



ALVOGEN'S METHODOLOGY FOR TRANSFERS OF VALUE DISCLOSURE IN THE UNITED STATES

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Alvogen's Methodology for Transfers of Value Disclosure in the United States

This memorandum documents Alvogen's methodology for complying with the Physician Payments Sunshine Act, commonly known as the Sunshine Act or Open Payments (Sunshine Act), as it pertains to Transfers of Value (ToV) to U.S physicians and U.S. teaching hospitals (defined as Covered Recipients).

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A. Introduction

Enacted by Congress in 2010, the Sunshine Act is part of the Patient Protection and Affordable Care Act of 2010. Beginning August 1, 2013, the Sunshine Act requires manufacturers of drugs, medical devices, and biologicals that participate in U.S. federal health care programs to track and then report certain payments and items of value given to Covered Recipients. The Sunshine Act requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services (CMS) by the 90th day of each subsequent year. On June 30th of each year, CMS posts the reported payments and other transfers of value on its public website (<https://openpaymentsdata.cms.gov/>).

Alvogen works with Covered Recipients who provide advice on a range of topics; these working relationships are essential to gaining real-world information in order to deliver treatment choices that improve the health of patients and to share information that may be relevant to clinical decision making. This collaboration with these Covered Recipients ensures our medicines meet the needs of patients and help drive peer-to-peer education. In this context and guided by the highest ethical standards highlighted in Alvogen's policies and Code of Conduct & Ethics, Alvogen appropriately compensate U.S. licensed physicians for the time, expertise and services they provide to conduct industry-sponsored research or educate their peers about medicines, which advance clinical knowledge and ultimately benefit patients.

B. Covered Recipients

Manufacturers are required to report payments and transfers of value made to Covered Recipients. The Sunshine Act defines a physician as any of the following types of professionals who are legally authorized to practice:

- Doctor of Medicine
- Doctor of Osteopathy
- Doctor of Dental Surgery
- Doctor of Podiatry
- Doctor of Optometry
- Doctor of Chiropractic Medicine

Medical residents, nurse practitioners, pharmacists and office staff are NOT included in the definition of Covered Recipients. CMS annually publishes a list of hospitals that meet the definition of a teaching hospital for Sunshine Act reporting purposes.

C. Disclosed Information

The following disclosures are required under the Sunshine Act:

- Physician name, primary business address, specialty, National Provider Identifier (NPI) number, and state license number,
- Amount, date, nature of payment (fees paid for speaker and consulting services and related hospitality (travel, lodging and out-of-pocket expenses), food and beverage provided in-office or out-of-office, grants, research payments) and the form of payment or other transfer of value (cash, in-kind item, stock, dividend),
- Any covered products related to the payment or other transfers of value.

CMS encourages U.S. physicians and teaching hospitals to register on its website to review the reported payments and transfers of value attributed to them before public release of the data. On the CMS site, U.S. physicians and teaching hospitals have an opportunity to dispute payments and transfers of value if they believe there are inaccuracies. The CMS website has more information about the review and dispute process: <http://www.cms.gov/OpenPayments/Program-Participants/Physicians-and-Teaching-Hospitals/Physicians-and-Teaching-Hospitals.html>

In addition, there are specific thresholds for reporting for applicable manufacturers. CMS Open Payments reporting thresholds are adjusted annually based on the consumer price index. This means that for a calendar year (January 1 – December 31), if a small payment or other transfer of value is less than a certain minimum amount, it is excluded from the reporting requirements under Open Payments. However, if the amount exceeds an aggregate total amount for the calendar year all payments or transfers of value must be reported.

Please refer to the link below for current year information: <https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Data-Collection.html>

Certain items are excluded from reporting, including:

- Payments or other transfers of value (individual or aggregate), including small and incidental items (food and educational items) that are less than the annual threshold,
- Education materials and items which directly benefit patients or are intended for patient use,
- Discounts and rebates,
- Samples.