



User Guide For Industry

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY - PHYSICIAN
FINANCIAL RELATIONSHIPS

Disclaimer: The Centers for Medicare & Medicaid Services (CMS) is providing this guidance document as informational material for industry on OPEN PAYMENTS. Although every reasonable effort has been made to assure the accuracy of the information, it is the responsibility of the industry user to ensure adherence to the requirements of the OPEN PAYMENTS implementing regulations, the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests Final Rule codified at 42 CFR Parts 402 and 403 [CMS-5060-F]. This Guide is not intended as a supplement or replacement of the final rule.

Purpose of this OPEN PAYMENTS Guide

This **OPEN PAYMENTS User Guide (Guide) for Industry** includes definitions, descriptions, screenshots, tables, tools, and tips designed to assist medical industry manufacturers and group purchasing organizations (GPOs) to better understand the rules and comply with OPEN PAYMENTS, including how to operationalize collecting and reporting data. The complete Guide consists of the following chapters:



- **Introduction**
- **General Payments Data Collection**
- **Research Payments Data Collection**
- **Physician Ownership or Investment Interests Data Collection**
- **Registration**
- **Submission and Attestation**
- **Dispute and Resolution**
- **Audits**
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- **Additional Information and Resources**

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INTRODUCTION

For Industry

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Chapter 1: Introduction

This Guide's **Introduction** chapter provides an overview to OPEN PAYMENTS, including general information about the program and how to determine if an entity is required to report certain payments or transfers of value to physicians and hospitals or certain physician ownership or investment interests as required by OPEN PAYMENTS.

Section 1.1: Program Overview

1.1a: What is the Patient Protection and Affordable Care Act Section 6002?

Section 6002 of the Patient Protection and Affordable Care Act [P.L. 110-148] amends Title XI of the Social Security Act to add a new section 1128G and mandates the creation of a program for (1) reporting payments and other transfers of value to [Covered recipients](#), [teaching hospitals](#), and [physician owners or investors](#) made by manufacturers of drugs, devices, biological, or medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) and for (2) reporting physician ownership or investment interests held by physicians or the immediate family members of physicians in such manufacturers and group purchasing organizations (GPOs) as well as reporting payments or transfers of value made by these manufacturers and GPOs to such physicians. The implementing program, previously popularly referred to as "The Sunshine Act" and now referred to as [OPEN PAYMENTS](#), establishes a system for annually reporting this information to the Centers for Medicare & Medicaid Services (CMS).

1.1b: What is the purpose of OPEN PAYMENTS?

OPEN PAYMENTS establishes a national disclosure program that promotes transparency by publishing the financial relationships between the medical industry and healthcare providers (physicians and hospitals) on a publicly accessible website developed by CMS. This public website is organized and designed to increase access to and knowledge about these relationships and to provide information to enable consumers to make informed decisions. The public can search, download, and evaluate the reported

data. Disclosure of the financial relationships between the medical industry and healthcare providers is not intended to signify an inappropriate relationship. Collaborations among the medical industry, physicians, and hospitals contribute to the design and delivery of life-saving drugs and devices. However, these relationships may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care and may potentially lead to increased health care costs. While disclosure alone is not sufficient to differentiate between the beneficial financial relationships and those that may create conflicts of interests, transparency will shed light on the nature and extent of the relationships that exist and hopefully discourage development of inappropriate relationships.

1.1c: Who participates in OPEN PAYMENTS?

OPEN PAYMENTS *requires* certain manufacturers of drugs, devices, biologicals, or medical supplies covered under Title XVIII of the Social Security Act (Medicare) or a State plan under Title XIX (Medicaid) or XXI of the Social Security Act (the Children's Health Insurance Program, or CHIP) or applicable manufacturers and certain GPOs or applicable GPOs to report as required by the program requirements. While not required to report in the program, OPEN PAYMENTS *encourages* physicians and hospitals to participate by tracking their financial relationships with applicable manufacturers and applicable GPOs and by reviewing data reported about them to ensure the accuracy of the information. Finally, OPEN PAYMENTS also *encourages* the general public and healthcare consumers to access, review, and utilize the data to make informed health care decisions.

1.1d: When are the key deadlines for OPEN PAYMENTS?

During 2013, the first program year, the OPEN PAYMENTS data collection occurs between August 1 and December 31, 2013 and the data must be reported to CMS by March 31, 2014. Beginning in 2014 and each year thereafter, data collection occurs between January 1 and ends on December 31. Applicable manufacturers and applicable GPOs are required to submit the annual reports to CMS electronically on or before March 31 for data collected during the preceding year.

Section 1.2: Determining if an entity is an Applicable Manufacturer or Applicable GPO

OPEN PAYMENTS requires certain entities, which make payments or transfers of value to certain physicians or hospitals, to report relevant data for the payment or transfer of value to CMS. In order to determine if a particular entity or organization is required to report, follow these easy steps:

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Step 1: Determine if the entity operates in the United States (includes any territory, possession or commonwealth of the United States) using Figure 1.1.

Step 2: Determine if the entity engages in activities of a Type 1 or Type 2 applicable manufacturer using Figure 1.1.

Step 3: Determine if the entity's products are covered drugs, devices, biological, or medical supplies or covered products using Figure 1.1.

Step 4: If the entity possesses the characteristics illustrated in Figure 1.1, **the entity is determined to be an applicable manufacturer in OPEN PAYMENTS.**

If the entity does not meet these characteristics, the entity is not determined to be an applicable manufacturer. Note: the entity still may be an applicable GPO in OPEN PAYMENTS.

Proceed to step 5 to determine if the entity is an applicable GPO.

Step 5: Determine if the entity operates in the United States (includes any territory, possession or commonwealth of the United States) using Figure 1.2.

Step 6: Determine if the entity engages in activities of an applicable GPO using Figure 1.2.

Step 7: Determine if the entity's products are covered drugs, devices, biological, or medical supplies or covered products using Figure 1.2.

Step 8: If the entity possesses the characteristics illustrated in Figure 1.2, **the entity is determined to be an applicable group purchasing organization (GPO) in OPEN PAYMENTS.**

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If the entity does not possess the characteristics as illustrated in Figure 1.2, the entity is not determined to be an applicable GPO in OPEN PAYMENTS.

Figure 1.1 provides an easy reference guide for determining if a drug, device, biological, or medical supply manufacturer is an applicable manufacturer in accordance with OPEN PAYMENTS. **Figure 1.1** outlines the characteristics for two types of applicable manufacturers.

Figure 1.1: Determining if an entity is an Applicable Manufacturer

Characteristic	Type 1 Manufacturer IF	Type 2 Manufacturer IF
Operate in the United States	Physical location within the United States or conducts activities within the United States (includes 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 This includes distributors or wholesalers that hold title to a covered drug, device, biological or medical supply.	Under <i>common ownership</i> with a Type 1 applicable manufacturers AND Provides <i>assistance or support</i> 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 <i>biologicals</i> , requires a prescription (or doctor’s authorization) to administer OR For devices and medical supplies, requires premarket approval or premarket notification by the FDA	

Figure 1.2 provides an easy reference guide for determining if a drug, device, biological, or medical supply purchasing entity is an applicable GPO in accordance with OPEN PAYMENTS. Figure 1.2 outlines the characteristics of applicable GPOs.

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Figure 1.2: Determine if an entity is an Applicable GPO	
Characteristic	Group Purchasing Organization IF
Operate in the United States	Physical location within the United States or conducts activities within the United States (includes any territory, possession or commonwealth of the United States)
Activities	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
Covered products	Reimbursed by Medicare, Medicaid or Children’s Health Insurance Program AND For drugs and biologics , requires a prescription (or doctor’s authorization) to administer OR For devices and medical supplies, requires premarket approval or premarket notification by the FDA

Section 1.3: Determining who is reported about in OPEN PAYMENTS

Applicable manufacturers are required to report payments or transfers of values to covered recipients. [Covered recipients](#) in OPEN PAYMENTS include physicians, except for physicians, who are bona fide employees of the reporting entity, and teaching hospitals, which are defined as the institutions that received a payment under Medicare, Medicaid, or Children’s Health Insurance Program (CHIP) during the last calendar year for which such information is available. Additionally, applicable manufacturers and applicable GPOs are required to report ownership or investment interests in the entity held by physicians, specifically [physician owners or investors](#) of the entity or the physician’s immediate family members, and also to report payments or transfers of value to these physicians. A physician’s immediate family member is the physician’s (1) spouse, (2) natural or adoptive parent, child, or sibling, (3) stepparent, stepchild, stepbrother, or stepsister, (4) father-, mother-, daughter-, son-, brother-, or sister-in-law, (5) grandparent or grandchild, or the (6) spouse of a grandparent or grandchild.

GENERAL PAYMENTS

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Chapter 2: General Payments

This Guide's **General Payments** chapter provides information on reporting for entities required to report certain payments or transfers of value in OPEN PAYMENTS, including specific detailed descriptions of the information, which must be collected for reporting by such entities. Specifically, this Guide chapter is organized in categories shown in the bulleted list of categories below for specific data elements and contains guidance and instructions for reporting [General Payments](#) made by applicable manufacturers and applicable GPOs to recipient physicians and teaching hospitals as defined in OPEN PAYMENTS. The General Payments data file specification is posted on the CMS OPEN PAYMENTS [website](#) along with the Research Payments and Physician Ownership data submission file specifications (OMB# 0938-1173). These were referred to as “templates” in the final rule.

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.
- **Recipient Demographic Information** identifies the recipient of the payments or other transfers of value.
- **Associated Drug, Device, Biological or Medical Supply Information** identifies the drug, device, biological or medical supply that is related to the payments or other transfers of value.
- **Payment or Transfer of Value Information** specifies information regarding the payments or other transfers of value.
- **General Record Information** captures other general information about the payments or other transfers of value.

Section 2.1: Reporting General Payments

CMS has provided data submission file specifications to assist applicable manufacturers and applicable GPOs for collecting and reporting the required data. The General Payments (non-research) data submission file specification (OMB# 0938-1173) provides a description of each of the data elements that should be collected and reported.

2.1a: Submission File Information

This category contains the five (5) metadata elements collected to properly identify the submitted file.

A description of the information the data element captures is also provided in Figure 2.1.

Figure 2.1: Submission File (Header) Data Elements and Descriptions

	Data Element	Description/Instructions
1	Applicable Manufacturer or Applicable GPO Submitting File Name	The name of the applicable manufacturer or applicable GPO submitting the file to CMS. The name of the applicable manufacturer or applicable GPO should be the textual proper name (legal business name) such as the name under which business activities are conducted.
2	Applicable Manufacturer or Applicable GPO Submitting File Registration ID	Upon successful registration in the OPEN PAYMENTS Program, CMS will assign this unique identifier to each registered entity. All applicable manufactures and applicable GPOs must register, regardless if the entity is part of a consolidated report. This is the registration ID for the entity submitting the payment.
3	<u>Consolidated Report</u> Indicator	Indicate whether or not the file being submitted is a consolidated report.
4	Resubmission File Indicator	Indicate whether or not the file being submitted is a resubmission (correction, amendment, replacement, or other update) of a previously submitted file. This field should be “no” during the initial file submission.
5	Original File Submission ID	Upon submission of each file, CMS will issue a file submission ID and provide this number to applicable manufacturers and applicable GPOs as part of our submission response/acknowledgement. When a resubmission is made, the applicable manufacturer or applicable GPO should include this Original File Submission ID for which the resubmission file is correcting, amending, replacing, or updating.

2.1b: Recipient Demographic Information

This category identifies the recipient of the payments or other transfers of value and contains the following twenty (20) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 2.2.

Figure 2.2: Recipient Demographic Information

	Data Element	Description/Instructions
1	Recipient Type	Indicate whether the recipient of the payment or transfer of value is (1) a physician or (2) a teaching hospital.
2	Teaching Hospital Name	Indicate the name of the teaching hospital from the standardized list for the reporting year. The standardized list may be found on the OPEN PAYMENTS website: http://go.cms.gov/openpayments in the Downloads section.
3	Teaching Hospital Tax ID Number (TIN)	Indicate the TIN for the teaching hospital as provided on the standardized list for the reporting year. The standardized list may be found on the OPEN PAYMENTS website: http://go.cms.gov/openpayments in the Downloads section.
4-7	Physician First Name, Middle Name, Last Name and Suffix	Provide the full legal name of the physician as listed in National Plan & Provider Enumeration System (NPPES). The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do
8-15	Recipient Primary Business Address, including Street, City, State, Zip Code, Country (Province and Postal Code, if applicable)	Provide the primary business address or practice location of the physician or teaching hospital.
16	Recipient Email Address	Provide the email address of the physician. The physician's email address is optional and will allow the OPEN PAYMENTS system to contact physicians that have not already registered and notify these physicians that an applicable manufacturer or applicable GPO submitted information about them.
17	Physician Primary Type	Provide the primary type of medicine practiced by the physician. The physician primary type may be any of the following: <ul style="list-style-type: none"> • Doctor of Medicine/Osteopathy • Doctor of Dental Surgery/Dental Medicine • Doctor of Podiatric Medicine • Doctor of Optometry • Licensed Chiropractor
18	Physician NPI	Provide the NPI of the physician as listed in NPPES. If the physician does not have an NPI, leave this field blank. The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do

19	Physician Specialty	<p>Provide the health care provider taxonomy code of the physician. The Health Care Taxonomy (Provider Type) may be found using the following link for the NPPES website: https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions.</p> <p>Also, cut and paste the following address for additional information available from CMS: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf</p>
20	Physician License State and License Number	<p>Provide the two-letter state abbreviation followed by the state professional license number of the physician. May report up to five (5) distinct license number.</p> <p>For example, DE-12345678901234567 indicates a license held in Delaware, followed by the license number, and separated by the dash symbol.</p>

2.1c: 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 the following four (4) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 2.3.

Figure 2.3: Associated Drug, Device, Biological or Medical Supply Information		
	Data Element	Description/Instructions
1	Product Indicator	<p>Indicate if the payment or other transfer of value is associated with: (1) “covered” when only covered drugs, biological, devices, or medical supplies, (2) “non-covered” when only non-covered drugs, biologicals, devices, or medical supplies, (3) “none” when no drugs, biologicals, devices, or medical supplies, or (4) “combination” when a combination of both covered and non-covered drugs, biologicals, devices, or medical supplies.</p> <p>Additionally, applicable manufacturers or applicable GPOs may also choose covered (1) even if the payment or other transfer of value is associated with covered and non-covered drugs, biological, devices, or medical supplies. This allows applicable manufacturers and applicable GPOs not to report that the payment or other transfer of value is actually associated with both covered and non-covered drugs, biologicals, devices, and medical supplies.</p>
2	Name of Associated Covered Drug or Biological	<p>Provide the marketed name for each covered drug or biological that was associated with the payment or other transfer of value.</p> <p>Applicable manufacturers and applicable GPOs can list up to five (5) covered drugs, biologicals, devices, or medical supplies. Applicable</p>

		manufacturers or applicable GPOs indicating covered or combination of both covered and non-covered in the data element Product Indicator must list the name of at least one covered drug, biological, device or medical supply in either data element, Name of Associated Covered Drug or Biological or the data element, Name of Associated Covered Device or Medical Supply.
3	NDC of Associated Covered Drug or Biological	Provide the National Drug Codes (NDCs) for each covered drug or biological listed in the data element, Name of Associated Covered Drug or Biological.
4	Name of Associated Covered Device or Medical Supply	Provide the marketed name, therapeutic area or product category for each device or medical supply that is associated with the payment or other transfer of value. Applicable manufacturers and applicable GPOs can list up to five (5) covered drugs, biologicals, devices, or medical supplies. Applicable manufacturers or applicable GPOs indicating covered or combination of both covered and non-covered in the data element, Product Indicator must list the name of at least one covered drug, biological, device or medical supply in either data element, Name of Associated Covered Drug or Biological or the data element, Name of Associated Covered Device or Medical Supply.

2.1d: Payment or Transfer of Value Information

This category specifies information regarding the payments or other transfers of value and contains the following eleven (11) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 2.4.

Figure 2.4: Payment or Transfer of Value Information		
	Data Element	Description/Instructions
1	Applicable Manufacturer or Applicable GPO Making Payment Name	The name of the applicable manufacturer or applicable GPO submitting the file to CMS. The name of the applicable manufacturer or applicable GPO should be the textual proper name (legal business name) such as the name under which business activities are conducted. This data element will be the same name reported in the header information as outlined in Section 1a: Submission File Information if this report is not part of a consolidated report.
2	Applicable Manufacturer or Applicable GPO Making Payment Registration ID	Upon successful registration in OPEN PAYMENTS, CMS will assign this unique identifier to each registered entity. All applicable manufactures and applicable GPOs must register, regardless if the entity is part of a consolidated report. This is the registration ID for the entity making the payment.

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3	Resubmitted Payment Record ID	This data element will be left blank for initial file submissions. For resubmission files – this data element will either be blank (indicating an omitted record is being submitted in the Resubmission file) or will contain the original payment/transfer of value record ID indicating which record is to be corrected. The original payment/transfer of value record ID is provided by the CMS OPEN PAYMENTS system.
4	Total Amount of Payment	Provide the total amount of payment in U.S. dollars.
5	Date of Payment	Provide the date of payment or other transfer of value. Report the date of the first payment or other transfer of value if the payment or other transfer of value was provided as a series of payments, for example, a consulting fee that is paid every month for three months.
6	Number of Payments Included in Total Amount	Provide the number of payments provided to a covered recipient or physician owner/investor if an applicable manufacturer or applicable GPO provided the payment or other transfer of value in a series of payments. Report one (1) if a payment or other transfer of value was only provided once to a covered recipient or physician owner or investor as opposed to a series of payments.
7	Form of Payment or Transfer of Value	Report the form of payment or other transfer of value as: (1) cash or cash equivalent, (2) in-kind items and services, (3) stock, stock option, or any other ownership interest, (4) dividend, profit or other return on investment.
8	Nature of Payment or Transfer of Value	Report the nature of payment or other transfer of value as: (1) Consulting Fee, (2) Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program, (3) Honoraria, (4) Gift, (5) Entertainment, (6) Food and Beverage, (7) Travel and Lodging, (8) Education, (9) Charitable Contribution, (10) Royalty or License, (11) Current or prospective ownership or investment interest, (12) Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program, (13) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program, (14) Grant, or (15) Space rental or facility fees (teaching hospital only).
9-11	City, State and Country of Travel	Provide the city, state, and country of travel, if the nature of payment or other transfer of value is (7) Travel and Lodging.

2.1e: General Record Information

This category captures other general information about the payments or other transfers of value and contains the following seven (7) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 2.5.

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Figure 2.5: General Record Information

	Data Element	Description/Instructions
1	Physician Ownership Indicator	Indicate yes if the payment or other transfer of value is provided to a physician covered recipient that also has an ownership or investment interest in the applicable manufacturer or applicable GPO.
2	Third Party Payment Recipient Indicator	Indicate (1) Entity or (2) Individual, if the covered recipient or physician owner or investor designated or requested a payment or other transfer of value to be made to a third party, either an entity or individual. Indicate (3) No Third Party Payment, if the covered recipient or physician owner or investor did not designate or request the payment or other transfer to be made to a third party.
3	Name of Third Party Entity Receiving Payment or Transfer of Value	Provide the name of the entity that received the third party payment from the applicable manufacturer or applicable GPO on behalf of the covered recipient or physician owner or investor.
4	Charity Indicator	Indicate yes, if the covered recipient or physician owner or investor requested or designated the payment or other transfer of value to be provided to a third party entity that is a charity.
5	Third Party Equals Covered Recipient Indicator	Indicate yes, if the covered recipient or physician owner or investor requested or designated the payment or other transfer of value to be provided to an entity or individual that is a covered recipient.
6	Contextual Information	Provide free form text than an applicable manufacturer or applicable GPO deems helpful or appropriate regarding the payment or other transfer of value. AND Provide the name of the research study associated with the payment or other transfer of value, if requesting a delay in publication by indicating such using the Delay in Publication of Research Payment Indicator.
7	Delay in Publication of Research Payment Indicator	Indicator showing if an applicable manufacturer or applicable GPO is requesting a delay in publication of a payment or other transfer of value when the payment or transfer of value is made in connection with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply). If the Delay in Publication of Research Payment Indicator equals "1" or "2", provide the name of the related research study in the data element "Contextual Information." Applicable manufacturers or applicable GPOs not requesting a delay in publication of a payment or other transfer of value should select (3) not requesting a delay in publication to indicate that no delay is requested. CMS will display payments or other transfers of value no later than four years after the initial request for delay in publication of the payment or transfer of value.

RESEARCH PAYMENTS

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Chapter 3: Research Payments

This Guide's **Research Payments** chapter provides information on reporting for entities required to report certain payments or transfers of value in OPEN PAYMENTS, including specific detailed descriptions of the information, which must be collected and reported by such entities. Specifically, this Guide chapter is organized in categories shown in the bulleted list of categories below for specific data elements and contains guidance and instructions for reporting [Research Payments](#) made by applicable manufacturers and applicable GPOs to recipient physicians and teaching hospitals as defined in OPEN PAYMENTS. The Research Payments data file specification is posted on the CMS OPEN PAYMENTS [website](#) along with the General Payments and Physician Ownership data submission file specifications (OMB# 0938-1173). These were referred to as “templates” in the final rule.

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.
- **Recipient Demographic Information** identifies the recipient of the payments or other transfers of value.
- **Associated Drug, Device, Biological or Medical Supply Information** identifies the drug, device, biological or medical supply that is related to the payments or other transfers of value.
- **Payment or Transfer of Value Information** specifies information regarding the payments or other transfers of value.
- **Research Related Information** captures specific information about payments or other transfers of value for research activities.

Section 3.1: Reporting Research Payments

CMS has provided data submission file specifications to assist applicable manufacturers and applicable GPOs to track or collect and report the required data. The Research Payments data submission file specification (OMB# 0938-1173) provides a description of each of the data elements that should be reported.

3.1a: Submission File Information

This category contains the five (5) metadata elements collected to properly identify the submitted file. A description of the information the data element captures is also provided in Figure 3.1.

Figure 3.1: Submission File (Header) Data Elements and Descriptions

	Data Element	Description/Instructions
1	Applicable Manufacturer or Applicable GPO Submitting File Name	The name of the applicable manufacturer or applicable GPO submitting the file to CMS. The name of the applicable manufacturer or applicable GPO should be the textual proper name (legal business name) such as the name under which business activities are conducted.
2	Applicable Manufacturer or Applicable GPO Submitting File Registration ID	Upon successful registration in the OPEN PAYMENTS Program, CMS will assign this unique identifier to each registered entity. All applicable manufactures and applicable GPOs must register, regardless if the entity is part of a consolidated report. This is the registration ID for the entity submitting the payment.
3	Consolidated Report Indicator	Indicate whether or not the file being submitted is a consolidated report.
4	Resubmission File Indicator	Indicate whether or not the file being submitted is a resubmission (correction, amendment, replacement, or other update) of a previously submitted file. This file should be “no” during the initial file submission.
5	Original File Submission ID	Upon submission of each file, CMS will issue a file submission ID and provide this number to applicable manufacturers and applicable GPOs as part of our submission response/acknowledgement. When a resubmission is made, the applicable manufacturer or applicable GPO should include this Original File Submission ID for which the resubmission is correcting, amending, replacing, or updating.

3.1b: Recipient Demographic Information

This category identifies the recipient of the payments or other transfers of value and contains the following twenty-one (21) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 3.2.

Figure 3.2: Recipient Demographic Information		
	Data Element	Description/Instructions
1	Recipient Type	Indicate the recipient type of the payment or transfer of value is (1) a physician or (2) a teaching hospital or (3) a non-covered recipient entity, or (4) a non-covered recipient individual.
2	Non-Covered Recipient Entity Name	Provide the name of the Non-covered Recipient Entity receiving the payment or transfer of value if the recipient type is Non-covered Recipient Entity.
3	Teaching Hospital Name	Indicate the name of the teaching hospital from the standardized list for the reporting year. The standardized list may be found on the OPEN PAYMENTS website: http://go.cms.gov/openpayments in the Downloads section.
4	Teaching Hospital Tax ID Number (TIN)	Indicate the TIN for the teaching hospital as provided on the standardized list for the reporting year. The standardized list may be found on the OPEN PAYMENTS website: http://go.cms.gov/openpayments in the Downloads section.
5-8	Physician First Name, Middle Name, Last Name and Suffix	Provide the full legal name of the physician as listed in National Plan & Provider Enumeration System (NPPES). The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do
8-16	Recipient Primary Business Address, including Street, City, State, Zip Code, Country (Province and Postal Code, if applicable)	Provide the primary business address or practice location of the physician or teaching hospital.
17	Recipient Email Address	Provide the email address of the physician. The physician's email address is optional and will allow the OPEN PAYMENTS system to contact physicians that have not already registered and to notify these physicians that an applicable manufacturer or applicable GPO submitted information about them.
18	Physician Primary Type	Provide the primary type of medicine practiced by the physician. The physician primary type may be any of the following: Doctor of Medicine/Osteopathy Doctor of Dental Surgery/Dental Medicine Doctor of Podiatric Medicine Doctor of Optometry Licensed Chiropractor

19	Physician NPI	Provide the NPI of the physician as listed in NPPES. If the physician does not have an NPI, leave this field blank. The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do
20	Physician Specialty	Provide the health care provider taxonomy code of the physician. The Health Care Taxonomy (Provider Type) may be found using the following link for the NPPES website: https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions . Also, cut and paste the following address for additional information available from CMS: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf
21	Physician License State and License Number	Provide the two-letter state abbreviation followed by the state professional license number of the physician. May report up to five (5) distinct license numbers, if known. For example, DE-12345678901234567 indicates a license held in Delaware, followed by the license number, and separated by the dash symbol.

3.1c: 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 the following four (4) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 3.3.

Figure 3.3: Associated Drug, Device, Biological or Medical Supply Information		
	Data Element	Description
1	Product Indicator	Indicate if the payment or other transfer of value is associated with: (1) "covered" when only covered drugs, biological, devices, or medical supplies, (2) "non-covered" when only non-covered drugs, biologicals, devices, or medical supplies, (3) "none" when no drugs, biologicals, devices, or medical supplies, or (4) "combination" when a combination of both covered and non-covered drugs, biologicals, devices, or medical supplies. Additionally, applicable manufacturers or applicable GPOs may also choose covered even if the payment or other transfer of value is associated with covered and non-covered drugs, biological, devices, or medical supplies. This allows applicable manufacturers and applicable GPOs not to report that the payment or other transfer of value is actually associated with both covered and non-covered drugs, biologicals, devices, and medical supplies.

2	Name of Associated Covered Drug or Biological	Provide the marketed name for each covered drug or biological that is associated with the payment or other transfer of value. Applicable manufacturers and applicable GPOs can list up to five (5) covered drugs, biologicals, devices, or medical supplies. Applicable manufacturers or applicable GPOs indicating covered or combination of both covered and non-covered in the data element Product Indicator must list the name of at least one covered drug, biological, device or medical supply in either data element, Name of Associated Covered Drug or Biological or the data element, Name of Associated Covered Device or Medical Supply.
3	NDC of Associated Covered Drug or Biological	Provide the National Drug Codes (NDCs) for each covered drug or biological listed in the data element Name of Associated Covered Drug or Biological.
4	Name of Associated Covered Device or Medical Supply	Provide the marketed name, therapeutic area, or product category for each device or medical supply that was associated with the payment or other transfer of value. Applicable manufacturers and applicable GPOs can list up to five (5) covered drugs, biologicals, devices, or medical supplies. Applicable manufacturers or applicable GPOs indicating covered or a combination of both covered and non-covered in the data element Product Indicator must list at least one covered drug, biological, device or medical supply in either data element, Name of Associated Covered Drug or Biological or the data element, Name of Associated Covered Device or Medical Supply.

3.1d: Payment or Transfer of Value Information

This category specifies information regarding the payments or other transfers of value and contains the following seven (7) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 3.4.

Figure 3.4: Transfer of Value (Research Payment) Information		
	Data Element	Description
1	Applicable Manufacturer or Applicable GPO Making Payment Name	The name of the applicable manufacturer or applicable GPO submitting the file to CMS. The name of the applicable manufacturer or applicable GPO should be the textual proper name (legal business name) such as the name under which business activities are conducted. This data element will be the same name reported in the header information as outlined in Section 1a: Submission File Information if this report is not part of a consolidated report.

2	Applicable Manufacturer or Applicable GPO Making Payment Registration ID	Upon successful registration in OPEN PAYMENTS, CMS will assign this unique identifier to each registered entity. All applicable manufactures and applicable GPOs must register, regardless if the entity is part of a consolidated report. This is the registration ID for the entity making the payment.
3	Resubmitted Payment Record ID	This data element will be left blank for initial file submissions. For resubmission files – this data element will either be blank (indicating an omitted record is being submitted in the Resubmission file) or will contain the original payment/transfer of value record ID (indicating which record is to be corrected). The original payment/transfer of value record ID is provided by the CMS OPEN PAYMENTS system.
4	Total Amount of Payment	Provide the total amount of payment in U.S. dollars.
5	Date of Payment	Provide the date of payment or other transfer of value. Report the date of the first payment or other transfer of value, if the payment or other transfer of value was provided as a series of payments; for example, a consulting fee that is paid every month for three months.
6	Form of Payment or Transfer of Value	Report the form of payment or other transfer of value as: (1) cash or cash equivalent, (2) in-kind items and services, (3) stock, stock option, or any other ownership interest, (4) dividend, profit or other return on investment.
7	Expenditure Category	Provide the Expenditure Category for the research payment or transfer of value. There can be multiple categories for this research reported; however, for every Expenditure Category reported, an Expenditure Category percentage must also be reported. The expenditure categories are: (1) professional salary support, (2) medical research writing or publication, (3) patient care, (4) non-patient care, (5) overhead, and/or (6) other. The reporting format is the Expenditure Category, which is represented as a single number for the category followed by the 2 or 3 digit percentage value (e.g. 1-90 or 1-100).

3.1e: Research Related Information

This category captures other general information about the payments or other transfers of value and contains the following twenty-three (23) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 3.5.

Figure 3.5: Research Related Information		
	Data Element	Description
1	Pre-Clinical Research Indicator	Indicate yes, if payment or transfer of value is related to research, which is pre-clinical.

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2	Delay in Publication of Research Payment Indicator	<p>Indicator showing if an applicable manufacturer or applicable GPO is requesting a delay in publication of a payment or other transfer of value when the payment or transfer of value is made in connection with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply). If the Delay in Publication of Research Payment Indicator equals "1" or "2", provide the name of the related research study in the date element "Contextual information."</p> <p>Applicable manufacturers or applicable GPOs not requesting a delay in publication of a payment or other transfer of value should select (3) not requesting a delay in publication to indicate that no delay is requested. CMS will display payments or other transfers of value no later than four years after the initial request for delay in publication of the payment or transfer of value.</p>
3	Name of Study	Provide the textual name of the study for which the covered recipient is receiving this payment or transfer of value. If the payment or other transfer of value is related to pre-clinical research, the name of the study is not required.
4	Context of Research	Provide a textual description of research context or research objectives.
5	ClinicalTrials.gov Identifier	Provide the identifier assigned if research study is registered on clinicaltrials.gov.
6	Research Information Link	Optional link to information relevant to the research study for which this payment or transfer of value is being reported; a maximum of five links may be reported.
7	Principal Investigator Covered Recipient Physician Indicator	<p>Indicate yes, if the Principal Investigator of the research study is a covered recipient physician.</p> <p>If there are multiple Principal Investigators, indicate "Yes" if at least one (1) is a covered recipient physician and provide the identifiers for each Principal Investigator (up to 5), who is a covered recipient physician. The Principal Investigator identifiers are: Principal Investigator's First, Middle, Last Name and Suffix, Principal Investigator's Address, Principal Investigator Physician Primary Type, Principal Investigator NPI, Principal Investigator Specialty, and Principal Investigator License State and License Number.</p> <p>It is not necessary to duplicate the identifiers for the Principal Investigator if the principal investigator is the same as the recipient physician receiving the payment and provided in the Recipient Demographic Information category.</p>
8-11*	Principal Investigator's First, Middle, Last Name and Suffix	<p>Provide the full legal name of the physician (covered recipient) as listed in National Plan & Provider Enumeration System (NPPES). The NPPES website:</p> <p>https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do</p>
12-	Principal Investigator's	Provide the primary business address or practice location of the

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19*	Address	physician principal investigator.
20*	Principal Investigator Physician Primary Type	Provide the primary type of medicine practiced by the physician principal investigator. The physician primary type may be any of the following: Doctor of Medicine/Osteopathy Doctor of Dental Surgery/Dental Medicine Doctor of Podiatric Medicine Doctor of Optometry Licensed Chiropractor
21*	Principal Investigator NPI	Provide the NPI of the physician as listed in NPPES. If the physician does not have an NPI, leave this field blank. The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do
22*	Principal Investigator Specialty	Provide the health care provider taxonomy code of the physician. The Health care Taxonomy (Provider Type) may be found using the following link for the NPPES website: https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions . Also, cut and paste the following address for additional information available from CMS: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf
23*	Principal Investigator License State and License Number	Provide the two-letter state abbreviation followed by the state professional license number of the physician covered recipient principal investigator. May report up to five (5) distinct license numbers, if known. For example, DE-12345678901234567 indicates a license held in Delaware, followed by the license number, and separated by the dash symbol.
*	For Multiple Principal Investigators	Name, Address, Primary and Specialty Type, NPI, and State and State License Number

PHYSICIAN OWNERSHIP

For Industry

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Chapter 4: Physician Ownership

This Guide's **Physician Ownership** chapter provides information on reporting for entities required to report certain payments or transfers of value in OPEN PAYMENTS, including specific detailed descriptions of the information, which must be collected and reported by such entities. Specifically, this Guide chapter is organized in categories shown in the bulleted list of categories below for specific data elements and contains guidance and instructions for reporting Physician Ownership made by applicable manufacturers and applicable GPOs to covered recipient physicians and teaching hospitals as defined in OPEN PAYMENTS. The Physician Ownership data file specification is posted on the CMS OPEN PAYMENTS [website](#) along with the General Payments and Research Payments data submission file specifications (OMB# 0938-1173). These were referred to as “templates” in the final rule.

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.
- **Physician Demographic Information** identifies the recipient of the payments or other transfers of value.
- **Ownership or Investment Information** captures information about the ownership or investment.

Section 4.1: Reporting Physician Ownership

CMS has provided data submission file specifications to assist applicable manufacturers and applicable GPOs to track or collect and report the required data. The Physician Ownership data submission file specification (OMB# 0938-1173) provides a description of each of the data elements that should be reported.

4.1a: Submission File Information

This category contains the five (5) metadata elements collected to properly identify the submitted file. A description of the information the data element captures is also provided in Figure 4.1.

Figure 4.1: Submission File (Header) Data Elements and Descriptions		
	Data Element	Description/Instructions
1	Applicable Manufacturer or Applicable GPO Submitting File Name	The name of the applicable manufacturer or GPO submitting the file to CMS. The name of the applicable manufacturer or GPO should be the textual proper name (legal business name) such as the name under which business activities are conducted.
2	Applicable Manufacturer or Applicable GPO Submitting File Registration ID	Upon successful registration in the OPEN PAYMENTS Program, CMS will assign this unique identifier to each registered entity. All applicable manufactures and applicable GPOs must register, regardless if the entity is part of a consolidated report. This is the registration ID for the entity submitting the payment.
3	Consolidated Report Indicator	Indicate whether or not the file being submitted is a consolidated report.
4	Resubmission File Indicator	Indicate whether or not the file being submitted is a resubmission (correction, amendment, replacement or other update) of a previously submitted file.
5	Original File Submission ID	Upon submission of each file, CMS will issue a file submission ID and provide this number to applicable manufacturers and applicable GPOs as part of our submission response/acknowledgement. When a resubmission is made, the AM or GPO should include the File ID for which the resubmission is correcting, amending, replacing, or updating.

4.1b: Physician Demographic Information

This category identifies the physician recipient of the ownership or investment and contains the following seventeen (17) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 4.2.

Figure 4.2: Recipient Demographic Information

	Data Element	Description/Instructions
1-4	Ownership/Investment Physician's First Name, Middle Name, Last Name and Suffix	Provide the full legal name of the physician as listed in National Plan & Provider Enumeration System (NPPES). The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do
5-12	Ownership/Investment Physician's Primary Business Address, including Street, City, State, Zip Code, Country (Province and Postal Code, if applicable)	Provide the primary business address or practice location of the physician.
13	Ownership/Investment Physician's Email Address	Provide the email address of the physician. The physician's email address is optional and will allow the OPEN PAYMENTS system to contact physicians that have not already registered and to notify these physicians that an applicable manufacturer or applicable GPO submitted information about them.
14	Ownership/Investment Physician's Primary Type	Provide the primary type of medicine practiced by the physician. The physician primary type may be any of the following: Doctor of Medicine/Osteopathy Doctor of Dental Surgery/Dental Medicine Doctor of Podiatric Medicine Doctor of Optometry Licensed Chiropractor
15	Ownership/Investment Physician's NPI	Provide the NPI of the physician as listed in NPPES. If the physician does not have an NPI, leave this field blank. The NPPES website: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do
16	Ownership/Investment Physician's Specialty	Provide the health care provider taxonomy code of the physician. The Health Care Taxonomy (Provider Type) may be found using the following link for the NPPES website: https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions . Also, cut and paste the following address for additional information available from CMS: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf
17	Ownership/Investment Physician's License State and License Number	Provide the two-letter state abbreviation followed by the state professional license number of the physician. May report up to five (5) distinct license numbers, if known. For example, DE-12345678901234567 indicates a license held in Delaware, followed by the license number, and separated by the dash symbol.

Section 4.1c: Ownership or Investment Information

This category captures ownership or investment information and contains the following seven (7) data elements. A description of the information the data element captures or an instruction regarding the data element is also provided in Figure 4.3.

Figure 4.3: Ownership or Investment Information

	Data Element	Description/Instruction
1	Applicable Manufacturer or Applicable GPO Reporting Ownership Name	The name of the applicable manufacturer or GPO submitting the file to CMS. The name of the applicable manufacturer or GPO should be the textual proper name (legal business name) such as the name under which business activities are conducted.
2	Applicable Manufacturer or Applicable GPO Reporting Ownership Registration ID	Upon successful registration in OPEN PAYMENTS, CMS will assign this unique identifier to each registered entity. All applicable manufactures and applicable GPOs must register, regardless if the entity is part of a consolidated report.
3	Resubmitted Ownership Record ID	This data element will be left blank for initial file submissions. For resubmission files – this data element will either be blank (indicating an omitted record is being submitted in the Resubmission file) or will contain the original payment/transfer of value record ID (indicating which record is to be corrected). The original ownership record ID is provided by the CMS OPEN PAYMENTS system.
4	Interest Held by Physician or an Immediate Family Member	Indicate “1,” if the ownership of investment interest is held by a physician or “2,” if the ownership or investment interest is held by a physician’s immediate family member.
5	Dollar Amount Invested	Provide the dollar amount the physician or immediate family member has invested in the applicable manufacturer and applicable GPO in U.S. Dollars.
6	Value of Interest	Provide the current value of the ownership or investment interest of the physician or immediate family member. Applicable manufacturers and applicable GPOs have some flexibility to decide how to report the value of such interest. However, they must document the method used to estimate the value of the ownership or investment and may include such documentation if they submit an assumptions document with their annual report.

Figure 4.3: Ownership or Investment Information

	Data Element	Description/Instruction
7	Terms of Interest	Provide a description of any applicable terms of the ownership or investment interest. When reporting the terms of an ownership or investment interest applicable manufacturers and applicable GPOs should report the type of ownership or investment interest, including but not limited to stock, stock options, partnership shares, loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

Appendix: Additional Information

Glossary for OPEN PAYMENTS

Applicable Manufacturer:

Either of two (2) types of entities that operate in the United States (includes any territory, possession or commonwealth of the United States):

(1) an entity, which operates is in the United States and 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. This definition does include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that hold title to any covered drug, device, biological or medical supply, or

(2) an entity under common ownership with an entity in paragraph (1) (a type 1 applicable manufacturer) of this definition, 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 drug, device, biological or medical supply.

Applicable Group Purchasing Organization (GPO):

An entity that (1) operates in the United States and (2) 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.

Assistance or Support:

Providing a service or services necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Biologicals:

For the purpose of OPEN PAYMENTS, biologicals are defined as in Section 1927(k)(2)(B) of the Social Security Act, which includes a cross-reference to licensure under Section 351 of the Public Health Service Act ("PHS Act").

Common Ownership:

The same individual, individuals, entity or entities directly or indirectly own five 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.

Consolidated Report:

A submission report from an entity, who submits payment or other transfer of value information on behalf of an entity with which they are under common ownership. This file contains all reportable payment or other transfer of value information required by OPEN PAYMENTS for each of the entities for which the consolidated report represents.

Covered Recipients:

In OPEN PAYMENTS, covered recipients include physicians (except for physicians who are bona fide employees of the reporting entity) and teaching hospitals (institutions that received a payment under Medicare, Medicaid, or Children's Health Insurance Program (CHIP) during the last calendar year for which such information is available).

General Payments or General Payments (non-research):

Payments or other transfers of value not made in connection with a research agreement or research protocol as required in OPEN PAYMENTS.

OPEN PAYMENTS:

A national transparency program implementing the regulation, the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests Final Rule codified at 42 CFR Parts 402 and 403 [CMS-5060-F, published February 08, 2013] as required by Section 6002 of the Patient Protection and Affordable Care Act.

Physician Owners or Investors:

Physicians, who have an ownership or investment interest in an applicable manufacturer or applicable group purchasing organization. Applicable manufacturers and applicable group purchasing organizations are required to report ownership or investment interests held by a physician or a physician's immediate family member in an applicable manufacturer or applicable group purchasing organization.

Research Payments:

Payments or other transfers of value made in connection with a research agreement or research protocol as required in OPEN PAYMENTS.

Teaching Hospital:

Any institution that received a payment under 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. CMS will post the teaching hospital list annually on the OPEN PAYMENTS website (<http://go.cms.gov/openpayments>).