

 OhioHealth		POLICY and PROCEDURE	
TITLE: Physician-Owned Distributorships		NUMBER: OH.POL.SC-5100.010	
ISSUE DATE: 9/22/15		EFFECTIVE DATE: 10/28/19	
DEVELOPED BY: Office of the General Counsel			
REVIEWED BY: Office of the General Counsel Ethics and Compliance Supply Chain Services Ethics and Compliance Steering Committee		DATE REVIEWED: Oct 2019 Oct 2019 Aug 2019 Nov 2019	
APPROVED BY: Ethics and Compliance Senior Leadership Committee			

SCOPE:

This policy applies to all OhioHealth hospitals, businesses, and wholly-owned subsidiaries (hereinafter “OhioHealth”).

STATEMENT OF PURPOSE:

The Office of Inspector General has expressed concern that physician investments in implantable medical device and distribution entities should be closely scrutinized under the fraud and abuse laws. In light of the national scrutiny against physician-owned implantable medical device and distribution entities, this policy is intended to prevent OhioHealth (absent special exceptions) from entering into relationships with such entities.

DEFINITIONS:

- **Physician Owned Distributorship or “POD”** - Any entity in which a Physician (as defined in this policy) or his or her Immediate Family Member:
 - Has control, profit sharing, or an ownership interest (other than through publicly traded stock of 5% or less)
 - Is compensated or rewarded based on OhioHealth purchases
 - Has control, profit sharing, or an ownership interest (other than through publicly traded stock of 5% or less) in any distributor of the product in any market
- **Immediate Family Member** – An Immediate Family Member of a physician includes the physician’s spouse, parents, grandparents, children, grandchildren, great grandchildren, siblings (whether step, whole or half-blood), and the spouses of children, grandchildren, great grandchildren and siblings.
- **Physician** – A Physician who is a member of the medical staff of any OhioHealth hospital, who has a financial relationship with OhioHealth, or is reasonably in a position to refer patients to an OhioHealth hospital

POLICY:

I. **General Policy:**

- A. Absent an exception as provided in this policy, OhioHealth prohibits the purchase of implantable medical devices from any POD, whether the purchase is handled through Supply Chain or otherwise. OhioHealth will also scrutinize purchases of other goods or services from a POD.
- B. OhioHealth will not contract for or purchase any goods or services from any POD or physician if any purpose of the contract or purchase is to generate, pay for, or maintain referrals from a physician who has, directly or indirectly, a financial interest in the utilization of the goods or services purchased.

II. **Vendor Questionnaire to Determine POD status:**

- A. All vendors selling any implantable medical devices used at OhioHealth are required to complete a questionnaire to determine whether or not they are a POD, using a form developed by the Office of the General Counsel and administered by Supply Chain, and to update the questionnaire as needed for any changes in pertinent facts and circumstances.
- B. The questionnaire will also be used for companies that sell goods and services other than implantable medical devices, if the purchase of such goods or services could potentially be influenced by a Physician.
- C. Supply Chain will report any positive response to such questionnaires to the Office of the General Counsel for advice and disposition.
 - 1. For companies selling implantable medical devices, the Office of the General Counsel will determine the level of scrutiny for any positive responses and, if it determines the company may be a POD, any transaction with the company will only be permitted pursuant to the process outlined below for exceptions to this policy.
 - 2. For companies other than those selling implantable medical devices, the Office of the General Counsel will determine the level of scrutiny needed for any positive responses and will approve or disapprove any transactions with the company.

III. Physicians Participating in Vendor Selection:

- A. Any OhioHealth physician participating in any OhioHealth vendor selection process shall, as a prerequisite to such participation, complete a questionnaire and certification form that discloses all of the physician's and his Immediate Family Member's relationships with any POD and all vendors involved in the selection process.
- B. The form will be developed by the General Counsel in cooperation with the Chief Compliance Officer and Supply Chain.
- C. Supply Chain will report any positive response to such questionnaire and certification form to the General Counsel and Chief Compliance Officer for advice and disposition.

IV. Exceptions:

- A. Subject to the requirements of IV.A.3 below, this policy is not intended to prevent the purchase of an item from:
 - 1. A medical staff member or his or her company where the item was originally developed and marketed by such medical staff member; or
 - 2. A third party where the medical staff member originally developed and sold rights to that third party and receives a royalty or other payment for those rights (e.g., where a physician has sold intellectual property rights to a manufacturer and that manufacturer in turn sells a product to OhioHealth).
 - 3. In either case above, the item and the circumstances of the marketing and sale must be disclosed in writing by the medical staff member and the vendor in question (if any) and previously approved by the OhioHealth General Counsel (after consultation with the OhioHealth Vice President of Shared Services, the OhioHealth Chief Medical Officer and the OhioHealth Chief Compliance Officer) as a permitted exception to this policy.
- B. Further, in rare circumstances other exceptions to this policy may be warranted.
 - 1. A request for an exception under this policy must be made through the Vice President of Shared Services, and should include details surrounding the arrangement to be considered, the parties involved and information known about the ownership interest by the physician(s) or their Immediate Family Members.

2. Such exception to this policy shall be submitted for consideration to the OhioHealth General Counsel, who shall either approve the request (after consultation with the OhioHealth Chief Medical Officer and the OhioHealth Chief Compliance Officer) as a permitted exception to this policy, or deny the request.
3. Where relationships with PODs are necessary and granted as an exception to this policy as previously described, the relationship must be consistent with fair market value and satisfy all other applicable legal standards. Contracts with PODs granted an exception shall contain an ongoing obligation to disclose, during the term of the contract, any financial relationship (whether direct or indirect) involving Physicians (or their Immediate Family Members), and shall also include provisions for the prompt termination of the business relationship in the event of a failure to disclose or the disclosure of a financial relationship which may be prohibited under this policy.