

CORPORATE POLICY

Manual/Library Name: Law Department	No: L-19
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Title: Purchasing Implantable Medical Devices from Physician-Owned Distributorships (PODs)	Effective Date: 02/08/2022
	Previous Versions: 10-05-20; 5-21-15; 06-27-13
	Approved By: Executive Leadership Team
	Approval Date: 02/03/2022

I. Scope:

This policy applies to Tenet Healthcare Corporation and its subsidiaries and affiliates other than Conifer Holdings Inc. and its direct and indirect subsidiaries (each, an “Affiliate”), any other entity or organization in which Tenet or an Affiliate owns a direct or indirect equity interest of greater than 50%, and any entity in which an Affiliate either manages or controls the day-to-day operations of the entity (each, a “Tenet Entity”) (collectively, “Tenet”). This Policy also applies to group purchasing organizations that purchase medical devices, pharmaceuticals and/or biologics and related instrumentation on behalf of a Tenet Facility.

II. Purpose:

To ensure that Tenet Facilities do not purchase the items designated in this Policy from Physician-Owned Distributorships except as permitted.

III. Definitions:

Immediate Family Member: 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.

Implantable Medical Devices: Any device implanted into the human body including biologic products, external fixation devices, and related instrumentation.

Physician: A duly licensed and authorized chiropractor or doctor of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, optometry and his or her Immediate Family Members.

Physician-Owned Distributorship or POD: An entity of any kind (e.g. a corporation, partnership, joint venture or limited liability company) that is (1) owned, in full or in part, directly by ownership interest or indirectly by any other contractual arrangement conferring ownership-like rights, by a Physician Referral Source; (2) purchases or distributes items from a Physician Referral Source and seeks to sell Implantable Medical Devices, other medical devices, pharmaceuticals, or biologics to a Tenet Facility; or (3) which is obligated to pay a Physician Referral Source a royalty related to Implantable Medical Devices purchased by the Tenet Facility.

Physician Referral Source: A Physician who can influence or recommend that the Tenet Facility or any other Tenet Facility located within the same Tenet Market to purchase or arrange for any goods, facility, item or service paid for, in whole or in part, by a federal or state healthcare program. In the case

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of a Tenet Facility which is a free-standing ambulatory surgery center, a Physician Referral Source is a Physician who is a member of the center’s medical staff or the immediate family member of a Physician on the center’s medical staff.

Publicly Traded Company: A company that is publicly held and both (1) listed for trading on the New York Stock Exchange (“NYSE”), any regional, national, or foreign exchange in which quotations are published on a daily basis, or on the National Association of Securities Dealers Automated Quotation System (“NASDAQ”); and (2) had at least \$75 million in stockholder’s equity at the end of its most recent fiscal year or on average during the previous three fiscal years.

Tenet Facility Leader: The Tenet Entity CEO, ASC Administrator, or other senior facility leader.

IV. Policy:

- A. Tenet Facilities and the Tenet Sourcing Department cannot purchase Implantable Medical Devices, other medical devices, pharmaceuticals, or biologics from a Physician-Owned Distributorship directly or indirectly, including through a group purchasing organization, unless:
 - a. The POD is a Publicly-Traded Company;
 - b. The POD is contracted through a group purchasing organization which independently validates the quality of the product and establishes the pricing for its participating buyers;
 - c. The owners in the POD are not Physician Referral Sources to the Tenet Facility; or
 - d. The POD and the relevant Physician Referral Source demonstrate or otherwise represent that no royalty or other payment will be made to a Physician Referral Source based upon items purchased by the Facility for use by the Physician Referral Source or by any Physician employed by or otherwise engaged in the practice of medicine with the Physician Referral Source; or
 - e. The Implantable Medical Device is a replacement part for (but not a complete replacement of) or addition to, an Implantable Medical Device already implanted in the patient.
 - f. Instrumentation required for use of a replacement part is from the same manufacturer and the Implantable Medical Device is not reasonably available from a resource that is not a POD; or
 - g. Tenet’s Chief Medical Officer, Chief Compliance Officer and Chief Legal Operations Officer or their designees make an exception.

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V. Procedure:

- A. The Material Resource Manager and the Tenet Sourcing Department shall implement a process to identify and track potential PODs to ensure that the Tenet Facility does not purchase Implantable Medical Devices from them except as permitted above.
- B. The Tenet Facility’s Operations Counsel must make the final determination on whether an entity meets the definition of a POD as set forth in this Policy.
- C. An exception to the policy may be granted for general use or for a specific use and patient upon a finding that:
 1. The use of the Implantable Medical Device is determined to be medically necessary;
 2. No reasonably comparable alternative exists to the Implantable Medical Device;
 3. The Tenet Facility Leader confirms in writing that there is no intention to induce referrals or otherwise benefit the Physician holding an interest in the POD; and
 4. The arrangement does not otherwise appear to violate the Anti-Kickback Statute.

VI. Enforcement:

All employees whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable policies and procedures, up to and including termination. Such performance management may also include modification of compensation, including any merit or discretionary compensation awards, as allowed by applicable law.

VII. 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)
 Law Department policy L-15 Electronic Contract Approval Term Sheet (eCATS)