CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ASHLAND HOSPITAL CORPORATION
DBA KING'S DAUGHTERS MEDICAL CENTER

I. PREAMBLE

Ashland Hospital Corporation dba King's Daughters Medical Center (KDMC) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, KDMC 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 KDMC 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) KDMC's final annual report; or (2) any additional materials submitted by KDMC 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 KDMC; 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 KDMC excluding vendors whose sole connection with KDMC is selling or otherwise providing medical supplies or equipment to KDMC 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 KDMC and other non-physician practitioners who work in the KDMC 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 at KDMC 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 KDMC and any actual or potential source of health care business or referrals to KDMC or any actual or potential recipient of health care business or referrals from KDMC. 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 KDMC refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom KDMC 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 KDMC 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 KDMC for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

4. "Focus Arrangements" means every Arrangement that:

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

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

c. is between KDMC and any physician (or a physician's immediate family member) or medical practice that involves, directly or indirectly, the offer, payment, or provision of anything of value in anticipation of that physician becoming an actual source of health care business or referrals (e.g., for purposes of recruitment).

Notwithstanding the foregoing provisions of Section II.C.3, 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.

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

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Hospital Management: Compliance Officer and Committee

1. *Compliance Officer*. To the extent not already accomplished, within 90 days after the Effective Date, KDMC 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 KDMC, shall report directly to the Chief Executive Officer of KDMC, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of KDMC, 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 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 or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for KDMC. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by KDMC 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.

KDMC 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.

2. *Compliance Committee*. To the extent not already accomplished, within 90 days after the Effective Date, KDMC 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 KDMC'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.

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

3. *Board of Directors Compliance Obligations*. The Board of Directors (or a committee of the Board) of KDMC (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 KDMC's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. reviewing the Peer Review Consultant's Systems Review Report and Monitoring Reports on the effectiveness of KDMC's peer review, credentialing, and privileging practices for each Reporting Period of the CIA;

c. for the first, third, and fifth Reporting Periods, considering the results of the Compliance Program Reviews (as described in Section III.A.4.a.v of this CIA); and

d. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of KDMC'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 KDMC'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, KDMC 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 KDMC.

KDMC 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. *Board Compliance Expert*. Within 60 days after the Effective Date, the Board shall retain an expert in corporate governance and compliance (Compliance Expert) to assist the Board in fulfilling the responsibilities described in Section III.A.3 of this CIA.

a. Compliance Expert Obligations. At a minimum, the Compliance Expert shall:

i. meet with the Audit Committee quarterly and all members of the Board at least once per year to assist each Board member in meeting his or her obligation to review and oversee matters related to KDMC's compliance with Federal health care program requirements and the obligations of this CIA;

ii. be kept apprised of any direct reports that the Compliance Officer otherwise makes to the Board;

iii. assist the Board in reviewing and assessing KDMC's Compliance Program;

iv. offer recommendations periodically, as appropriate, to improve the effectiveness of KDMC's Compliance Program; and

v. for the first, third, and fifth Reporting Periods, conduct a comprehensive review of the effectiveness of KDMC's Compliance Program and prepare a report describing the results of such review (Compliance Program Review Report). A copy of the Compliance Program Review Report shall be provided to OIG along with the Annual Report for the applicable Reporting Period.

b. Engagement of Compliance Expert. Within 30 days of the Board engaging the Compliance Expert, KDMC shall provide the following information to OIG:

i. the identity, address, and phone number of the Compliance Expert;

ii. a copy of the engagement letter between the Board and the Compliance Expert;

iii. information demonstrating that the Compliance Expert has the background and qualifications necessary to assist the Board in fulfilling the responsibilities described in Section III.A.3 of this CIA; and

iv. a certification from the Compliance Expert that neither he or she nor his or her firm has a relationship to KDMC or its employees, officers, or directors that would cause a reasonable person to question the Compliance Expert's impartiality.

Within 30 days of receiving the above information, or any additional information submitted by KDMC in response to a request by OIG, whichever is later, OIG will notify KDMC if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Board may continue to engage the Compliance Expert.

If a new Compliance Expert is engaged, KDMC shall submit the above information to OIG within 30 days of engagement of the Compliance Expert. Within 30 days after receiving this information or any additional information submitted by KDMC at the request of OIG, whichever is later, OIG will notify KDMC if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Board may continue to engage the Compliance Expert.

5. *Management Accountability and Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain KDMC officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within the hospital and shall certify annually that the areas under their authority are compliant with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the President & Chief Executive Officer; VP, Chief Legal & Regulatory Officer; VP, Chief Strategy Officer/CIO; VP, CFO; VP, Chief Medical Officer; VP, Chief Administrative Officer; VP, Facilities; VP, Chief Nursing Officer; VP, Quality; and VP, Executive Director King's Daughters Integrated Practices, and any other employees of KDMC with the title of Vice President or higher.

For each Reporting Period, each Certifying Employee shall sign a certification that states as follows:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring that the [department or functional area] remains compliant with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and KDMC Policies and Procedures, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [department or functional area] of KDMC is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a conclusion in the certification, he or she shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issues identified.

6. *Physician Executive(s)*. Within 60 days of the Effective Date, KDMC 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 KDMC, 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 KDMC, shall make periodic (at least quarterly) reports regarding quality of care matters directly to the Board of Directors of KDMC, 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.

KDMC 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.

7. *Medical Director of the Cardiac Catheterization Laboratory*. KDMC 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 KDMC'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 KDMC at any time.

KDMC 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 KDMC is unable to fully comply with this Section III.A.7 at any point in time during the term of the CIA, KDMC 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.7. If KDMC is not in compliance with this Section III.A.7 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.5 of the CIA.

B. Written Standards

1. *Code of Conduct*. To the extent not already accomplished, within 90 days after the Effective Date, KDMC shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. KDMC 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. KDMC'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. KDMC's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with KDMC's own Policies and Procedures;

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

d. the possible consequences to both KDMC and Covered Persons of failure to comply with Federal health care program requirements and with KDMC'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 KDMC'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 KDMC'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 KDMC under this Section III.B.1 with respect to physicians who have active medical staff membership but with whom KDMC does not have a financial relationship ("Excepted Physicians"): (i) KDMC 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) KDMC 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 KDMC's Code of Conduct; and (iii) KDMC shall keep records of the percentage of Excepted Physicians, and the names of Excepted Physicians, who have completed the certification requirement.

KDMC 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 60 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures*. To the extent not already accomplished, within 90 days after the Effective Date, KDMC shall implement written Policies and Procedures regarding the operation of KDMC's compliance program, including the compliance program requirements outlined in this CIA and KDMC'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 KDMC 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 KDMC 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 KDMC on a regular basis;

f. Management and oversight of KDMC'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. 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

h. 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), KDMC 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 120 days after the Effective Date, KDMC shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain KDMC'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 KDMC's own Policies and Procedures; and (ii) to report to the Compliance Officer or other appropriate individual designated by KDMC suspected violations of any Federal health care program requirements or of KDMC's own Policies and Procedures.

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

To the extent that General Training provided to Covered Persons during the four months immediately prior to the Effective Date satisfies the requirements set forth above, OIG shall credit the training towards the General Training requirements for the first Reporting Period. KDMC may satisfy its remaining General Training obligations for those Covered Persons who received training as described above by notifying the

Covered Persons of the fact that KDMC has entered into a CIA and notifying them of KDMC's requirements under the CIA.

2. *Specific Training*. Within 120 days after the Effective Date, KDMC 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 four 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;

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 120 days after the Effective Date, whichever is later. A KDMC 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 KDMC, 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 120 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. KDMC'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 KDMC's Arrangements to know the applicable legal requirements and the KDMC's policies and procedures;

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

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

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. New Arrangements Covered Persons shall not develop, approve, manage, or review KDMC's Arrangements until after they have completed the 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 120 days after the Effective Date, KDMC shall provide at least three hours of training to each member of the Board of Directors of KDMC, in addition to the General Training. Two hours of this training shall address the responsibilities of board members and corporate governance. One hour of this training shall include an overview of peer review, credentialing, quality assessment and improvement, the Anti-Kickback Statute, and the Stark Law. The Board Member

Training represents the total number of mandated hours for members of the Board of Directors of KDMC.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

After receiving the initial Board Member Training described in this Section, each member of the Board of Directors of KDMC shall receive at least two hours of Board Member Training in addition to the General Training, in each subsequent Reporting Period.

5. *Executive Management Training*. Within 120 days after the Effective Date, KDMC shall provide at least three hours of specialized training to KDMC's executive management, in addition to the General Training. Two hours of this training shall address the responsibilities of executive management related to the Compliance Program, Medical Staff Peer Review Process, including the findings of the Peer Review Consultant, as well as an overview of credentialing, quality assessment and improvement, the Anti-Kickback Statute, and the Stark Law. This training shall also address the topics addressed in the Specific Training (Section III.C.2) related to the functional area of the manager and the responsibility of Management to promote compliance and to identify and mitigate compliance-related risks.

New members of KDMC's executive management shall receive the Executive Management Training described above within 30 days after becoming a member of KDMC's executive management or within 120 days after the Effective Date, whichever is later.

After receiving the initial Executive Management Training described in this Section, each member of KDMC's executive management shall receive at least two hours of Executive Management Training in addition to the General Training, in each subsequent Reporting Period.

6. *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.

7. *Qualifications of Trainer.* Persons preparing or providing the General Training and Specific Training shall be knowledgeable about the subject area. Persons preparing or providing the Arrangements Training shall have expertise in the

Anti-Kickback Statute and Stark Law, as well as the regulations, directives, and guidance related to those laws.

8. *Update of Training.* KDMC 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 Interventional Cardiac Procedures Review, Arrangements Review, Compliance Program Review, or Unallowable Cost Review and any other relevant information.

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

10. *Excepted Physicians*. KDMC 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. KDMC 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 90 days after the Effective Date, KDMC shall engage an entity (or entities) (hereinafter "Peer Review Consultant"), to perform reviews to assist KDMC 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 KDMC if the Peer Review Consultant is unacceptable. Absent notification from OIG that the Peer Review Consultant is unacceptable, KDMC may continue to engage the Peer Review Consultant. The engagement of the Peer Review Consultant shall be for the term of the CIA. If KDMC terminates the Peer Review Consultant during the course of the engagement, KDMC must submit a notice explaining its reasons to OIG no later than 30 days after termination and KDMC must engage a new Peer Review Consultant in accordance with this Paragraph III.D.l.

2. *Systems Review*. The Peer Review Consultant shall conduct a review of the current processes undertaken by KDMC 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 KDMC's policies and procedures, practices, bylaws, meeting minutes, case reviews, corrective actions, disciplinary records, medical staff participation, ongoing quality-monitoring data, and oversight by KDMC's senior management and the Board of Directors of KDMC. 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. its assessment of KDMC's peer review policies and procedures, medical staff credentialing and privileging, and medical staff training and discipline based on the Systems Review; and

b. 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 KDMC 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, KDMC shall implement the recommendation or provide a written explanation of why the recommendation was not implemented. KDMC 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 KDMC. The Peer Review Consultant may make additional Peer Review Recommendations in the course of his or her monitoring of the implementation of Peer Review Recommendations.

5. *Monitoring of Peer Review Recommendations 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 KDMC a report within 60 days of the end of each Reporting Period that evaluates KDMC'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*. KDMC 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 KDMC 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, KDMC shall engage an entity (or entities) (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. KDMC shall engage an Interventional Cardiac Procedures IRO to conduct the Interventional Cardiac Procedures Review, and a Legal IRO to conduct the Arrangements Review and the Unallowable Cost Review. The applicable requirements relating to the IROs are outlined in Appendix A to this CIA, which is incorporated by reference.

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

c. *Responsibilities and Liabilities*. Nothing in this Section III.E affects KDMC'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. *Interventional Cardiac Procedures Review*. The Interventional Cardiac Procedures IRO shall evaluate and analyze the medical necessity and

appropriateness of interventional cardiac procedures performed in the KDMC Cardiac Catheterization Lab, or any other designated area for such procedures, (Interventional Cardiac Procedures Review) and shall prepare an Interventional Cardiac Procedures Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Arrangements Review*. The Legal 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.

4. *Unallowable Cost Review*. For the first Reporting Period, the Legal IRO shall conduct a review of KDMC's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether KDMC 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 KDMC 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 Legal IRO shall prepare a report based upon the Unallowable Cost Review performed (Unallowable Cost Review Report). The Unallowable Cost Review Report shall include the Legal IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether KDMC 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) KDMC's Interventional Cardiac Procedures Review, Arrangements Review, or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Interventional Cardiac Procedures Review, Arrangements Review, or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Interventional Cardiac Procedures Review, Arrangements Review, or Unallowable Cost Review complied with the requirements of

the CIA and/or the findings or Interventional Cardiac Procedures Review, Arrangements Review, or Unallowable Cost Review results are inaccurate (Validation Review). KDMC 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 KDMC's final Annual Report shall be initiated no later than one year after KDMC's final submission (as described in Section II) is received by OIG.

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

8. *Certification Regarding Legal IRO's Independence and Objectivity and IRO's Relationship to KDMC.* The Legal IRO shall include in its report(s) to KDMC a certification that the Legal IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA; and (c) does not have a relationship to KDMC or its employees, officers, or directors that would cause a reasonable person to question the Legal IRO's impartiality.

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

1. *Focus Arrangements Procedures*. Within 120 days after the Effective Date, KDMC 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, KDMC shall comply with the following requirements (Focus Arrangements Requirements):

a. Ensure that each Focus Arrangement is set forth in writing and signed by KDMC 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, KDMC 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; and

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. *Focus Arrangements Tracking System Verification and Certification*. For each Reporting Period, the Compliance Officer shall review the entries in KDMC's Focus Arrangements Tracking System and certify in writing to OIG that, to the best of his or her knowledge, the Focus Arrangements Tracking System is complete and accurate, except for any discrepancies identified. The Compliance Officer shall provide an explanation for: (1) any Focus Arrangements found to have been missing from the Focus Arrangements Tracking System; and (2) any entries in the Focus Arrangements Tracking System found to have been incomplete or inaccurate.

4. *Records Retention and Access*. KDMC 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

To the extent not already accomplished, within 90 days after the Effective Date, KDMC 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 KDMC'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. KDMC 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, KDMC 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.* KDMC shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

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

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

3. *Removal Requirement.* If KDMC has actual notice that a Covered Person has become an Ineligible Person, KDMC shall remove such Covered Person from responsibility for, or involvement with, KDMC'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 KDMC 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, KDMC 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, KDMC shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to KDMC conducted or brought by a governmental entity or its agents involving an allegation that KDMC 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. KDMC 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 KDMC 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, KDMC identifies any Overpayment, KDMC 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, KDMC 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;

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; or

e. the filing of a bankruptcy petition by KDMC.

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

2. *Reporting of Reportable Events*. If KDMC determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, KDMC shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. To the extent the Reportable Event involves a probable violation of the Anti-Kickback Statute or the Stark Law, KDMC also shall notify the Legal IRO, in writing, concurrently with the notification to OIG.

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 KDMC 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 KDMC's actions taken to correct the Reportable Event; and

e. any further steps KDMC 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 KDMC's actions taken to correct the Reportable Event;

c. any further steps KDMC 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 KDMC 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 KDMC 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 KDMC identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then KDMC 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, KDMC 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, KDMC shall notify OIG of the proposed sale at least 60 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, KDMC 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, KDMC 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, KDMC 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, KDMC shall notify OIG at least 60 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 KDMC 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, KDMC 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.6, 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.7, and a summary of other job responsibilities the Medical Director may have;

6. a copy of KDMC'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 information pertaining to the Board Compliance Expert set forth in Section III.A.4.b;

13. 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 KDMC and the IROs; and (e) a certification from the Interventional Cardiac Procedures IRO regarding its professional independence and objectivity with respect to KDMC, and a certification from the Legal IRO regarding its professional independence and objectivity with respect to KDMC and its relationship with KDMC as set forth in Section III.E.8;

14. 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 KDMC 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 KDMC;

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

16. a list of all of KDMC'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 KDMC currently submits claims;

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

18. the certifications required by Section V.C.

B. Annual Reports

KDMC shall submit to OIG annually a report with respect to the status of, and findings regarding, KDMC'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 copy of the Compliance Program Review Report required by Section III.A.4.a.v for the first, third, and fifth Reporting Periods;

4. the management certifications required by Section III.A.5;

5. a summary of any changes or amendments to KDMC'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;

6. 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);

7. 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);

8. 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.

9. 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;

10. the certification regarding the completeness and accuracy of the Focus Arrangements Tracking System required by Section III.F.3, as well as an explanation of: (1) any Focus Arrangements found to have been missing from the Focus Arrangements Tracking System; and (2) any entries in the Focus Arrangements Tracking System found to have been incomplete or inaccurate;

11. a complete copy of all IRO reports prepared pursuant to Section III.E, along with a copy of the IROs' engagement letters;

12. 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);

13. KDMC'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;

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

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

16. a certification from the Board Compliance Expert regarding its relationship to KDMC as set forth in Section III.4.b.iv;

17. a certification from the Interventional Cardiac Procedures IRO regarding its professional independence and objectivity with respect to KDMC;

18. a certification from the Legal IRO regarding its professional independence and objectivity with respect to KDMC and its relationship with KDMC as set forth in Section III.E.8;

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

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

21. 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;

22. 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;

23. 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);

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

25. 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;

26. a description of all changes to the most recently provided list of KDMC's locations (including addresses) as required by Section V.A.16; 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 KDMC currently submits claims; and

27. 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, KDMC 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;

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

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

KDMC 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. KDMC 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

KDMC: Mona Thompson
VP, Corporate Compliance
2201 Lexington Avenue
Ashland, KY 41101
(606) 408-4496 (office)
(606) 408-6100 (fax)

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

KDMC 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, KDMC 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 KDMC 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, Board Members, and Executive Management;

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 KDMC 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 KDMC 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 KDMC fails to engage and use the Physician Executive(s), as required in Section III.A.6.

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 KDMC fails to engage and use a Medical Director of the Cardiac Catheterization Laboratory, as required in Section III.A.7.

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 KDMC fails to engage and use the Board Compliance Expert, as required in Section III.A.4.

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 KDMC 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.

8. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day KDMC fails to submit the Compliance Program Review Report, as required in Section III.A.4.a.v for the first, third, and fifth Reporting Periods.

9. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day KDMC fails to submit the Systems Review Report by the Peer Review Consultant, the annual Monitoring Reports by the Peer Review Consultant, the annual Interventional Cardiac Procedures 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.

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

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

12. A Stipulated Penalty of $1,000 for each day KDMC fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to KDMC stating the specific grounds for its determination that KDMC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps KDMC shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after KDMC 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 1-11 of this Section.

B. Timely Written Requests for Extensions

KDMC 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 KDMC 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 KDMC 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 KDMC 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 KDMC of: (a) KDMC'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, KDMC 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 KDMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until KDMC 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 KDMC 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 KDMC 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 KDMC constitutes an independent basis for KDMC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that KDMC has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify KDMC of: (a) KDMC'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*. KDMC 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. KDMC 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) KDMC has begun to take action to cure the material breach; (ii) KDMC is pursuing such action with due diligence; and (iii) KDMC has provided to OIG a reasonable timetable for curing the material breach.

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

KDMC 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 KDMC's obligations under this CIA based on a certification by KDMC 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 KDMC is relieved of its CIA obligations, KDMC will be required to notify OIG in writing at least 30 days in advance if KDMC 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 KDMC 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 ASHLAND HOSPITAL CORPORATION
DBA KING'S DAUGHTERS MEDICAL CENTER

/Kristie Whitlatch/ 5/16/14

KRISTIE WHITLATCH DATE
President/CEO of King's Daughters Health System

/Ashley W. Ward/ 5/16/14

ASHLEY WARD DATE
Counsel for King's Daughters Medical Center
Stites & Harbison, PLLC

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

/Robert K. DeConti/ 5/27/14

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

/Jill Wright/ 5/21/14

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

APPENDIX A

INDEPENDENT REVIEW ORGANIZATIONS

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

I. IRO Engagement

A. For each review, KDMC shall engage an IRO that possesses the qualifications set forth in Section II, below, to perform the responsibilities in Section III, below. Each IRO shall conduct its review in a professionally independent and objective fashion, as set forth in Section IV, below. The Legal IRO shall not have a prohibited relationship to KDMC. Within 30 days after OIG receives the information identified in Section V.A.13 of the CIA or any additional information submitted by KDMC in response to a request by OIG, whichever is later, OIG will notify KDMC if either IRO is unacceptable. Absent notification from OIG that an IRO is unacceptable, KDMC may continue to engage the IRO.

B. If KDMC 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, KDMC shall submit the information identified in Section V.A.13 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 KDMC at the request of OIG, whichever is later, OIG will notify KDMC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, KDMC may continue to engage the IRO.

II. IRO Qualifications

A. The Interventional Cardiac Procedures IRO shall:

1. assign individuals to conduct the Interventional 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 KDMC seeks reimbursement;

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

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

B. The Legal IRO shall:

1. be a law firm;

2. 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, directives, and other guidance documents related to these statutes;

3. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review;

4. have expertise in the cost reporting requirements applicable to KDMC and in the general requirements of the Federal health care programs from which KDMC seeks reimbursement or have the ability to associate a firm with such expertise to assist in conducting the Unallowable Cost Review; and

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

III. IRO Responsibilities

A. The Interventional Cardiac Procedures IRO shall:

1. perform each Interventional Cardiac Procedures 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 Interventional Cardiac Procedures 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 Appendix B to the CIA.

B. The Legal IRO shall:

1. perform each Arrangements Review and Unallowable Cost Review in accordance with the specific requirements of the CIA;

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

3. prepare timely, clear, well-written reports that include all the information required by Section III.E of the CIA and Appendix C to the CIA.

IV. IRO Independence and Objectivity

A. Interventional Cardiac Procedures IRO

The Interventional Cardiac Procedures IRO must perform the Interventional Cardiac Procedures 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.

B. Legal IRO's Independence and Objectivity and Relationship to KDMC

The entity that KDMC selects to serve as the Legal IRO must perform the Arrangements 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. Additionally, the Legal IRO shall not have a relationship to KDMC or its employees, officers, or directors that would cause a reasonable person to question the Legal IRO's impartiality.

V. Assertions of Privilege

KDMC shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from its engagement of the Legal IRO. KDMC's engagement letter with the Legal IRO shall include a provision stating that the Legal IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

VI. IRO Removal/Termination

1. *KDMC and IRO*. If KDMC terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, KDMC 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. KDMC must engage a new IRO in accordance with Section I 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 Section II, is not independent and objective as set forth in Section IV (or that the Legal IRO has a relationship to KDMC prohibited under Section IV), or has failed to carry out its responsibilities as described in Section III, OIG may, at its sole discretion, require KDMC to engage a new IRO in accordance with Section I of this Appendix. KDMC must engage a new IRO within 60 days of termination of the IRO.

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

APPENDIX B

INTERVENTIONAL CARDIAC PROCEDURES REVIEW

A. Interventional Cardiac Procedures Review. The IRO shall perform the Interventional Cardiac Procedures Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Interventional Cardiac Procedures Review.

1. *Definitions*. For the purposes of the Interventional Cardiac Procedures 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, and implantation of intracoronary stenting performed at KDMC's Cardiac Catheterization Laboratory (or any other designated area for such procedures).

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

2. *Sample.* The IRO shall randomly select and review a sample of 100 Interventional Cardiac Procedures performed at the KDMC 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 KDMC or under KDMC'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 Interventional Cardiac Procedures Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by KDMC for the Interventional Cardiac Procedures Review shall have expertise in the medical necessity and appropriateness of Interventional Cardiac Procedures. The IRO shall have expertise

in the general requirements of the Federal health care program(s) from which KDMC 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 selected as part of the Sample, and KDMC 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 KDMC after the IRO has completed its initial review of the Sample (Supplemental Materials), the IRO shall identify in the Interventional Cardiac Procedures 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 Interventional Cardiac Procedures 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 without Supporting Documentation. Any Interventional Cardiac Procedure for which KDMC cannot produce documentation sufficient to support the medical necessity or appropriateness of the procedure shall be considered an error and the total reimbursement received by KDMC for such procedure shall be deemed an Overpayment. Replacement sampling for Interventional Cardiac Procedures with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of the Sample discussed in this Appendix, the Interventional Cardiac Procedures 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 Sample).

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

1. *Interventional Cardiac Procedures Review Methodology*

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

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

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

d. Sampling Frame. A description of the sampling frame, which is the totality of Interventional Cardiac Procedures from which the Interventional 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 Interventional 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 Interventional 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. *Interventional 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 Interventional Cardiac Procedures Review, including the results of the 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 Interventional Cardiac Procedures Review results that includes the following information for each Interventional Cardiac Procedure appraised:
      i. type of Interventional Cardiac Procedure performed,
      ii. whether the Interventional 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 KDMC'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 Interventional Cardiac Procedures Review and (2) performed the Interventional Cardiac Procedures Review.

APPENDIX C

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The Legal IRO shall perform all components of each Arrangements Review. If there are no material changes to KDMC's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If KDMC materially changes the Arrangements systems, processes, policies, and procedures, the Legal IRO shall perform an Arrangements Systems Review of the material changes 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 KDMC's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the Legal IRO shall review the following:

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

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

4. KDMC'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. KDMC'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. KDMC'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 KDMC, 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 annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, KDMC's internal review and approval process, and other Arrangements systems, policies, processes, and procedures;

8. KDMC'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. KDMC'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 Legal 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 KDMC'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 KDMC's systems, policies, processes, and procedures relating to Arrangements described in Section A.1–9, above; and

4. recommendations to improve KDMC'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 Legal IRO of 75 Focus Arrangements that were entered into or renewed by KDMC during the Reporting Period with: (1) physicians or other health care professionals; or (2) entities owned or controlled, in whole or in part, by physicians or other health care professionals. The Legal IRO shall select its sample of Focus Arrangements for review in consultation with OIG. The Legal IRO shall assess whether KDMC 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 Legal 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 KDMC's centralized tracking system in a manner that permits the Legal 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 terms of the Focus Arrangement are in effect in accordance with the written agreement;

3. 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;

4. verifying that the remuneration related to the Focus Arrangement is properly documented, consistent with the underlying agreement, and supported by a sound fair market valuation methodology;

5. verifying that the Focus Arrangement is supported by a valid and properly documented business need or business rationale;

6. verifying that the service and activity logs are properly completed and reviewed by KDMC, and that the parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement (if applicable);

7. verifying that the use of leased space, medical supplies, medical devices, equipment, and other patient care items is properly monitored by

KDMC, and that such use is consistent with the terms of the applicable Focus Arrangement (if applicable); and

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

D. Arrangements Transactions Review Report. The Legal IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transactions 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 Legal IRO in performing the Arrangements Transactions Review.

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

2. *Review Findings*. The Arrangements Transactions Review Report shall include the Legal IRO's findings with respect to each of the items set forth in Section C.1–8, above. In addition, the Legal IRO shall identify in the Arrangements Transactions Review Report any Focus Arrangement(s) reviewed that a reasonable person would consider a probable violation of the Anti-Kickback Statute or Stark Law, along with the Legal IRO's basis for reaching that conclusion.

The Arrangements Transactions Review Report also shall include observations, findings, and recommendations on possible improvements to KDMC's systems, policies, processes, and procedures in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.