



Vistas: A View from the High Ground

Physician Owned Distributorships – Part II (part one was our March 27, 2013 edition – email if you would like a copy)

An Editorial from High Ground Medical, Inc.

PODs (Physician Owned Distributorships). One estimate suggested there were as many as 500 PODs operating in the US. The theory behind the POD is that the surgeon can negotiate a better price from the company and thereby pass the savings onto the hospital. The Senate Finance Committee has returned with a list of recommendations after reviewing the POD issue.

Regardless of how you individually feel about the concept you need to read the recommendations from the Senate Report:

“FINDING 1: LACK OF TRANSPARENCY Federal law does not currently require disclosure of physician ownership directly to hospitals or patients. Hospitals and patients furthermore face many challenges identifying if physicians have a financial relationship with PODs. Overall, PODs operate in a very opaque environment and some PODs have taken steps to conceal their financial relationships.

Recommendation 1: Federal law should require physicians to disclose any ownership that they or their family members have in non-publicly traded device companies to the hospitals where they practice, and should also require disclosure to patients. Patients should also be notified and instructed of the implications and risks associated with physician ownership in device companies specifically including the risks of unnecessary procedures and patient harm.

Recommendation 2: CMS should require hospitals and ambulatory surgical centers to examine the Open Payments data collected under the Sunshine Act, and document that they have taken such data into account when making device purchasing decisions.

Recommendation 3: CMS and HHS OIG should examine whether current compliance guidance about PODs is sufficient, or if it should be supplemented in response to changes in the industry. In particular, consideration should be given to amending the HHS OIG compliance guidance for hospitals to recommend that hospitals adopt policies that would restrict dealing with PODs to circumstances that avoid any of the suspect characteristics identified in the OIG HHS SFA.

FINDING 2: PODS RESULT IN OVERUTILIZATION When hospitals purchase products from PODs, the number of surgeries goes up, suggesting that some of the surgeries performed are medically unnecessary or overly complex.

Recommendation 1: GAO should examine the costs and benefits of CMS requiring hospitals that choose to purchase from PODs to perform enhanced quality assurance and utilization review activities in connection with surgeries using POD-supplied products.

FINDING 3: POD ILLEGAL BEHAVIOR The business structure and payments associated with certain PODs have been found to be illegal. Furthermore, overt or implied threats made by



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physicians to move their practice unless a hospital accepts their POD would likely violate fraud and abuse laws.

Recommendation 1: Law enforcement should continue and expand their efforts to charge and prosecute those doctors, PODs, and hospitals that violate the law.

FINDING 4: HOSPITAL POLICIES Many large hospitals and hospital systems have adopted policies to govern their relationships with PODs. However, many small hospitals do not have a POD-specific policy governing their interactions with PODs, and as a result PODs are migrating from large hospitals to small hospitals.

Recommendation 1: All hospitals should establish their own hospital-specific policies to manage their relationship with PODs consistent with the OIG HHS SFA and any further guidance to be promulgated by OIG under Finding 1/Recommendation 3. Hospitals should draft comprehensive policies to address PODs and should rigorously enforce them. CMS should establish a date whereby all hospitals must implement POD policies, and non-compliant hospitals should not be reimbursed for surgeries involving POD supplied devices until they have developed and implemented a POD-specific policy.

FINDING 5: PODS' CHANGING PAYMENT STRUCTURES PODs have shifted to alternative payment structures in an attempt to circumvent the AKS and the Sunshine Act. Some PODs are declaring physicians to be employees rather than investors and having companies make payments to physicians under the name of a family member or friend.

Recommendation 1: CMS should undertake increased enforcement actions to ensure compliance with Sunshine Act reporting requirements. CMS and Congress should examine the benefit of increased penalties for intentional violations of the Sunshine Act. HHS OIG and law enforcement should investigate potential violations of the Stark Law and the AKS.

Recommendation 2: HHS OIG should study the impact of the SFA and recent litigation on PODs and update its 2013 report and SFA as needed. In particular, HHS OIG should consider whether the list of suspect POD characteristics in the SFA should be revised or expanded to account for developments since the SFA's issuance.

Recommendation 3: CMS should provide additional Sunshine Act guidance or rulemaking to make clear that the exception from reporting requirements for employment applies only to manufacturers (not GPOs), and only to bona fide employment, including standards that would preclude sham "employment" relationships from qualifying."