or otherwise providing medical supplies or equipment to SJL and who do not bill the Federal health care programs for such medical supplies or equipment; and

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

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

2. "Relevant Covered Persons" shall mean any Covered Person involved, directly or indirectly, in the oversight, management, or provision of interventional cardiac care or cardiac surgeries (as defined in Appendix B) at SJL or who is involved in the quality assurance, credentialing, or peer review process.

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 SJL and any actual or potential source of health care business or referrals to SJL or any actual or potential recipient of health care business or referrals from SJL. The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term "recipient of health care business or referrals" shall mean any individual or entity (1) to whom SJL refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom SJL purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or

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

4. "Focus Arrangements" means every Arrangement that:

a. is between SJL and any actual source of health care business or referrals to SJL and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

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

Notwithstanding the foregoing provisions of Section II.C.4, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests), 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits), 42 C.F.R. § 411.357(o) (compliance training), 42 C.F.R. § 411.357(q) (referral services), 42 C.F.R. § 411.357(s) (professional courtesy), 42 C.F.R. § 357(u) (community-wide health information systems), or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA. In addition, Focus Arrangements shall not include any Arrangement between SJL and any employee of SJL (i) who is not a licensed or certified health care provider at SJL; (ii) who does not provide health care items or services on behalf of SJL for which payment may be made in whole or in part by a Federal health care program; and (iii) whose employment relationship with SJL meets the safe harbor set forth at 42 CFR § 1001.952(i).

5. "Arrangements Covered Persons" includes each Covered Person who is involved with the development, approval, management, or review of SJL's Arrangements.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Hospital Management: Compliance Officer and Committee

1. *Compliance Officer*. Within 90 days after the Effective Date, SJL shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of SJL, shall have direct access to the President of SJL, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Saint Joseph Health System, Inc., and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors of Saint Joseph Health System, Inc. shall be made available to OIG upon request. 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 SJL as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

SJL 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 five days after such a change.

Catholic Health Initiatives directs the Saint Joseph Health System, Inc. corporate compliance program, and SJL's Compliance Officer reports directly to a Vice President and Division Corporate Responsibility Officer for KentuckyOne Health, Inc., who is employed by Catholic Health Initiatives, rather than to SJL senior management. SJL's Compliance Officer is part of senior management at SJL. SJL's Compliance Officer may report compliance issues to management of Catholic Health Initiatives, KentuckyOne Health, Inc., Saint Joseph Health System, Inc., or SJL's senior management, along with the Board of Saint Joseph Health System, Inc.

2. *Compliance Committee*. Within 90 days after the Effective Date, SJL shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer, 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 SJL's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* Saint Joseph Health System, Inc. has a Board of Directors, Saint Joseph London located at 1001 Saint Joseph Drive, London, Kentucky, does not have a separate Board of Directors. References in this CIA to the Board of Directors refer to the Saint Joseph Health System, Inc. Board of Directors. The Board of Directors (or a committee of the Board) of Saint Joseph Health System, Inc. (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

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

a. meeting at least quarterly to review and oversee SJL's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and

b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of SJL's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of SJL's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, SJL has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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

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

4. *Physician Executive(s).* Within 60 days of the Effective Date, SJL shall appoint, and 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 SJL, 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 SJL, shall make periodic (at least quarterly) reports regarding quality of care matters directly to the Board of Directors of Saint Joseph Health System, Inc., 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.

SJL 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 SJL is unable to fully comply with this Section III.A.4 at any point in time during the term of the CIA, SJL shall have 90 days to recruit and appoint Physician Executive(s) in order to comply with this Section III.A.4. If SJL is not in compliance with this Section III.A.4 by the end of the 90 day time period, the OIG may, at its sole discretion, grant additional extensions pursuant to timely requests for extensions under Section X.B of the CIA or seek stipulated penalties in accordance with Section X.A.1 of the CIA.

5. *Medical Director of the Cardiac Catheterization Laboratory.* SJL shall appoint, 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 SJL's Cardiac Catheterization Laboratory (Medical Director). The Medical Director shall be responsible for the clinical management and oversight of the Cardiac Catheterization Laboratory (including any other designated area for interventional cardiac procedures). The Medical Director shall make periodic (at least quarterly) reports to the Physician Executive(s) 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 Executive(s), Compliance Officer, Compliance Committee, or Board of Directors of Saint Joseph Health System, Inc. at any time.

SJL 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 SJL is unable to fully comply with this Section III.A.5 at any point in time during the term of the CIA, SJL shall have 90 days to recruit and appoint a Medical Director for the Cardiac Catheterization Laboratory in order to comply with this Section III.A.5. If SJL is not in compliance with this Section III.A.5 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.

B. Written Standards

1. *Code of Conduct.* Within 90 days after the Effective Date, SJL shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. SJL 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. SJL'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. SJL's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with SJL's own Policies and Procedures;

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

d. the possible consequences to both SJL and Covered Persons of failure to comply with Federal health care program requirements and with SJL'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.G, and SJL's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by SJL'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.

Additionally, the following shall constitute the obligations of SJL under this Section III.B.1 with respect to physicians who have active medical staff membership but with whom SJL does not have a financial relationship ("Excepted Physicians"): (i) SJL shall make available or distribute the Code of Conduct to Excepted Physicians in accordance with the time requirements for other Covered Persons as set forth in this Section III.B.1; (ii) SJL shall also use its best efforts to obtain written or electronic certification from each Excepted Physician indicating that he or she has received, read, understood, and shall abide by SJL's Code of Conduct; and (iii) SJL shall keep records of the percentage of Excepted Physicians who have completed the certification requirement.

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

2. *Policies and Procedures*. Within 90 days after the Effective Date, SJL shall implement written Policies and Procedures regarding the operation of SJL's compliance program, including the compliance program requirements outlined in this CIA and SJL's 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, including but not limited to: (i) measuring, analyzing, and tracking

quality indicators; (ii) setting priorities for performance improvement activities; (iii) tracking medical errors and adverse patient events; (iv) conducting quality assessment and performance improvement projects; and (v) reporting data to the Board of Directors of Saint Joseph Health System, Inc. 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 Executive(s) and Medical Executive Committee; (v) appropriate corrective action and disciplinary procedures; and (vi) reporting peer review activities to the Board of Directors of Saint Joseph Health System, Inc. 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 Executive(s) and Medical Executive Committee; and (iv) reporting credentialing and privileging activities to the Board of Directors of Saint Joseph Health System, Inc. on a regular basis.

f. Management and oversight of SJL'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.

g. Management and oversight of SJL's cardiac surgeries (as defined in Appendix B), including but not limited to: (i) ensuring appropriate recordkeeping of cardiac surgeries; (ii) ensuring cardiac surgeries are peer reviewed for quality and outcomes; (iii) developing criteria for assessment of clinical appropriateness of cardiac surgeries; (iv) assessing procedural outcomes with appropriate risk adjustment; (v) tabulating results achieved by individual physicians and by the cardiac surgery team as a whole; (vi) comparing individual physician results with national benchmark standards with appropriate risk adjustment; (vii) reporting results to relevant registries for benchmarking purposes; (viii) tracking volume of cardiac surgeries by individual physician and by SJL; (ix) reviewing physician competence to perform cardiac surgeries through credentialing and privileging; (x) implementing appropriate corrective actions for individual physicians who substantially deviate from national benchmark standards or otherwise are found to provide substandard care; and (xi) monitoring relevant industry practice guidelines for changes, updates, and improvements.

h. 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

i. the requirements set forth in Section III.F (Compliance with the Anti-Kickback Statute and Stark Law).

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

At least annually (and more frequently, if appropriate), SJL shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *General Training.* Within 90 days after the Effective Date, SJL shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain SJL's:

a. CIA requirements; and

b. Compliance Program, including the Code of Conduct and Policies and Procedures as they pertain to general compliance issues. In particular, the General Training shall include discussion of the Code of Conduct's requirement that all Covered Persons are expected (i) to comply with all Federal health care program requirements and with SJL's own Policies and Procedures; and (ii) to report to the Compliance Officer or other appropriate individual designated by SJL suspected violations of any Federal health care program requirements or of SJL'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 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, SJL shall initiate the provision of Specific Training to each Relevant Covered Person. Within the first Reporting Period, each Relevant Covered Person shall receive at least three hours of Specific Training pertinent to their responsibilities in addition to the General Training required above. This Specific Training shall include a discussion of:

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 interventional cardiac procedures and cardiac surgeries;

f. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; and

g. the legal sanctions for violations of the Federal health care program requirements.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An SJL 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 and services and/or the provision of interventional cardiac procedures at SJL, 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 addition to the General Training, in each subsequent Reporting Period.

3. *Arrangements Training.* Within 90 days after the Effective Date, each Arrangements Covered Person shall receive at least three 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. SJL's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, 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.F of the CIA;

c. the personal obligation of each individual involved in the development, approval, management, or review of SJL's

Arrangements to know the applicable legal requirements and the SJL'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 90 days after the Effective Date, whichever is later. An SJL 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 addition to the General Training, in each subsequent Reporting Period.

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

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

5. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, 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 materials shall be made available to OIG, upon request.

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

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

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

9. *Excepted Physicians.* SJL shall make the General Training and Specific Training (where appropriate) available to all Excepted Physicians, as defined at Section III.B.1, and shall use its best efforts to encourage their attendance and participation. SJL shall keep records of the percentage of Excepted Physicians, and the names of Excepted Physicians, who attend such training and shall include such records in each Annual Report to the OIG.

D. Peer Review Consultant

1. *Engagement of Peer Review Consultant.* Within 60 days after the Effective Date, SJL shall engage an entity (or entities) (hereinafter "Peer Review Consultant"), to perform reviews to assist SJL 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 SLJ if the Peer Review Consultant is unacceptable. Absent notification from OIG that the Peer Review Consultant is unacceptable, SJL may continue to engage the Peer Review Consultant. The engagement of the Peer Review Consultant shall be for the term of the CIA. If SJL terminates the Peer Review Consultant during the course of the engagement, SJL must submit a notice explaining its reasons to OIG no later than 30 days after termination and SJL 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 SJL 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 SJL's policies and procedures, practices, bylaws, meeting minutes, case reviews, corrective actions, disciplinary records, medical staff participation, ongoing quality-monitoring data, and oversight by SJL's senior management and the Board of Directors of Saint Joseph Health System, Inc. 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 SJL'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 SJL 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, SJL shall implement the recommendation or provide a written explanation of why the recommendation was not implemented. SJL 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 SJL.

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 SJL a report within 60 days of the end of each Reporting Period that evaluates SJL'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.

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

E. Independent Review Organizations

1. *General Description.*

a. *Engagement of Independent Review Organization(s).* Within 90 days after the Effective Date, SJL shall engage an individual or entity (or entities), such as an accounting, auditing, or consulting firm[1] (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E (Cardiac Procedures Review, Cardiac Surgeries Review, Arrangements Review, Unallowable Cost Review). The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects SJL's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Cardiac Procedures Review and Cardiac Surgeries Review.* The IRO shall evaluate and analyze the medical necessity and appropriateness of interventional cardiac procedures performed in the SJL Cardiac Catheterization Lab, or any other designated area for such procedures, (Cardiac Procedures Review) and shall prepare a Cardiac Procedures Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference. The IRO shall also evaluate and analyze the medical necessity and appropriateness of cardiac surgeries (as defined in Appendix B) performed at SJL (Cardiac Surgeries Review) and shall prepare a Cardiac Surgeries Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

[1] SJL may engage a law firm for the Arrangements Review.

4. *Unallowable Cost Review.* For the first Reporting Period, the IRO shall conduct a review of SJL's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether SJL 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 SJL 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.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed (Unallowable Cost Review Report). The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether SJL 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.

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

Prior to initiating a Validation Review, OIG shall notify SJL 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, SJL may request a meeting with OIG to: (a) discuss the results of any Cardiac Procedures Review, Cardiac Surgeries Review, Arrangements

Review, or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Cardiac Procedures Review, Cardiac Surgeries Review, Arrangements Review, or Unallowable Cost Review or to correct the inaccuracy of the Cardiac Procedures Review, Cardiac Surgeries Review, Arrangements Review, or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. SJL agrees to provide any additional information as may be requested by OIG under this Section III.E.6 in an expedited manner. OIG will attempt in good faith to resolve any Cardiac Procedures Review, Cardiac Surgeries Review, Arrangements Review, or Unallowable Cost Review issues with SJL 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.

7. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to SJL a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

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

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, SJL shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);

b. tracking remuneration to and from all parties to Focus Arrangements;

c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

e. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;

f. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Sections III.J and III.K when appropriate.

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

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

b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required by Section III.C.3 of this CIA. Additionally, SJL shall provide each party to the Focus 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 Focus 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.* SJL shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

G. Disclosure Program

Within 90 days after the Effective Date, SJL 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 SJL'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. SJL 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, SJL 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.

H. 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 scope 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 System for Award Management (available through the Internet at http://www.sam.gov).

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

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

b. SJL shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter.

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

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

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

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

I. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, SJL shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to SJL conducted or brought by a governmental entity or its agents involving an allegation that SJL 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. SJL 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.

J. Repayment of Overpayments

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

2. *Repayment of Overpayments.*

a. If, at any time, SJL identifies any Overpayment, SJL shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 60 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, SJL 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.

b. 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.

K. Reportable Events

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

a. a substantial Overpayment;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or

d. 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.

e. the filing of a bankruptcy petition by SJL.

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

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

3. *Reportable Events under Section III.K.1.a.* For Reportable Events under Section III.K.1.a, the report to the OIG shall be made at the same time as the repayment to the payor required under Section III.J, and shall include:

a. a copy of the notification and repayment to the payor required in Section III.J.2;

b. a description of the steps taken by SJL to identify and quantify the Overpayment;

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

d. a description of SJL's actions taken to correct the Reportable Event; and

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

4. *Reportable Events under Section III.K.1.b, c, and d.* For Reportable Events under Section III.K.1.b, III.K.1.c, and III.K.1.d, the report to OIG shall include:

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

b. a description of SJL's actions taken to correct the Reportable Event;

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

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

e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by SJL to identify and quantify the Overpayment.

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

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by SJL to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.J.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If SJL identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then SJL is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit or Location.

In the event that, after the Effective Date, SJL proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, SJL shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit or Location

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

C. Purchase or Establishment of New Business, Business Unit or Location

In the event that, after the Effective Date, SJL purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, SJL shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which SJL currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, SJL 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 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.2;

3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. the names, addresses, phone numbers, and position descriptions of the Physician Executive(s) required by Section III.A.4, and a summary of other job responsibilities that each Physician Executive may have;

5. the name, address, phone number, and position description of the Medical Director of the Cardiac Catheterization Laboratory required by Section III.A.5, and a summary of other job responsibilities the Medical Director may have;

6. a copy of SJL's Code of Conduct required by Section III.B.1;

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 made available to OIG upon request);

8. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);

9. 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; and

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 made available to OIG upon request.

10. a description of (a) the Focus Arrangements Tracking System required by Section III.F.1.a, (b) the internal review and approval process required by Section III.F.1.e; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.F.1;

11. a description of the Disclosure Program required by Section III.G;

12. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA, (d) a summary and description of any and all current and prior engagements and agreements between SJL and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to SJL;

13. the following information regarding the Peer Review Consultant: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the Peer Review Consultant has the qualifications outlined in Section III.D, (d) a summary and description of any and all current and prior engagements and agreements between SJL and the Peer Review Consultant; and (e) a certification from the Peer Review Consultant regarding his or her professional independence and objectivity with respect to SJL;

14. a description of the process by which SJL fulfills the requirements of Section III.H regarding Ineligible Persons;

15. a list of all of SJL's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which SJL currently submits claims;

16. a description of SJL'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

SJL shall submit to OIG annually a report with respect to the status of, and findings regarding, SJL'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. the Board resolution required by Section III.A.3;

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

4. 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 made available to OIG upon request);

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

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

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

   b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

7. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.F.1.a; (b) any changes to the internal review and approval

process required by Section III.F.1.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.F.1;

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

9. a complete copy of the Systems Review Report prepared by the Peer Review Consultant pursuant to Section III.D (first reporting period); a complete copy of the Monitoring Report prepared by the Peer Review Consultant pursuant to Section III.D (subsequent reporting periods);

10. SJL's response to the reports prepared pursuant to Section III.E., along with corrective action plan(s) related to any issues raised by the reports;

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

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

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

14. a certification from the Peer Review Consultant regarding his or her professional independence and objectivity with respect to SJL;

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

16. 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;

17. a summary of the disclosures in the disclosure log required by Section III.G 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 (the complete disclosure log shall be made available to OIG upon request);

18. any changes to the process by which SJL fulfills the requirements of Section III.H regarding Ineligible Persons;

19. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. 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;

20. a description of all changes to the most recently provided list of SJL'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 and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which SJL currently submits claims; and

21. 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, SJL 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, SJL has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.F of the CIA;

4. to the best of his or her knowledge, SJL has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.F.2 of the CIA;

5. to the best of his or her knowledge, SJL 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

SJL 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. SJL 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

SJL: Heather N. Lovelace, MBA, CHC
Corporate Responsibility Officer
Saint Joseph London
1001 Saint Joseph Lane
London, KY 40741
Telephone: 606.330.6771
Facsimile: 606.330.6039

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations;

d. a written Code of Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons, Relevant Covered Persons, Arrangements Covered Persons, and Board Members;

g. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.F.1 and III.F.2;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings; and

k. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SJL fails to engage and use an IRO, as required in Section III.E, Appendix A, Appendix B, and Appendix 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 SJL fails to engage and use a Peer Review Consultant, as required in Section III.D.

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 SJL fails to engage and use the Physician Executive(s), as required in Section III.A.4.

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 SJL fails to engage and use a Medical Director of the Cardiac Catheterization Laboratory, as required in Section III.A.5.

6. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SJL fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

7. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SJL fails to submit the Systems Review Report by the Peer Review Consultant, the annual Monitoring Reports by the Peer Review Consultant, the annual Cardiac Procedures Review Report, Cardiac Surgeries Review Report, Arrangements Review Report, or Unallowable Cost Review Report in accordance with the requirements of Section III.D, Section III.E and Appendices B and C by the deadlines for submission.

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

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

10. A Stipulated Penalty of $1,000 for each day SJL fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to SJL stating the specific grounds for its determination that SJL has failed to comply fully and adequately with the CIA obligation(s) at issue and steps SJL shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after SJL 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 1-9 of this Section.

B. Timely Written Requests for Extensions

SJL 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 SJL 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 SJL 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 SJL 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 SJL of: (a) SJL's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, SJL 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 SJL elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until SJL cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that SJL 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 SJL to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.K;

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;

e. a failure to engage and use the Physician Executive(s) in accordance with Section III.A;

f. a failure to engage and use a Medical Director of the Cardiac Catheterization Laboratory in accordance with Section III.A; or

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

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

3. *Opportunity to Cure.* SJL 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. SJL 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) SJL has begun to take action to cure the material breach; (ii) SJL is pursuing such action with due diligence; and (iii) SJL has provided to OIG a reasonable timetable for curing the material breach.

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

SJL and OIG agree as follows:

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

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

C. OIG may agree to a suspension of SJL's obligations under this CIA based on a certification by SJL that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If SJL is relieved of its CIA obligations, SJL will be required to notify OIG in writing at least 30 days in advance if SJL plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. The undersigned SJL signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. 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 SAINT JOSEPH HEALTH SYSTEM, INC.
D/B/A SAINT JOSEPH LONDON

/Greg Gerard/	1/16/14
GREG D. GERARD President	DATE
/Daniel Reinberg/	1/17/14
DANIEL REINBERG Counsel for Saint Joseph London Polsinelli PC 161 N. Clark Street, Suite 4200 Chicago, IL 60601	DATE

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

/Robert K. DeConti/ 1/22/14

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Jill Wright/ 1/22/14

JILL WRIGHT
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. SJL shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by SJL in response to a request by OIG, whichever is later, OIG will notify SJL if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SJL may continue to engage the IRO.

2. If SJL 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, SJL shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by SJL at the request of OIG, whichever is later, OIG will notify SJL if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SJL 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 SJL seeks reimbursement;

2. assign individuals to conduct the Cardiac Surgeries Review engagement who have expertise in the medical necessity and appropriateness of Cardiac Surgeries (as defined in Appendix B), 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 SJL seeks reimbursement;

3. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes;

4. assign individuals to conduct the Unallowable Cost Review engagement who have expertise in the cost reporting requirements applicable to SJL and in the general requirements of the Federal health care programs from which SJL seeks reimbursement;

5. assign individuals to design and select the Cardiac Procedures Review, the Cardiac Surgeries Review, and the Arrangement Review samples who are knowledgeable about the appropriate statistical sampling techniques; and

6. 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, Cardiac Surgeries Review, Arrangements 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, Cardiac Surgeries Review, Arrangements 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., Medicare contractor);

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 Appendices B and C to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Cardiac Procedures Review, Cardiac Surgeries Review, Arrangements Review, and Unallowable Cost Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *SJL and IRO.* If SJL terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, SJL must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. SJL must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe 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 SJL to engage a new IRO in accordance with Paragraph A of this Appendix. SJL must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring SJL to engage a new IRO, OIG shall notify SJL 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, SJL may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with SJL prior to requiring SJL to terminate the IRO. However, the final determination as to whether or not to require SJL to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CARDIAC PROCEDURES REVIEW AND CARDIAC SURGERIES REVIEW

A. Cardiac Procedures Review and Cardiac Surgeries Review. The IRO, or IROs, shall perform the Cardiac Procedures Review and the Cardiac Surgeries Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Cardiac Procedures Review and Cardiac Surgeries Review.

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

   a. Interventional Cardiac Procedures: Any percutanaeous coronary interventions, including but not limited to diagnostic cardiac catheterizations, percutaneous transluminal coronary angioplasties, balloon angioplasties, implantation of intracoronary stenting, and any implantation of temporary or permanent pacemaker devices performed at SJL's Cardiac Catheterization Laboratory (or any other designated area for such procedures).

   b. Cardiac Surgeries: Coronary artery bypass graft surgeries (CABGs).

   c. Population: The Population shall be defined as all 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. *Samples.* The IRO shall randomly select and review two samples.

   a. Cardiac Procedures Sample: A sample of 50 Interventional Cardiac Procedures performed at the SJL Cardiac Catheterization Lab (or any other designated area for such procedures). 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 Interventional Cardiac Procedures shall be reviewed based on the supporting documentation available at SJL or under SJL'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.

b. Cardiac Surgeries Sample: A sample of 50 Cardiac Surgeries performed at SJL. The Cardiac Surgeries 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 Cardiac Surgeries shall be reviewed based on the supporting documentation available at SJL or under SJL'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 and the Cardiac Surgeries Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by SJL for the Cardiac Procedures Review shall have expertise in the medical necessity and appropriateness of Interventional Cardiac Procedures, and the IRO engaged by SJL for the Cardiac Surgeries Review shall have expertise in the medical necessity and appropriateness of Cardiac Surgeries. Each IRO shall have expertise in the general requirements of the Federal health care program(s) from which SJL seeks reimbursement.

3. *Other Requirements*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Interventional Cardiac Procedures and Cardiac Surgeries selected as part of the Cardiac Procedures Sample or Cardiac Surgeries Sample, and SJL shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the sample. If the IRO accepts any supplemental documentation or materials from SJL after the IRO has completed its initial review of either sample (Supplemental Materials), the IRO shall identify in the applicable report (Cardiac Procedures Review Report or Cardiac Surgeries Review Report) the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its

review. In addition, the IRO shall include a narrative in the applicable report (Cardiac Procedures Review Report or Cardiac Surgeries Review Report) describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Interventional Cardiac Procedures and Cardiac Surgeries without Supporting Documentation. Any Interventional Cardiac Procedure or Cardiac Surgery for which SJL cannot produce documentation sufficient to support the medical necessity or appropriateness of the procedure or surgery shall be considered an error and the total reimbursement received by SJL for such procedure or surgery shall be deemed an Overpayment. Replacement sampling for Interventional Cardiac Procedures or Cardiac Surgeries with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Cardiac Procedures Sample and Cardiac Surgeries Sample) discussed in this Appendix, the Interventional Cardiac Procedures or Cardiac Surgeries selected in the first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Cardiac Procedures Sample or Cardiac Surgeries Sample).

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

1. *Cardiac Procedures Review Methodology*

a. Sampling Unit. A description of the Interventional Cardiac Procedures as that term is defined above.

b. Cardiac Procedures Review Population. A description of the Interventional Cardiac Procedures 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 Cardiac Procedures 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.

g. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.

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., and the identification, by position description, of the physicians involved) regarding the Cardiac Procedures Review, including the results of the Cardiac Procedures Sample.

b. Total number and percentage 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 Procedure appraised:

i. type of Cardiac Procedure performed,
ii. whether the Cardiac Procedure was medically necessary and appropriate,
iii. beneficiary name,
iv. beneficiary health insurance claim number,
v. date of service,
vi. procedure code submitted,
vii. Federal health program billed, and
viii. amount reimbursed.

4. *Recommendations*. The IRO's report shall include any observations, findings, and recommendations on possible improvements to SJL's systems and processes.

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.

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

1. *Cardiac Surgeries Review Methodology*

a. Sampling Unit. A description of the Cardiac Surgeries as that term is defined above.

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

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

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

g. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.

2. *Statistical Sampling Documentation*

a. The number of Cardiac Surgeries 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 Cardiac Surgeries Sample.

4. *Cardiac Surgeries Review Findings*

a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.,

and the identification, by position description, of the physicians involved) regarding the Cardiac Surgeries Review, including the results of the Sample.

b. Total number and percentage of instances in which the IRO determined that the Cardiac Surgery 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 Surgeries Review results that includes the following information for each Cardiac Surgery appraised:

i. whether the Cardiac Surgery was medically necessary and appropriate,
ii. beneficiary name,
iii. beneficiary health insurance claim number,
iv. date of service,
v. procedure code submitted,
vi. Federal health program billed, and
vii. amount reimbursed.

4. *Recommendations*. The IRO's report shall include any observations, findings, and recommendations on possible improvements to SJL's systems and processes.

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

APPENDIX C

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to SJL's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If SJL materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of SJL's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. SJL's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;

2. SJL's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;

3. SJL's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

4. SJL's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

5. SJL's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with

authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

6. SJL's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by SJL, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

7. the Compliance Officer's quarterly review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, SJL's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

8. SJL's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

9. SJL's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.F.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of SJL's systems, policies, processes, and procedures relating to the items identified in Section A.1-9 above;

3. findings and supporting rationale regarding weaknesses in SJL's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve SJL's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-9 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus Arrangements that were entered into or renewed by SJL during the Reporting Period. (If less than 50 Focus Arrangements were entered into or renewed by SJL during the Reporting Period, the IRO shall review the actual number.) The IRO shall assess whether SJL has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.F.1 and III.F.2 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in SJL's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (i.e., the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.)

2. verifying that the Focus 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;

3. verifying that the remuneration related to the Focus Arrangement is properly tracked;

4. verifying that the service and activity logs are properly completed and reviewed (if applicable);

5. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

6. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.F.2 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*

a. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.

b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.

c. Supplemental Materials: The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and SJL shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from SJL after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The IRO's findings with respect to whether SJL has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to SJL's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.