

 <p>Hilo Medical Center <i>We Care for Our Community</i></p> <p>Policy and Procedure</p>	Subject / Title:	Policy No.: 850-101-36
	<p>CORPORATE ARRANGEMENTS</p>	Origin Date: 8/07 Last Revision Date: Last Review Date: By: <u>Stephen Palmore</u> , <u>Regional Compliance Officer</u> Name and Title Plan for revision <input type="checkbox"/> yes <input type="checkbox"/> no
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	COMPLIANCE	

I. PURPOSE:

- A. To establish standard procedures for drafting, reviewing and approving arrangements that are entered into by the Hawaii Health Systems Corporation (HHSC) involving goods, facility, items or services to be provided to or from Hilo Medical Center (HMC) for which a party to the arrangement is or may be a potential source of health care business or referrals to or from HMC as defined in the Anti-Kickback Statute and Stark Law.
- B. To establish standard monitoring procedures to ensure that arrangements for goods, facility, items or services to be provided to or from HMC are drafted, reviewed, approved and executed in accordance with the terms of the applicable corporate arrangement.
- C. To establish standard procedures for the above that are executed in accordance with the requirements of the Corporate Integrity Agreement (CIA) dated July 27, 2007 between Hilo Medical Center and the Office of Inspector General (OIG) of the Department of Health and Human Services.

II. DEFINITION:

- A. Covered Persons includes all owners, officers, directors, employees of HMC, contractors, subcontractors, agents and other persons who provide patient care items or services or who perform billing or coding functions on behalf of HMC and physicians with active medical staff privileges at HMC.

Covered Persons 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.

- B. Arrangements shall mean every arrangement or transaction that:
 - 1. Involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between HMC and any actual or potential

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source of health care business or referrals to HMC or any actual or potential recipient of health care business or referrals from HMC. The term “source” shall mean any physician, contractor, vendor, or agent and the term “health care business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing 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

2. Is between HMC 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 HMC for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
 - a. A physician’s immediate family member includes a 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 (42 C.F.R. § 411.351).
 - b. Referrals are defined as the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician) or the request or establishment of a plan of care by a physician which includes the provision of the designated health service (42 U.S.C. § 1395nn(h)(5)).
 - c. Designated health services include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including magnetic resonance imaging, computerized axial tomography scans, ultrasound services, and nuclear medicine and supplies); radiation therapy services and supplies (including nuclear medicine and supplies); durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs and inpatient and outpatient hospital services (42 U.S.C. § 1395nn(h)(6)).
- C. Corporate arrangements include arrangements that are drafted and executed by HHSC involving goods, facility, items or services that are provided to or from HMC.
- D. Ineligible Person shall include an individual or entity who:

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1. Is currently excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in federal procurement or nonprocurement programs; or
 2. Has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- E. Exclusion Lists identify Ineligible Persons and include:
1. The HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 2. The General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).
- F. A federal health care program includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government or a state health care program. Examples of federal health care programs are Medicare, Medicaid, Tricare and the Veterans programs.
- G. 42 U.S.C. § 1320a-7(a) mandates exclusion for the following criminal offenses and are included on the HHS/OIG List of Excluded Individuals/Entities:
1. Conviction of healthcare related crimes;
 2. Conviction relating to patient abuse or neglect;
 3. Felony conviction relating to healthcare fraud; or
 4. Felony conviction relating to controlled substances.

III. POLICY:

- A. HMC shall monitor the activities performed by HHSC to ensure that all arrangements involving goods, facility, items or services to be provided to or from HMC are drafted, reviewed, approved and executed in accordance with the requirements of the Corporate Integrity Agreement (CIA) dated July 27, 2007 between Hilo Medical Center and the Office of Inspector General (OIG) of the Department of Health and Human Services. This includes the following:
1. All corporate arrangements involving services or items to be provided to HMC will comply with state and federal rules and regulations including the Anti-Kickback Statute and the Stark Law.

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2. Corporate arrangements are in writing and undergo legal review and approval by HHSC and/or HMC legal counsel with knowledge of the appropriate state and federal rules and regulations to ensure that the arrangement does not violate the Anti-Kickback Statute and Stark Law
 3. Corporate arrangements will include a certification by the parties to the arrangement that the parties shall not violate the Anti-Kickback Statute and Stark Law with respect to the performance of the arrangement.
 4. Corporate arrangements will include a requirement that Covered Persons will immediately notify HHSC of any exclusion, debarment, suspension or other ineligibility to participate in the federal health care programs or in federal procurement or nonprocurement programs or of any conviction of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a) but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Refer to Policy No.: 850-101-25 Screening and Removal of Ineligible Persons for the exclusion lists.
 5. Covered Persons shall comply with HMC's compliance program including any training requirements. Refer to Policy No.: 850-101-21 Compliance Training Program for a description of the training requirements.
 6. Payments related to corporate arrangements involving services or items provided to HMC are processed only upon review and approval by HMC that the services and items were provided in accordance with the applicable corporate arrangement.
- B. If HMC identifies that a corporate arrangement involving services or items to be provided to or from HMC do not satisfy all of the requirements stated in the CIA dated July 27, 2007 between HMC and the OIG, HMC shall notify HHSC that HMC shall be excluded as a party to the corporate arrangement.
- C. Information pertaining to all HMC arrangements will be entered by HMC into the HMC Arrangements Tracking Database. To accomplish this, HMC requires that HHSC provide the following information on corporate arrangements involving HMC:
1. Timely communication of arrangement information prior to contract execution.
 2. Hard copies of the executed corporate arrangements and any supporting and monitoring documentation.

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IV. PROCEDURE:

A. Creating or Renewing Corporate Arrangements

1. When HHSC creates or renews corporate arrangements that involve goods, facility, items or services to be provided to or from HMC, HMC will monitor HHSC activities to verify that the following are completed:
 - a. Certification that:
 - i. HMC needs the items and/or services to function properly.
 - ii. The amount(s) that HMC will purchase are reasonable.
 - iii. The price(s) that HMC will pay are reasonable and approximate the fair market value of what HMC is receiving in return.
 - iv. The pricing in the Arrangement is accurate; there are no unwritten “side deals.”
 - v. The vendor did not offer or pay, or solicit or accept, any kickbacks or improper inducements.
 - vi. No one acting on behalf of HMC offered or paid, or solicited or accepted, any kickbacks or improper inducements.
 - vii. The price HMC will pay is not conditioned on receiving any other business or referrals from the vendor.
 - viii. The price HMC will pay is not conditioned on sending any other business or referrals to the vendor.
 - ix. HMC is not entering this Arrangement to induce or reward referrals.
 - b. All parties to the corporate arrangement have been screened against the Exclusion Lists and were not identified as Ineligible Persons.
 - c. A written review and approval process for all corporate arrangements including legal review and approval by HHSC legal counsel and/or HMC legal counsel with knowledge of the appropriate state and federal rules and regulations to ensure that the arrangement does not violate the Anti-Kickback Statute and Stark Law.

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- d. The corporate arrangement is in writing, signed by all parties, and includes the following terms:
 - i. Covered Persons shall comply with HMC's compliance program including any training if required. Refer to Policy No.: 850-101-21 Compliance Training Program for a description of the training requirements.
 - ii. Certification by the parties to the arrangement that the parties shall not violate the Anti-Kickback Statute and Stark Law with respect to the performance of the arrangement.
 - iii. A requirement that Covered Persons will immediately notify HHSC of any exclusion, debarment, suspension or other ineligibility to participate in the federal health care programs or in federal procurement or nonprocurement programs or of any conviction of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a) but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Refer to Policy No.: 850-101-25 Screening and Removal of Ineligible Persons for the exclusion lists.
 - e. A copy of the HMC Code of Conduct and Anti-Kickback Statute and Stark Law policies and procedures have been provided to each party of the arrangement.
 - f. A copy of the signed contract with the supporting documentation (e.g., FMV analysis, contract routing sheet, etc.) has been provided to the HMC Senior Contract Manager.
 - g. The executed contract and any supporting documents (e.g. FMV analysis, contract routing sheet, Officer Certification Form) is retained for at least four years as stated in the CIA or longer if otherwise required by state or federal law or HHSC's or HMC's policies.
2. The HMC Senior Contract Manager enters the executed contract information into the HMC Arrangement Tracking Database.
 3. If the HMC Senior Contract Manager or other HMC staff identifies an issue with the contract or other compliance concerns, the HMC Compliance Officer is notified. The HMC Compliance Officer or designee conducts an investigation. Refer to HMC Policy No.: 850-101-26 Investigation of Suspected Violations and Appropriate Resolution.

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B. Monitoring and Remuneration for Corporate Arrangements

1. When requests for payments related to corporate arrangements that involve goods, facility, items or services to be provided to or from HMC, HMC will monitor HHSC activities to ensure that the following are completed:
 - a. Requests for payments are processed only upon approval from HMC that the goods, facility, items or services were provided in accordance with the applicable corporate arrangement.
 - b. Necessary remuneration information is provided for HMC to track all remuneration to and from all parties to the corporate arrangement related to the provision of goods, facility, items or services to and from HMC.
 - c. Tracking and monitoring documentation is retained for at least four years as stated in the CIA or longer if otherwise required by state or federal law or HHSC's or HMC's policies.
2. HMC enters the remuneration information into the HMC Arrangements Tracking Database under the appropriate corporate arrangement.
3. If HMC staff identifies an issue with the contract or other compliance concerns, the HMC Compliance Officer is notified. The HMC Compliance Officer or designee conducts an investigation. Refer to HMC Policy No.: 850-101-26 Investigation of Suspected Violations and Appropriate Resolution.

- C. If HMC is notified by HHSC that it has actual notice or has knowledge of any pending charges or exclusion, debarment, suspension or other ineligibility to participate in the federal health care programs or in federal procurement or nonprocurement programs or of any conviction of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a) but has not yet been excluded, debarred, suspended, or otherwise declared ineligible by any party to a corporate arrangement, HMC shall take the appropriate action in accordance with Policy No.: 850-101-25 Screening and Removal of Ineligible Persons.