

## OIG'S FIRST AUDIT OF OPEN PAYMENTS PROGRAM: COMPLIANCE RATE HIGH, BUT DATA NEEDS IMPROVEMENT

Recently, the Department of Health and Human Services Office of Inspector General ("OIG") released findings of an **audit** of the **Centers for Medicare and Medicaid Services ("CMS") Open Payments program**. The **OIG** audit revealed that of 11.9 million records published on the Open Payments website for 2015, only less than one percent were missing required data elements. Although the Open Payments data elements reported to CMS were complete overall, **OIG** identified some records that contained inaccurate, imprecise or inconsistent information. In response to these deficiencies, **OIG** provided CMS with practical recommendations to improve the accuracy, precision and consistency of the data to better help consumers use the information contained in the Open Payments program.

### BACKGROUND

The Physician Payments Sunshine Act (the "Sunshine Act") aims to increase transparency and accountability of financial relationships between physicians, teaching hospitals and applicable manufacturers and/or group purchasing organizations ("GPOs"). Applicable financial relationships include consulting fees, research payments, ownership or investment interests or other forms of compensation. Although these financial relationships may provide opportunities to increase medical research and enhance medical knowledge, they also have the potential to influence the decision-making of health care providers. CMS implemented the mandates of the Sunshine Act by requiring applicable health care providers, manufacturers and GPOs to report information regarding these financial relationships to the Open Payments program.

The Open Payments program requires manufacturers that produce at least one covered product to report all payments that they make to physicians and teaching hospitals. Covered products include drugs, devices, biologicals or medical supplies that are eligible for reimbursement by Medicare, Medicaid or the Children's Health Insurance Program ("CHIP") and require a prescription or approval by the Food and Drug Administration ("FDA"). Manufacturers, as well as GPOs that purchase or negotiate the purchase of covered products, are required to report ownership and investment interests held by physicians or their immediate family members. GPOs are required to report payments made to physicians who hold ownership interests in the GPO at any point in the reporting year. Manufacturers and GPOs subject to Open Payments reporting requirements must register with the Open Payments system to submit data and recertify annually.

### REVIEW FINDINGS

OIG reviewed Open Payments data from 2015 to determine the extent to which reported data were inaccurate, inconsistent or missing elements. **OIG** also reviewed CMS policies and procedures to determine CMS's role in validating the Open Payments data received from manufacturers and GPOs. **OIG** reviewed 11.9 million records published on the Open Payments website and found that less than one percent of data were missing one or more required data elements. Deficient records contained imprecise or inaccurate product names, national drug codes ("NDCs") that were not found in multiple FDA databases or other drug information resources and payment dates from a different reporting year. Thousands of records contained product name data elements that did not appear to be names of specific products. For example, manufacturers and GPOs indicated that a payment was related to a covered product, but the corresponding drug name or device name field included text such as "no product discussed" or "no product specified."

### OIG RECOMMENDATIONS

OIG recommended to CMS the following practical steps to improve the accuracy, precision and consistency of Open Payments data to better help consumers use the information:

1. Ensure that records contain all required data. Specifically, CMS should review its current validation process to determine why records that were missing required data elements were accepted by the Open Payments system and make necessary adjustments.
2. Strengthen validation rules and revise data element definitions so that actual drug and device names must be reported. This change would prevent manufacturers and GPOs from entering invalid text in fields for drug or device names.
3. Revise the definition of the device name data element so that the information reported is required to be more specific. More specific device names would enable patients to determine whether their providers received payments related to devices that the provider used

as part of the patient's care.

4. Ensure that manufacturers and GPOs report valid NDCs for drugs. Requiring valid NDCs will enable researchers to perform more thorough analysis of Open Payments data.

CMS Administrator Seema Verma wrote a letter to OIG in response to the review and concurred with OIG's recommendations to improve Open Payments data. Notably, CMS is working to strengthen validation processes to ensure that actual drug names are reported and accurate. With respect to devices, CMS is exploring various options to implement a unique device identification system to validate reported device names. CMS conducted outreach to address data concerns with manufacturers and GPOs and is compiling a list of noncompliant manufacturers and GPOs for further investigation.

## **PRACTICAL TAKEAWAYS**

Based on the audit of Open Payments data, manufacturers and GPOs subject to the Sunshine Act are performing well with respect to reporting data historically required by CMS. Nevertheless, OIG is clear that transparency of relationships subject to the Sunshine Act remains imperative, as patients desire as much information as possible about their physicians. Manufacturers and GPOs should continue to ensure that applicable data is accurate prior to submission to the Open Payments program. Further, physicians and teaching hospitals should carefully review all data submitted by manufacturers and GPOs in order to timely dispute any inaccurate data prior to publication by CMS on the Open Payments website.

Given OIG's recommendations to CMS, the majority of the burden will be on CMS to strengthen the validation process and require additional detail for reportable data elements. CMS's implementation of OIG's recommendations could result in a more streamlined reporting process for manufacturers and GPOs in the long term, but applicable reporting entities should be cognizant of additional detail that may be required as CMS works to improve the validation process.

If you have any questions or would like additional information about this topic, please contact:

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