

## **QUALITY IMPLANT COALITION BACKGROUNDER**

### **Key Issues Concerning PODs Under the Federal Sunshine Law**

The final regulation implementing Section 6002 of the Affordable Care Act (Section 1128G of the Social Security Act), published in the Federal Register on February 8, 2013, includes provisions setting forth requirements for reporting on physician ownership and investment interests in Applicable Manufacturers (herein, AMs) (of drugs, medical devices, biologicals and medical supplies) (herein, Covered Products) and Applicable Group Purchasing Organizations (herein, AGPOs). These provisions will be codified largely at 42 C.F.R. § 403.906 (definitions at 403.902).

In general, the regulation tracks the statute in requiring AMs and AGPOs to annually report direct or indirect ownership and investment interests held by physicians and their immediate family members. These reports are in addition to those for payments and other transfers of value made to physicians under § 403.904 of the regulations.

**The regulatory preamble specifically notes on several occasions that physician-owned distributors of Covered Products (including implantable medical devices) (PODs) are AMs if they take title (buy-and-resell or “stocking distributor” PODs). All other POD models are AGPOs under the new law, whether they purchase product or negotiate prices/arrange for purchase in exchange for commissions or administrative fees. (78 Fed. Reg. 9458, 9493, 9461-62 (Feb. 8, 2013))** The preamble goes on to state that CMS “intend[s] for [the definition of AGPO] to capture as many PODs as possible, while still aligning with the statutory language.” (78 Fed. Reg. at 9493) Accordingly, when the obligation to collect data on payments and ownership interests takes effect (August 1, 2013), all PODs will be obliged to collect this information and report annually on the full extent of their financial relationships with owner physicians, and PODs that are AMs will be obligated to report not only financial relationships with owner physicians, but also payments or transfers of value to all physicians whether or not the physicians have ownership interests.

A few key points about the obligation of PODs to report under Sunshine follow:

1. **Ownership or Investment Interest:** Broadly defined to include stock, stock options (except when paid as compensation till exercised), partnership and LLC interests, loans secured with property or revenue (42 C.F.R. § 403.902).
  - a. Such interests must be reported if held by physicians or immediate family members even if such persons are employees of the AM or AGPO (78 Fed. Reg. at 9493).
2. **Exclusions from Reporting:** No ownership reporting is required for
  - a. Ownership of publicly-traded securities
  - b. Stock options received as compensation until exercised (these must however be reported as compensation to the physician owners)
  - c. Ownership/investment that the reporting entity does not “know” about (“knowledge” is defined to include deliberate ignorance or reckless disregard)
  - d. Ownership/investment through an employee retirement plan and unsecured loans to credit facilities (§ 403.902).
3. **Covered Product.** All drugs and biologicals requiring a prescription, all medical devices requiring FDA premarket approval or notification (including most IDE investigational devices), and all medical supplies, in each case for which payment is available under Medicare, Medicaid or SCHIP, including bundled and composite payments such as MS-DRGs and APCs under Medicare’s inpatient and outpatient hospital prospective payment systems (§ 403.902). Excludes components and raw materials.

4. Applicable Manufacturers: Broadly defined as any US-operating entity engaged in production, preparation, propagation, compounding or conversion of a Covered Product
  - a. Excludes distributors or wholesalers that do not hold title to the Covered Product (§ 403.902); but
  - b. Preamble expressly includes distributors or wholesalers that do take title to the Covered Product (78 Fed. Reg. at 9461-62);
5. All Buy-and-Resell PODs are AMs. Accordingly, all buy-and-resell or “stocking distributor” PODs are AMs, obligated to report not only ownership interests under § 403.905, but payments and other transfers of value to any physician regardless of ownership interest as well as ownership interests under § 403.904.
6. Applicable GPOs: Broadly defined as any US-operating entity that purchases, or arranges for or negotiates the purchase of, a Covered Product for a group of individuals or entities (§ 403.902).
  - a. CMS obviously chose deliberately to adopt a definition that, consistent with the Sunshine statute, is broader than that of the anti-kickback law exception or safe harbor for GPO payments; the antikickback law definition requires the GPO to act as the “purchasing agent” for the GPO members.
    - i. A broader definition of AGPO in Sunshine represents a sensible policy choice by Congress and CMS:
      1. the purpose of the GPO safe harbor is to authorize the well-established business practice of manufacturers making sales-based payments to GPOs to support the work of GPOs for their members without violating the antikickback law;
      2. in contrast, Congress and CMS included a broad definition of GPO in Sunshine to include all forms of PODs in particular to make transparent potential conflicts of interest
      3. Accordingly, the broad Sunshine definition of AGPO includes any POD that “arranges for or negotiates purchase . . . for a group of individuals or entities,” including the POD-owner physicians as well as any implant purchasers that buy from non-AM PODs. (Emphasis added)
        - a. Does not require holding title to the product as necessary element of being an AGPO: PODs that are not already obligated to report as AMs are AGPOs and must report if they purchase product and/or if they receive commissions or admin fees.
        - b. Does not require that the purchase be made by the “group” of individuals that the AGPO is acting “for.”
        - c. Does not require the entity act as an “agent” of a purchaser,
7. All PODs are AGPOs. Since all PODs either “purchase” and resell, or “arrange for or negotiate the purchase” of, Covered Products, all PODs that have more than one physician owner are AGPOs, because each such POD is acting “for a group of individuals” (i.e. the physician owners) to “arrange for or negotiate the purchase” of implants that those individuals have ordered, or requested or required a hospital or other buyer to purchase through their POD. Likewise, all non-AM PODs that have more than one customer are purchasing for a group of entities.
8. Reporting of Payments.
  - a. PODs that are AMs – all buy-and-resell PODs-- must report all payments or other transfers of value to any physicians (§ 403.904), as well as ownership or investment interests (§ 403.905).
  - b. Non-AM PODs that are AGPOs – all PODs that (i) have more than one physician owner but do not take title or (ii) sell to more than one customer, e.g., a hospital and its affiliated ASC -- must report ownership and investment interests, and all other payments and other transfers of value made to any physician owners (§ 403.906(b)(6)).

- i. PODs that are AGPOs but not AMs are exempt only from the need to report payments to physicians who are not owners (78 Fed. Reg. at 9493).

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