

Recommended Improvements to the U.S. Physician Payments Sunshine Act

1. Adopt new payment categories to enhance the accuracy of data disclosed under the Sunshine Act and to provide greater clarity for the public and patients.

- a. *Equipment Evaluation/Loan* – The Sunshine Act requires manufacturers to disclose capital equipment evaluations that extend beyond 90 days; however, neither the statute nor the regulations provide a nature of payment category that squarely fits these legitimate arrangements.
- b. *Debt Forgiveness* – CMS requires a manufacturer to disclose instances in which it has forgiven unpaid debts from customers who have defaulted on payments. No payment category other than “Gift” could apply to these payments, despite a debt write-off being a legitimate business transaction in any commercial operation. Requiring manufacturers to disclose these arrangements as “Gifts” is misleading and sends the wrong message about the manufacturer and the covered recipient to the public and to patients, especially as AdvaMed and the medical technology industry have banned “gifts” under the AdvaMed Code.
- c. *Acquisition Payments* – In the course of a corporate transaction in which a manufacturer purchases an innovator or start-up company, a manufacturer may be required to pay a physician owner for his/her shares in the small company in order to complete the transaction. There is no applicable category – other than “Gift” – under which to disclose these payments. Again, requiring disclosure of these legitimate payments as “Gifts” is misleading.
- d. *Other* – There may be occasional instances in which none of the payment categories accurately describes a payment or transfer of value, leaving companies to make a “best guess” or use the category that most closely approximates the transaction. AdvaMed recommends the addition of an “Other” or “Miscellaneous” category that would require manufacturers to include a free-text description of each payment the manufacturer intends to disclose under such category.

2. Fix the PODs loophole and require all PODs to report under the Sunshine Act.

- a. PODs – or physician-owned distributors – are defined as “GPOs” under the Sunshine Act regulations. GPOs, in turn, are defined as entities that sell to multiple hospitals. Most PODs, however, only sell to one hospital. Accordingly, many PODs consider themselves to be exempt from Sunshine Act reporting.
- b. AdvaMed encourages Congress to fill this “PODs loophole” by explicitly requiring all PODs to report under the Sunshine Act, not just those that sell to multiple hospitals.

3. Clarify requirements for reporting ownership interests in a privately held company.

- a. The Sunshine Act requires privately held entities to disclose physician ownership interests. This includes disclosing the “terms” of such ownership interest. CMS interprets this to mean simply disclosing whether the physician owns stock, a stock option, a partnership interest, etc. These are not the “terms” of ownership: these are the type of ownership.
- b. Requiring disclosure of the actual terms of ownership will help the government identify illicit PODs and distinguish PODs from legitimate manufacturers that may simply have a physician owner. Specifically,

to provide greater information to the public and patients, a more robust disclosure of the “terms” of physician ownership would include the duration of ownership; the ability of the physician owner to earn any commissions or other sales-related payments; whether ownership is contingent upon the physician undertaking any sales or marketing role for the company; whether the physician can earn a commission on procedures that he/she performs; and the like.

- c. These “terms” are reflective of the suspect characteristics of PODs identified by the OIG in its 2013 Special Fraud Alert.

4. Add better context to the Open Payments website that explains why manufacturers interact with physicians and teaching hospitals, describes industry codes of ethics, and highlights the importance of collaboration to develop innovative technologies and to provide high quality patient care.

- a. The Open Payments website currently includes some background information on industry-physician relationships; but, additional context is necessary to ensure that the legislative intent of the Open Payments Program is met without discouraging beneficial interactions that are critical to the development of and safe and effective use of medical technologies.
- b. For example, the Open Payments website should refer to the medical technology industry’s efforts to create effective compliance programs and to develop a workable and practical Code of Ethics that limits how companies can engage with physicians and teaching hospitals.

5. Provide clear guidance on the use of the Open Payments List of Teaching Hospitals and a comprehensive list of teaching hospitals, identified by their Tax Identification Number.

- a. When a manufacturer interacts with a hospital or a component of a hospital, it is frequently difficult to identify which covered recipient should be included on the Sunshine Act disclosure.
- b. AdvaMed’s members have experienced several issues, including teaching hospitals requesting that manufacturers make payments to alternative branches of an institution or foundation to prevent the disclosure of the payment under Sunshine; teaching hospitals using D/B/A names so that correlation to the published list of teaching hospitals is difficult or impossible; teaching hospitals using multiple Tax Identification Numbers; and teaching hospitals with fluid corporate structures making it difficult to identify the appropriate covered recipient to be reported.
- c. Accordingly, CMS should publish a more comprehensive list of all Teaching Hospital covered recipients and their component organizations to ensure accurate and comprehensive reporting.

6. Clarify the preemption language under the Sunshine Act.

- a. While the Sunshine Act includes federal preemption language to help ensure consistent reporting requirements and consistent data, some states have continued to issue industry transparency requirements and/or to modify their existing requirement to require continued reporting from manufacturers.
- b. AdvaMed recommends that CMS consider adopting stronger, clearer preemption language that would prohibit states from creating any separate transparency reporting obligations or modifying existing ones.