

**MAY 15 2019**

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

Dear Chairman Grassley:

Thank you for your letter regarding the Open Payments program and sharing your concerns regarding physician-owned distributorships (PODs). The Centers for Medicare & Medicaid Services (CMS) appreciates your continued interest in this program. The Department of Health and Human Services' Office of Inspector General (HHS-OIG) will be responding to you separately.

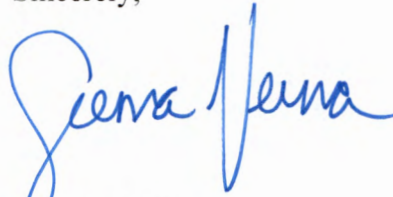
CMS has taken substantial steps to enhance compliance in the Open Payments program, specifically by analyzing data trends that have emerged after multiple years of reporting. Informed by this data analysis, CMS has conducted educational outreach and issued guidance in an effort to increase awareness and understanding of the program. The March 2013 HHS-OIG special fraud alert on physician-owned entities enriched both CMS' analysis and outreach strategies related to physician ownership and investment interest. As a part of these efforts, CMS researched potential PODs that were not reporting to Open Payments. The findings of this research resulted in the educational outreach campaigns conducted in 2018. CMS sent letters to potential PODs and physicians to increase awareness of the Open Payments reporting requirements for PODs. These analyses and outreach efforts have provided a critical foundation for identifying potential cases of failures to report required POD-related information to Open Payments.

CMS is conducting an analysis of any changes in POD-related disclosures following these outreach campaigns. This analysis encompasses data through Program Year 2018, the first program year for which disclosures would have been made after the outreach occurred. CMS also plans to continue working on initiatives focused on POD compliance with the Open Payments reporting requirements. While CMS has no plans to pursue regulatory changes or issue additional guidance related to PODs at this time, CMS will consider options for additional guidance or regulatory or other changes based on this analysis.

While PODs are currently required to report if they meet the definition of an Applicable Manufacturer or Applicable Group Purchasing Organization (GPO), PODs are not expressly mentioned in the Open Payments statute. The President's FY2020 Budget includes a proposal that would require that all PODs report and identify themselves in the Open Payments program. We would be pleased to provide technical assistance on this issue.

Thank you for your leadership on the Open Payments program. CMS is constantly striving to improve both the validity of the data for the public as well as decrease burden for stakeholders. I value your feedback on Open Payments and POD compliance with the reporting requirements, and look forward to continuing to work with you. I will share this response with the co-signer of your letter.

Sincerely,

A handwritten signature in blue ink that reads "Seema Verma". The signature is fluid and cursive, with the first name "Seema" and the last name "Verma" clearly distinguishable.

Seema Verma