

Open Payments Program

By: James Orlando, Chief Attorney
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Issue

Briefly summarize the federal "Open Payments Program" that requires drug manufacturers to report on certain payments to physicians and other health care providers.

Summary

Federal law requires manufacturers of covered drugs, devices, biologicals, and medical supplies ("drug manufacturers") to report electronically each quarter on payments or other transfers of value they make to physicians, certain other providers, and teaching hospitals ([42 U.S.C.A. § 1320a-7h](#)). This law applies to manufacturers of these products that are covered by (1) Medicare or (2) the state Medicaid or Children's Health Insurance Program plan, including a plan waiver. Manufacturers must report to the federal Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services.

This program began in August 2013 and is referred to as the "Open Payments Program" or "Physician Payments Sunshine Act." The law defines "physicians" broadly to include medical and osteopathic doctors, dentists, podiatrists, optometrists, and chiropractors. In addition, starting in 2022, federal law expands the program by requiring drug manufacturers to also report on payments to the following professionals: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

The Open Payments law generally allows states to require additional disclosures beyond those required by the federal law. Some states have enacted these laws, generally expanding the types of (1) payments that these manufacturers must report or (2) recipients covered by such laws. Connecticut has passed the latter type of law, requiring drug manufacturers to report on certain

payments they make to independently practicing advanced practice registered nurses (APRNs) ([CGS § 21a-70f](#)). (As noted above, federal law adds APRNs to the Open Payments Program reporting requirements starting in 2022.)

More information on the program, including data for 2018 reported payments and CMS's most recent report to Congress on the program, is available on the CMS [website](#).

Federal Open Payments Program

Reporting Requirements and Exemptions

Under the Open Payments Program, drug manufacturers generally must report the following information to CMS:

1. the amount and date of the payment or other transfer of value;
2. the recipient's name and business address;
3. the form of the payment or transfer (e.g., cash, in-kind items);
4. the nature of the payment or transfer (e.g., consulting fees, gifts, entertainment, food);
5. if the payment or other transfer is related to marketing, education, or research specific to a covered product, the name of that product; and
6. any other information determined appropriate by the federal Health and Human Services secretary.

In addition, drug manufacturers must electronically report to CMS specified information on ownership and certain investment interests that physicians or physicians' immediate family members have in the manufacturers ([42 U.S.C.A. § 1320a-7h\(a\)](#)).

The law excludes certain transfers from the reporting requirement, such as:

1. transfers under \$10, unless the aggregate amount provided by the manufacturer to that recipient exceeds \$100 in a calendar year, indexed for inflation starting in 2013 (the [2020 limit](#) is \$109.69);
2. product samples that are intended for patient use and not intended for sale;
3. educational materials that directly benefit patients or that are intended for patient use; or
4. transfers to the manufacturer's employees ([42 U.S.C.A. § 1320a-7h\(e\)\(6\), \(10\)](#)).

The law requires the Health and Human Services secretary to make the reported information available to the public online ([42 U.S.C.A. § 1320a-7h\(c\)](#)).

Penalty for Noncompliance

Manufacturers that fail to report as required are subject to civil penalties, as follows:

1. a \$1,000 to \$10,000 penalty for each unreported payment, transfer of value, or ownership or investment interest, with an annual maximum penalty of \$150,000, or
2. for knowing violations, a \$10,000 to \$100,000 penalty for each unreported payment, transfer of value, or ownership or investment interest, with an annual maximum penalty of \$1 million ([42 U.S.C.A. § 1320a-7h\(b\)](#)).

Relation to State Laws

The Open Payments law generally preempts states from establishing reporting requirements for drug manufacturers for payments covered by the federal law. But the law specifies that it does not preempt state laws that require reporting (1) of information not covered by the federal law (with one exception, see below); (2) by entities or persons other than drug manufacturers or covered recipients; or (3) to government agencies for public health surveillance, investigation, oversight, and related purposes.

The law specifically preempts states from requiring reporting of transfers to a covered recipient valued at under \$10 that do not exceed the \$100 annual threshold described above, as adjusted for inflation ([42 U.S.C.A. § 1320a-7h\(d\)\(3\)](#)).

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