

TO: MSSNY's Officers, Councilors and Trustees

FROM: MSSNY Legislative & Physician Advocacy Committee

DATE: November 7, 2019

RE: Resolution 122 – 2019 House of Delegates
Introduced by Dr. Michael Brisman, Nassau County Delegate

The following resolution was referred to the Council by the House of Delegates. The resolution was forwarded to the Legislative and Physician Advocacy Committee for further study and recommendation for the Council's consideration.

RESOLVED, that the Medical Society the State of New York develop policy that supports Physician Owned Distributorships (POD's), when the following criteria are met: (1) the POD is disclosed to the hospital and patient; (2) the overall cost to the hospital and patient is no higher with the POD than it would be through a traditional vendor; (3) standards of care are strictly met and be it further

RESOLVED, that the Medical Society the State of New York advocate that the AMA also support Physician Owned Distributorships (POD's), when the following criteria are met: (1) the POD is disclosed to the hospital and patient; (2) the overall cost to the hospital and patient is no higher with the POD than it would be through a traditional vendor; (3) standards of care are strictly met.

At the House of Delegates, the reference committee heard split testimony on this resolution. Many physicians were concerned about the possibility of misuse and overuse and a perception of conflict of interest. However, other physicians noted that laws should not constrict the ability for a physician to seek economic gain where appropriate. Furthermore, some physicians expressed that POD's can function to bring about better value of care.

POD's have been under increasing scrutiny by federal regulators because of the inherent possibility for conflicts of interest. Some studies have determined that certain surgeries for hospitals purchasing medical devices from PODs increased significantly faster than for hospitals overall. The HHS OIG has also reported that PODs may be driving up healthcare costs due to overutilization and that surgeries that use POD devices were more expensive than non-POD surgeries. It is quite possible that PODs will be further targeted by lawmakers and regulators as Chairman Grassley and Ranking Member Wyden on the US Senate Judiciary Committee recently sent a letter to the HHS OIG asking them to look into PODs and their reporting related to the Physician Payment Sunshine Act.

Further, the AMA has policy (9.6.4 - Sale of Health-Related Products) that states the following:
"The sale of health-related products by physicians can offer convenience for patients, but can also pose ethical challenges. "Health-related products" are any products other than prescription items that, according to the manufacturer or distributor, benefit health. "Selling" refers to dispensing items from the physician's office or website in exchange for money or endorsing a product that the patient may order or purchase elsewhere that results in remuneration for the physician.

Physician sale of health-related products raises ethical concerns about financial conflict of interest, risks placing undue pressure on the patient, threatens to erode patient trust, undermine the primary obligation of physicians to serve the interests of their patients before their own, and demean the profession of medicine.

Physicians who choose to sell health-related products from their offices or through their office website or other online venues have ethical obligations to:

(a) Offer only products whose claims of benefit are based on peer-reviewed literature or other sources of scientific review of efficacy that are unbiased, sound, systematic, and reliable. Physicians should not offer products whose claims to benefit lack scientific validity.

(b) Address conflict of interest and possible exploitation of patients by:

- 1. Fully disclosing the nature of their financial interest in the sale of the product(s), either in person or through written notification, and informing patients of the availability of the product or other equivalent products elsewhere.*
- 2. Limiting sales to products that serve immediate and pressing needs of their patients (e.g., to avoid requiring a patient on crutches to travel to a local pharmacy to purchase the product). Distributing products free of charge or at cost makes products readily available and helps to eliminate the elements of personal gain and financial conflict of interest that may interfere, or appear to interfere with the physician's independent medical judgment.*

(c) Provide information about the risks, benefits, and limits of scientific knowledge regarding the products in language that is understandable to patients.

(d) Avoid exclusive distributorship arrangements that make the products available only through physician offices. Physicians should encourage manufacturers to make products widely accessible to patients.

Finally, Section 238-A of New York's Public Health Law sets forth restrictions on self-referrals which could conflict with the legality of PODs.

The reference committee understood that the complexities of the healthcare industry have created differing models by which physicians operate to develop efficiencies and work toward profitable operations. However, due to the possibility of further legal, legislative or regulatory action on this topic, it was referred to the MSSNY Council for further research and debate. During the September 11 Legislative & Physician Advocacy Committee meeting, there was discussion that the goal of the resolution is valid, as long as PODs are operated in an ethical and legal manner. However, concern was expressed regarding MSSNY's expertise to set forth specific criteria for the operation of such POD. Those points were reiterated during the October 17 meeting of the Committee. Therefore, the Committee recommended that MSSNY endorse the concept of a POD, provided it is operated consistent with ethical principles, such as those that have developed pursuant to the AMA's Code of Ethics, and assuring that those who contract with a POD are fully aware of the physician's financial stake in that entity.

RECOMMENDATION: That the MSSNY Legislative & Physician Advocacy Committee recommend that the MSSNY Council adopt the following resolution in lieu of the original resolution:

RESOLVED, that the Medical Society the State of New York support the concept of Physician Owned Distributorships (PODs), provided that they are operated consistently with generally accepted principles of physician ethical conduct (such as the AMA Code of Medical Ethics), including assuring that patients and other potential contractors are sufficiently notified of the physician's financial interest in such POD.