

KING'S DAUGHTERS MEDICAL CENTER

**MEDICAL STAFF &
ADMINISTRATIVE POLICY**

POLICY AND PROCEDURE

EFFECTIVE DATE: 02/08/16

REVIEWED: 9/26/18

SUPERCEDES POLICY: 8/25/14

FILE: SECTION I (49)

**SUBJECT: COMPLIANCE
WITH THE FEDERAL ANTI-
KICKBACK STATUTE AND
STARK LAW**

POLICY:

King's Daughters Medical Center (Medical Center) is committed to compliance with applicable laws, rules and regulations, including the Anti-Kickback Statute and the Stark Law. These laws, while complex, relate primarily to relationships between the Medical Center and Referral Sources, including physicians. The Medical Center may, from time to time, develop other policies regarding these relationships.

This Policy provides general information about the federal Anti-Kickback Statute, the Stark Law, and the regulations and other related guidance and explains how these laws relate to relationships between the Medical Center and referral sources.

DEFINITIONS

1. **Focus Arrangement** means every arrangement or transaction that:
 - a. Involves, directly or indirectly, the offer or payment of anything of value; and is between the Medical Center and any actual source of health care business or referrals to the Medical Center; or
 - b. Is between the Medical Center and a physician (or a physician's Immediate Family Member) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to the Medical Center for Designated Health Services.
2. **Overpayment** means the amount of money the Medical Center has received in excess of the amount due and payable under any Federal health care program requirements.
3. **Referral Source** means (a) a physician; (b) a physician's Immediate Family Member; (c) any entity that is controlled by a physician or a physician's Immediate Family Member; or (d) any non-physician who may be capable of making referrals to the Medical Center.

4. **Immediate Family Member** means husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.
5. **Reportable Event** means any isolated event or a series of occurrence that involve:
 - a. A substantial Overpayment;
 - b. A matter that a reasonable person would consider a probably 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;
 - * 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 the Medical Center.

POLICY

1. The Medical Center does not offer, pay, provide or accept any remuneration, including any payment of any type, for referrals of patients. The Medical Center is committed to ensuring that its relationships with physicians and other Referral Sources do not violate the Anti-Kickback Statute (AKS), the Stark Law, or any other applicable Federal or state laws.
2. The Medical Center has established a Code of Conduct and policies and procedures demonstrating the Medical Center's commitment to full compliance with all federal health care program requirements, including the AKS and Stark Law.
3. The Legal Services Department maintains a centralized tracking system of all contractual relationships with Referral Sources that are considered Focus Arrangements.
4. Any known or suspected violations of the AKS and Stark Law must be reported, investigated, and remediated in accordance with the Medical Center's Reporting and Investigating Potential Compliance Concerns Policy.
5. The attachment to this Policy provides an overview of the AKS and Stark Law which may be amended or modified from time to time.

PROCEDURES

- * 1. The Vice President/Chief Compliance Officer shall review at least annually the Focus Arrangements tracking system, the Medical Center's internal review and approval process, and certain other procedures to monitor the Medical Center's compliance with the requirements of the Corporate Integrity Agreement between the Office of the Inspector General (OIG) of the Department of Health and Human Services and Ashland Hospital Corporation d/b/a King's Daughters Medical Center.
- * 2. The Vice President/Chief Compliance Officer shall report the results of the review to the Medical Center's Compliance & Integrity Committee and Board Planning and Finance Committee.
3. The Medical Center's Legal Services Department shall regularly track remuneration to and from all parties to Focus Arrangements, including tracking service and activity logs to ensure that parties to the Focus Arrangements are performing the services required under the applicable Focus Arrangement.
- * 4. The Medical Center will provide training and information, as applicable, regarding the requirements of the AKS and the Stark Law and reporting obligations.
5. If at any time, the Medical Center identifies an Overpayment, the Medical Center shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within sixty (60) days after identification of the Overpayment and take remedial steps within sixty (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 sixty (60) days after identification, the Medical Center 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 payors policies. Notwithstanding the foregoing, 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.
6. If, after a reasonable opportunity to conduct an appropriate review or investigation of an activity that may violate the AKS or the Stark Law, the Medical Center determines that there is a Reportable Event, the Vice President/Chief Compliance Officer shall notify the OIG of the Reportable Event, in writing, within thirty (30) days after making the determination that the Reportable Event exists.

7. Notwithstanding the reporting requirements outlined in this Policy, any Reportable Event that involves only a probable violation of the Stark Law shall be submitted by the Medical Center to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. Further, the repayment requirement within sixty (60) days of identification of the Overpayment 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.

William Boykin, MD
President, Medical Staff

Kristie Whitlatch
President/CEO

ATTACHMENT

The Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving anything of value as an inducement or reward to refer items or services for which payment is available under the federal or state healthcare programs, such as Medicare and Medicaid. Violations of the Anti-Kickback Statute are classified as felonies and are punishable by fines of up to \$25,000 and up to 5 years in prison. Violations of the Anti-Kickback Statute may also cause participants to be excluded from participating in federal health care programs or from working for entities that participate in federal healthcare programs.

The Department of Health and Human Services Office of Inspector General (“OIG”) is the federal governmental agency responsible for interpreting and enforcing the Anti-Kickback Statute. The OIG has issued regulations that contain “safe harbor” provisions describing various payment and business practices that the OIG has deemed acceptable. Unless all elements of a safe harbor are met, these practices might otherwise be viewed to implicate, and potentially violate, the Anti-Kickback Statute. Compliance with a safe harbor is not mandatory; rather, arrangements that could violate the Anti-Kickback Statute which do not fit into a safe harbor are evaluated by the OIG on a case-by-case basis.

Guidance Related to the Anti-Kickback Statute

To assist health care providers in complying with the Anti-Kickback Statute, the OIG has, and continues from time to time, to publish guidance.

1. Advisory Opinions. The OIG issues advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the federal and state healthcare programs, including (a) what constitutes prohibited remuneration under the Anti-Kickback Statute and (b) whether an arrangement or proposed arrangement falls within a safe harbor. Advisory opinions provide guidance, but they only apply to the parties requesting them. However, they offer meaningful advice on the application of the Anti-Kickback Statute. Additional information about the OIG’s advisory opinion process and a link to all published advisory opinions is located at <http://oig.hhs.gov/>.
2. Other Guidance. The OIG periodically develops and issues guidance, including Special Advisory Bulletins, Fraud Alerts, and other industry guidance to alert and inform the health care industry about potential problems or areas of special interest. Guidance is located at <http://oig.hhs.gov/>.

The Limitation on Certain Physician Referrals (The Stark Law)

The Stark Law prohibits physicians from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician's immediate family has a financial relationship--unless an exception applies. It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for a DHS furnished as a result of a prohibited referral. Notably, DHS includes all inpatient and outpatient hospital services. Sanctions for violating the Stark Law include disallowing all Medicare payments for any DHS provided pursuant to a referral from the physician and possible penalties of up to \$15,000 per DHS item or service plus three times the amount claimed for payment from Medicare; circumvention schemes can result in a penalty of up to \$100,000 and exclusion from participation in federal health care programs.

The Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for interpreting and enforcing the Stark Law, has issued regulations that contain exceptions for relationships with physicians that will be deemed not to violate the statute. Unlike the Anti-Kickback Statute, a physician's financial relationship with the entity providing DHS must fit within an exception to the Stark Law and meet all of the criteria of the exception. If it does not, the entity may not bill for any DHS provided pursuant to a referral from the physician.

Guidance Related to the Stark Law

CMS issues advisory opinions to outside parties regarding whether a physician's referrals relating to certain DHS are prohibited under the Medicare program. While the advisory opinions are only binding on the person or entity who requested the opinion, the advisory opinions offer meaningful advice on the application of the Stark Law. Additional information about CMS's advisory opinion process, a link to CMS's published advisory opinions, and other Stark Law guidance is located at <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/>.