Physician-Owned Distributors: Are They Harmful to Patients and Payers?

The Experience of Intermountain Healthcare

The United States Senate Committee on Finance
Tuesday, November 17, 2015 – 2:15 p.m.

Suzie Draper, Vice President of Business Ethics and Compliance

Intermountain Healthcare
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The United States Senate Committee on Finance, Tuesday, November 17, 2015 – 2:15 p.m. The Intermountain Healthcare Experience

Written Testimony – Suzie Draper, Vice President of Business Ethics & Compliance, Intermountain Healthcare

Intermountain Healthcare appreciates the opportunity to describe its experience with the development and implementation of policies for dealing with physician-owned entities. My name is Suzie Draper, and I am the Vice President of Business Ethics & Compliance at Intermountain Healthcare in Salt Lake City, Utah. Intermountain is a not-for-profit 501(c)(3) integrated healthcare system that operates 22 hospitals in Utah and Idaho; more than 185 clinics; and an insurance plan, SelectHealth, which covers more than 750,000 lives in Utah and Idaho. Intermountain's Medical Group employs approximately 1,200 physicians, and about 4,000 other physicians affiliate with Intermountain.

Intermountain has become well-known nationally and internationally for identifying best clinical practices and applying them consistently. Dr. John E. Wennberg of the Dartmouth Institute for Health Policy and Clinical Practice said, "Intermountain is the best model in the country of how you can actually change healthcare for the better." Dartmouth estimated that if healthcare were provided nationally in the way it is provided at Intermountain, "the nation could reduce healthcare spending for acute and chronic illnesses by more than 40%."

Intermountain's focus is on providing high-value healthcare and helping people live the healthiest lives possible. To that end:

- We have developed physician-led clinical programs so that medicine at Intermountain is practiced by collaborative teams and is based on the best available data.
- We establish specific clinical improvement goals, with accountability for accomplishing these goals reaching all the way to Intermountain's Board of Trustees.
- We have developed information technology that allows us to track, compare, and improve outcomes—and eliminate inappropriate variation.
- We view variation as an opportunity to improve, whether we find it in our clinical processes, our business processes, or our supply chain.

1 Objective

This testimony describes Intermountain Healthcare's challenges in implementing policies and procedures regarding physician-owned distributors (PODs) and physician-owned entities (POEs).

2 Process and History

2.1 The Evolution of a Centralized Supply Chain Organization (SCO)

Originally, Intermountain's supply chain processes were largely decentralized, with contracting authority at the individual facility level. In 2006, Intermountain created a Supply Chain Organization (SCO) to more effectively manage its annual spend on goods and services purchased from outside vendors. The SCO is responsible for more than $1.5 billion in annual spending and oversees the distribution of more than two million medical devices annually. Creation of the SCO has resulted in significant efficiencies, and Intermountain's SCO was ranked third in the United States in the most recent annual top 25 list of healthcare supply chains ranked by Gartner, Inc.

2.2 Contracting Challenges and PODs

In the early years of the SCO, resources were devoted to centralizing the purchasing process and to significantly increasing the evaluation of current and potential vendors. Typically, information regarding physician ownership of vendors was sought, but physician ownership was not viewed as an absolute impediment to contracting. Over time, however, there were increasing reports from the field regarding suspected and non-disclosed financial arrangements between vendors and physicians who were in a position to order the vendor's products.

2.3 The POD Regulatory Landscape Prior to the Special Fraud Alert

Prior to the issuance of the Special Fraud Alert on March 26, 2013, there was no statute, regulation, or clear agency guidance limiting hospitals from contracting with PODs. In 2006, AdvaMed requested additional guidance from the Office of Inspector General (OIG), which replied only that OIG "would take [AdvaMed's] views . . . into consideration as we contemplate future OIG guidance projects." In 2008, CMS was asked by a commenter on the CY 2008 PFS proposed rule (identified by CMS as a "large medical device manufacturer") to define PODs to be designated health services (DHS) entities subject to the Stark Law; in the 2009 Inpatient Prospective Payment System (IPPS) final rule, CMS declined to do so. In response to a Senate inquiry to CMS and OIG on PODs, in 2011 CMS stated it would "consider this issue carefully" but at that time declined to define PODs to be GPOs subject to the Sunshine Act. OIG similarly responded in 2011 that it would initiate a study but that "OIG's ability to issue guidance about the application of the [kickback] statute to these business structures is limited."

2.4 Intermountain's Evolving Approach to PODs Prior to the Special Fraud Alert

As the 2011 Senate Finance Committee Minority analysis (the Hatch Report) noted, there was a general lack of clear regulatory guidance to hospitals in this area. In connection with Intermountain's self-disclosure and ongoing discussions with the DOJ and OIG, a policy review of all hospital-physician arrangements was undertaken. Intermountain struggled to reach consensus on the proper approach to PODs that struck the appropriate balance of competing interests. The Hatch Report identified potential vulnerabilities in the typical POD model, while the Sunshine Act viewed disclosure as a means to limit the risk of abuse. A May 2012 Food and Drug Policy Forum article by Joseph Truhe, Esq., arguing that PODs were not only lawful but beneficial to the supply chain, was widely disseminated. From a strictly legal perspective, fair market arrangements between PODs and hospitals arguably satisfied the discount safe harbor to the Kickback Law and the relevant Stark Law rules, but there was growing discomfort with the potential conflicts of interest involved.

2.5 Special Fraud Alert

With the publication of the Special Fraud Alert, consensus at Intermountain crystallized around a bright-line policy that would be straightforward to implement. Prior to March of 2013, Intermountain was still unclear on how to best minimize the uneasiness caused by all the factors identified above. Intermountain's uneasiness was greatly alleviated by the OIG's Special Fraud Alert: Physician Owned Entities (the "SFA"). The SFA stated that the OIG was particularly concerned about the financial incentives present in physician-owned distributorships ("PODs") of implantable medical devices "because such devices typically are 'physician preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed."

The SFA went on to identify eight "suspect characteristics" of PODs that might run afoul of the Anti-kickback Statute, which characteristics are as follows:

1. The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
2. 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.

3. Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD'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 POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
4. Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
5. The POD 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 POD's devices.
6. The POD 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.
7. The POD does not maintain continuous oversight of all distribution functions.
8. When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

The SFA also stated that "hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute." Based on the SFA's warning, Intermountain elected to follow the course of action suggested in Footnote 1 of the SFA and develop a revised policy governing Intermountain's relationships with not just PODs but all physician-owned entities ("POEs").

2.6 Policy Revision

In May 2013, Intermountain revised its policy entitled the "Physician Owned Entities Financial Arrangements Policy" (the "POE Policy"). Under the POE Policy, Intermountain will not enter into any agreement to purchase from a POE any item or service other than professional medical services personally furnished by the physician owner or other health professional employed by the POE, unless the POE falls into one of two exceptions. The first exception applies to POEs whose physician owner (or physician who is an immediate family member of any owner) is not in a position to generate business for Intermountain. This exception also requires that prior to purchasing any item or service that meets the exception, Intermountain must enter into a written contract with the POE that includes the following representations and warranties and ongoing covenants from the POE: (1) that the entity does not have and will not have any of the eight suspect characteristics identified in the SFA, and (2) that no physician owner or physician who is an immediate family member of an owner in the POE be in a position to generate business for Intermountain, and that the POE will notify Intermountain if that representation is no longer true.

The second exception to the POE Policy is an exception made for disruptive technologies that are pre-approved by Intermountain's Senior Management Team in accordance with Intermountain's Disruptive Technologies Exception Guideline. This exception allows Intermountain the flexibility to make exceptions for products and services that if not purchased by Intermountain may pose a risk to the quality of care an Intermountain patient may receive as more fully described in Section 2.8 below.

Finally, the POE Policy also requires Intermountain's compliance team to work with Intermountain's Supply Chain staff to develop a plan to terminate or not renew existing arrangements that do not meet the requirements of the POE Policy, with first priority given to terminating and not renewing non-compliant arrangements for implantable medical devices. The implementation of the POE Policy has helped Intermountain to avoid relationships with the types of suspect POE identified in the SFA; however, the implementation has not been without costs to Intermountain. Implementation of the POE Policy has also led to other obstacles and challenges that were not present prior to the OIG's release of the SFA and Intermountain's implementation of its policy as a response to the SFA.

2.7 Balancing Competition and Standardization

In many instances Intermountain's implementation of the POE Policy narrows the field of suppliers that are qualified to receive and respond to RFPs for certain products and services. This decrease in qualified suppliers naturally increases product and supplier rationalization and standardization. These are generally viewed as positive, cost-saving measures. However, in this situation Intermountain may be standardizing on a legacy supply chain, which some argue is anti-competitive and potentially subject to abuse. Extending RFPs to compliant POEs may resolve those flaws, but that extension is often prohibited by the POE Policy.

2.8 The Disruptive Technologies Exception

Intermountain's Disruptive Technology Exception is limited to the disruptive technology in question (not the POE's entire catalog of items or services) and does not apply where a substantially equivalent product or service is available from a non-POE or, for example, where a device obtains 510k clearance. The challenge with this exception is its narrow scope. There have been only a handful of products and suppliers that have met these requirements—not because the suppliers are unwilling to comply with the Special Fraud Alert but, rather, because their items or services are not truly disruptive technologies.

2.9 Promoting Innovation and Collaboration

Another challenge is the potential chilling effect the POE Policy might have on Intermountain's innovative and collaborative culture. In an effort to reaffirm that culture and to insert appropriate safeguards, Intermountain is considering adding another exception to the POE Policy for technologies that are co-developed by the POE and Intermountain. This new exception would be available for items or services that are innovative, distinguishable, potentially superior, and otherwise compliant with the exception and Intermountain policy. We recognize that many of Intermountain's own physicians are in the best position to invent disruptive and innovative technologies, and we hope that this exception will provide a compliant model for those activities.

3 Ongoing Implementation

3.1 Attestation Form

Defining the policy prohibiting purchasing products or services from physician-owned entities was only the first step; implementing the policy presented additional challenges and opportunities. One challenge was to determine the process for inquiring regarding an entity's ownership. In collaboration with legal counsel, Intermountain developed a form letter that references the OIG Special Fraud Alert and outlines Intermountain's policy regarding purchasing from physician-owned entities. The letter then asks the supplier to attest to not having physician ownership and to meeting the policy's other provisions; the supplier makes this attestation by completing and signing a Compliance and Attestation form.

3.2 Implants, then what?

Due to the large number of suppliers Intermountain purchases from, the attestation form is being implemented in several phases beginning with total joint and spinal implants and then other categories of implants. The next area of specific focus is being developed.

3.3 AP Database and AP Payments – Invoices, Contracts

When Intermountain sets up a supplier in its payment database, there is a field to indicate whether the supplier has physician ownership. That information may have come from an Intermountain Supply Chain employee, the supplier, or a

local sales representative (who may not have actual knowledge of the supplier's ownership). There is ongoing effort to ensure the database is accurate and complete.

3.4 Exceptions to the Policy

As noted above, Intermountain's policy includes two exceptions to prohibiting purchases for POEs: 1) the physician-owner is not in a position to generate business for intermountain, and 2) the product purchased is a "disruptive technology." Additionally, professional services provided personally by a physician are categorically exempt from the policy. The first exception presumes that any physician practicing within Intermountain's service area is in a position to generate business for Intermountain Healthcare. For a supplier to meet the first exception, the supplier must attest to the physician-owner's not being in a position to generate business and must adduce sufficient supporting evidence.

3.5 Divestitures

Implementation of this policy by Intermountain has affected the local medical device market. A few physician-owned companies have chosen to have their physician-owners divest in order to continue supplying Intermountain. Other companies have combined divestiture with ongoing financial arrangements with the divesting physician owners, including employment. Analyzing these evolving arrangements under the POE Policy is an ongoing challenge.

3.6 Operational Wind Down

In a system the size of Intermountain, it is very difficult to simply stop purchasing a product for reasons outside the normal procurement channels. In the case of ending purchases from POEs, we chose to stop purchasing products that are, in some instances, widely used and possibly the preferred product. Prior to telling a supplier that we would no longer purchase items or services because of physician ownership, we worked through a process to notify all the users of those items or services of the change—particularly physicians—and to find satisfactory replacements. After those notifications are made, we then notify the manufacturer that we will discontinue purchases from them due to their being a physician-owned entity. Additionally, all stock on hand that was not already purchased from the POE is removed and returned.

We discovered a few issues with discontinuing some purchases. Primarily, orthopedic surgeons prefer to replace an implant, if replacement is necessary, with the same device from the same manufacturer. Similarly, orthopedic surgeons prefer to implant the same device in the bilateral body part after the first implant is placed. For example, if a patient has had a hip replacement using a device from a POE and then requires a hip replacement on the other hip, the surgeon prefers to use the same device from the same manufacturer for the second hip. To meet these demands, we have authorized one-time purchases of those devices and maintained contracts with the suppliers in order to make those purchases. Some flexibility is needed to meet the medical needs of patients.

In addition to the issue of orthopedic surgeon preferences, some items or services are arguably superior to their supposed equivalents and yet do not meet the high bar of a disruptive technology. To date we have not finalized a satisfactory resolution to this issue.

EXHIBITS

- Office of Inspector General - Special Fraud Alert: Physician-Owned Entities……Pgs. 7-10
- Intermountain's Physician Owned Entities Financial Arrangements Policy……Pgs. 11-13
- Intermountain's letter and attestation that is sent to Physician Owned Entities……Pgs. 14-16

Special Fraud Alert: Physician-Owned Entities

March 26, 2013

I. Introduction

This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). These entities frequently are referred to as physician-owned distributorships, or "PODs."[1] The Office of Inspector General (OIG) has issued a number of guidance documents on the general subject of physician investments in entities to which they refer, including the 1989 Special Fraud Alert on Joint Venture Arrangements[2] and various other publications. OIG also provided guidance specifically addressing physician investments in medical device manufacturers and distributors in an October 6, 2006 letter.[3] In that letter, we noted "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such ventures "should be closely scrutinized under the fraud and abuse laws."[4] This Special Fraud Alert focuses on the specific attributes and practices of PODs that we believe produce substantial fraud and abuse risk and pose dangers to patient safety.

II. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal

[1] The physician-owned entities addressed in this Special Fraud Alert are sometimes referred to as "physician-owned companies" or by other terminology. For purposes of this Special Fraud Alert, a "POD" is any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation. Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of physician-owned entities.

[2] Special Fraud Alert: Joint Venture Arrangements (August 1989), *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

[3] Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG, Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

[4] Id.

offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

III. Physician-Owned Distributorships

Longstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. The anti-kickback statute is violated if even one purpose of the remuneration is to induce such referrals.

OIG has repeatedly expressed concerns about arrangements that exhibit questionable features with regard to the selection and retention of investors, the solicitation of capital contributions, and the distribution of profits. Such questionable features may include, but are not limited to: (1) selecting investors because they are in a position to generate substantial business for the entity, (2) requiring investors who cease practicing in the service area to divest their ownership interests, and (3) distributing extraordinary returns on investment compared to the level of risk involved.

PODs that exhibit any of these or other questionable features potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices. We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are "physician preference items," meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed.

We do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns. As we noted in the preamble to the final regulation for the safe harbor relating to ASCs:

> …disclosure in and of itself does not provide sufficient assurance against fraud and abuse…[because] disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients

are not put on guard against the potential conflict of interest, i.e., the possible effect of financial considerations on the physician's medical judgment.

See 64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999). Although these statements were made with respect to ASCs, the same principles apply in the POD context.

OIG recognizes that the lawfulness of any particular POD under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by a POD's characteristics, including the details of its legal structure; its operational safeguards; and the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. Nonetheless, we believe that PODs are inherently suspect under the anti-kickback statute. We are particularly concerned when PODs, or their physician-owners, exhibit any of the following suspect characteristics:

- 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 ASCs on their purchase of the POD'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 POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD 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 POD's devices.
- The POD 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 POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

These criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect characteristics and yet still be found to be unlawful. Other characteristics not listed above may increase the risk of fraud and abuse

associated with a particular POD or provide evidence of unlawful intent. For example, a POD that exclusively serves its physician-owners' patient base poses a higher risk of fraud and abuse than a POD that sells to hospitals and ASCs on the basis of referrals from nonowner physicians.

The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives. Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

We are aware that some PODs purport to design or manufacture their own devices. OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

IV. Conclusion

OIG is concerned about the proliferation of PODs. This Special Fraud Alert reiterates our longstanding position that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. OIG views PODs as inherently suspect under the anti-kickback statute. Should a POD, or an actual or potential physician-owner, continue to have questions about the structure of a particular POD arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.

To report suspected fraud involving physician-owned entities, contact the OIG Hotline at http://oig.hhs.gov/fraud/report-fraud/index.asp or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

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.

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 Statute (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

Document Created: May 2013

Subsequent Review Date(s):

Approver Name(s): Laura Kaiser

Effective Date: June 2013

Next Scheduled Review Date: May 2016

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.

Intermountain® Healthcare

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«Letter_Date»

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AND EMAIL IF AVAILABLE «COMPANY_EMAIL»**

«Company_Name»
«Company_Address»
«City», «ST» «Zip»

Re: Action Required: Intermountain Policy on Physician-Owned Entities

To Whom It May Concern:

As you may know, on March 26, 2013, the Office of Inspector General, U.S. Department of Health and Human Services (OIG) published a Fraud Alert entitled "Special Fraud Alert: Physician-Owned Entities." A copy is attached for your reference. The Fraud Alert addresses physician-owned entities that derive revenue from "selling, or arranging for the sale of, implantable medical devices" and "includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices, or instrumentation." The OIG refers to such entities as "PODs," but notes that the same principles would apply when evaluating arrangements involving other types of Physician-Owned Entities (POEs).

Prior guidance from the OIG on the subject of POEs had been equivocal, indicating only that such arrangements could potentially implicate the federal anti-kickback statute and should be evaluated based on the particular facts and circumstances. By contrast, the Fraud Alert suggests heightened concern about POEs, which the OIG describes as "inherently suspect under the anti-kickback statute."

In response, under the direction of Intermountain's President and CEO, Intermountain has adopted an updated policy regarding contracting with POEs. A copy of the policy is attached for your reference.

The basic thrust of the policy is quite simple: Intermountain will no longer contract with POEs and will discontinue purchases under existing contracts with POEs.

Under the policy, a POE includes any entity owned in any part by a physician or an immediate family member of a physician. There is no minimum percentage required to trigger the prohibition. "Ownership" can mean shares, partnership units, bonds and other forms of debt, or royalties based on purchases by the ordering physician.

We are writing you to reconfirm that «Company_Name» is not a POE under the policy's definition, as you have previously represented. «Company_Name» will qualify as a POE if it has any owner who is a physician, or whose immediate family member is a physician. Under the policy, "immediate family member" means 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.

Please take a moment to review the policy and, if «Company_Name» is not a POE, sign the attached attestation. Other than filling in information where denoted by a blank line, please do not modify the attestation. False or incomplete attestations will be taken seriously, and will be treated both as a breach of the purchase agreement between «Company_Name» and Intermountain and, depending on the facts, unprofessional conduct that may result in disciplinary action through the medical staff process. **If Intermountain does not receive a signed copy of the attached attestation prior to «Due_Date», Intermountain will initiate a process to terminate any further purchases from «Company_Name».**

If «Company_Name» is a POE, but you believe the prohibition should not apply as set forth in Provision 1 (no physician owner is in a position to generate business for Intermountain) or Provision 2 (disruptive technologies) of the policy, please contact Mr. Jeramy Green at (801) 442-3557 to discuss the procedures under the policy to allow purchases to continue.

We recognize that this Policy will change some existing arrangements, but believe that ultimately this is the right thing to do. We very much value «Company_Name»'s contribution over the years, and the contribution made by every supplier and physician at Intermountain in providing the care for which Intermountain is known.

If you have any questions about this letter or the policy, please contact Mr. Green at the number referenced above or me at (801) 442-1502.

Sincerely,

Suzie Draper
Vice President of Business Ethics and Compliance
Intermountain Healthcare

cc: Jeramy Green, Esq., Intermountain Healthcare

ATTESTATION AND COMPLIANCE CERTIFICATE

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

- I have read the Intermountain Policy entitled "Financial Arrangements with Physician-Owned Entities." I understand that it is my responsibility to read and understand the Policy or seek guidance should I require clarification about the standards and requirements set forth in the Policy.
- I hereby certify that Supplier does not meet the definition of a Physician-Owned Entity as described in the Policy.
- If at any time Supplier becomes a Physician-Owned Entity, I agree to report that change within five (5) working days to the Intermountain Healthcare Compliance Hotline at (800) 442-4845.
- 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 Intermountain, 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.

Company Name: _____
Signature: _____ Date: _____
Name: _____
Title: _____

Please return a signed copy electronically to brad.nokes@imail.org and the signed original to

Attn: Brad Nokes
Intermountain Healthcare
Central Office – Corporate Compliance
36 South State Street, Tenth floor
Salt Lake City, UT 84111-1486