

Physician Owned Entities Financial Arrangements Policy

Policy Statement

Except as set forth in this Policy, Intermountain will not enter into any agreement to purchase from a Physician-Owned Entity any item or service other than a professional medical service personally furnished by a Physician or by an allied health professional employed by the Physician-Owned Entity under a Physician's supervision.

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Scope

IHC Health Services, Inc.

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 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.

Provisions

- 1 If no Physician owner (or Physician who is an Immediate Family Member of any owner) of the POE is in a position to generate business for Intermountain, the prohibition does not apply. Utah-based physicians are presumed to be in a position to generate business for Intermountain.
 - 1.1 Evidence that the POE satisfies provision 1 above must be submitted to and approved by the Anti-Kickback Statue (AKS) Committee before entering into any financial arrangement with the POE.
 - 1.2 Intermountain may contract for an item or service meeting this exception so long as the contract:
 - 1.2.1 is in writing;
 - 1.2.2 is fully executed and effective prior to the first purchase;
 - 1.2.3 includes a representation and warranty and ongoing covenant from the Physician-Owned Entity that the entity does not and will not have any of the following 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;
 - The size of the investment offered to each Physician varies with the expected or actual volume or value of devices used by the Physician.
 - Distributions are not made in proportion to ownership interest, or Physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the Physicians.
 - Physician-owners condition their referrals to hospitals or ambulatory surgical centers (ASCs) on their purchase of the POE's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POE, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POE, or by requiring a hospital or an ASC to enter into an

exclusive purchase arrangement with the POE.

- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POE or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POE's devices for their patients.
- The POE retains the right to repurchase a Physician-owner's interest for the Physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POE's devices.
- The POE is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POE does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires Physicians to disclose conflicts of interest, the POE's Physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POE.

1.2.4 includes a representation and warranty and ongoing covenant that no Physician owner or Physician who is an Immediate Family Member of any owner of the POE is in a position to generate business for Intermountain, and requires immediate notice to Intermountain if that is no longer true; and

1.2.5 provides for the right of Intermountain to terminate the agreement no later than ten (10) days after any such notice.

- 2 An exception to this policy may also be made for disruptive technologies when approved by the Intermountain President/Chief Executive Officer, Chief Medical Officer, and General Counsel (see *Disruptive Technologies Exception Guideline*).
- 3 The Vice President of Business Ethics and Compliance works with Supply Chain Organization staff to terminate or non-renew existing arrangements that do not meet the requirements of this Policy in an orderly fashion, with first priority given to implantable medical devices.

Exceptions

None

Primary Sources

[Special Fraud Alert: Physician-Owned Entities](#)

42 C.F.R. § 411.354(b)

42 C.F.R. § 411.356(a) and (b)

Secondary Materials

["Physician Investment in Medical Device Manufacturers and Distributors"](#) (Letter from the OIG) (Oct. 6, 2006)

[Disruptive Technologies Exception Guideline](#)

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Effective Date:

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Reasonable efforts will be made to keep employees informed of policy changes; however, Intermountain Healthcare reserves the right in its sole discretion to amend, replace, and/or terminate this policy at any time.

Intermountain Healthcare is an At-Will Employer. The terms of this policy do not, either directly or indirectly, constitute any form of employment contract or other binding agreement between any employee and Intermountain.

Contact Intermountain Healthcare's Legal Department for questions.