

UNIVERSITY HEALTHCARE ALLIANCE	Approval Date: 10/02/2012 Revision Date: 00/00/2013 Approval Signature: _____
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I. PURPOSE

The purpose of this policy is to provide guidance on the federal and California anti-kickback laws so that University Healthcare Alliance (“UHA”), and its employees will develop and maintain business and financial transactions and arrangements in conformity with the law.

II. SCOPE

This policy applies to UHA, its employees, and physicians, working at UHA clinic sites collectively referred to as “UHA”.

III. POLICY STATEMENT

All business and financial arrangements and transactions by UHA must comply with the federal and California anti-kickback statutes (“AKS”).

Under the federal anti-kickback statute, it is illegal for individuals or entities to *knowingly and willfully* offer, pay, solicit or receive *remuneration* in order to *induce* business that is reimbursed under a *federally-funded health care program*. Conduct that is prohibited includes not only *remuneration* intended to induce referrals of patients, but also *remuneration* intended to induce the purchasing, leasing, ordering or arrangement for any good, facility, service, or item paid for by a *federally-funded health care program*. The California anti-kickback statute has the same prohibition but applies to all payors, not just the federal government (e.g., includes private insurance). Violation of the AKS is subject to civil and criminal penalties.¹

Unless otherwise specifically noted, the reference to AKS in this policy shall include both the federal and California statutes.

¹ Violation of the federal AKS is punishable as a felony by up to five years in prison, criminal fines up to \$25,000, or by both imprisonment and fines. Civil money penalties of up to \$50,000 may also be imposed plus up to three times the amount of the kickback. Violators of the federal anti-kickback law also may be excluded from participation in the Medicare and Medicaid programs, as well as other federal health care programs. Violation of the California anti-kickback law is also punishable by imprisonment, fines or both. Criminal convictions under state law also may result in exclusion from participation in Medicare and Medicaid.

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III. DEFINITIONS

- A. Knowingly and willfully means that a person/entity has the intent to offer or pay remuneration to induce a referral; it does not require that a person/entity have a specific intent to violate the AKS, or even know about the AKS.
- B. Remuneration means anything of value in any form. It can be, for example, cash, gifts, meals, trips, entertainment, rebates, discounts, consultant fees, grants, debt write-offs, reduced space or equipment rent, excessive payments for items or services, supplies, equipment, subsidized continuing education, subsidized parking (where others are charged), and long-term credit arrangements. Some specific examples (but not an exhaustive list) of remuneration that could potentially trigger the AKS and must be evaluated in consultation with the Legal Department include:
 - Vendor or other referral source paying for travel or other such expenses of UHA employees or Physicians who are in a position to make or influence purchasing decisions of UHA.
 - UHA paying Physicians directly for consulting, call, directorships, administrative or other such services.
 - UHA routinely waiving insurance co-payments or deductibles.
 - A space or equipment lease, such as a medical office lease, between UHA and a referral source, for either less than or more than fair market value.
 - Vendor or manufacturer offering to provide equipment to UHA for free or at a reduced rate for marketing or research purposes.
 - UHA purchasing services from a clinical laboratory, outside hospital, surgery center, imaging center or other healthcare provider.
- C. Induce means virtually any act that is intended to exercise influence over another in an effort to cause the referral of a patient or other program-related item or service. The fact that there are legitimate reasons for the payment is irrelevant as long as even “one of the purposes” of the payment is to induce the referral of patients or program-related items or services (the “One Purpose Rule”). Even a payment at fair market value could violate the AKS if the payment is intended, at least in part, to induce referrals.
- D. Referral Source is not limited to physicians, a physician owned-entity or medical group, but also includes any health care facility, contractor, vendor, clinical laboratory, or any other person or entity that is in a position to make a referral to, or receive referrals from, UHA.

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- E. Referral means any recommendation of, or arrangement for, requesting, ordering, purchasing, or leasing any item or service that is payable by any federal health care program. For the purpose of the AKS and this policy, a referral is relevant if it is in the context of a business transaction that involves some sort of remuneration.
- F. Federal Health Care Program includes any program that provides health benefits (whether directly, through insurance, or otherwise) which are funded directly, in whole or in part, by the federal government, other than health insurance programs provided to federal employees. It includes but is not limited to Medicare.² It also includes state health care programs that are at least partially funded by the federal government such as Medi-Cal.³

IV. PROCEDURE

- A. Since some relatively innocuous or even beneficial financial arrangements may be prohibited by the AKS, any and all such arrangements between UHA and any referral source that might involve referrals must be evaluated in the context of this policy and should be reviewed by the Legal Department to ensure that it complies with the AKS.
- B. General Guidelines: For all financial transactions and arrangements, UHA should ensure that:
 - 1. The arrangement is commercially reasonable and necessary to serve a purpose other than obtaining referrals;
 - 2. Confirm that the remuneration is at fair market value and does not vary with the volume or value of referrals (as described in C below), and that UHA could not obtain the items or services elsewhere at a lower price;
 - 3. The fair market valuation methodology used can be documented as being reasonable; and
 - 4. The referral source in the arrangement has not been selected because of its referrals.

² Other examples of federal health care programs are managed Medicare, TRICARE, Veterans Administration, Indian Health Services, health services for Peace Corps volunteers, Railroad Retirement Benefits Black Lung Program, and services to federal prisoners.

³ Other such state health care programs partially funded by the federal government include Maternal and Child Health Services Block grant programs, and State Children’s Health Insurance Program.

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- C. Value or Volume of Referrals: UHA may only enter financial arrangements and transactions with a referral source for reasons entirely unrelated to the value or volume of referrals from the referral source. Examples of the value of a referral include, but are not limited to:
- If UHA is considering acquiring a medical practice, or is contracting with a community physician or a medical group, UHA cannot consider the dollar value of the referrals from that physician, medical practice or group.
 - If UHA is entering an outreach agreement which includes placing a faculty physician at a hospital or medical group, UHA cannot consider the dollar value of the referrals from that outside hospital or medical group to UHA.
1. Collection and Use May Be Used to Prove “Bad Intent”.
While there are many legitimate reasons to gather or use information on the value or volume of referrals or other business generated (or that may be generated) by a referral source, the collection and use of such information can be used as to establish the parties’ bad intent to enter a financial transaction or arrangement in exchange for referrals.
 2. Legitimate Reasons Do Not Matter if One Purpose Is Related to Referrals.
In light of the One Purpose Rule (as described above under the definition of induce), this is true even if there are legitimate reasons to produce or use such information that are completely unrelated to decisions regarding financial transactions or arrangements.
 3. Impermissible to Produce or Use Such Information in Connection with Financial Arrangement with Referral Source.
Accordingly, UHA may not produce or use information regarding the value or volume of referrals or business generated (or that may be generated) by a referral source in connection with any decision regarding financial transactions and arrangements with that referral source.

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4. Examples of impermissible use of such information include:
 - a. Explaining or justifying (financially or otherwise) a proposed transaction or arrangement between UHA and a referral source (e.g., purchase of medical practice, joint venture, etc.);
 - b. Calculating the potential or expected “return on investment” to UHA or Stanford Hospital and Clinics (“SHC”) from a transaction or arrangement between UHA or SHC and a referral source;
 - c. Determining compensation payable by UHA to a referral source;
 - d. Selecting a particular referral source to provide services to UHA;
 - e. Selecting physicians or medical groups to receive donations or subsidies of electronic health record or e-Prescribing technology.
5. Collection and Use Is Permitted if Completely Unrelated to Any Financial Arrangement.
 UHA must be extremely careful to avoid gathering, producing and using information regarding the value or volume of referrals or other business generated (or that may be generated) by a referral source. It may collect and use such information only if there is a valid reason wholly unrelated to any financial transaction or arrangement between UHA and the referral source. For example, using such information solely for quality of care/utilization review is permitted.
6. UHA should contact the Legal Department for guidance on the appropriate collection and use of the value or volume of referrals.
- D. Safe Harbor: The federal AKS contains exceptions and safe harbors which, if satisfied, can protect the financial transaction or arrangement from violating the statute. For this to occur, all of the particular requirements of a “safe harbor” must be met.
 1. Even If No Safe Harbor, Might Not Be Illegal.
 Just because a financial transaction or arrangement does not fall within a safe harbor, it is not necessarily illegal. Instead, it means that the arrangement must be analyzed under the AKS to confirm that it does not violate the statute.

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2. The federal AKS includes statutory and regulatory safe harbors. The following is a partial list of some that might be relevant to UHA. Contact the Legal Department for further information and analysis.
 - a. Space and Equipment Lease Arrangements/Rentals.
If specific requirements are met, remuneration does not include any payment made between UHA and a referral source for the use of space or equipment. For further discussion on this topic, see the Physician Referral - Stark Law Policy.
 - b. Personal Services and Management Contracts, and Professional and Administrative Services Arrangements.
As long as certain specific conditions are met, this safe harbor can protect arrangements where payment is being made for services being provided to UHA by a referral source. (This does not apply to bona fide employment arrangements which are an exception to the AKS.)
 - c. Providing Electronic Health Records Items and Services.
In certain circumstances, remuneration does not include software or information technology and training services that UHA provides to a referral source if the software, technology and training are used predominantly to create, maintain, transmit or receive “electronic health records.”
 - d. Discounts.
Remuneration does not include a discount on an item or service for which payment may be made in whole or in part under Medicare, Medi-Cal or any other Federal Health Care Program to a buyer as long as the buyer, seller and offeror comply with specific standards.
 - e. Group Purchasing Arrangements.
Remuneration does not include a payment by a vendor to a Group Purchasing Organization, as defined by AKS, as part of an agreement to furnish goods or service, as long as requirements are met.

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f. Waiver of Beneficiary Coinsurance and Deductible Amounts.

A reduction or waiver of a Medicare, Medicaid, or other Federal Health Care Program beneficiary’s obligation to pay coinsurance or deductible amounts is not considered remuneration as long as applicable standards are met.

g. Ambulatory Surgical Center Investment.

Under certain conditions, remuneration does not include a payment to a UHA that is a return on UHA’s investment in an ambulatory surgical center.

E. Relationship to Stark Law.

In conjunction with this policy, UHA must also consult the Physician Referral - Stark Law Policy.

In general, compliance with an AKS safe harbor does not ensure compliance with the physician self-referral, or Stark, law. UHA should review business and payment arrangements under both the anti-kickback and Stark laws in consultation with the Legal Department.

V. REFERENCES