

 Henry Ford Health System	Policy Name/Subject: Tier I: Physician Owned Distributors Financial Arrangements Policy		Policy No:	
	Document includes: <input checked="" type="checkbox"/> Policy <input type="checkbox"/> Procedure <input type="checkbox"/> Other:			
	Applies to: <input checked="" type="checkbox"/> All HFHS <input type="checkbox"/> Business Unit: <input type="checkbox"/> Service Line: <input type="checkbox"/> Dept:			
	Category:		Current Approval Date:	
	Owner (Title): Vice President HFHS Supply Chain Management		Approver (Title):	
	Related Tiered Policy/Procedure:			
	Last Revision Date & Key Change(s):			
	Key Word(s):			

1. Philosophy/Purpose:

1.1. Henry Ford Health System is devoted to the quality and safety of our patients, and the limiting and/or elimination of regulatory risk and therefore has determined a need to establish a policy to track and monitor relationships with supplier firms that have Physician Ownership Interest and/or Physician Owned Distributorship involvement.

2. Scope:

2.1. This policy is applicable for all of Henry Ford health System which includes but is not limited to, Henry Ford Hospital, Henry Ford Medical Group and all of its locations, Henry Ford West Bloomfield Hospital, Henry Ford Wyandotte Hospital, Henry Ford Macomb Hospital, Henry Ford Behavioral Health Services, and Henry Ford Community Care Services
 2.2. This policy directly applies to all Medical Device and Implant Supplier Firms

3. Responsibility:

3.1. Application of this policy and ongoing monitoring is the responsibility of the Business Integrity Office and Supply Chain Management
 3.2. All Medical Device and Implant supplier firms must adhere to this policy

4. Policy:

Henry Ford Health System (HFHS) has concluded that there is substantial regulatory risk associated with purchasing arrangements that involve physician owned distributorships (PODs). Accordingly, HFHS will identify any existing relationships for potential involvement of a POD and evaluate each situation on a case by case basis in accordance with Section 1 referenced herein, and effective with this policy, will no longer enter into any such arrangements, unless POD and/or supplier firm with POD involvement meets exceptions as outlined within this policy and/or referenced herein.

5. Procedure:

- 5.1. HFHS will institute a process to identify the existence of any PODS, (entities with ownership interest by a physicians or physician's family member) in the supply chain cycle for each of its major supplier relationships
- 17.2. This will be accomplished by requiring the supplier to complete an attestation statement
 - 17.2.1. If confirmation is received that no POD is involved with supplier firm the process ceases
 - 17.2.2. If confirmation is received that a POD is involved with supplier firm, further effort will be undertaken by HFHS to gain an understanding of the ownership interest and relationship of the POD to the contracted supplier firm
 - 17.2.2.1. If it can be ascertained that the POD has no owners with any business connection to HFHS the prohibition is waived
 - 17.2.2.2. Michigan based physicians are assumed to be in a position of influence with HFHS unless evidence to the contrary is available
- 17.3. Evidence of a POD, including any exceptions, as referenced in Section 5.2.2.1 above, or submitted in response to Section 5.2.2.2 above must be reviewed and approved by the Conflict of Interest Panel Committee before HFHS can enter into any financial arrangement with supplier firm and/or related POD
- 17.4. HFHS may contract for an item or service from a supplier firm with POD involvement, meeting exception as approved by AKS) Committee as referenced in Section 1.2 providing the contract meets all of the following:
 - 17.4.1. is in writing;
 - 17.4.2. is fully executed and effective prior to the first purchase
 - 17.4.3. includes a representation and warranty and ongoing covenant from POD that the entity does not and will not have any of the eight suspect characteristics identified in the Department of Health and Human Services' Office of Inspector General's "Special Fraud Alert: Physician-Owned Entities" or later related regulations or guidance.
 - 17.4.4. includes a representation and warranty and ongoing covenant that no Physician with ownership interest or Physician family member with ownership interest in POD is in a position to generate business for HFHS, and requires immediate notice to HFHS such becomes untrue
 - 17.4.4.1. provides for the right of HFHS to terminate the agreement no later than ten (10) days after any such notice as referenced above in Section 5.4.4

18. Exception:

- 42.1. An exception to this policy may be made for disruptive technologies when approved by the HFHS President/Chief Executive Officer, Chief Medical Officer, and General Counsel
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43. Compliance and Monitoring:

- 43.1. The Vice President and Chief Compliance Officer – Business Integrity Office works with Supply Chain Management to terminate or not renew existing arrangements that do not meet the requirements of this Policy in an orderly fashion, with first priority given to implantable medical devices.

44. Definition(s):

- 44.1. **Immediate Family Member** - 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 grandparent or grandchild
- 44.2. **Ownership or Investment Interest** - Has the same meaning set forth in 42 C.F.R. § 411.354(b) or any successor regulation. For these purposes, ownership may be direct or indirect, and may be by means of equity or debt; There is no minimum percentage ownership below which this policy would not apply; Investments in publicly-traded securities or mutual funds are excluded from the definition so long as they meet the requirements of 42 C.F.R. § 411.356(a) or (b) or any successor regulation
- 44.3. **Royalty Interest** - Payments made to the creator/owner of an item or intellectual property for each unit/copy of the property sold
- 44.4. **Physician** - A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor
- 44.5. **Physician-Owned Distributor (POD)** – Physician-owned entities that derive revenue from selling, or arranging for sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their patients at hospitals or ambulatory surgical center (ASCs)
- 44.6. **Physician-Owned Entity (POE)** - Any entity in which a Physician or Immediate Family Member of a Physician holds an ownership, investment, or royalty interest if royalties are paid on purchases resulting from the royalty holder's order

45. Reference(s)/Source(s)

- 45.1. Special Fraud Alert: Physician-Owned Entities
42 C.F.R. § 411.354(b)
42 C.F.R. § 411.356(a) and (b)
“Physician Investment in Medical Device Manufacturers and Distributors” (Letter from the OIG) (Oct. 6, 2006)

10. **Attachment(s)** - *Only use attachments when links are not possible.*

ATTESTATION AND COMPLIANCE CERTIFICATE

Mr. Contact Name
Company Name
RNovember 15, 2014
Page 2

I, _____, hereby attest as an authorized officer of _____
("Supplier") that:

- I have read the Henry Ford Health System (HFHS) Policy entitled Physician-Owned Distributors." I understand that it is my responsibility to read, understand and seek guidance, should I require clarification, with regard to the standards and requirements set forth in the Policy.
- I hereby certify that Supplier does not meet the definition of a Physician-Owned Distributor as described in the Policy.
- If at any time Supplier becomes a Physician-Owned Distributor, I agree to report that change within five (5) working days to the HFHS Compliance Hotline at (313) 876-2605.
- I understand and acknowledge that failure to complete this Certificate truthfully and accurately or to update this Certificate as required constitutes a breach of Supplier's agreement with HFHS, and may also subject its physician owners to disciplinary review and action.

I have read this Attestation and Compliance Certificate and do hereby demonstrate my understanding and agreement to abide by its terms by affixing my signature on the date indicated below. I hereby attest and certify that Supplier is not a Physician-Owned Distributor as defined by the Policy.

Company Name: _____

Signature: _____

Date: _____

Name: _____

Title: _____

Please return a signed copy electronically to *Glenn Croxton*, gcroxtol@hfhs.org and the signed original to

Henry Ford Health System
Attn: Glenn Croxton
1 Ford Place
5EF
Detroit, MI 48202
