

Sunshine Act Reporting Update: De Minimis Amounts

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The Centers for Medicare & Medicaid Services (CMS) issued updated guidance on the thresholds that Applicable Manufacturers and Group Purchasing Organizations are required to report annually under the Sunshine Act ([42 U.S.C. § 1320a-7h](#); [42 C.F.R. Part 403 et. seq.](#)). Specifically, if Applicable Manufacturers or Group Purchasing Organizations spend [\\$11.04](#) or less, an increase from \$10.49 in 2020, on a Reportable Activity for a given Covered Recipient from January 1, 2021 – December 31, 2021, the payment will not need to be reported unless the payments to a Covered Recipient exceeds [\\$110.40](#), an increase from \$109.69 in 2020, in the aggregate for the reportable calendar year. If the aggregate sum is exceeded for a given Covered Recipient during the reportable calendar year, *all* payments or other transfers of value made to that Covered Recipient must be reported. CMS updates its de minimis threshold on an annual basis based on the consumer price index.

Who: Applicable Manufacturers and Group Purchasing Organizations

The Sunshine Act requires Applicable Manufacturers and Group Purchasing Organizations to report payments or other transfers of value to Covered Recipients.

- A Group Purchasing Organization is an organization that operates in the United States and that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.
- An Applicable Manufacturer is an entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients, or an entity that provides assistance or support to such an organization.
- Before 2021, a Covered Recipient is 1) any physician, except for a physician who is a bona

fide employee of the applicable manufacturer that is reporting the payment; or 2) a teaching hospital, which is any institution that received a payment under Sections 1886(d)(5)(B), 1886(h), or 1886(s) of the Social Security Act during the last calendar year for which such information is available.

- Beginning in 2021, Open Payments is expanding the definition of Covered Recipient to include five new provider types:
 1. Physician Assistants;
 2. Nurse Practitioners;
 3. Clinical Nurse Specialists;
 4. Certified Registered Nurse Anesthetists & Anesthesiologist Assistants; and
 5. Certified Nurse-Midwives (See 42 U.S.C. § 1320a-7h(e)(6)(a)).

What: Reportable Activities

Applicable Manufacturers and Group Purchasing Organization must report:

1. Direct and indirect payments or other transfers of value provided by an Applicable Manufacturer to a Covered Recipient (e.g., lunch); and
2. Direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the Applicable Manufacturer on behalf of a Covered Recipient (e.g., contribution to a charity).

When: Data Collection Due Date

Applicable Manufacturers and Group Purchasing Organization must report data from the prior calendar year by to CMS by March 31st each year.

Penalties

Failure to timely, accurately or completely report the required information under Open Payments may subject a Applicable Manufacturer or Applicable Group Purchasing Organization to Civil Monetary Penalties (CMPs) of not less than \$1,000, but not more than \$10,000, as adjusted annually, for each payment or other transfer of value or ownership investment interest not reported timely, accurately, or completely. The total amount of CMPs imposed on an Applicable Manufacturer or an Applicable Group Purchasing Organization annually will not exceed \$150,000, as adjusted annually (See 42 CFR § 403.912(a)).

Knowing failure to timely, accurately or completely report the required information under Open Payments may subject a Applicable Manufacturer or Applicable Group Purchasing Organization to CMPs of not less than \$10,000, but not more than \$100,000, as adjusted annually, for each payment or other transfer of value, or ownership or investment interest not reported timely, accurately, or completely. The total amount of CMPs imposed on an Applicable Manufacturer or an Applicable

Group Purchasing Organization annually will not exceed \$1,150,000, as adjusted annually (See 42 CFR § 403.912(b)).

Enforcement: [U.S. Department of Justice Settlement with Medtronic](#)

The U.S. Department of Justice (DOJ) announced on October 29, 2020 it reached a more than \$9.2 million settlement with Medtronic USA Inc. to resolve allegations it violated the Open Payment Program and the False Claims Act (FCA). In relevant part, Medtronic agreed to pay an additional \$1,110,000 to resolve allegations that the medical device manufacturer violated the Open Payments Program by failing to accurately report to CMS payments it made to a neurosurgeon in connection with Medtronic sponsored social events at a restaurant owned by the physician and his wife.

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National Law Review, Volume X, Number 323

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