



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



APR 16 2019

The Honorable Charles E. Grassley  
Chairman, Committee on Finance  
United States Senate  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member, Committee on Finance  
United States Senate  
Washington, DC 20510

Dear Mr. Chairman and Mr. Ranking Member:

I am writing in response to your March 19, 2019, letter to Administrator Verma and me in which you expressed concerns that some physician-owned distributorships (PODs) may be failing to disclose physician ownership or investment interests as required by the Physician Payment Sunshine Act. The integrity of Federal healthcare programs is of the utmost importance to OIG, and we are committed to taking actions, either enforcement or administrative, when appropriate. In your letter, you asked us to respond to several questions with a stated goal of ensuring that all PODs report physician ownership or investment interests. OIG's responses to your questions are enclosed.

My staff has spoken with the Centers for Medicare & Medicaid Services (CMS), and we have indicated where CMS will respond directly to specific questions. If you have any questions, please call me at (202) 619-3148, or your staff may contact Christopher Seagle, Director of Congressional Affairs, at (202) 260-7006 or [Christopher.Seagle@oig.hhs.gov](mailto:Christopher.Seagle@oig.hhs.gov).

Sincerely,

*Daniel R. Levinson*  
Daniel R. Levinson  
Inspector General

Enclosure

**Answers to the Five Questions Chairman Grassley and Ranking Member Wyden Asked  
of U.S. Department of Health and Human Services Inspector General  
Daniel R. Levinson In Correspondence Dated March 19, 2019**

**Question 1: In 2015, HHS OIG issued a memorandum titled, “Overlap Between Physician-Owned Hospitals and Physician Owned Distributorships.” In this memorandum, HHS OIG described plans to monitor CMS’s Sunshine Act database and determine how best to assess its impact on transparency within Medicare.**

- a. Has HHS OIG conducted a detailed review and audit of the CMS sunshine database to determine whether PODs are reporting physician ownership or investment interest? If so, please provide these to the Committee.**

**Answer:** OIG has not conducted a review of CMS’s Sunshine Act database to determine whether PODs are reporting physician ownership or investment interests. OIG would be happy to further discuss your interest in this area to inform potential future work.

- b. Please describe the steps that HHS OIG has taken, or plans to take, to ensure the quality of data reported under the Sunshine Act relating to PODs.**

**Answer:** Although OIG has not conducted specific work reviewing Open Payments data related to PODs, we did publish a report in August 2018<sup>1</sup> that determined the extent to which data published on the Open Payments website were missing elements, or were inaccurate or inconsistent.

Although the scope of this work did not include determining whether all providers who should be reporting to the Open Payments database are doing so, we did find that almost all the 2015 data reported in the Open Payments program met requirements. However, we identified several areas where CMS could improve data accuracy, precision, and consistency to better help consumers use the information.

In this report, OIG identified records that contained inaccurate, imprecise, or inconsistent information. Examples include records containing drug and device names that did not match the definitions of these data elements, national drug codes (NDCs) that were not found in multiple Food and Drug Administration databases or other drug information resources, and payment dates from a different reporting year.

OIG recommended that CMS: (1) ensure that records contain all required data; (2) strengthen validation rules and revise data-element definitions so that actual drug and device names must be reported; (3) revise the definition of the device-name data element so that the information reported is required to be more specific; and (4) ensure that manufacturers and group purchasing organizations report valid NDCs for drugs.

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<sup>1</sup> Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting, (OEI-03-15-00220), <https://oig.hhs.gov/oei/reports/oei-03-15-00220.asp>. Open Payments is the name of the Federal program for reporting as required by the Sunshine Act.

CMS concurred with all four of our recommendations and stated that it will continue to implement strategies to improve the completeness of data submissions. CMS also stated that it is working to strengthen validation processes to ensure that actual drug names are reported and are accurate. With respect to devices, CMS stated that a unique device identification system is necessary to validate reported device names. CMS is exploring various options to incorporate this information. OIG will continue to follow up with CMS annually to review its progress on implementing these recommendations.

- c. Will CMS commit to conducting a detailed review of Sunshine Act filings to determine the extent to which the 2018 special notices had an effect on POD-related disclosures?**

**Answer:** CMS will be responding to this question.

- d. How can the Sunshine Act be improved to ensure that PODs are reporting physician ownership or investment interest?**

**Answer:** CMS will be responding to this question. OIG does not have any recommendations specific to PODs. Our 2018 report discussed in response to Question 1.b. relates to Accuracy, Precision, and Consistency in Reporting into the Open Payments Database, generally.

**Question 2: Please describe in detail any anticipated regulatory changes or issuance of additional guidance designed to ensure that PODs are reporting physician ownership or investment interest as required under the Sunshine Act.**

**Answer:** CMS will be responding to this question.

**Question 3: Has HHS OIG updated its Compliance Program Guidance (CPG) for hospitals and other healthcare entities to account for PODs? If so, please provide a copy of that guidance. If not, please explain.**

**Answer:** OIG has not updated its CPG for hospitals (or any of its other CPGs) to account for PODs. In general, we believe existing guidance in the CPGs regarding identifying potential kickback arrangements would apply to potential POD arrangements. Moreover, CPGs are only one type of voluntary OIG guidance. Other, more recent guidance addresses this issue specifically. OIG has stated that PODs are inherently suspect under the anti-kickback statute.<sup>2</sup> With respect to hospitals and ambulatory surgical centers (ASCs), the Special Fraud Alert<sup>3</sup> states as follows:

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying

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<sup>2</sup> Special Fraud Alert: Physician-Owned Entities, [https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD\\_Special\\_Fraud\\_Alert.pdf](https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf).

<sup>3</sup> Id.



a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

**Question 4: When HHS OIG is alerted that a POD failed to report a physician's ownership or investment interest to CMS's sunshine database, what steps does HHS OIG take to validate these claims?**

**Answer:** If OIG were to receive information that an entity may be failing to report information that is required under the Sunshine Act, OIG would review the allegation to determine appropriate next steps, including assessing potential enforcement actions or referral to CMS for possible administrative action.

**Question 5: What actions have HHS OIG and CMS taken to enforce the March 2013 HHS OIG special fraud alert?**

**Answer:** OIG's Special Fraud Alerts do not create legal obligations or requirements, and as such, OIG does not enforce them. Instead, Special Fraud Alerts notify the public of risks that OIG recognizes in certain situations, which could lead to fraud and abuse under relevant laws. In the case of the March 2013 Special Fraud Alert, OIG noted the fraud risks posed by PODs under the anti-kickback statute. When OIG receives information that indicates that an entity has violated the anti-kickback statute, OIG reviews the allegation to determine appropriate next steps, including assessing potential enforcement actions. For example, in *United States ex rel. Cairns et al. v. DS Medical et al.*, the Government established violations of the False Claims Act and anti-kickback statute by a spinal implant distributorship relating to 228 spinal surgeries involving Medicare and Medicaid patients. A civil judgment of nearly \$5.5 million was entered against neurosurgeon Dr. Sonjay Fonn, his fiancée, and their professional corporations DS Medical and Midwest Neurosurgeons. Dr. Fonn used spinal implants during surgeries ordered from a spinal implant distributorship owned by his fiancée. Dr. Fonn ordered most of his spinal implants through this distributorship, and Dr. Fonn's fiancée typically received 50-percent commissions on implants Dr. Fonn used during his surgeries. Additional information on this case is available at <https://www.justice.gov/usao-edmo/pr/federal-judge-trebles-damages-and-imposes-civil-penalties-against-cape-girardeau>.

CMS will separately respond to this question with respect to its actions.