

## **Contact Lens Institute Website Content—Resources > Open Payments Q&A**

### **What is the Open Payments / Sunshine Act?**

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act (the “Sunshine Law”) requires manufacturers, including certain distributors of medical devices, drugs, biologicals, and medical supplies to track and report certain payments made to and transfers of value provided to physicians and teaching hospitals.

The Sunshine Law also requires manufacturers and Group Purchasing Organizations (GPOs) to report certain ownership and investment interests held by physicians and their immediate family members.

### **Why was Open Payments put in place?**

The main purpose of the Sunshine Law is to provide patients with enhanced transparency into the relationships their health care providers have with life science manufacturers, including medical technology companies. It’s important to note that the Sunshine Law does not restrict industry-physician collaboration or interactions, or prohibit payments or transfers of value. Rather, it requires tracking and reporting of payments and transfers of value that result from these interactions.

### **What is an applicable manufacturer?**

Manufacturers of medical devices, drugs, biologicals, and medical supplies operating in the United States, including certain wholesalers/distributors and certain entities under common ownership (5% or more) with a Manufacturer (collectively, “Manufacturers”) must submit Transparency Reports annually to U.S. Centers for Medicare and Medicaid Services (CMS) on Payments / Transfers of Value given to Physicians and Teaching Hospitals.

### **Why are Contact Lens Institute members required to report under Open Payments?**

Each member independently evaluated the legislation and determined that based on the criteria provided regarding applicable products, they would have to report under Open Payments. While most contact lenses that are prescribed in the U.S. are not reimbursed by the government, the products may be eligible for reimbursements for certain medical uses. Additionally, manufacturers of contact lenses may be covered by the Open Payment requirements because they also manufacture or distribute other types of covered medical products.

### **Do all companies have to report value exchanges?**

Only applicable manufacturers of drugs, devices, biologicals, and medical supplies covered by the three federal health care programs Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) must report payments or other transfers of value they make to physicians and teaching hospitals to CMS.

In addition, manufacturers and group purchasing organizations (GPOs) must report certain ownership interests held by physicians and their immediate family members.

### **Is an applicable manufacturer with both covered and non-covered products required to report payments or other transfers of value associated with a non-covered device?**

Yes, applicable manufacturers of at least one covered drug, device, biological or medical supply are required to report all payments or other transfers of value, unless the applicable manufacturer meets one of the reporting limitations defined in the statute apply.

### **If a device that is still in its development phase, does the company have to report research related expenses?**

Yes, the applicable manufacturer would be required to report the research institution/account, principal investigator and total payment. The manufacturer may defer public reporting until such time as the product is approved.

### **What are the penalties for non-compliance?**

Reporting incomplete or inaccurate information has the potential to mislead patients and other stakeholders and damage the reputation of manufacturers, physicians and teaching hospitals.

Depending on the circumstances, non-compliance with the Sunshine Law's reporting requirements could subject a manufacturer to financial penalties ranging from:

- (1) \$1,000 to \$10,000 for each payment or transfer of value not reported; and
- (2) \$10,000 to \$100,000 for "knowingly" failing to report a payment or transfer of value.

The total maximum penalties which may be imposed against a Manufacturer or GPO is \$1,150,000 per year.

### **For Eye Care Professionals**

#### **What types of value transfers are included in Open Payments?**

Applicable manufacturers must report payments and "transfers of value" made directly to physicians and teaching hospitals. Applicable manufacturers are required to describe how the recipient received the payment such as cash or cash equivalent, in-kind items or services, or stock, stock option(s), or any other ownership interest, dividend, profit, or other return on investment. In addition, manufacturers must specify the nature of the payment or transfer of value.

There are 14 categories manufacturers are required to use to describe the nature of payments or transfers of value including:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contribution
- Royalty for license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grant

In addition to direct payments, manufacturers must report certain payments and transfers of value that are made indirectly to a physician or that are made to a third party as requested by a physician or designated as being made on behalf of the physician.

#### **How do I find out about what industry is reporting about me?**

The best place to go is the CMS website. Data that has already been reported and posted will be there for anyone to review. Covered recipients have a chance to review and dispute previous year data during the review period which is typically in early April and May. Additionally, covered recipients may dispute items

posted for public review until December 31 of the following year. Many reporting companies also have resources / websites to handle specific questions, however all disputes must be submitted through the CMS web site.

**How do I know if a meal or item will be reportable by a Company? For example, I attend a meal at a meeting that is coordinated by a third party (e.g., a CE or Promotional meeting).**

This has probably been the most frequent source of confusion as ECPs attend various meals and functions and may not be aware of the tracking and reporting. This often happens when a doctor attends a function that is managed through a third party such as a speaker program and, for Optometry, even COPE approved programs. As applicable manufacturers under CMS, CLI Members make every effort to utilize sign-in sheets and post signs regarding any event that could result in disclosure under open payments.

**How do I access the CMS website?**

Please visit <http://www.cms.gov/openpayments/index.html>

**What do I do if the information reported about me is incorrect?**

The best time to review and dispute data is when it is in the doctor review period which is typically open from early April through May following the reporting year. Doctors have until the end of the calendar year to initiate a dispute. (42 CFR 403.908(g)(3)(v))

For example, if an applicable manufacturer reports to CMS all reportable payments or other transfers it provided to covered recipients during the 2023 calendar year, a covered recipient has until December 31, 2024, to initiate a dispute.

**How long do I have to initiate a dispute?**

Covered recipients have only until the end of the calendar year to initiate a dispute. (42 CFR 403.908(g)(3)(v)) For example, if an applicable manufacturer reports to CMS for the calendar year of 2023 all reportable payments or other transfers it provided to covered recipients during the previous year, covered recipients only have until December 31, 2024, to initiate a dispute.

**If a doctor no longer has an active license, are payments or other transfers of value still reportable?**

No, only licensed “physicians” who are legally authorized to practice are reportable under the Act. For the Physician Payments Sunshine Act (the “Sunshine Law”), a “physician” is any of the following healthcare professionals (HCPs):

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

Note: Residents are excluded from the definition of physician for the purpose of the Open Payment / Sunshine Act.

**What if I don't want to be on the report?**

By law, licensed practitioners falling within any of the categories listed above, and who are legally authorized to practice, are reportable under the Sunshine Act, unless they are excluded or deferred.

### **Why does it appear that some items are reported and others not?**

There are several rules that allow some items to be excluded or deferred. Here are some:

- (a) Less than \$10 when the total value for the year is less than or equal to \$100
- (b) Educational Materials That Directly Benefit Patients or are Intended for Patient Use
- (c) In-Kind Items for the Provision of Charity Care
- (d) Product Samples (including coupons and vouchers) where there is an agreement in writing that the products will be provided to patients
- (e) Items received by the Physician as a Patient (e.g., Product Samples, Coupons, or Vouchers or as a subject in a research study)
- (f) Items received for the Provision of Healthcare Services provided to a manufacturer's employees or their family ( e.g., on-site clinic)

Companies that submit research payments may defer public reporting related to new product development until the year of launch or up to four calendar years.

Please note, due to the CMS data review process, there may be differences between the data posted by companies and aggregated totals derived from currently available data on the CMS website.

### **Is there a minimum value threshold that needs to be met in order for applicable manufacturers and applicable group purchasing organizations to be required to report?**

There is no minimum value threshold for reporting. However, payments or other transfers of value less than \$10 are excluded from reporting unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 in the calendar year.

### **Are expenses paid to prospective employees reportable?**

Yes, expenses related to recruiting of prospective employees would be reportable. This would include air travel, meals, lodging any other out of pocket costs. Note that reporting is done annually so, for example, any recruiting expenses for 2023 would be publicly available on CMS site on June 30, 2024.

### **For Doctors who purchase and dispense lenses from their offices, are the values of discounts and rebates reportable?**

Discounts and Rebates are excluded from Open Payments Reporting.

### **Are the items reported taxable?**

Currently, there are no provisions in the Act that would render reported items as being taxable. As always, however, HCPs should consult with their CPAs or tax attorneys to determine personal tax liabilities.

### **Can a physician reimburse an applicable manufacturer for payments so that no information is reported about them in Open Payments?**

No exclusion exists for payments or transfers of value that are later reimbursed.

### **Is a physician located outside of the United States considered a physician covered recipient for purposes of Open Payments?**

If a physician maintains a current state license to practice medicine in any state in the United States, the physician will be considered a covered recipient for purposes of Open Payments. Within Open Payments,

the term “physician” has the same meaning as under Section 1861(r) of the Social Security Act, which generally includes doctors of medicine, osteopathy, dentists, podiatrists, optometrists and chiropractors who are legally authorized to practice by a state. A current state license would render the physician “legally authorized” to practice medicine, regardless of the extent to which they do so. Therefore, a physician who maintains an active license to practice in the United States would be considered a covered recipient, and payments made to such a person would have to be reported, even for services rendered (such as speaking at a public seminar) outside of the U.S. An exception to this covered recipient classification is when a physician is a bona fide employee of an applicable manufacturer that is required to submit reporting information under subsection (a) of Section 1128G of the Social Security Act.

### **What do I say if a patient asks me about it?**

Many AdvaMed member companies have certified to compliance with the AdvaMed Code of Ethics on Interactions with Health Care Professionals which also supports ethical collaborations. It is by driving ethical collaborations that we help protect patients.

### **CMS Information**

#### **How often will a report be issued?**

Data will be available and posted annually.

#### **What will be done with the reported information?**

Most of what is provided in the Transparency Reports will be published annually on a public website that is searchable.

#### **Are payments provided to a consulting firm or third party, who in turn provide the payment (in whole or part), to a physician, reportable under the Open Payments?**

Yes, Open Payments requires reporting of both direct and indirect payments and other transfers of value provided by an applicable manufacturer or applicable group purchasing organization to a covered recipient. An indirect payment is a payment or transfer of value made by an applicable manufacturer, or an applicable group purchasing organization, to a covered recipient, or a physician owner or investor, through a third party, where the applicable manufacturer, or applicable group purchasing organization, requires, instructs, directs, or otherwise causes the third party to provide the payment.

#### **What items or materials are considered educational materials and are not reportable transfers of value?**

Education materials and items that directly benefit patients, or are intended to be used by or with patients, are not reportable transfers of value. Additionally, the value of an applicable manufacturer’s services to educate patients regarding a covered drug, device, biological, or medical supply are not reportable transfers of value. For example, overhead expense, such as printing and time development of educational materials, which directly benefit patients or are intended for patient use are not reportable transfers of value.

#### **Will CMS notify physicians and teaching hospitals that applicable manufactures or applicable GPO’s reported data about them?**

Physicians, teaching hospitals, and physician owners or investors will receive a general notification when the reported information is ready for review. However, the physician, teaching hospital, and physician owners or physician investors will only receive this notification if they have previously registered with CMS. We encourage physicians, teaching hospitals, and physician owners or physician investors to

register to allow for notification. Additionally, CMS will utilize a general online posting (<http://go.cms.gov/openpayments>) and notifications on CMS' investor(s).

**Is a medical device considered eligible for payment by Medicare, Medicaid, or CHIP for purposes of Open Payments reporting requirements if a test performed using the device is eligible for payment, but not the device itself (e.g., MRI machines, CT, x-rays, ultrasounds machines)?**

Yes, if a medical device is used to perform a service that is reimbursable under Medicare, Medicaid, or CHIP, the device is considered a covered device for purposes of Open Payments, so long as it is of the type that by law requires premarket approval by or premarket notification to the FDA, per the definition in 42 C.F.R. § 403.902.

**Can a physician reimburse an applicable manufacturer for payments so that no information is reported about them in Open Payments?**

No exclusion exists for payments or transfers of value that are later reimbursed.

**Is the loan of a covered device by an applicable manufacturer for training purposes at a CME or non-CME event considered a payment or other transfer of value to covered recipients?**

No. A loan of a covered device by an applicable manufacturer for training purposes at a CME or non-CME event is not considered a payment or other transfer of value provided to a covered recipient if the device was loaned to the CME vendor for training covered recipients at a CME event and the covered recipient did not take possession of the covered device.

*Updated 03/2023*