



THE ESSENTIAL GUIDE TO OPEN PAYMENTS COMPLIANCE

Developed by Concur &
R-Squared Services & Solutions, Inc.



Open Payments Guide

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Introduction

To quote Justice Brandeis, “Sunshine is the best disinfectant.”

Originally proposed by former Senator Kohl and Senator Grassley, Open Payments, formally known as The Physicians Payment Sunshine Act, was made to help add visibility and transparency of spend between manufacturers and healthcare providers of drugs, devices or medical supplies.

This guide helps simplify what this new legislation means to the medical manufacturing community and provide easy ways to make sure you are in compliance with Open Payments, a.k.a. The Sunshine Act. By adding transparency, Open Payments cleans up the cloudy, complicated healthcare system by shining the light on how and where money and other transactions of value happen — thus, adding greater accountability to all involved.

“I believe transparency
in the healthcare
system leads to greater
accountability”

Senator Grassley

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What Is Open Payments

Open Payments is the name of the federal disclosure program administered by the Centers for Medicare and Medicaid Services (CMS) to implement the section of the Patient Protection and Affordable Care Act commonly known as “The Physician Payments Sunshine Law” or the “Sunshine Act.” The law establishes a national disclosure program to promote transparency by publishing the financial relationships between the medical industry and healthcare providers (physicians and teaching hospitals) on a publicly accessible website developed by CMS.

By adding visibility to spend, Open Payments aids government enforcement and will:

- Encourage transparency of reporting financial ties
- Reveal the nature and extent of relationships
- Prevent inappropriate influence on research, education, and clinical decision-making
- Avoid conflicts of interest that can compromise clinical integrity and patient care
- Minimize risk of increased health care costs

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Who Open Payments Affects

Does Open Payments, formally known as the Sunshine Act, pertain to you?

Open Payments requires “**Applicable Manufacturers**” to disclose annually to CMS any payments or other transfers of value provided to, or at the request of, or on behalf of a “**Covered Recipient**”.

Applicable Manufacturer – An entity that is operating in the United States and that falls within one of the following categories:

- A company that produces, prepares, reproduces or compounds pharmaceuticals, medical devices, biological or medical supplies
- A company under common ownership such as a charity, non-profit organization or voluntary association; providing assistance or support, marketing, promotion, sale or distribution on behalf of such a manufacturer as listed above

This term is defined broadly to include (i) any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered product supply is solely for use by or within the entity itself or by the entity’s own patients (i.e., doesn’t include hospitals, pharmacies, or labs); or (ii) any entity under **common ownership** with such entity which provides **assistance or support** to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.

*(Under the law, **common ownership** means the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. Where as **assistance and/or support** is defined as providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.)*

COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY

Any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid or a state children's health insurance program either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a:

- Drug or biological, by law, requires a prescription to be dispensed; or
- Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

Under Open Payments, a **“Covered Recipient”** is a current licensed physician or a teaching hospital that receives Medicare graduate medical education (GME) payments (CMS will annually publish a list of hospitals that meet the definition of a teaching hospital).

The law also requires non-public manufacturers, as well as pharmaceutical and device supplier group purchasing organizations (GPOs), to annually disclose ownership interest physicians or their immediate family members have in those entities.

Not included as a **“Covered Recipient”** are nurse practitioners, pharmacists, medical residents and office staff.

FOLLOW THESE 4 STEPS TO DETERMINE IF OPEN PAYMENTS, FORMALLY THE SUNSHINE ACT, APPLIES TO YOUR ORGANIZATION

Step 1: Does the organization operate in the United States (includes any territory, possession or commonwealth of the United States)?

Step 2: Does the organization do any of the following types of activities?

- **Type 1:** Engages in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply.
- **Type 2:** Under “common ownership” (ownership by the same individuals or entities of 5 percent or more in two entities) with Type 1 AND provides assistance or support with such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply.

Step 3: Are any of the organization’s products covered by insurance, such as Medicare, Medicaid or Children’s Health Insurance Program? If so, does the drug or biological require a doctor’s prescription? Or, if they are medical devices and supplies, do they require premarket approval or notification by the FDA?

Step 4: If the answer is yes to the above, **then your organization is considered to be an *applicable manufacturer*** for Open Payments.

FIGURE 1.1: DETERMINING IF AN ENTITY IS AN APPLICABLE MANUFACTURER

Operate in the United States	Physical location within the United States or conducts activities within the United States (included any territory, possession or commonwealth of the United States)	
Activities	Engages in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply Includes distributors or wholesalers that hold title to a covered drug, device, biological or medical supply.	Under common ownership with a Type 1 applicable manufacturers AND Provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.
Covered products	Reimbursed by Medicare, Medicaid or Children’s Health Insurance Program AND For drugs and biologicals, requires a prescription (or doctor’s authorization) to administer OR For devices and medical supplies, requires premarket approval or premarket notification by the FDA	

LET'S DIG DEEPER INTO COVERED RECIPIENTS

Knowing when to report payments or other transfers of value all depends on who receives or directs the payment or transfer of value (TOV).

The term "Covered Recipient" is defined as any currently licensed physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or a teaching hospital, which is any institution that received a payment under a graduate medical education funding from CMS during the last calendar year for which such information is available.

A physician need only possess a current license to practice; it does not matter whether he or she is enrolled in the Medicare program or actively practices medicine.

The term "physician" includes the following professions, as defined in the Social Security Act:

- Medical Doctor (MD)
- Doctor of Osteopathy (DO)
- Doctor of Dentistry (DDM)
- Doctor of Dental Surgery (DDS)
- Doctor of Podiatry (DPM)
- Doctor of Optometry (OD)
- Doctor of Chiropractic Medicine (DC)

Payments or other transfers of value do not need to be reported when made to residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic), nurses or office staff.

Physicians or teaching hospitals are not required to register with, send any information to, or otherwise participate with Open Payments, but in order to view and/or dispute information that will be published, they must register with the Open Payments system using a CMS secure website.










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What To Report

GENERAL PAYMENTS

It can be hard to know what is and is not a transfer of value (TOV) in the eyes of CMS. Remember, transfers of value can include all payments or other transfers of value given to a Covered Recipient, regardless of whether the Covered Recipient specifically requested them.

Examples of payments or other transfers of value, which must be reported:

-  Consulting fees
-  Gifts
-  Entertainment
-  Food
-  Travel and lodging
-  Educational grants
-  Research payments and expenses
-  Charitable contributions
-  Royalty or license fees

Be aware that indirect payments (TOV made through a third party) also need to be reported when the manufacturer requires, directs or otherwise causes them to be provided and knows or becomes aware of the identity of the Covered Recipient on or before June 30th of the following reporting year.

Examples of indirect payments:

- Manufacturer provides payment to medical professional society that is earmarked for grants to physicians.
- Manufacturer pays a meeting planning company that in turn pays a fee-for-service to a physician.

WHAT IS EXCLUDED

Applicable Manufacturers are not required to report the following payments and other transfers of value because they are expressly excluded in Open Payments, also known as the Sunshine Act:

- Transfers of value less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the Covered Recipient exceeds \$100 in a calendar year;
- Payments or other transfers of value of less than \$10 provided at large-scale conferences and similar large-scale events, as well as events open to the public where it is difficult to determine the identity of the recipient (even if the aggregate total for a covered recipient exceeds the \$100 aggregate threshold for the calendar year);
- Product samples (including coupons and vouchers) not intended to be sold and are for patient use;
- Educational materials that directly benefit patients or are intended for patient use;
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the Covered Recipient;
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device;
- A transfer of anything of value to a Covered Recipient when the Covered Recipient is a patient and not acting in the professional capacity of a Covered Recipient;
- Discounts, including rebates;
- In-kind items used for the provision of charity care;
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund;
- In the case of an Applicable Manufacturer who offers a self-insured plan, payments for the provision of health care to employee under the plan;

- In the case of a Covered Recipient who is a licensed non-medical professional, a transfer of anything of value to the Covered Recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional;
- A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship;
- In the case of a Covered Recipient who is a physician, a transfer of anything of value to the Covered Recipient if the transfer is payment solely for the services of the Covered Recipient with respect to a civil or criminal action or administrative proceedings; and
- Transfers of value made indirectly to a Covered Recipient through a third party in cases when the Applicable Manufacturer is unaware of the identity of the Covered Recipient.

“With Concur’s convenient web-based services and integrated access to healthcare databases, we were able to streamline our data collection efforts into a single, automated system that will help ensure we have accurately captured and reported all information required for compliance with the Sunshine Act.”

Sarah Tulk, CPA, MBA, Corporate Controller — AlloSource

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3 Separate Data Submission File Specs, Established by CMS

One is for the submission of General Payments, the second for the submission of research-related TOVs, and the third for ownership and investment interests.

1. The General Payments report, which includes travel and meal-related expenses, contains the following metadata elements:

- Submission File (Header) Data Elements – this includes the name and Registration ID for the manufacturer, and file related identifiers;
- Recipient Demographic Information — there are twenty specific elements in this section to cover names, addresses, types, specialties, and identifiers for the Covered Recipient;
- Associated Drug, Device, Biological or Medical Supply — this category identifies the drug, device, biological or medical supply that is related to the payments or other transfers of value and contains four data elements, including product type indicator, name or category, and for drugs/ biologicals, the NDC(s) for the product;
- Payment or Transfer of Value Information – these eleven data elements specify the name and ID of the payer, transaction ID, the amount, date, number of payments, nature, form, and location for travel and lodging; and
- General Record Information – this catchall category captures information such as whether the recipient also is an owner/investor, whether a directed payment was involved (including the identity receiving the TOV), delay publication flag (for research-related TOVs), and contextual information.

2. Research Payments

CMS defines research as “a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.” This includes pre-clinical research and FDA Phases I-IV research, in addition to investigator-initiated investigations.

If a payment falls within the nature of payment category for research, it only needs to be subject to a written agreement or contract or a research protocol. This may include an unbroken chain of agreements (instead of a single agreement between the Applicable Manufacturer and the Covered Recipient) which link the Applicable Manufacturer with the Covered Recipient, such as when the Applicable Manufacturer uses a contract research organization (CRO) who contracts with the Covered Recipient.

Reporting on Research Payments

Applicable manufacturers must report research payments separately in a different template (i.e., “research template”) since CMS is requiring the reporting of modified information and recognizes that research payments are typically larger payments, which are more difficult to itemize. For detailed instruction on Research Payments reporting, refer to the CMS website on Open Payments.

3. Reportable Ownership and Investment Interest

In addition to reporting payments and other transfers of value to Covered Recipients, Applicable Manufacturers (and GPOs) must report certain information concerning ownership or investment interest held by a physician or their immediate family members in the Applicable Manufacturers (or GPOs), and payments or other transfers value to such physician owners or investors during the preceding year. An ownership or investment interest may be direct or indirect and through debt, equity or other means.

CMS Defined Ownership or Investment Interest:

1. Stock, stock option(s) (other than those received as compensation, until exercised)
2. Partnership share(s)
3. Limited liability company membership(s)
4. Loans, bonds, or other financial instruments secured with an entity’s property or revenue or a portion of that property or revenue

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Important Dates To Know

- August 1, 2013 — Applicable Manufacturers and GPOs were to begin collecting financial relationship data
- March 31, 2014 — Reports due to CMS of spend from August 1, 2013 through December 31, 2013
- 90th day of each calendar year — Beginning in 2015, reports for the prior calendar year are due
- September 30, 2014 — CMS will release the first set of data publicly
- June 30, 2015 and beyond — Release of data by CMS

Concerned about getting everything right the first time? Don't worry. You have 45 days to review everything and make any edits before the data is publically available. Plus, if any disputes come up, CMS provides an additional 15 days to make any final corrections.

CMS will notify Covered Recipients about the opportunity to review payments reported by Applicable Manufacturers using e-mail list serves and online postings, including the CMS website and the Federal Register.

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Penalties for non-compliance

TIME DELAYS

Open Payments, a.k.a. the Sunshine Act, imposes what is essentially “strict liability” for Applicable Manufacturers that fail to report the necessary information on a timely basis. Specifically, any Applicable Manufacturer that fails to submit the information in a timely manner in accordance with rules or regulations declared in Open Payments shall be subject to a civil money penalty (CMP) of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value (or ownership or investment interest) not reported as required. The total amount of civil money penalties imposed with respect to each annual submission by an Applicable Manufacturer shall not exceed \$150,000, an amount that can be reached with a mere 15 errors.

Avoid Penalties: With Concur’s real-time automated fetching of all attendee and HCP data – the potential for errors with manually reporting is substantially lessened. Concur’s web services collect the data needed from designated lists of Healthcare Providers – including Medical ID Numbers and attaches this data to each record in real-time. Some legal requirements are automatically taken care of for you.

FAILURE TO SUBMIT

Any Applicable Manufacturer that knowingly fails to submit the information, however, in a timely manner in accordance with rules or regulations described in Open Payments shall be subject to a civil money penalty of not less than \$10,000, but not more than \$100,000, for each payment or other transfer of value (or ownership or investment interest) not reported as required. For this type of “knowing” failure, the total amount of civil money penalties imposed with respect to each annual submission by an Applicable Manufacturer shall not exceed \$1,000,000.

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International Transparency Developments

Although the United States may have been one of the first to require disclosure of TOVs, many other countries are following suit. The chart below summarizes some of the transparency initiatives worldwide.

Authority	Law, Reg, or Industry Code?	Responsibilities	Products Covered	Penalties?
ABPI (UK Pharmaceutical Association)	Industry Code	Speaker, Mkt research, Consultant, Ad Board fee reporting, meeting sponsorships	All pharmaceuticals	Self-regulation
France (Law enacted 12/29/11)	Law	Sunshine-like reporting obligations and reporting of agreements	Pharmaceuticals and medical devices	45,000€ for knowing violations
CGR/Netfarma (Dutch Pharmaceutical Association)	Industry Code	Sunshine-like reporting related to non-clinical activities	All pharmaceuticals	Self-regulation
JPMA (Japan Pharmaceutical Association)	Industry Code	Sunshine-like reporting	All pharmaceuticals (med devices expected)	Self-regulation
MAA (Australia Pharmaceutical Association)	Industry Code	Educational Events reporting	Prescription pharmaceuticals	Self-regulation
Portugal (Medicinal Products Act)	Law	Requires both pharmaceutical manufacturers and HCPs to report transfers of value	All pharmaceuticals	Up to € 44.891,81 plus additional sanctions
Slovakia (Act 362/2011)	Law	Sunshine-like reporting	All pharmaceuticals	Administrative offense
EFPIA (European Pharmaceutical Association)	Industry Code	Sunshine-like reporting	All pharmaceuticals	Self-regulation
Denmark (ENLI)	Industry Code	Disclosure of events, sponsorships, printed promotional materials and exhibitions at congresses	All pharmaceuticals	Self-regulation
Ireland (Irish Pharmaceutical Healthcare Association)	Industry Code	Disclosure of financial support to patient organizations	Patient associations	Self-regulation
Hungary (Hungarian National Code)	Industry Code	Disclosure of financial support to patient organizations	Patient associations	Self-regulation

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Open Payments Compliance Solutions

To understand the compliance solution appropriate for your organization, one must first adequately define the problem. In the aggregate spend context, the organization must capture a lot of data for each transfer of value (TOV), which occur throughout the organization. TOVs must be processed in conformity with differing legal requirements, and ultimately reported in the specific format required by the jurisdiction. For example, the CMS Open Payments requirements differ from those required by Massachusetts, which differ from those required in France and so-on.

An effective aggregate spend Compliance Solution:

- Promotes consistent, accurate, and complete data capture
- Validates key information such as identity of recipient
- Contains well-researched and up-to-date rule sets and report formats
- Allows for quick and easy audit, review, and correction, as appropriate, of every reported spend item (so as to address HCP disputes)

First, your organization will need to catalog all of the TOVs that occur, identifying who makes them, why, and where is the data about the TOV captured and stored, if at all. You'll need to assess ease and completeness of the required capture; quality and accuracy of the data, especially the data that identifies the physician or other recipient of the TOV, data exportability (into a reporting tool), and then, use unique system and transaction identifiers. With all of this information, you can set out a plan to address policy, process, data, personnel and system gaps. As it relates to the latter, the more information about the HCP that can be presented at the front-end source system (i.e., to allow users to select HCPs from the NPI or other data list as with the Concur automated solution) mitigates the need for complicated matching and validation on the back-end.

Once you are confident that you have identified all of the situations, people, systems and data relevant to spend capture and reporting, the next step is to bring all of the data together in a consistent manner so as to permit the processing of the data using rules designed to produce the reports consistent with the law. The application of the reporting rules against the spend data will yield a raw report, which then needs to be formatted and presented consistent with government requirements.

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Become Open Payments compliant with Concur and R-Squared

“With Concur, there’s no option for error. Healthcare Professionals and attendee names, addresses, license numbers and associated details are accessible in the solution, along with our categories of spend and spending limits. Everything’s been integrated into Concur Travel & Expense. That’s a big plus for our employees. Tracking attendee data—quickly and easily—is just a routine part of expense reporting for us now.”

Acumed

With so much at stake, it is more important than ever to adopt an automated and flexible system that streamlines the expense reporting process – driving down costs and saving time. Trying to manually collect, calculate and report on all business expenditures, especially when using a manual spreadsheet, can be extremely time consuming and can result in potential errors in reporting.

With Concur’s versatile and complete cloud-based solution, each physician attendee is uniquely identified through a standardized/consolidated Health Care Providers (HCP) list. Automated access to such a list eliminates not only time, but also the challenges involved in aggregate spend. Concur’s automated travel and expense reporting tracks spend per attendee, reports costs and provides a comprehensive report per physician at the end of each year — all helping with Open Payments compliance.

CONCUR PROVIDES:

- **Data for Effective Management:** Access to the right information, in a timely and easily understandable format to help you make informed decisions on how to save money in key areas while ensuring compliance and identifying non-compliance.
- **Real-Time Reports:** Provide real-time visibility into compliance and expense reporting through automation, ensuring reports are on schedule and on budget. Real-time visibility in the form of complete data for analysis and reporting allows you to make the timely decisions that better control costs.
- **Flexible Reporting:** Stay efficient and keep ahead of a changing regulatory landscape with customized data satisfying internal, state, and federal requirements.
- **On the Go Access:** Make your smartphone even smarter — and life a little easier with Concur’s mobile apps.

R-SQUARED PROVIDES:

The full array of services and solutions to comply with Open Payments, state and international disclosure laws. From “Spend Discovery,” identification of all of the TOVs and related data, systems, and personnel; to the implementation of SpendTracker®, an end-to-end aggregate spend solution with sophisticated real-time Concur integration, R-Squared is the trusted expert in Transparency Disclosure Compliance. R-Squared additionally provides:

- **Concur Transparency Report Connector:** Generate CMS Open Payments and state reports using a Concur connector that transfers information to R-Squared’s technology for creation of state and federal reports consistent with legal requirements.
- **Concur NPI Attendee Fetch Connector:** Search and select HCP attendees from an up-to-date copy of the NPI database to ensure correct and accurate identification of the HCP attendees.
- **SpendTracker® with Concur Connector:** Includes all of the functionality included in the Report and NPI Attendee Fetch Connector as well as the ability to add HCP affiliates and other key attendees simultaneously to the expense and CiR²us customer master. The solution is kept up-to-date with the evolving transparency requirements by the experts at R-Squared maintaining the rules and reports on a continual basis.

Don’t waste any more valuable time documenting expenses or worrying about Open Payments compliance. Automated solutions like Concur and R-Squared empower you with increased efficiency—so you can focus on driving revenue while educating doctors on the benefits of your solution.

Find out more about Concur’s Healthcare solutions with our Life Sciences and technology partners at:

<https://www.concur.com/en-us/pharmaceutical-sunshine-act-compliance>



Additional Resources

[Watch this short video](#) to see how Concur helps you stay compliant.

Learn key steps on [Concur's blog](#) to help you prepare for Open Payments.

Find out how [Acumed](#) utilizes Concur and R-Squared.

Watch this short video to learn how [Stryker Medical](#) stays compliant.

Dive deeper into [tracking and reporting healthcare professional spend](#) with this whitepaper.

Watch this webinar to learn more about [The Sunshine Act: Best Practices for Expense Management and Compliance](#) presented by Concur and R-Squared.

Download [frequently asked questions](#) from our Best Practices for Expense Management and Compliance Webinar.

Listen to [Open Payments Compliance](#) Webinars by R-Squared.

ABOUT CONCUR

Concur is a leading provider of integrated travel and expense management solutions. Concur's adaptable Web-based and mobile solutions help companies and their employees control costs and save time. **Learn more at www.concur.com**

ABOUT R-SQUARED

R-Squared Services & Solutions, Inc. (R-Squared) is a software and consulting company that develops more efficient and effective ways to ensure evidence-based compliance with the web of regulations and laws affecting the organization. R-Squared is especially good at translating regulatory requirements into workable tools and practices that simplify the task of abiding by regulations — while generating solid evidence of compliance at the same time. We're about tighter compliance, with fewer burdens. For more information, **visit www.r2ss.com**.

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