

 <p>Hilo Medical Center <i>We Care for Our Community</i></p> <p>Policy and Procedure</p>	Subject / Title:	Policy No.: 850-101-31
	NON-PHYSICIAN ARRANGEMENTS	Origination Date: 8/07
		Last Revision Date:
		Last Review Date:
		By: <u>Stephen Palmore,</u> <u>Regional Compliance Officer</u> Name and Title
Department:	Plan for revision <input type="checkbox"/> yes <input type="checkbox"/> no	
COMPLIANCE	Supersedes Policy:	
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I. PURPOSE: To establish standard procedures for drafting, reviewing and approving non-physician arrangements for which the vendor is or may be a potential source of health care business or referrals to or from the Hilo Medical Center (HMC).

II. DEFINITION:

A. Non-physician arrangements include new and renewed arrangements executed after the effective date 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.

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 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).

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- 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)).

III. POLICY:

- A. HMC shall ensure that non-physician arrangements comply with state and federal rules and regulations including the Anti-Kickback Statute and the Stark Law.
- B. The non-physician arrangements will be documented in writing, signed by all parties to the arrangement and will include the following terms:
 - 1. A specific and comprehensive description of the services or goods to be provided;
 - 2. The term of the non-physician contract;
 - 3. The contract remuneration;
 - 4. A requirement that the parties to the non-physician arrangement comply with the HMC compliance program and any state and federal rules and regulations including the Anti-Kickback Statute and the Stark Law.
- C. HMC shall ensure that the goods or services to be purchased do not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the arrangement.
- D. HMC shall ensure the storage and maintenance of all non-physician arrangements and any supporting documentation.

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IV. PROCEDURE:

- A. The HMC technical representative (TR) identifies a need to purchase goods and/or services.
- B. The HMC TR completes a purchase request or purchase requisition and any certifications required.
 1. The HMC TR completes a purchase request or purchase requisition to adequately define the scope of services or the specifications of goods being requested, the value of the goods and/or services, and the period during which the services or services will be provided. Refer to Appendix A for a sample of the Purchase Request Form. Refer to Appendix B for a sample of the Purchase Requisition Form.
 2. The HMC TR or designee also certifies that the goods or services to be purchased are reasonable and necessary by completing and signing the Non-Physician Vendor Compliance Certification Form. Refer to Appendix C for a sample of this certification form.
 3. The HMC TR or designee also completes additional certifications as needed based upon the requirements of the Anti-Kickback Statute safe harbors
- C. For purchase requests, the following steps are completed:
 1. The HMC Chief Financial Officer (CFO) reviews and signs the purchase request to indicate that funds are available and will be expended for the requested goods or services.
 2. The HMC Chief Executive Officer (CEO) reviews and signs the purchase request to indicate notification of the requested goods or services.
- D. The HMC TR forwards the purchase request or purchase requisition with the required certifications to Materials Management (MM).
- E. MM reviews the purchase request or purchase requisition for completeness and verifies that the required certifications are attached.
 1. If the purchase request or purchase requisition or required certifications are not complete, the following steps are performed:
 - a. MM returns the purchase request or purchase requisition and certifications to the HMC TR.
 - b. The HMC TR completes the purchase request or purchase requisition and/or required certifications. Return to Step D.

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2. If the purchase request or purchase requisition and required certifications are complete, proceed to the next step.
- F. MM determines whether a purchase order (PO) or a contract is required in accordance with HRS section 103D.
1. For a PO, the following steps are completed:
 - a. MM screens new vendors listed on the purchase request or purchase requisition against the Exclusion Lists. Refer to Policy No.: 850-101-25 Screening and Removal of Ineligible Persons for the screening procedures.
 - i. If the vendor is identified on an Exclusion List, the following steps are completed:
 - a) MM notifies the HMC TR of the exclusion.
 - b) The HMC TR notifies the vendor of the exclusion. Stop.
 - ii. If the vendor is not identified on an Exclusion List, proceed to the next step.
 - b. MM determines whether the vendor is included as a vendor under the Group Purchasing Organization (GPO) contract or previously signed an HMC vendor letter agreement.
 - i. If the vendor is included as a vendor under the GPO contract, proceed to Step F.1.h.
 - ii. If the vendor previously signed an HMC vendor letter agreement and the agreement is still in effect, proceed to Step F.1.g.
 - iii. If the vendor has not signed an HMC vendor letter agreement or previously signed an HMC vendor letter agreement for which the agreement has expired, proceed to the next step.
 - c. MM forwards two signed copies of the HMC vendor letter agreement to the vendor for review along with copies of the HMC Code of Conduct and the Anti-Kickback Statute and Stark Law policies and procedures. The HMC vendor letter agreement must contain or comply with the following:

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- i. The HMC vendor form letter has been reviewed by 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.
- ii. The HMC vendor letter agreement is signed by the HMC CEO or designee.
- iii. The HMC vendor letter agreement lists the following vendor compliance obligations:
 - a) The vendor shall comply with HMC's compliance program including any training requirements.
 - b) Certification by the vendor to the arrangement that the parties shall not violate the Anti-Kickback Statute and Stark Law with respect to the performance of the arrangement.
 - c) A requirement that the vendor will immediately notify the HMC TR 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 screening procedures.
- d. The prospective vendor reviews the HMC vendor letter agreement.
 - i. If the vendor does not sign the HMC vendor letter agreement, MM notifies a Senior Manager to resolve the issue. Stop.
 - ii. If the vendor signs and returns the HMC vendor letter agreement, proceed to the next step.
- e. MM files the executed HMC vendor letter agreement and any supporting documentation in the corresponding vendor's file. Refer to Policy No.: 85-101-22 Compliance Record Management for the procedures to retain, store, retrieve and destroy documents and records relating to the HMC compliance program.

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- f. MM forwards a copy of the executed HMC vendor letter agreement (hard copy or electronic) to Accounts Payable.
 - g. MM enters the following information for the PO into the Arrangements Tracking database:
 - i. Vendor arrangement information (e.g., vendor name, contract no., etc.);
 - ii. Date of exclusion screening (Exclusion Date);
 - iii. Effective date and expiration date of the vendor letter to indicate that the vendor letter was executed;
 - iv. Other required arrangement information (e.g., screening criteria for the Anti-Kickback Statute and Stark Law)
 - h. MM completes the PO and forwards the order to the vendor. Stop, the PO process is complete.
 2. For a contract, MM forwards the purchase request or purchase requisition with the required certifications to the HMC Contract Manager.
- G. The HMC Contract Manager screens the vendors against the Exclusion Lists. Refer to Policy No.: 850-101-25 Screening and Removal of Ineligible Persons for the screening procedures.
 1. If a vendor is identified on an Exclusion List, the following steps are completed:
 - a. The HMC Contract Manager notifies the HMC TR.
 - b. The HMC TR notifies the vendor of the exclusion. Stop.
 2. If the vendor is not identified on an Exclusion List, proceed to the next step.
- H. The HMC Contract Manager ensures that a fair market pricing (FMP) analysis is completed. The HMC Contract Manager also ensures that any data and materials used in the FMP analysis are documented.
 1. For the purchase of equipment, MM completes an FMP analysis by obtaining equipment purchasing information from the ECRI database. MM provides the FMP analysis to the HMC Contract Manager.

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2. The solicitation process serves as the FMP analysis for services or goods that are purchased via solicitation (e.g., Request for Proposal, Request for Quotation, etc.).
- I. The HMC Contract Manager drafts the contract for the non-physician arrangement and completes the Contract Routing Form. Refer to Appendix D for a sample of the Contract Routing Form. The written contract must include the following terms:
1. A specific and comprehensive description of the service(s) and/or good(s) to be provided.
 2. The term or period of the contract.
 3. The contract remuneration.
 4. The vendor's compliance obligations:
 - a. The vendor shall comply with HMC's compliance program including any training if required.
 - b. Certification by the vendor to the arrangement that the parties shall not violate the Anti-Kickback Statute and Stark Law with respect to the performance of the arrangement.
 - c. A requirement that the vendor will immediately notify the HMC TR 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 screening procedures.
- J. The HMC Contract Manager preliminarily screens the non-physician contract against the Anti-Kickback Statute and Stark Law by entering the contract information into the Arrangements Tracking database. The following information is entered into the Arrangements Tracking database:
1. Vendor arrangement information (e.g., vendor name, contract no., etc.);
 2. Date of exclusion screening (Exclusion Date);
 3. Other required arrangement information.

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- K. The HMC Contract Manager forwards a draft of the contract and all supporting documentation to the HMC legal counsel for review.
- L. The HMC legal counsel with knowledge of the appropriate state and federal rules and regulations reviews all non-physician contracts to ensure that the arrangement does not violate the Anti-Kickback Statute and Stark Law. If issues or questions result from the legal review, the HMC legal counsel works with the HMC Contract Manager to resolve the issue(s). The HMC legal counsel revises the non-physician contract accordingly and returns it to the HMC Contract Manager.
- M. The HMC legal counsel signs the Contract Routing Form or provides an email notification to the HMC Contract Manager to indicate that the legal review of the non-physician arrangement was completed.
- N. If necessary, the HMC Contract Manager revises the information previously entered into the Arrangements Tracking database to reflect any changes made to the non-physician arrangement.
- O. If the remuneration for the non-physician arrangement is greater than \$2,000,000, the HMC Contract Manager forwards the non-physician arrangement and the supporting documents to the Board responsible for HMC activities for review.
 - 1. If the Board does not approve the non-physician arrangement, the following steps are completed:
 - a. The denial is documented in the meeting minutes and the Board notifies the HMC Contract Manager of the denial and reason.
 - b. The HMC Contract Manager notifies the HMC TR. Stop.
 - 2. If the Board approves the non-physician arrangement, the approval is documented in the meeting minutes. The Board forwards a copy of the meeting minutes to the HMC Contract Manager to include in the appropriate contract file. Proceed to the next step.
- P. The HMC Contract Manager forwards two copies of the non-physician contract to the prospective vendor for review along with copies of the HMC Code of Conduct and the Anti-Kickback Statute and Stark Law policies and procedures.
- Q. The prospective vendor reviews the contract.
 - 1. If the vendor requests changes to the contract language, the HMC Contract Manager reviews the contract language changes to determine whether to revise the non-physician contract.
 - a. If the HMC Contract Manager decides to request changes to the contract language, the HMC Contract Manager emails the contract

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language changes to the HMC legal counsel for review. Return to Step L.

- b. If the HMC Contract Manager decides not to modify the contract language, the HMC Contract Manager notifies the vendor of this decision.
 - i. If the vendor wants to proceed with contracting, go to Step Q.2.
 - ii. If the vendor does not want to continue with contracting, stop.

2. If the vendor requests changes to the arrangement remuneration, the following are performed:

- a. If the revised arrangement remuneration is less than or equal to \$2,000,000, the HMC Contract Manager reviews the changes with the HMC CEO and the HMC CFO.
 - i. If the HMC CEO and the HMC CFO approve the remuneration change, the HMC Contract Manager ensures that the FMP analysis is revised. The HMC Contract Manager notifies the HMC legal counsel of the change. Return to Step L.
 - ii. If the HMC CEO and the HMC CFO deny the remuneration change, the HMC Contract Manager notifies the vendor of this decision.
 - a) If the vendor wants to proceed with contracting, go to Step Q.3.
 - b) If the vendor does not want to continue with contracting, stop.
- b. If the revised arrangement remuneration is greater than \$2,000,000, the HMC Contract Manager reviews the changes with the Board responsible for HMC activities.
 - i. If the Board approves the remuneration change, the HMC Contract Manager ensures that the FMP analysis is revised. The HMC Contract Manager notifies the HMC legal counsel of the change. Return to Step L.
 - ii. If the Board denies the remuneration change, the HMC Contract Manager notifies the vendor of this decision.

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- a) If the vendor wants to proceed with contracting, go to Step Q.3.
 - b) If the vendor does not want to continue with contracting, stop.
3. If the vendor does not request changes to the non-physician contract, the vendor signs the non-physician contract and forwards the signed contract to the HMC Contract Manager.
- R. The HMC CFO signs the Contract Routing Form.
- S. The Hawaii Health Systems Corporation (HHSC) President/CEO or HMC CEO signs the non-physician contract.
 1. If the remuneration is greater than \$2,000,000, the HHSC President/CEO signs the contract.
 2. If the remuneration is less than or equal to \$2,000,000, the HMC CEO signs the contract.
- T. The HMC Contract Manager indicates that the non-physician arrangement was executed in the Arrangements Tracking database by entering the contract effective date and expiration date.
- U. The HMC Contract Manager forwards one executed copy of the contract to the vendor.
- V. The HMC Contract Manager files the other copy of the executed non-physician arrangement and the supporting documents in the corresponding vendor's file. Refer to Policy No.: 850-101-22 Compliance Record Management for the procedures to retain, store, retrieve and destroy documents and records relating to the HMC compliance program. The supporting documents include but are not limited to:
 1. Executed non-physician contract signed by all parties;
 2. The FMP analysis;
 3. The original purchase request or purchase requisition form;
 4. Non-Physician Vendor Compliance Certification Form and other certifications as required; and
 5. The Contract Routing Form (includes proof of legal review if required).

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- W. The HMC Contract Manager forwards a copy of the contract (hard copy or electronic) to the following:
1. The HMC TR;
 2. MM;
 3. Accounts Payable; and
 4. The HHSC Contracting department, if required.

Appendix A - Purchase Request Form

HAWAII HEALTH SYSTEMS CORPORATION **HILO MEDICAL CENTER**

PURCHASE REQUEST

1. Date Prepared: *Please Check One: New PR <input type="checkbox"/> - OR - Revised PR <input type="checkbox"/>		Regional Materials Manager Initials _____
2. REQUESTING FACILITY or System Wide: Name: _____ Title: _____ Phone No.: _____ Fax No.: _____ <hr/> Technical Rep. Name: _____ Phone: _____	3. REQUIREMENTS <input type="checkbox"/> New Contract - OR - <input type="checkbox"/> Contract Amendment - Identify Existing Contract # <input type="checkbox"/> Goods <input type="checkbox"/> Services <input type="checkbox"/> Construction <input type="checkbox"/> Physician Services <input type="checkbox"/> Direct Patient Related Goods/Services <hr/> Total Contract Value (Current NTE): \$ _____ Estimated Amended Contract NTE: \$ _____ Quantity: _____	
4. DETAIL DESCRIPTION OF GOODS AND SERVICES REQUESTED: a. <u>Contract Time of Performance/Delivery Dates:</u> > Begin Date: mm/dd/year > End Date, including option years: mm/dd/year b. Recommended Vendors: c. If Pre-Existing Contract - Identify the Contract Manager/Purchasing Agent if known: d. Miscellaneous Documents/Approval Requirements (e.g. Sole Source, Exemption, Ref. Policy and Procedure PUR 0019).		
5. REQUIRED ATTACHMENTS <input type="checkbox"/> a) Scope of Services <input type="checkbox"/> b) Specifications <input type="checkbox"/> c) Vendor Quote/Proposal <input type="checkbox"/> d) Vendor Contract		
6. SIGNATURES		
_____ <i>(Printed Name)</i>	<u>Member Corp. Compliance Committee</u> _____ <i>(Title)</i>	_____ <i>(Signature) Date)</i>
_____ <i>(Printed Name)</i>	_____ <i>(Title)</i>	_____ <i>(Signature) Date)</i>
_____ <i>(Printed Name)</i>	_____ <i>(Title)</i>	_____ <i>(Signature) Date)</i>
_____ <i>(Printed Name)</i>	_____ <i>(Title)</i>	_____ <i>(Signature) Date)</i>
7. DIRECTOR OF CONTRACTS MANAGEMENT USE ONLY		
Date Received: _____ <input type="checkbox"/> Accepted <input type="checkbox"/> Rejected Purchase Tracking No. _____	Comments: _____	
Assigned To: _____ <div style="display: flex; justify-content: space-between;"> (Contract Manager/Purchasing Agent) (Date) (Dir of Contracts Mgt) </div>		

Appendix C – Non-Physician Vendor Compliance Certification Form

NON-PHYSICIAN VENDOR COMPLIANCE CERTIFICATION FORM

This Arrangement is with _____

for _____

and can be identified by _____

To the best of my knowledge, with respect to this Arrangement, I certify that:

1. The Hospital needs the items and/or services to function properly.
2. The amount(s) that the Hospital will purchase are reasonable.
3. The price(s) that the Hospital will pay are reasonable and approximate the fair market value of what the Hospital is receiving in return.
4. The pricing in the Arrangement is accurate; there are no unwritten "side deals."
5. The vendor did not offer or pay, or solicit or accept, any kickbacks or improper inducements.
6. No one acting on behalf of the Hospital offered or paid, or solicited or accepted, any kickbacks or improper inducements.
7. The price the Hospital is paying is not conditioned on receiving any other business or referrals from the vendor.
8. The price the Hospital is paying is not conditioned on sending any other business or referrals to the vendor.
9. The Hospital is not entering this Arrangement to induce or reward referrals.

Date: _____

Signature: _____

Title: _____

CONTRACT ROUTING FORM

HHSC Log No. : _____

Name of Contractor: _____ Corporate Facility: _____

Brief Description of Goods/Services:

Contract Highlight Only:

1. Term: _____

2. Total Cost (current NTE): \$ _____, New NTE: \$ _____

Documents or Information obtained, as applicable				Comments
(completed by CM):	Yes	No	N/A	
1. Tax Clearance Certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Federal Exclusion Check	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. W-9 Form Sent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Certificate of Compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Certificate of Good Standing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Fair Market Value Completed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Physician Officer Certification Completed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<p style="text-align: center;"><u>Legal Review</u></p> <p>I have reviewed the recommended action and conclude that it (is/is not) consistent with applicable legal requirements and good purchasing practices.</p>	Yes	No	<p style="text-align: center;">Procurement Attorney</p> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <p style="display: flex; justify-content: space-between; font-size: small;"> Print Name/Signature Date </p>
<input type="checkbox"/>	<input type="checkbox"/>		

Comments:

<p style="text-align: center;"><u>Contract Manager</u></p> <p>As responsible contract manager, I have reviewed this contract, and I believe, based upon my professional judgment and experience, that it is consistent with applicable procurement procedures and good purchasing practices.</p>	Yes	No	<p style="text-align: center;">Contract Manager</p> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <p style="display: flex; justify-content: space-between; font-size: small;"> Print Name/Signature Date </p>
<input type="checkbox"/>	<input type="checkbox"/>		

Comments:

CFO Regional <small>(as required)</small>	Signature: _____
CFO Corporate <small>(as required)</small>	Signature: _____