



1.0) Policy Title

Physician-Owned Distributorship (POD) Policy

Owner of Policy: Rani Gill, Compliance Officer

2.0) Dates

Effective Date: 02/26/2020

Last Revised: 11/25/2019

Next Review: 11/2022

3.0) Responsible Department

Contracts and Materials Management, Corporate Compliance

4.0) Subject

This policy describes UMC purchasing restrictions related to entities where there is a physician related ownership as defined within.

5.0) Purpose

In a 2013 Special Fraud Alert issued by the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG"), OIG identified a strong potential for improper inducements between and among physicians who invest in distributors of medical devices, the entities in which they invest, and providers that purchase devices from entities with physician investors. The purpose of this policy is to ensure that UMC does not purchase the items designated in this Policy from Physician-Owned Distributorships (PODs) except as permitted by this Policy.

6.0) Scope

Hospital-Wide

7.0) Policy

1. Except as set forth as an exception, UMC will not enter into any agreement to purchase from a POD for any item or service other than a professional medical service personally furnished by a Physician or by an allied health professional employed by the POD under a Physician's supervision.

2. UMC will not purchase items or services if any purpose of the purchase is to generate or maintain referrals from a physician who has, directly or indirectly, a financial interest in the utilization of the item purchased.

8.0) Procedures

1. **Attestation:** All suppliers will provide an attestation of physician ownership to UMC that such ownership is in compliance with this policy and will update such attestation if a change occurs. Attestation form is maintained by the Director of Contracts Management.
2. **POD Database:** UMC Contracting Department will maintain a POD database. The database will contain a record of each POD that has been identified through any of the following manners:
 - a. The submission of an Attestation form;
 - b. The utilization of the Medical Staff Services Conflict of Interest Policy (MSS-361); or
 - c. The utilization of the CMS Open Payments system, regardless of whether the POD has indicated a desire to sell items, pharmaceuticals or biologics to UMC.

UMC will not purchase from a supplier in the POD database unless it meets an exception within this policy.

3. **Corporate Compliance Review:** The Corporate Compliance Department of UMC will execute a review of CMS Open Payments data and verify that data is assessed in relation to Medical Staff Services Conflict of Interest Policy (MSS-361) submissions, supplier attestations, POD database and purchasing decisions.
4. **Exceptions:**
 1. If a Physician (or an Immediate Family Member of any owner) of the POD is not in a position to generate business or be a referral source for UMC the prohibition under this policy does not apply. Nevada based physicians are presumed to be in a position to generate business for UMC.
 - a. The POD must submit evidence in the form of an Attestation to satisfy this provision before UMC can enter into a financial arrangement with the POD.
 2. An exception to this policy may be made for disruptive technologies when approved by the CEO. This exception does not apply where a substantially equivalent product or service is available from a non-POD or, for example, where a device obtains 510k clearance.

Any agreement meeting the requirements of an exclusion stated above, must also be consistent with fair market value and satisfy all other applicable legal standards.

In rare circumstances, an exception to this policy not contained herein may be warranted. A request for an exception under this policy must be made through the Contracts Department and should include details surrounding the arrangement to be considered, the parties involved and information known about the ownership interest by the physician(s). Any exception to this policy must be approved by the Chief Executive Officer.

9.0) Definitions

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.

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.

Royalty Interest - Payments made to the creator/owner of an item or intellectual property for each unit/copy of the property sold.

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.

Physician-Owned Distributor (POD) - Any entity (e.g., a corporation, partnership, joint venture or limited liability company) in which a Physician or Immediate Family Member of a Physician holds a direct or indirect ownership (by any contractual arrangement conferring ownership-like right) in full or part, an investment, or royalty interest if royalties are paid on purchases resulting from the royalty holder's order, (b) purchases or distributes items from a Physician and seeks to sell such item, pharmaceutical or biologic to UMC, or (c) is obligated to pay a royalty related to an item purchased by UMC.

10.0) References

- Stark Law, 42 U.S.C. § 1395nn and implementing regulations
- Anti-Kickback Statute, 42 U.S.C § 1320a-7b(b)
- OIG Special Fraud Alert: Physician-Owned Entities (2013)

11.0) Approvals

CEO: 11/25/2019

UMC Policy and Procedures Committee: 01/22/2020