California Orthopaedic Association

White Paper
Physician-Owned Distributorships

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There is increasing pressure from state and federal regulators and other payors on physicians to take an active role in managing the health care resources for their patients and reducing the overall health care costs.

Implantable devices and implants are a significant cost for patients undergoing joint replacement and/or spine surgeries—common surgical procedures for orthopaedic surgeons. These surgeries are expected to increase as our population ages and people want to continue more active lives.

Hospitals have not been very effective in negotiating better pricing with the device manufacturing and distribution companies to reduce the costs of these devices; thus, implant costs have remained at very high levels. A single pedicle screw, for instance, can cost over $1,000.

Orthopaedic surgeons in some communities are coming together in an effort to reduce these unsustainable costs. They are forming “Physician-Owned Distributorships” (PODs). The physicians involved form a distributorship that buys the implantable devices directly from the manufacturer, eliminating the middleman; thus, reducing costs. The POD then sells the devices. The resulting savings are shared between the POD investors and the hospital. In spite of these savings, PODs remain highly scrutinized. Conflicts of interest are inherently possible when physicians are both the distributor and the user of a product. Some hospitals have questioned the legality of these entities and have refused to participate in these programs. Some have even adopted policies that prohibit surgeons on their medical staff from participating.

PODs have a real potential to reduce implant costs and make the manufacturer more directly responsible to the surgeons and hospitals for the performance of their devices. One controversy is whether the POD is purchasing inferior implants just to save costs and potentially not selecting the device most appropriate for the patient. Many of these relationships negotiate an exclusive contract with a single manufacturer.

COA is currently working with the California Healthcare Foundation and the Pacific Business Group on Health to establish the California Joint Replacement Registry which will track patient outcomes and satisfaction for different implanted devices used during

joint replacement surgery. Hopefully we will have more outcome data in the next few years to help the surgeons make more informed choices.

While PODs present an opportunity for orthopaedic surgeons and hospitals to control implant costs, there is also the potential for abuse if the distributorship is not structured with the highest ethical standards and the goal of reducing implant costs. Orthopaedic surgeons need to understand that unless they ensure they are listed as "also insured" by the manufacturer, they may be exposing themselves to potential product liability which is not covered by medical malpractice insurance. There is also the potential for charges of self-referral violations if the arrangements are not properly structured. There are excellent healthcare attorneys with opinions on both sides of the question of whether or not these entities can be legally structured to avoid violation of Stark Self-Referral and Anti-Kickback statutes. Some PODs have contacted federal regulators for guidance and clearer regulation of the industry.

One approach to control implant cost is for hospitals to have preferred lists of implants. This allows the hospital to competitively negotiate better rates for implants directly with manufacturers, distributors, or a POD. While implant selection should always be a physician choice, physicians can involve patients in this decision. When a patient is scheduled for a joint replacement, the hospital can provide a selection of implants that would be suitable for their surgery. The hospital preferred or contracted implant, which may be provided by a manufacturer, a distributor, or a POD, would be included in the facility charge. If an alternative, more expensive implant, is chosen, the patient would potentially be responsible for paying the difference in cost of the higher priced components. Patient cost-sharing may not be permitted for some patients depending on their insurance coverage and physician rules of participation (e.g., Medicare or Workers' Compensation).

We are already seeing group health carriers implement a similar program to decrease hospital facility fees for CalPERS beneficiaries. Blue Cross and Blue Shield allow a contracted reimbursement amount for the facility fee component of a hip or knee replacement surgery. If the health facility charges higher fees, the patient is liable for the difference in costs. It would not be unexpected to see a similar policy on implant costs. In these arrangements, the patient would have access and be informed about all devices that would be appropriate and they would be involved in the decision-making process. COA believes that surgeons who choose to participate in a POD should consider this type of arrangement to increase transparency and they must be comfortable implanting all alternative devices available to the patient at the facility where the surgery will be performed. This will make the patient a more informed purchaser and let the market decide which implants are utilized.

COA supports the ethical, transparent, and value driven development of Physician Owned Distributorships (PODs) which would serve to leverage market forces to drive down the overall cost of healthcare.

The Physicians Alliance for Responsible Distributorships has developed the following suggested guidelines for PODs to ensure transparency and uniform ethical standards. COA encourages its members involved in PODs to adopt these model guidelines.

Physicians Alliance for Responsible Distributorships Model Guidelines

1. PODs shall show evidence of compliance with Federal Anti-Kickback and Self Referral laws. Mandatory adherence to these and other relevant federal statutes will ensure the operation of POD models that are ethical, transparent, and dedicated to patient safety. PODs must have on premises a formal opinion from a law firm with recognized experience in health care that has reviewed the structure and operational set-up of the POD and concludes that the POD complies with Federal Stark and Anti-kickback statutes.

2. PODs shall create cost savings and provide transparency in pricing. To ensure transparency around implant pricing and cost savings, PODs shall provide a product and price list to all market hospitals demonstrating quantifiable cost savings. Price lists shall demonstrate that there is no perceived incentive to refer to a particular hospital and POD pricing and agreements shall be validated in a fully transparent manner. Hospital/POD contracts shall allow for an independent annual audit.

3. PODs shall comply with American Association of Surgeon Distributors disclosure policies. In order to ensure full transparency to its patients and colleagues, PODs shall agree to the following:
    a. PODs shall provide all patients with a written disclosure about the surgeon's financial interest in the distributorship.
    b. POD ownership disclosure shall be visibly displayed in all relevant physician office space.
    c. All contracted hospitals must be informed, in writing, that the distributorship has surgeon ownership.
    d. Colleagues within the relevant departments of all hospitals where physician owners have practice privileges must be informed that the distributorship has surgeon ownership.

4. PODs shall obtain utilization data annually and shall be subject to audit by an independent third party. In order to ensure ethical operation, physician investors must obtain and review clinical practice data for the 12 months preceding the start of the distributorship and annually thereafter. This utilization data must cover all products distributed and must include total patient visits as a measure of practice activity. Where there is the potential to use or not use instrumentation, such as lumbar spine surgery, the POD shall obtain implant and non-implant data.

5. PODs shall not leverage referrals to any hospital or surgery center. In order to ensure ethical operation, PODs will provide written attestation from their hospital on an annual basis that there was not any instance whereby the distributorship leveraged referrals inappropriately to gain favor in the contract.

6. PODs shall be a legitimate, free standing stocking Distribution Company. In order to ensure legitimate operation and business risk, PODs must include employees, hospital, vendor and employment contracts, a verifiable address, business license, reasonable inventory, and proper insurance. A POD shall not be a "shell business" with significantly outsourced operations, personnel, and management.

7. PODs shall not discriminate against Federal health care program beneficiaries. PODs shall not specifically exclude providing implants to a payor type, such as Medicare, Medicaid, or private insurance.

8. PODs shall adhere to an agreed upon product evaluation policy. In order to ensure patient safety, a documented product evaluation policy shall be implemented to ensure that PODs evaluate the

quality of an implant before its use. A product evaluation policy may include the following provisions:

a. Surgeons shall define their design criteria and identify companies that produce products that meet those criteria.
b. Surgeons shall inspect and review the implants and all related instruments.
c. Surgeons shall review relevant testing data and U.S. Food and Drug Administration clearance documents.

9. PODs shall adhere to agreed upon product representative training requirements. In order to ensure patient safety and legal/ethical compliance, PODs shall develop and document stringent product representative training requirements. This may include, but is not limited to:
    a. Training in sterilization technique;
    b. Training on each product from the medical device company;
    c. Rigorous company compliance training;
    d. Training in Health Insurance Portability and Accountability Act compliance; and
    e. Training on the AdvaMed Code of Ethics and Compliance.

10. When and if made available by the U.S. government, Medical Device Distributorships, including all PODs shall register with the federal government and be subject to audit and federal registration fees. The U.S. Department of Health and Human Services shall consider requiring all medical device distributorships, including PODs, to publicly register with the Department, or other federal oversight agency (such as the U.S. Food and Drug Administration), in order to maximize public transparency. This requirement shall extend to all distributorships regardless of payer. All hospitals shall require such registration for all distributorships doing business with them. This registration process should also consider an annual registration fee to enable the Department to self fund necessary oversight functions.

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