

CHUCK GRASSLEY, IOWA, CHAIRMAN

MIKE CRAPO, IDAHO
PAT ROBERTS, KANSAS
MICHAEL B. ENZI, WYOMING
JOHN CORNYN, TEXAS
JOHN THUNE, SOUTH DAKOTA
RICHARD BURR, NORTH CAROLINA
JOHNNY ISAKSON, GEORGIA
ROB PORTMAN, OHIO
PATRICK J. TOOMEY, PENNSYLVANIA
TIM SCOTT, SOUTH CAROLINA
BILL CASSIDY, LOUISIANA
JAMES LANKFORD, OKLAHOMA
STEVE DAINES, MONTANA
TODD YOUNG, INDIANA

RON WYDEN, OREGON
DEBBIE STABENOW, MICHIGAN
MARIA CANTWELL, WASHINGTON
ROBERT MENENDEZ, NEW JERSEY
THOMAS R. CARPER, DELAWARE
BENJAMIN L. CARDIN, MARYLAND
SHERROD BROWN, OHIO
MICHAEL F. BENNET, COLORADO
ROBERT P. CASEY, JR., PENNSYLVANIA
MARK R. WARNER, VIRGINIA
SHeldon WHITEHOUSE, RHODE ISLAND
MAGGIE HASSAN, NEW HAMPSHIRE
CATHERINE CORTEZ MASTO, NEVADA

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL
JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

March 19, 2019

The Honorable Daniel R. Levinson
Office of Inspector General
Department of Health and Human Services
330 Independence Ave, SW
Washington, DC 20201

The Honorable Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Inspector General Levinson and Administrator Verma:

It has come to our attention that some physician owned distributorships (PODs) may be failing to disclose physician ownership or investment interest as required by the Physician Payment Sunshine Act (Sunshine Act).¹ As you know, a POD is an arrangement where a physician purchases ownership shares in an entity that sells implantable medical devices used in the physician's surgeries. This relationship is inherently suspect because it could encourage physicians to perform unnecessary surgeries or to choose a device in which they have a financial interest for the purposes of generating more profit for the POD and thereby themselves.²

In 2011, Senator Grassley, along with Senators Hatch, Baucus, Kohl, and Corker, became concerned about the proliferation of PODs, particularly those selling devices for spinal surgeries, and about their potential to run afoul of the Anti-Kickback Statute. The Senators requested that the Department of Health and Human Services, Office of Inspector General (HHS OIG) review the "structures and activities" of PODs, including their relationships with hospitals and potential effects on patient care.³ HHS OIG found that spinal surgeries for hospitals that purchase medical

¹ The Physician Payments Sunshine Act was part of the Patient Protection and Affordable Care Act, P.L. 111-148 § 6002, Social Security Act, § 1128G.

² *Special Fraud Alert: Physician-Owned Entities*, HHS OIG (March 26, 2013), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/pod_special_fraud_alert.pdf.

³ *Letter from Senator Grassley et al. to HHS OIG*, (June 9, 2011), <https://www.finance.senate.gov/imo/media/doc/LevinsonPOD.060911.FINAL.pdf>.

devices from PODs increased at a rate three times faster than for hospitals overall in FY 2011.⁴ HHS OIG also reported that PODs may be driving up healthcare costs due to overutilization and that surgeries that used POD devices were more expensive than non-POD surgeries.⁵ In November 2015, then-Chairman Hatch and Ranking Member Wyden held a Finance Committee hearing on the medical and financial risks to patients and healthcare payers associated with PODs.⁶

Congress passed the Sunshine Act to promote transparency and accountability in taxpayer-funded government healthcare programs. The Act requires manufacturers of pharmaceuticals, biologics, medical devices and medical supplies that participate in Federal healthcare programs to report to the Centers for Medicare and Medicaid Services (CMS) any transfer of value to physicians or teaching hospitals. Group purchasing organizations, of which PODs are a subset, also must report ownership or investment interests to CMS. A covered entity that knowingly fails to submit payment information is subject to civil monetary penalties. In August 2018, CMS sent out special advisories to physicians and PODs reminding them that ownership and investment interest payments associated with the POD must report under the Sunshine Act.

We want to work with you to ensure that all PODs report physician ownership or investment interest to CMS as required by law so that stakeholders can have confidence in the integrity of Federal healthcare programs and patients can trust the quality of care they receive. Accordingly, please respond to the following questions no later than April 15, 2019:

1. In 2015, HHS OIG issued a memorandum titled, “Overlap Between Physician-Owned Hospitals and Physician Owned Distributorships.”⁷ 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.
 - 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.
 - 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?
 - d. How can the Sunshine Act be improved to ensure that PODs are reporting physician ownership or investment interest?

⁴ *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use*, (Oct. 2013), <https://oig.hhs.gov/oei/reports/oei-01-11-00660.pdf>.

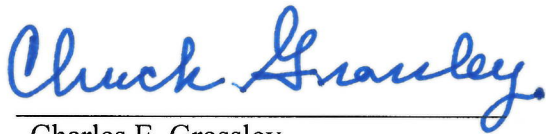
⁵ *Id.*

⁶ *Physician Owned Distributors: Are They Harmful to Patients and Payers*, Full Committee Hearing, Senate Finance Committee, November 17, 2015, <https://www.finance.senate.gov/hearings/physician-owned-distributors-are-they-harmful-to-patients-and-payers>.

⁷ *Memorandum Report: Overlap Between Physician-Owned Hospitals and Physician-Owned Distributorships*, (Aug. 13, 2015), <https://oig.hhs.gov/oei/reports/oei-01-14-00270.pdf>.

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

We look forward to working with the Administration to ensure that the Sunshine Act is up-to-date and that the penalties for non-disclosure are implemented against bad actors who fail to report. We ask that you respond to the Committee no later than April 15, 2019. We also ask that you answer the questions on a question-by-question basis, indicating which questions you are answering. If you have any questions, please contact Caitlin Soto of Senator Grassley's staff or Dave Berick of Senator Wyden's staff.



Charles E. Grassley
Chairman
Senate Finance Committee



Ron Wyden
Ranking Member
Senate Finance Committee