

**Alliance Surgical Distributors, LLC**

March 10, 2014

**VIA ELECTRONIC FILING**

Mr. Donald S. Clark  
Secretary  
Federal Trad Commission  
600 Pennsylvania Avenue, NW Room H-113, (Annex X)  
Washington, DC 20580

*Re: Health Care Workshop Project No. P131207*

Dear Mr. Clark,

Alliance Surgical Distributors, the United States most experienced organizer and operator of accredited physician owned medical device distributorships, and dedicated to promoting competition and cost effectiveness in the field of medical device distribution, is pleased to submit these comments to the Federal Trade Commission in response to the agency's request for comments on issues raised in the Federal Register, Vol 79 Issue 26, with regard to the Federal Trade Commission's Announcement of Public Workshop "Examining Health Care Competition.

Background: Emergence of Physician Owned Medical Device Distribution

The cost of orthopedic medical devices has become a topic of great interest. Between 1991 and 2006, while orthopedic implant list prices increased 171%, hospitals experienced only a 19% corresponding increase in reimbursement. This has placed the profitability of many orthopedic service lines in jeopardy. Since 2006, prices have stabilized to single digit increases, but true cost reduction has been elusive due to the absence of effective competition and market forces.

Orthopedic implant choice is most often driven by surgeon preference. Once the surgeon identifies the preferred implant system for the patient, the hospital must arrange that implant to be brought into the hospital on a case by case basis. Because each surgeon may choose an implant system manufactured by a different company, it is not practical nor cost manageable to purchase inventory in advance to support the wide range of surgeon preferences. This results in a disconnect between the decision maker and the purchaser, with resulting high medical device costs.

An August 2013 New York Times article "In Need of a New Hip but Priced Out of the U.S." highlights an amazing fact: five companies maintain a near monopoly on total joint replacements resulting in suppressed competition and no price transparency:

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*“The thousands of hospitals and clinics that purchase implants try to bargain for deep discounts from manufacturers, but they have limited leverage since each buys a relatively small quantity from any one company. In addition, device makers typically require doctors’ groups and hospitals to sign nondisclosure agreements about prices, which means institutions do not know what their competitors are paying.”*

*“The basic design of artificial joints has not changed for decades. But increased volume — about **one million knee and hip replacements are performed in the United States annually** — and competition have not lowered prices, as would typically happen with products like clothes or cars.”* ([http://www.nytimes.com/2013/08/04/health/for-medical-tourists-simple-math.html?\\_r=0](http://www.nytimes.com/2013/08/04/health/for-medical-tourists-simple-math.html?_r=0))

The opportunity to insert efficiency and market forces into medical device delivery was the stimulus for our physician owned medical device distribution model. This model is based on placing the surgeon who is most knowledgeable of implant features and the decision maker, in the position of purchaser and manager of distribution functions. The physician also bears the responsibility for the patient outcome.

Appropriately structured physician owned distributorships adhere to strict processes and standards for transparency / full disclosure to hospitals and patients, cost savings, patient outcomes, utilization monitoring, product quality assurance and strict legal compliance. The American Association of Surgeon Distributorships an accrediting body that has developed these standards following the example of other healthcare accrediting bodies such as the Accreditation Association of Ambulatory Healthcare (AAAHC).

Our accredited physician owned distributorships purchase directly from contract manufacturers, assume the financial risk of inventory, and reduce sales force costs. These actions result in cost savings that are, in large part, passed directly to the hospital in the form of reduced prices per implant.

### **□ To what extent are health care services being delivered in new formats and locations, such as retail clinics? What trends are projected in the future?**

One new format or model for health care delivery that establishes physician/hospital alignment resulting in more effective competition is physician owned medical device distributorships.

An October 2013 OIG Report “Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use” found that nearly one in five spinal implants for Medicare beneficiaries was supplied by a physician owned distributorship. The report further identified spinal surgeries using devices from PODs occurred in 35 U.S. states, suggesting a broad national penetration of the model.

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The American Association of Surgeon Distributors (AASD) confirms accredited distributorships in eight states. AASD accredits distributorships supplying total joint implants, orthopedic implants for trauma, as well as spinal implants.

### □ **What are the competitive implications of the increased use of retail clinics on the supply of services, cost, quality, and access to care?**

Accredited physician owned medical device distributorships (ePODs), which are properly structured physician owned distributorships, provide cost savings to payers that have been unavailable through other means, and inserts true competition into a market that has lacked price competition. ePODs achieve cost savings on the products supplied, create price pressure on other suppliers, while providing recognized quality products that advance patient health.

Accredited physician owned distributorships succeed by harnessing the expertise of the most knowledgeable evaluator of implants, the surgeon, and directing that expertise into economies of scale and efficiency. The surgeon is in the ideal position to appropriately value technologies and bears the responsibility of the patient outcome. By purchasing directly from contract manufacturers, assuming the financial risk of inventory, and reducing sales force costs, the physician owners eliminate the multiple and costly layers of sales and marketing embedded in traditional distributorships. These actions result in cost savings that are, in large part, passed directly to the hospital in the form of reduced prices per implant, ultimately reducing the costs to insurance carriers and payers.

Proof of the competitive effect of this model can be found in an October 4, 2012, Wall Street Journal Market Watch reported on spinal implant company NuVasive, which experienced declining share price due to the emergence of small company competitors and physician distributors. The article stated: “About half of the sales decline is driven by the increasing market share of PODs, which the company estimated now controls 15% of the U.S. market, up from 10% last year.”

(<http://www.marketwatch.com/story/nuvasive-shares-plunge-as-customers-defect-2012-10-04>)

A similar report by Mizuho Securities USA Healthcare Research Medical Supplies and Devices Industry Update, November 14, 2012, stated “Our checks indicate that physician owned (device) entities (POEs) do sell to hospitals at lower prices than their competitors.” The report went on to identify that if the OIG did not condemn all POEs, it would be “negative for the public spine companies since it would allow POEs to continue to grow and take share at their expense.”

The October 2013 OIG report noted that surgeons using devices supplied by physician owned distributorships implanted fewer devices than surgeons using devices supplied by traditional manufacturer distributorships. A report by the American Association of Surgeon Distributors demonstrates that in a study of AASD accredited physician owned distributorships the **cost savings exceeded 30 percent**.

The potential impact of expanding the accredited physician owned device model is dramatic and significant. It is truly one of the few delivery systems that create real dollar savings without reducing service, staff or access.

The 2010-2011 Orthopaedic Industry Annual Report (OrthoWorld 2011) cited total United States orthopedic product sales of \$23.7 billion, with total joint reconstruction sales at \$7.3 billion. The escalation in total joint implant price over the 14-year period from 1994 through 2006 was reported to be 171% (an average of 13% a year) (Healy 2006). Physician owned medical device distributorships have shown the ability to save 36% the first year and to keep annual escalations at or below 1.0%.

([https://www.orthoworld.com/index.php/products/oiar\\_archive](https://www.orthoworld.com/index.php/products/oiar_archive) - membership required)

The report “Surgeon Ownership in Medical Device Distribution: An analysis of cost savings” (<http://www.aasdonline.org/HOME.aspx>) calculated that over the next 20 years, the accredited physician owned distributorship model has the potential to save the U.S. healthcare system more than \$734 billion dollars (report attached as an addendum).

Payments made to hospitals for total joint arthroplasties are not enough to keep up with inflation (Scott and others 2009), causing concern for the financial feasibility of total joint procedures. With fewer surgeons to provide total joint procedures (Fehring 2010) and the economic disincentive for hospitals to provide total joint reconstruction services, continued access to these valuable surgical procedures will be threatened, particularly for seniors who represent the majority of total joint reconstruction patients. This threat to access further intensifies the need for significant change in the methods in which these products are sourced, acquired and paid for in the immediate and long-term future.

**□ Are there regulatory or commercial barriers that may restrict the use of retail clinics, telemedicine, or other new models of health care delivery? If so, are there any valid justifications to support such restrictions?**

Preserving access to quality care at a fair price is a critical goal of the U.S. healthcare system. Regulatory and commercial barriers exist to many innovative models seeking to introduce meaningful and effective competition.

As the primary driver of access and quality, hospitals and physicians are uniquely positioned to find solutions. Physician owned medical device distributorships represent such a solution – again only when these entities follow processes and standards that ensure lower costs and protect all parties.

Ventures with physician ownership that provide products or services to Federally sponsored beneficiaries are subject to Federal Self-Referral and Anti-Kickback laws. The Anti-Kickback Statute lacks clarity when applied to physician owned distributorships, creating concern for payers interested in doing business with this delivery model. Inspector General Daniel Levinson, highlighted this challenge in his September 13, 2011 interim response to the Senate Finance Committee’s inquiry on Physician Owned Distributorships. “The Federal Anti-Kickback Statute is a criminal, intent-based statute that plays a central role in addressing improprieties in physician-industry relationships. The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity’s particular characteristics,

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including the details of its legal structure; its operational safeguards, and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. For these reasons, the OIG's ability to issue guidance about the application of the statute to these business structures is limited."

We look for endorsement of the standards of the American Association of Surgeon Distributors to bring forth the benefits of competition to the medical device sector of healthcare while ensuring patient safety and product quality.

### **□ How do professional regulations affect telemedicine or other innovations in delivering health care services or expertise across geographic areas or jurisdictional boundaries, especially in rural or underserved areas?**

Other than Federal Self-Referral and Anti-Kickback regulations targeted at physician ownership, physicians are regulated by State business and professions codes as well as licensing regulations. These professional regulations are less likely to be restricted to Federal payers, and therefore include Workers' Compensation and commercial insurance payers. Because physician owned medical device distribution is a new and emerging model, current professional regulations do not specifically address the characteristics of the model. Unlike Safe Harbor Regulations which generally do not apply to these payers, widespread adoption of accreditation standards for physician owned distributorships would address the ambiguity of professional regulations with regard to physician owned medical device distributorships.

The ambiguity of current regulations restrains hospitals and other payers from doing business with PODs. Hospitals in metropolitan and suburban areas benefit from sufficient volume to create some economies of scale when purchasing medical devices. Rural hospitals, however, do not have that benefit. The recent cost study available through the American Association of Surgeon Distributors identified that the physician distributorships that produced the highest percentage of savings supplied medical devices to rural hospitals.

As a stocking distributorship, even a small-volume physician owned model purchases in greater economies of scale than the hospital. With adoption of accrediting standards, this model offers a true opportunity for competition and lower prices where almost no competition would otherwise exist.

### **□ What, if any, changes in government regulations would facilitate the emergence of new health care delivery models, enhance competition among health care providers, and encourage additional innovation?**

Revision of the Federal Stark and Anti-kickback statutes that allow closer alignment of healthcare providers to their innovations would bring true market forces, and healthy competition, to the healthcare sector. This is an ambitious but worthy goal.

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For specific sectors, healthcare can benefit from changes in targeted regulation. Ambulatory surgery centers are a good example of an innovation that significantly changed the health care delivery, despite challenges from business enterprise that profited from the status quo. Ambulatory surgery centers succeeded because they offered a solution that was truly valuable. Ultimately, the mature model of ambulatory surgery centers that we recognize today was facilitated by Safe Harbor regulation and the advancement of ambulatory surgery center accrediting organizations that validated quality and compliance. The American Association of Surgeon Distributors is the only body trying to achieve the same thing for PODs.

Safe Harbor regulation specifically for physician owned medical device distributorship would foster much-needed price competition in the medical device industry while providing clear guidelines to protect against fraud and abuse. In the absence of Safe Harbor regulation, the widespread adoption of a recognized set of standards for quality and conduct for physician owned medical device distributorships will assure that POD models provide the cost savings, quality, full disclosure and patient protection benefits that are currently only assured by models accredited by the AASD.

Thank you for the opportunity to provide comments on this matter.

Sincerely,

*Angela Carlson*  
President