FIRST AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ASHLAND HOSPITAL CORPORATION D/B/A KING'S DAUGHTERS MEDICAL CENTER

I. <u>PREAMBLE</u>

The Office of Inspector General (OIG) of the Department of Health and Human Services and Ashland Hospital Corporation d/b/a King's Daughters Medical Center (KDMC) hereby enter into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) that was executed by and between KDMC and OIG and that became effective on May 27, 2014. Contemporaneously with this Amendment, KDMC is entering into a Settlement Agreement with the United States.

Pursuant to Section XI.B of the CIA, the CIA may not be amended except by written consent of KDMC and OIG. OIG and KDMC hereby agree that the CIA shall be amended as described below in this Amendment.

II. <u>AMENDMENTS</u>

A. Section II.C.4 of the CIA is amended as follows:

Notwithstanding the foregoing provisions of this Section II.C.4, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests); 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits); 42 C.F.R. § 411.357(o) (compliance training); 42 C.F.R. § 411.357(q) (referral services); 42 C.F.R. § 411.357(s) (professional courtesy); 42 C.F.R. § 357(u) (community-wide health information systems); or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date of the CIA that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.

- B. Section III.A.4.a.i of the CIA is amended to read as follows:
 - i. meet with the Planning and Finance 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.

C. Section V.A of the CIA (Implementation Report) is amended to add the following paragraph after Section V.A.18 of the CIA:

19. KDMC has previously submitted a written report to OIG summarizing the status of its implementation of the requirements of the CIA effective on May 27, 2014. Within 120 days after the Amendment Effective Date, KDMC shall submit a written report to OIG summarizing the status of its implementation of the additional requirements of this Amendment (Amendment Implementation Report). The Amendment Implementation Report shall include:

a. a summary of all not previously provided Policies and Procedures required by Section III.B.2 of the CIA that apply to any procedure involving implantable cardioverter defibrillator (ICD) devices and cardiac resynchronization therapy (CRT) devices (copies of the Policies and Procedures shall be made available to OIG upon request);

b. the following information regarding each type of training that applies to any procedure involving ICD devices and CRT devices required by Section III.C of the CIA:

- (1) a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- (2) 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; and

c. a certification from the Compliance Officer that (1) to the best of his or her knowledge, KDMC is in compliance with all of the requirements of this Amendment; and (2) he or she has reviewed the Amendment Implementation Report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

D. Section A.1.a of Appendix B of the CIA (the definition of "Interventional Cardiac Procedures") is amended to read as follows:

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

a. <u>Interventional Cardiac Procedures</u>: Any procedure involving implantable cardioverter defibrillator (ICD) devices, cardiac resynchronization therapy (CRT) devices, and/or any percutaneous 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).

III. EFFECTIVE AND BINDING AGREEMENT

A. All terms and conditions of the CIA not modified in this Amendment shall remain in effect. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date).

B. The undersigned KDMC signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatories represent that they are signing this Amendment in their official capacities and that they are authorized to execute this Amendment.

C. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.

ON BEHALF OF ASHLAND HOSPITAL CORPORATION D/B/A KING'S DAUGHTERS MEDICAL CENTER

/Sheryl Mahaney/

Sheryl Mahaney General Counsel 12/4/14

Date

/Michael F. Ruggio, Esq./

Michael F. Ruggio, Esq. Sarah Reimers McIntee, Esq. Nelson Mullins Riley & Scarborough LLP 101 Constitution Avenue, N.W., Suite 900 Washington, D.C. 20001

Counsel for KDMC

Date

12-4-14

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

/Robert K. DeConti/	12/12/14	
Robert K. DeConti Assistant Inspector General for Legal Affairs Office of Inspector General U.S. Department of Health and Human Services	Date	
/John W. O'Brien/	12/5/14	
John W. O'Brien Senior Counsel Office of Inspector General U.S. Department of Health and Human Services	Date	
/Nancy W. Brown/	12/3/14	
Nancy W. Brown Senior Counsel Office of Inspector General	Date	

U.S. Department of Health and Human Services