

Supporting Statement Part A

Data Collection and Submission, Registration, Attestation, Dispute and Resolution, Record Retention, and Assumptions Document Submission, for Open Payments

CMS-10495, OMB Control Number: 0938-1237

INTRODUCTION

Background

Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (the Act), which requires applicable manufacturers (AMs) of covered drugs, devices, biologicals, or medical supplies (as defined at 42 CFR 403.902) to report annually to the Secretary certain payments or other transfers of value to covered recipients.¹ Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Specifically, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to covered recipients during the course of the preceding calendar year (CY). Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors.

Applicable manufacturers must report the required payment and other transfer of value information annually to the Secretary of the Department of Health and Human Services (HHS) (the Secretary) in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to the Secretary the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. The Secretary is required by statute to publish the reported data on a public website. The data must be downloadable, easily searchable, and aggregated. In addition, CMS must submit annual reports to the Congress and each State summarizing the data reported. Finally, section 1128G of the Act generally preempts State laws that require disclosure of the same type of information by manufacturers.

¹ Prior to January 1, 2021 “covered recipients” included physicians and teaching hospitals. Beginning with data required collected on or after January 1, 2021, the definition of a covered recipient includes physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives.

This 2021 iteration incorporates four updates to the collection of information associated with the Open Payments program: (1) adjusted burden estimates, (2) revised data collection instruments, (3) an annual survey of OP program stakeholders, and (4) modifications to the Open Payments system. The first update reflects five changes being adopted in the CY 2022 Physician Fee Schedule (PFS) Final Rule (CMS-1751-P, RIN: 0938-AU42). The rule clarifies existing Open Payments requirements, as well as adds provisions that program stakeholders have requested and we agree will improve the quality of the data. The new provisions will be implemented for data collection in 2023 and reporting in 2024. They include:

Provision	Type of Activity	Effective Date
(1) adding a mandatory payment context field for records to teaching hospitals	Data Collection	Beginning of CY 2023
(2) adding the option to recertify annually even when no records are being reported	Reporting	Beginning of CY 2024
(3) disallowing record deletions without a substantiated reason	Reporting	Beginning of CY 2024
(4) requiring entities to update their contact information	Reporting	Beginning of CY 2024
5) removing the option to submit and attest to general payment records with an “Ownership” Nature of Payment category	Reporting	Beginning of CY 2024

CMS presented draft burden estimates for these new provisions in the CY 2022 PFS Notice of Proposed Rulemaking (NPRM), which we are updating in this document to reflect more recent data used to produce the estimates. We believe the new provisions will all have minimal burden, but will increase the usability of the data and address concerns we have heard from stakeholders.

Corresponding to these new provisions are several changes to the instruments used for data collection, reporting and other functions associated with the OP program. Draft versions of these revised instruments are presented as part of this package to allow the public to comment on them.

In addition to these updates associated with the new provisions in the CY 2022 PFS, we are also requesting to add a brief annual survey of stakeholders. The purpose of the annual survey is to formalize and improve our consultation with stakeholders on their views on availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. CMS regularly provides opportunity for consultation with representatives from entities that report to or use the

Open Payments program through avenues such as meetings and system previews. However, the primary source of consultation is the limited feedback we receive via the Open Payments Help Desk (openpayments@cms.hhs.gov / 1-855-326-8366 / TTY Line: 1-844-649-2766) and Open Payments Compliance (opcompliance@cms.hhs.gov). To more frequently obtain feedback from a larger number of stakeholders, we are proposing to add to this ICR an annual digital survey of stakeholders. This optional survey will consist of five open-ended questions. To administer the survey, an email with a link to the web-based survey will be emailed to all active stakeholders. CMS will begin implementing the survey in CY 2023.

Finally, this ICR also includes three OP system changes that will improve data quality and help facilitate data validation and analysis. We do not believe that these changes will increase the burden on users of the OP system. The changes will be implemented in the January 2024 application release, and will include the following:

System Change	Description
Add a way to track deleted records and link them to new records that are submitted.	In some cases, an entity that wishes to make a change (e.g., a covered recipient) currently must delete the old record and re-submit a new record, with no way to link the two. The system change will provide a way to link the "old" record ID to the "new" record when the entity resubmits it.
Update and Validate R&D Contact Information Fields for Reporting Entities	Entities currently use a free form text box to provide their R&D contact information. This will be replaced with specific fields for name, email, and phone number, which will be validated.
Create an 11-digit National Drug Code (NDC) file	Drug codes reported by entities are currently formatted and validated using a 10-digit NDC code file. This change will add an 11-digit NDC code file that can be used for the same purpose.

This package is to inform the public about information collected that is necessary for data collection and submission, registration, attestation, dispute resolution and corrections, record retention, and submitting an assumptions document within Open Payments.

Data Collection and Submission

Section 403.904 requires direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable

manufacturer on behalf of a covered recipient, must be reported by the applicable manufacturer to CMS on an annual basis.

Section 403.906 requires each applicable manufacturer and applicable group purchasing organization to report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

For both collections, the data templates provide detailed information about the data to be collected including the data element name, format, allowable values, required versus optional fields, and other associated rules intended to aid the applicable manufacturers and applicable group purchasing organizations as they prepare for and participate in data collection.

Registration

Section 403.908(c) states that applicable manufacturers and applicable group purchasing organizations that have reportable payments or other transfer of value, ownership or investment interests, or both, are required to register for Open Payments.² According to § 403.908(g)(2)(ii) (B) covered recipients and physician owners or investors may also register with Open Payments to receive notifications regarding the review process for data submitted about them. We describe in more detail in the system user guide,³ the information needed to register within the supplemental document. Additionally, during the registration process applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors will receive emails from the Open Payments system that will prompt individuals registering to verify information. We describe in more detail the emails covered recipients, and physician owners or investors will receive during the registration process in the supplemental document entitled “Registration-Physician-Hospitals-AMs- GPOs.”

Attestation

Section 403.908(e) requires applicable manufacturers and applicable GPOs to attest to each report, including any subsequent corrections to a filed report. A Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable GPO is required to attest that the information reported is timely, accurate, and complete to best of his or her knowledge and belief.

Dispute Resolution and Corrections

Section 403.908(g) provides covered recipients and physician owners or investors a 45-day review period to review data submitted about them prior to the data becoming available to the public. Additionally, § 403.908(g)(3) allows covered recipients and physician owners or investors to indicate if the information reported is accurate. Conversely, § 403.908(g)(3)(iv) and (v) provides covered recipients and physician owners or investors an opportunity to dispute information regarding a payment or other transfer of value. Covered recipients and physician

² Registration within Open Payments does not include registration within Enterprise Identity Management System (EIDM), but assumes that individuals and entities registering in Open Payments already have CMS user IDs and passwords.

³ [Open Payments User Guide for Reporting Entities](#) [Open Payments User Guide for Covered Recipients](#).

owners or investors will indicate which information regarding a specific payment or other transfer of value is being disputed. We specify what information covered recipients and physician owners or investors may dispute in the supplemental document entitled “Review and Dispute Screen Shots.” Applicable manufacturers and applicable GPOs will receive a notification that a covered recipient or physician owner or investor is disputing reported information. The dispute resolution process is between applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors. Consistent with § 403.908(g)(4) and (h)(1) applicable manufacturers or applicable GPOs are required to submit corrected data to CMS, either as a result of dispute resolution or if errors or omissions are discovered in their report. Resubmission of data is an aspect of data collection consistent with the data collection processes.

Record Retention

Section 403.912(e)(1) requires applicable manufacturers and applicable group purchasing organizations to maintain all books, contracts, records, documents and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturers and applicable group purchasing organization’s compliance with the requirement to timely, accurately or completely submit information for a period of at least five years from the date of payment or other transfer of value.

Assumptions Document

Section 403.908(f) provides an opportunity for applicable manufacturers or applicable GPOs to submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests.

The assumptions document will not be made available to covered recipients, physician owners or investors, or the public.

A. JUSTIFICATION

1. Need and Legal Basis

The Patient Protection and Affordable Care Act was enacted on March 23, 2010 (Pub. L. 111-148). This statute amended section 1128 of the Social Security Act (the Act) by adding a new subsection G that requires applicable manufacturers of drugs, devices, biologics, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX (Medicaid) or XXI of the Act (the Children’s Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities, as well as any payments provided to such physicians.

The final rule (February 8, 2013; 78 FR 9468; RIN 0938-AR33) implementing Section 1128G of the Social Security Act includes other information collections associated with (1) data collection

and submission (§§ 403.904 and 403.906), (2) the registration system for applicable manufacturers and applicable GPOs (§ 403.908) and physicians and teaching hospitals (§403.908(g)(2)(b)(ii)(B)); (3) the review process, in which registrants have an opportunity to review submitted information and certify accurate information (§ 403.908(g)(3)(iii)) or initiate a dispute (§ 403.908(g)(3)(iv)); (4) the requirements for applicable manufacturers and applicable GPOs to notify CMS of resolved disputes (§ 403.908(g)(4)) or upon discovering errors or omissions in their reports (§ 403.908(h)); (5) the five-year recordkeeping requirement for applicable manufacturers and applicable GPOs (§ 403.912); and (5) the process for applicable manufacturers and applicable GPOs to request submission extensions from CMS. Adjustments and clarifications to the regulations were made in the 2015 PFS (79 FR 67758).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115-270) was signed into law. Section 6111 of the SUPPORT Act amended the definition of “covered recipient” under section 1128G(e)(6) of the Act. The Open Payments rule was adjusted in the CY 2020 PFS to codify this change. CMS also updated the nature of payment categories and standardized data on reported products by adding a “device identifier” component for devices and medical supplies.

In 2021, CMS finalized eight Open Payments proposals in the 2022 Physician Fee Schedule, which were minor updates intended to improve reporting process and the quality of the data. The following changes were included: adding a mandatory payment context field for records to teaching hospitals; adding the option to recertify annually even when no records are being reported; disallowing record deletions without a substantiated reason; updating the definition of ownership and investment interest and adding a definition for a physician-owned distributorship as a subset of applicable manufacturers and group purchasing organizations; requiring reporting entities to update their contact information; disallowing publication delays for general payment records, clarifying the exception for short-term loans; and removing the option to submit and attest to general payment records with an “Ownership” Nature of Payment category.

2. Information Users

As noted in the February 8, 2013, final rule, public reporting of the extent and nature of relationships between covered recipients and industry manufacturers through increased transparency permits patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships.

The data reported to CMS is reviewed and then made available to the public. To date, the Open Payments program has published over seventy-eight million records totaling more than fifty-nine billion dollars. The website presents the data in a way that is easy to understand, and at minimum, is searchable, downloadable, and able to be aggregated based on various parameters. CMS believes this enables the public to realize the benefits noted above.

The submitted information facilitates various aspects of the program. The information collected through the registration process is used by CMS to validate registration for applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors that are registering for Open Payments. Details collected during the dispute resolution and correction process allows CMS to notify applicable manufacturers and applicable GPOs that a covered

recipient or physician owner or investor is initiating a dispute regarding data submitted about them and allow CMS to relay the nature of the dispute. The assumptions documents submitted by applicable manufacturers or applicable GPOs assist CMS in providing guidance (for example, determining form and nature of payment categories, calculating the value of a payment, determining the date of payment, and reporting the terms of an ownership or investment interest).

3. Use of Information Technology

The statute requires that the data be submitted electronically. Data may be submitted through an interactive online interface or through a bulk data submission in Character Separated Values (CSV) format. Providing two data submission options helps reduce burden on covered entities as the entity can assess their circumstances and choose the least costly way to report: e.g., entities with a large number of transactions can implement systems that allow them to report in bulk – reducing the costs that would otherwise be required to enter their transactions one-by-one in the interactive online interface.

Data is submitted in the formats defined in the Open Payments Submissions Data Mapping document. Any changes will be provided at least 90 days in advance of data collection in order to provide adequate time for relevant systems changes by applicable manufacturers and applicable GPOs. Research related transfers of value, general related transfers of value, and ownership interest transactions are submitted in separate files with a specific data format defined for each type. Each line in each file submitted (with the exception of file header information) represents a single unique transaction to a single covered recipient. Additional transfers of value to the same covered recipient should be submitted as additional data lines.

The information from the collection is reported publicly on a website (url: <https://www.cms.gov/OpenPayments/Explore-the-Data/Explore-the-Data.html>), as required by statute. Data on the public site is static as of a given date and is refreshed at least once annually beyond the initial publication of data. Registration, attestation, dispute resolution and correction process, and submission of an assumption document will also be completed electronically by applicable manufacturers, applicable GPOs, covered recipients, or physician owners or investors.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

In addition, § 403.914 defines that in the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a state or political subdivision of a state that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

5. Small Businesses

CMS has minimized the burden on small businesses by using the CMS Enterprise Portal. This provides easy access to data for internal, operational, and technical considerations, including

streamlined tools for registration and data submission. It improves and streamlines the user experience through an enterprise-level approach to the interface design.

Small businesses, which may have fewer payments, etc. to report, have the option to input their data manually for data submission. This provides flexibility for small businesses because they are not required to develop specialized IT systems to submit required data to CMS. Larger firms are permitted to use this technology too, but may find that specialized IT systems are more efficient for their purposes, especially if they have a large number of payments, etc. to report.

6. Less Frequent Collection

The table below outlines the frequency requirements for the various Open Payments processes covered in this package.

Process	Frequency
Data Collection and Submission	The statute requires that the data be collected and submitted to CMS annually. Data collection occurs throughout the calendar year or as payments or transfers of value occur. Data submission occurs annually in February and March.
Registration	Registration is required once, but upon filing the annual reports the system will prompt applicable manufacturers and applicable GPOs to confirm that the registration information is still accurate. 42 CFR 403.908(c) requires applicable manufacturers and applicable GPOs that are submitting data to register with CMS within 90 days of the end of the calendar year for which a report is required. Additionally, covered recipients may register anytime and will only be required to confirm that the registration is still accurate after the initial registration.
Attestation and Assumptions Document	The final rule specifies that applicable manufacturers and applicable GPOs must attest to information submitted, as well as have the opportunity to submit an assumptions document.
Dispute Resolution and Corrections	The final rule specifies that CMS is not involved in the dispute and resolution process, however, there are provisions to utilize the Open Payments system to initiate disputes regarding reported information.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day noticed published in the Federal Register on April 12, 2022 (87 FR 21660). CMS received one comment in response to the comment request, but it was not relevant to this data collection. A 30-day FR notice will publish in the Federal Register on April 4, 2023 (88 FR 19957).

Outside Consultation

CMS regularly provides opportunity for consultation with representatives from entities that report to or use the Open Payments program through avenues such as meetings and system

previews. CMS receives inquiries via the Open Payments Help Desk (openpayments@cms.hhs.gov / 1-855-326-8366 / TTY Line: 1-844-649-2766) and Open Payments Compliance (opcompliance@cms.hhs.gov) but the opportunity for constructive feedback does not exist. To increase consultation with stakeholders, we are proposing to add to this ICR an annual digital survey of stakeholders that will solicit their views on availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

We pledge privacy to the extent allowed by law. Open Payments is a system of record (SOR# 09-70-0507 published in Federal Register on June 5 2014 (Vol. 79, No. 108)). The vast majority of the required data is required to be reported publicly, as noted in the data templates.

Information not required to be reported publicly is safeguarded in accordance with Departmental standards and National Institute of Standards and Technology (NIST) Special Publication 800-53, Recommended Security Controls for Federal Information Systems and Organizations which limits access to only authorized personnel. The safeguards provide a level of security as required by Office of Management and Budget (OMB) Circular No. A- 130 (revised), Appendix III – Security of Federal Automated Information Systems.

11. Sensitive Questions

Under § 6002 of the Affordable Care Act, we are required to collect information about the financial payments to healthcare providers and the financial relationships of physicians and their families. While we are sensitive to the privacy concerns of covered recipients and physician family members, this reporting is required by statute. During the 45- day review period, covered recipients will be afforded the opportunity to review the information about them that will be disclosed, and they may dispute the information if it is not accurate. This information collection does not contain questions pertaining to sex, behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Burden Estimates

We estimate the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information according to §§ 403.902, 403.904, 403.906, and 403.908(c), (e), (g), (h), and (f). We utilize data from the U.S Bureau of Labor Statistics (BLS) to derive average costs for all estimates of salary in establishing the information collection requirements. Mean salary estimates are based on the BLS May 2020 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). We are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total

cost is a reasonably accurate estimation method. We assume the doubled 2020 wage figures will increase by 3 percent annually to produce the estimates for 2023 – 2025.

Adjusted Hourly Wage by Occupation (Current \$)

Occupation Title	Occ. code	2020	2023	2024	2025
Bookkeeping, Accounting, and Auditing Clerks	43-3031	\$42.40	\$46.33	\$47.72	\$49.15
Compliance Officer	13-1041	\$72.70	\$79.44	\$81.82	\$84.28
Office and Administrative Support Workers, All Other	43-9199	\$37.82	\$41.33	\$42.57	\$43.84
Anesthesiologist	29-1211	\$120.90	\$132.11	\$136.07	\$140.16
Family Medicine Physicians	29-1215	\$261.00	\$285.20	\$293.76	\$302.57
General Internal Medicine Physicians	29-1216	\$206.12	\$225.23	\$231.99	\$238.95
Obstetricians and Gynecologists	29-1218	\$202.84	\$221.65	\$228.30	\$235.15
Pediatricians, General	29-1221	\$229.92	\$251.24	\$258.78	\$266.54
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	\$177.48	\$193.94	\$199.76	\$205.75
Psychiatrists	29-1223	\$210.44	\$229.95	\$236.85	\$243.96
Surgeons, Except Ophthalmologists	29-1248	\$208.76	\$228.12	\$234.96	\$242.01
Physicians	Average of 29-*	\$217.32	\$237.47	\$244.59	\$251.93

In Program Year (PY) 2019, there were 1,589 applicable manufacturers that submitted data, and there were 23 GPOs that submitted data. Rather than relying on PY 2020 entity counts, which were affected by the Covid-19 pandemic, we used PY 2019 counts as a more appropriate proxy of average annual entities. In 2019, AM’s and GPO’s have reported data for 624,390 physicians. We estimate that just 5%, or 31,220 physicians, registered to review reported information. This information is based on records to date, so we estimate that many physicians will not devote any time in reviewing the aggregated reports from CMS. Physicians are defined in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, optometrists, and licensed chiropractors for the purposes of Open Payments. As of reporting year end for 2019, there were records for 1,201 teaching hospitals. The teaching hospitals list was created by evaluating CMS data to determine hospitals that have a payment under sections 1886(d)(5)(B), 1886(h), or 1886(s) of the Act. The record counts for AMs and GPOs have been updated to CY 2019 and are used to calculate the time burdens for collection and submission for both AMs and GPOs. The figures shown in the tables below (*Count of Entities* and *Count of Records*) are used for all calculations in Sections 12 – 15 of this Supporting Statement A.

Count of Entities (PY 2019)

Entity Type	PY 2019
Applicable Manufacturers (AMs)	1,589
Group Purchasing Organizations (GPOs)	23
<i>Total Physicians with Reported Data</i>	624,390
Physicians Registered to Review Information (5% of Total)	31,220
Teaching Hospitals	1,201

Count of Records (CY 2019)

Record Type	AM Records (CY 2019)	GPO Records (CY 2019)
General	12,685,921	691
Ownership	2,531	1,175
Research	719,190	0
Total	13,407,703	1,866

This estimation is a modified iteration of the previously approved calculation of burden hours. The previously approved package includes the addition of the new, one-time burden associated with the changes in the CY 2020 PFS. This package assumes those changes have already been accounted for by inclusion in the previous package. Furthermore, the increased burden created by the inclusion of advanced nurse covered recipients as created by the SUPPORT Act is excluded from the PRA burden estimates; therefore, the calculations are only inclusive of physician and teaching hospital covered recipient types.

Note that previous versions of the Open Payments PRA used numbers and assumptions from Program Year 2015 for the purposes of estimating burden. Program Year 2015 was only two years after the beginning of the program, and we now have a more complete understanding of the burden created by complying with program requirements. With this PRA, while we strove to maintain a consistent narrative, we are updating the numbers and logic used to be as relevant, accurate, and recent as possible, which have resulted in some minor adjustments to the burden calculations.

The sections below summarize burdens associated with data collection and submission, registration, attestation, record retention, dispute and resolution, submitting an assumptions document, and completing an annual survey. Estimates are presented by entity type (AMs, GPOs, physicians, and teaching hospitals) as applicable.

A. Burden Estimates (Data Collection & Submission Hours)

The information below estimates the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information according to §§ 403.904 and 403.906.

Total Estimated Applicable Manufacturer Burden (Hours)

	Labor	FTEs* per AM	Base Year (2020)	2023			2024			2025		
			# of Hours	Additional Hours	Total Hours	Hours per FTE	Additional Hours	Total Hours	Hours per FTE	Additional Hours	Total Hours	Hours per FTE
Burden by Action Type												
Collection	Support Staff	2	1,388,632	1,500	1,390,132	437	1,500	1,390,132	437	1,500	1,390,132	437
Reporting	Support Staff	2	347,158	0	347,158	109	1,810	348,968	110	1,810	348,968	110
Total Hours			1,735,790	1,500	1,737,290	547	3,310	1,739,100	547	3,310	1,739,100	547
Burden by Payment Type												
General	Support Staff	2	1,585,748	0	1,585,748	499	70	1,585,818	499	70	1,585,818	499
Ownership	Support Staff	2	211	0	211	0	240	451	0	240	451	0
Research	Support Staff	2	149,831	1,500	151,331	48	3,000	152,831	48	3,000	152,831	48
Total Hours			1,735,790	1,500	1,737,290	547	3,310	1,739,100	547	3,310	1,739,100	547

*This is the number of employees assigned to this process. This is not full-time equivalent employees.

Total Estimated Group Purchasing Organization Burden (Hours)

	Labor	FTEs* per GPO	Base Year (2020)	2023			2024			2025		
			# of Hours	Additional Hours	Total Hours	Hours per FTE	Additional Hours	Total Hours	Hours per FTE	Additional Hours	Total Hours	Hours per FTE
Burden by Action Type												
Collection	Support Staff	1	147	88	148	6	88	235	10	88	235	10
Reporting	Support Staff	1	37	0	38	2	134	171	7	134	171	7
Total Hours			184	88	186	8	222	406	18	222	406	18
Burden by Payment Type												
General	Support Staff	1	86	88	87	4	186	272	12	186	272	12
Ownership	Support Staff	1	98	0	99	4	36	134	6	36	134	6
Research	Support Staff	1	0	0	1	0	0	0	0	0	0	0
Total Hours			184	88	187	8	222	406	18	222	406	18

*This is the number of employees assigned to this process. This is not full-time equivalent employees.

Estimated Applicable Manufacturer Burden by Process (Cost in Current \$)

Process	# of AMs	2023		2024		2025	
		Total Per AM	Total - All AMs	Total Per AM	Total - All AMs	Total Per AM	Total - All AMs
General Payments							
Collection	1,589	\$36,989	\$58,776,216	\$38,099	\$60,539,502	\$39,242	\$62,355,687
Reporting	1,589	\$9,247	\$14,694,054	\$9,527	\$15,138,216	\$9,813	\$15,592,363
Subtotal		\$46,237	\$73,470,270	\$47,626	\$75,677,718	\$49,055	\$77,948,050
Ownership Payments							
Collection	1,589	\$5	\$7,818	\$5	\$8,052	\$5	\$8,294
Reporting	1,589	\$1	\$1,954	\$8	\$13,466	\$9	\$13,870
Subtotal		\$6	\$9,772	\$14	\$21,518	\$14	\$22,164
Research Payments							
Collection	1,589	\$3,539	\$5,623,038	\$3,645	\$5,791,729	\$3,754	\$5,965,481
Reporting	1,589	\$874	\$1,388,385	\$945	\$1,501,619	\$973	\$1,546,668
Subtotal		\$4,412	\$7,011,423	\$4,590	\$7,293,348	\$4,728	\$7,512,148
Total		\$50,655	\$80,491,465	\$52,229	\$82,992,585	\$53,796	\$85,482,362

Estimated Group Purchasing Organization Burden by Process (Cost in Current \$)

Process	# of GPOs	2023		2024		2025	
		Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs
General Payments							
Collection	23	\$316	\$7,279	\$326	\$7,497	\$336	\$7,722
Reporting	23	\$35	\$800	\$239	\$5,501	\$246	\$5,666
Subtotal		\$351	\$8,079	\$565	\$12,998	\$582	\$13,388
Ownership Payments							
Collection	23	\$158	\$3,629	\$163	\$3,738	\$167	\$3,850
Reporting	23	\$39	\$907	\$115	\$2,653	\$119	\$2,732
Subtotal		\$197	\$4,537	\$278	\$6,391	\$286	\$6,582
Research Payments							
Collection	23	\$0	\$0	\$0	\$0	\$0	\$0
Reporting	23	\$0	\$0	\$0	\$0	\$0	\$0
Subtotal		\$0	\$0	\$0	\$0	\$0	\$0
Total		\$549	\$12,616	\$843	\$19,389	\$868	\$19,971

General Estimation Assumptions

- The burden associated with these requirements is the time and effort spent by applicable manufacturers and applicable GPOs collecting the data, compiling reports, and submitting and re-submitting data to send to CMS. The assumptions, when applicable, generally utilize an upward estimation model to provide the likely maximum estimate. We realize that this may provide an estimate which may be higher than what is actually encountered through operational and procedural factors and capabilities which may help to minimize burden for various activities. Although the initial rule included a downward adjustment to reflect the potential time savings accrued through ability to query CMS and receive guidance on low cost methods of compliance, we did not adjust these estimates in the same fashion to remain consistent with our overall assumption regarding estimation.
- We assume that, on average, AMs will utilize two employees to comply with data collection and reporting requirements, whereas GPOs will utilize one employee. Furthermore, we assumed that these data collection and reporting activities will largely be conducted by supporting staff involved with bookkeeping, accounting and auditing. Estimated hours per employee are derived from the assumed number of employees and the estimated hours per entity needed to comply with the requirements.
- We estimate for applicable GPOs there is a significant reduction in burden over an applicable manufacturer since we believe companies will have fewer relationships with physician owners or investors (or immediate family members) and fewer transfers of value per physician. This will make it much easier for applicable GPOs to match ownership and investment interests to the appropriate physicians (or family members). Furthermore, we do not anticipate that GPOs will have any data to be reported under the Research data template.
- For wage rates, we used the following estimates, based on the BLS May 2020 National Occupational Employment and Wage Estimates: hourly rate for the compliance officer is \$36.35 and the hourly rate for support staff is \$21.20. After doubling to account for fringe and overhead, we also applied an annual 3 percent increase to account for change over time.

Data Collection Estimation Assumptions

- Data collection includes systems modifications and management, training, data tracking, data aggregation and all activities associated with tracking and collecting data external to CMS.
- Applicable manufacturers with less than 10% of revenue from covered products will likely face less data collection and storage burden than regular applicable manufacturers, but for purposes of PRA we will assume equivalent burden for both <10% applicable manufacturers and regular applicable manufacturers.
- We estimated that the changes to the nature of payment categories and the addition of the device identifier would have a one-time impact on data collection processes. Since this information was already included as a one-time burden in a previously approved package, we have not incorporated those numbers into this package.

Data Submission Estimation Assumptions

- Consolidated reporting is permissible under the regulation under certain conditions and will likely minimize burden for submitting entities. However, for purposes of PRA we will assume there will be no consolidated reporting.
- Data submission includes all error management (upload problems, surface edits, data validation, corrections due to system checks) all the way through the successful validation. The next step is attestation.
- Section 403.904(f) requires special reporting rules for research payments. Section 403.906 requires applicable manufacturers and applicable GPOs to submit annual reports information regarding ownership and investment interests held by physicians or their family members, as well as any payments provided to such physicians. The data submission process for research payments is the same as the process for data submission of non-research payments or ownership or investment interests. For purposes of the PRA we have not assumed a difference in burden depending on which type of data is being submitted.

B. Burden Estimates (Registration, Attestation, Record Retention, Dispute and Resolution, and Assumptions Document Submissions Hours and Wages)

Annually, we estimate the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information according to §§403.908(c), (e), (g), (h), and (f) is \$701 per applicable manufacturer, \$504 per applicable GPO, \$572 per teaching hospital, and \$677 per physician in 2023 and \$723 per applicable manufacturer, \$520 per applicable GPO, \$589 per teaching hospital, and \$697 per physician in 2024. The tables that follow and the supporting assumptions explain the methodology for these estimates.

Estimated Applicable Manufacturer Burden by Process (Hours)

	Labor	FTEs* per AM	Base Year (2020)	Annual (2023 – 2025)		
			# of Hours	Additional Hours	Total Hours	Hours per FTE
Registration / Recertification						
Registration – Support	Support Staff	2	795	0	795	0.3
Registration – Confirm	Compliance	1	795	0	795	0.5
Subtotal			1,589	0	1,589	0.8
Retention						
Retention	Support Staff	2	1,589	0	1,589	0.5
Subtotal			1,589	0	1,589	0.5
Attestation						
Attestation – Compliance	Compliance	1	3,178	0	3,178	2.0
Attestation – Support	Support Staff	2	3,178	128	3,306	1.0
Subtotal			6,356	128	6,484	3.0
Assumption						
Assumption – Compliance	Compliance	1	1,589	0	1,589	1.0
Assumption – Support	Support Staff	2	1,589	0	1,589	0.5
Subtotal			3,178	0	3,178	1.5
Dispute Resolution						
Dispute - Compliance	Compliance	1	2,669	0	2,669	1.7
Dispute – Support	Support Staff	2	2,669	0	2,669	0.8
Subtotal			5,337	0	5,337	2.5
Total			18,049	128	18,177	8.3

*This is the number of full-time employees assigned to this process. This is not full-time equivalent employees.

Estimated Group Purchasing Organization Burden by Process (Hour)

	Labor	FTEs* per GPO	Base Year (2020)	Annual (2023 – 2025)		
			# of Hours	Additional Hours	Total Hours	Hours per FTE
Registration / Recertification						
Registration - Support	Support Staff	1	12	0	12	0.5
Registration - Confirm	Compliance	1	12	0	12	0.5
Subtotal			23	0	23	1.0
Retention						
Retention	Support Staff	1	23	0	23	1.0
Subtotal			23	0	23	1.0
Attestation						
Attestation - Compliance	Compliance	1	46	0	46	2.0
Attestation – Support	Support Staff	1	46	8	54	2.3
Subtotal			92	8	100	4.3
Assumption						
Assumption - Compliance	Compliance	1	23	0	23	1.0
Assumption – Support	Support Staff	1	23	0	23	1.0
Subtotal			46	0	46	2.0
Dispute Resolution						
Dispute – Compliance	Compliance	1	0.5	0.0	0.5	0.0
Dispute – Support	Support Staff	1	0.5	0.0	0.5	0.0
Subtotal			1.0	0.0	1.0	0.0
Total			185	8	193	8.4

*This is the number of full-time employees assigned to this process. This is not full-time equivalent employees.

Estimated Physician Burden by Process (Hours)

	Labor	FTEs* per Physician	Base Year (2020)	Annual (2023 – 2025)		
			# of Hours	Additional Hours	Total Hours	Hours per FTE
Registration						
Registration - Confirm	Physician	1	15,610	0	15,610	0.5
Registration - Support	Support Staff	1	15,610	0	15,610	0.5
Subtotal			31,220	0	31,220	1.0
Review						
Review - Physician	Physician	1	55,667	0	55,667	1.8
Review - Support	Support Staff	1	55,667	0	55,667	1.8
Subtotal			111,335	0	111,335	3.6
Dispute						
Dispute - Physician	Physician	1	4,518	0	4,518	0.1
Dispute - Support	Support Staff	1	4,518	0	4,518	0.1
Subtotal			9,036	0	9,036	0.3
Total			151,590	0	151,590	4.9

*This is the number of full-time employees assigned to this process. This is not full-time equivalent employees.

Estimated Teaching Hospital Burden by Process (Hours)

	Labor	FTEs* per Hospital	Base Year (2020)	Annual (2023 – 2025)		
			# of Hours	Additional Hours	Total Hours	Hours per FTE
Registration						
Registration - Confirm	Compliance	1	601	0	601	0.5
Registration - Support	Support Staff	1	601	0	601	0.5
Subtotal			1,201	0	1,201	1.0
Review						
Review - Compliance Officer	Compliance	1	3,438	0	3,438	2.9
Review - Support	Support Staff	1	3,438	0	3,438	2.9
Subtotal			6,876	0	6,876	5.7
Dispute Resolution						
Dispute - Compliance Officer	Compliance	1	1,985	0	1,985	1.7
Dispute - Support	Support Staff	1	1,985	-993	993	0.8
Subtotal			3,970	-993	2,978	2.5
Total			12,047	-993	11,054	9.2

*This is the number of full-time employees assigned to this process. This is not full-time equivalent employees.

Estimated Applicable Manufacturer Burden by Process (Cost in Current \$)

Process	# of AMs	2023		2024		2025	
		Total Per AM	Total - All AMs	Total Per AM	Total - All AMs	Total Per AM	Total - All AMs
Registration / Recertification							
Registration - Support	1,589	\$23	\$36,810	\$24	\$37,915	\$25	\$39,052
Registration - Confirm	1,589	\$40	\$63,116	\$41	\$65,010	\$42	\$66,960
Subtotal		\$63	\$99,927	\$65	\$102,924	\$67	\$106,012
Retention							
Retention	1,589	\$46	\$73,621	\$48	\$75,830	\$49	\$78,104
Subtotal		\$46	\$73,621	\$48	\$75,830	\$49	\$78,104
Attestation							
Attestation - Compliance	1,589	\$159	\$252,464	\$164	\$260,038	\$169	\$267,839
Attestation - Support	1,589	\$96	\$153,189	\$99	\$157,785	\$102	\$162,518
Subtotal		\$255	\$405,653	\$263	\$417,823	\$271	\$430,358
Assumption							
Assumption - Compliance	1,589	\$79	\$126,232	\$82	\$130,019	\$84	\$133,920
Assumption - Support	1,589	\$46	\$73,621	\$48	\$75,830	\$49	\$78,104
Subtotal		\$126	\$199,853	\$130	\$205,849	\$133	\$212,024
Dispute Resolution							
Dispute - Compliance	1,589	\$133	\$211,989	\$137	\$218,349	\$142	\$224,899
Dispute - Support	1,589	\$78	\$123,636	\$80	\$127,345	\$83	\$131,165
Subtotal		\$211	\$335,625	\$218	\$345,694	\$224	\$356,064
Total		\$701	\$1,114,679	\$723	\$1,148,119	\$744	\$1,182,563

Estimated Group Purchasing Organization Burden by Process (Cost in Current \$)

Process	# of GPOs	2023		2024		2025	
		Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs
Registration / Recertification							
Registration – Support	23	\$23	\$533	\$24	\$549	\$25	\$565
Registration – Confirm	23	\$40	\$914	\$41	\$941	\$42	\$969
Subtotal		\$63	\$1,446	\$65	\$1,490	\$67	\$1,534
Retention							
Retention	23	\$46	\$1,066	\$48	\$1,098	\$49	\$1,131
Subtotal		\$46	\$1,066	\$48	\$1,098	\$49	\$1,131
Attestation							
Attestation - Compliance	23	\$159	\$3,654	\$164	\$3,764	\$169	\$3,877
Attestation – Support	23	\$108	\$2,480	\$111	\$2,555	\$114	\$2,632
Subtotal		\$267	\$6,135	\$275	\$6,319	\$283	\$6,508
Assumption							
Assumption - Compliance	23	\$79	\$1,827	\$82	\$1,882	\$84	\$1,938
Assumption – Support	23	\$46	\$1,066	\$48	\$1,098	\$49	\$1,131
Subtotal		\$126	\$2,893	\$130	\$2,980	\$133	\$3,069
Dispute							
Dispute Resolution - Compliance	23	\$2	\$40	\$2	\$41	\$2	\$42
Dispute Resolution - Support	23	\$1	\$23	\$1	\$24	\$1	\$25
Subtotal		\$3	\$63	\$3	\$65	\$3	\$67
Total		\$504	\$11,602	\$520	\$11,951	\$535	\$12,309

Estimated Physician Burden by Process (Cost in Current \$)

Process	# of Physicians	2023		2024		2025	
		Total Per Physician	Total - All Physicians	Total Per Physician	Total - All Physicians	Total Per Physician	Total - All Physicians
Registration							
Registration - Confirm	31,220	\$119	\$3,706,827	\$122	\$3,818,032	\$126	\$3,932,573
Registration - Support	31,220	\$21	\$645,103	\$21	\$664,456	\$22	\$684,390
Subtotal		\$139	\$4,351,930	\$144	\$4,482,488	\$148	\$4,616,963
Review							
Review - Physician	31,220	\$423	\$13,219,249	\$436	\$13,615,827	\$449	\$14,024,302
Review - Support	31,220	\$74	\$2,300,560	\$76	\$2,369,577	\$78	\$2,440,664
Subtotal		\$497	\$15,519,810	\$512	\$15,985,404	\$527	\$16,464,966
Dispute							
Dispute - Physician	31,220	\$34	\$1,072,884	\$35	\$1,105,070	\$36	\$1,138,222
Dispute - Support	31,220	\$6	\$186,715	\$6	\$192,317	\$6	\$198,086
Subtotal		\$40	\$1,259,599	\$42	\$1,297,387	\$43	\$1,336,308
Total		\$677	\$21,131,338	\$697	\$21,765,279	\$718	\$22,418,237

Estimated Teaching Hospital Burden by Process (Cost in Current \$)

Process	# of Hospitals	2023		2024		2025	
		Total Per Hospital	Total - All Hospitals	Total Per Hospital	Total - All Hospitals	Total Per Hospital	Total - All Hospitals
Registration							
Registration - Confirm	1,201	\$40	\$47,704	\$41	\$49,136	\$42	\$50,610
Registration - Support	1,201	\$21	\$24,817	\$21	\$25,561	\$22	\$26,328
Subtotal		\$60	\$72,521	\$62	\$74,697	\$64	\$76,938
Review							
Review - Compliance	1,201	\$227	\$273,112	\$234	\$281,306	\$241	\$289,745
Review - Support	1,201	\$118	\$142,079	\$122	\$146,341	\$126	\$150,731
Subtotal		\$346	\$415,191	\$356	\$427,647	\$367	\$440,476
Dispute							
Dispute - Compliance	1,201	\$131	\$157,691	\$135	\$162,422	\$139	\$167,294
Dispute - Support	1,201	\$34	\$41,017	\$35	\$42,247	\$36	\$43,515
Subtotal		\$165	\$198,708	\$170	\$204,669	\$176	\$210,809
Total		\$572	\$686,420	\$589	\$707,013	\$606	\$728,223

General Estimation Assumptions

- The burden associated with these requirements is the time and effort spent by applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors collecting data to register, and time necessary to complete the registration process. The assumptions, when applicable, generally utilize an upward estimation model to provide the likely maximum estimate. We realize that this may provide an estimate which may be higher than what is actually encountered through operational and procedural factors and capabilities which may help to minimize burden for various activities.
- For applicable manufacturers and applicable GPOs support staff wage rates, we used the following estimates, based on the BLS May 2020 National Occupational Employment and Wage Estimates: hourly rate for the compliance officer is \$36.35 and the hourly rate for support staff is \$21.20. After doubling to account for fringe and overhead, we applied an annual 3 percent increase to account for change over time.
- For physicians and teaching hospital support staff wage rates, we used the following estimates, based on the BLS May 2020 National Occupational Employment and Wage Estimates: hourly rate for support staff is \$18.91, hourly rate for compliance staff is \$36.35, and hourly rate for physicians is \$108.66. After doubling to account for fringe and overhead, we applied an annual 3 percent increase to account for change overtime.
- We are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.
- Note that burden estimates for advanced nurse covered recipients are not included in this ICR.

Registration Estimation Assumptions

- We assume three full-time employees (FTEs) per applicable manufacturer and two FTEs per applicable GPO will participate in the registration process. Additionally, we assume one physician and one support staff FTE will participate to register physicians and two FTEs for teaching hospitals will participate to register a teaching hospital.
- We estimate that it will take 1 hour for each entity to complete the registration process. This process will include 30 minutes of time from support staff and 30 minutes of time from a compliance officer or physician.

Record Retention Estimation Assumptions

- Applicable manufacturers and applicable GPOs would have developed the necessary infrastructure to retain records when developing the infrastructure to collect data. Therefore, we assume applicable manufacturers and applicable GPOs will have minimum burden imposed for creating a system for record retention. However, we assume applicable manufacturers and applicable GPOs will need a support staff person to assure records are retained for up to five years from the data of payment or other transfer of value as required in the final rule at § 403.912(e)(1)(ii). We assume two FTEs per applicable manufacturer and one FTE per applicable GPO is necessary for this process.

- We estimate that it will take 1 hour for each AM and GPO to complete this process.

Attestation Estimation Assumptions

- We estimate three FTEs per applicable manufacturer and two FTEs per applicable GPO will participate in the attestation process. We assume an applicable manufacturer's or applicable GPO's support staff will assist the compliance officer, which can be the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or another Officer, in ensuring the data is accurate prior to attesting. We assume the compliance officer will attest through a secure (electronic) mechanism attesting to each attestation statement that is relevant regarding data submitted. For example, if an applicable manufacturer is only reporting information regarding covered drugs, devices, biologicals or medical supplies we expect the applicable to attest that the applicable manufacturer met one of the reporting limitations outlined in § 403.904(b).
- We estimate that it will take 4 hours for each AM and GPO to complete this process. This will include 2 hours of time from support staff and 2 hours of time from a compliance officer.

Assumptions Document Estimation Assumptions

- Under § 403.908(f), applicable manufacturers are permitted, but not required, to submit a document outlining the assumptions made when describing payments. Because this is an optional provision, we do not expect all applicable manufacturers to submit this information. For the purposes of analysis, we estimate that 100% of applicable manufacturers will submit an assumptions document.
- We estimate that all AMs and GPOs will submit an assumptions document which will take 1 hour to prepare (compliance officer) and 1 hour to submit (2 support staff for AMs and 1 support staff for GPOs). We expect preparation of this document to essentially occur in conjunction with data collection.

Review, Dispute, and Resolution Estimation Assumptions

- We assume that 5% of the 13,360,160 physician records are reviewed ($13,360,160 \times 5\% = 668,008$). We estimate that each record will take 5 minutes for a physician to review. In total, 55,667 hours will be spent on physicians' review of records ($668,008 \times 0.0833$ hours). This equates to approximately 1.8 hours per physician ($55,667 \div 31,220$ physicians involved in the review process). We assume one support staff will assist every physician, dedicating another 1.8 hours each to review records.
- We assume that 50% of the 165,020 hospital records are reviewed ($165,020 \times 50\% = 82,510$). We estimate that each record will take 5 minutes total for a compliance officer and support staff to review. In total, 6,876 hours will be spent on teaching hospitals' review of records ($82,510 \times 0.0833$ hours). This equates to approximately 5.7 hours per teaching hospital ($6,876 \div 1,201$ hospitals). We assume one support staff will assist every compliance officer, each dedicating 2.9 hours to review records.
- We estimate that dispute resolution and data correction requires the compliance officer and support staff (two for applicable manufactures and one for applicable group purchasing organizations).

- In PY 2019, AMs addressed 5,337 disputes and GPOs addressed 1 dispute.⁴ We estimate that each dispute will take a compliance officer 0.5 hours. In total, compliance officers at AMs will spend 2,669 hours on disputes (5,337 x 0.5 hours) and compliance officers for GPOs will spend 0.5 hour on disputes (1 x 0.5 hours). This equates to approximately 1.7 hours per AM (2,669 ÷ 1,589 AMs) and 0.02 hours per GPO (0.5 ÷ 23 GPOs). We assume two support staff will assist every compliance officer at AMs, dedicating another 0.8 hour each to complete the dispute process. At GPOs, one support staff will assist every compliance officer, dedicating another 0.02 hours each to complete the dispute process.
- In PY 2019, physicians were involved in 4,518 disputes.⁵ We estimate that each dispute will take a physician 1 hour. In total, physicians will spend 4,518 hours on disputes (4,518 x 1 hour). This equates to approximately 0.14 hours per physician (4,518 ÷ 31,220 physicians involved in the dispute process). One support staff will assist every physician, dedicating another 0.14 hours each to complete the dispute and resolution process.
- Teaching hospitals were involved in 1,985 disputes.⁶ We estimate that each dispute will take a hospital compliance officer 1 hour. In total, these compliance officers will spend 1,985 hours on disputes (1,985 x 1 hour). This equates to approximately 1.65 hours per hospital compliance officer (1,985 ÷ 1,201 hospitals). One support staff will assist every compliance officer, dedicating another 1.65 hours each to complete the dispute and resolution process.

C. Annual Stakeholder Survey

To increase consultation with stakeholders, we are proposing to add to this ICR an annual digital survey of reporting entities. This optional survey will solicit views on availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. The population of active reporting entities will be divided into three groups and each group will be sent a different questionnaire consisting of five survey questions. To administer the survey, an email with a link to the web-based survey will be emailed to all AMs and GPOs, which have already provided contact information to CMS as part of the registration and recertification process. Covered recipients will be excluded from being surveyed since their participation in the program is voluntary and would require a separate survey.⁷

Estimation Assumptions

- 10% of the entities that receive the survey will respond.
- Covered recipients will not be included as participants in this annual survey.
- It will take a Compliance Officer 5 minutes (or 0.0833 hours) to complete the five-question survey.

⁴ These counts include only resolved disputes.

⁵ This includes all disputes, resolved and unresolved.

⁶ This includes all disputes, resolved and unresolved.

⁷ See Supporting Statement B for more information on the survey methodology.

- The hourly wage rate of the survey respondent is doubled to account for fringe and overhead.
- CMS will begin administering the survey in CY 2023.

Estimates

We calculate the estimated burden as the total number of reporting entities (AMs + GPOs = 1,612) x the survey response rate (10%) x the number of hours per respondent (5 minutes ÷ 60 = 0.0833 hours). The result is 13 hours per year. To convert the hours to a cost basis, the burden is multiplied by the hourly labor rate of the respondent (\$79.44 in 2023 and \$81.82 in 2024), which produces an estimate of \$1,067 for 2023 and \$1,099 for 2024.

D. Summary of Annual Collection of Information Requirements and Burden Estimates⁸

IC Requirements	Total Time (2023)	Labor Cost (\$/hr) (2023)	Total Cost (\$) (2023)	Total Time (2024)	Labor Cost (\$/hr) (2024)	Total Cost (\$) (2024)
AM (Data collection and submission)	1,735,790	\$46.33	\$80,421,967	1,735,790	\$47.72	\$82,834,626
GPO (Data collection and submission)	184	\$46.33	\$8,538.53	184	\$47.72	\$8,795
AM (Registration)	1,589	\$46.33 - \$79.44	\$99,927	1,589	\$47.72 - \$81.82	\$102,924
GPO (Registration)	23	\$46.33 - \$79.44	\$1,446	23	\$47.72 - \$81.82	\$1,490
Physicians (Registration)	31,220	\$41.33 - \$237.47	\$4,351,930	31,220	\$42.57 - \$244.59	\$4,482,488
Teaching Hospitals (Registration)	1,201	\$41.33 - \$79.44	\$72,521	1,201	\$42.57 - \$81.82	\$74,697
AM (Record Retention)	1,589	\$46.33	\$73,621	1,589	\$47.72	\$75,830
GPO (Record Retention)	23	\$46.33	\$1,066	23	\$47.72	\$1,098
AM (Attestation)	6,356	\$46.33 - \$79.44	\$399,706	6,356	\$47.72 - \$81.82	\$411,697
GPO (Attestation)	92	\$46.33 - \$79.44	\$5,786	92	\$47.72 - \$81.82	\$5,959
AM (Assumptions Document)	3,178	\$46.33 - \$79.44	\$199,853	3,178	\$47.72 - \$81.82	\$205,849
GPO (Assumptions Document)	46	\$46.33 - \$79.44	\$2,893	46	\$47.72 - \$81.82	\$2,980
AM (Dispute Resolution and Correction)	5,337	\$46.33 - \$79.44	\$335,625	5,337	\$47.72 - \$81.82	\$345,694
GPO (Dispute and Resolution Correction)	1	\$46.33 - \$79.44	\$63	1	\$47.72 - \$81.82	\$65
Physicians (Dispute Resolution and Correction)	9,036	\$41.33 - \$237.47	\$1,259,599	9,036	\$42.57 - \$244.59	\$1,297,387
Hospitals (Dispute and Resolution Correction)	3,970	\$41.33 - \$79.44	\$239,725	3,970	\$42.57 - \$81.82	\$246,917
Physicians (Review)	111,335	\$41.33 - \$237.47	\$15,519,810	111,335	\$42.57 - \$244.59	\$15,985,404
Hospitals (Review)	6,876	\$41.33 - \$79.44	\$415,191	6,876	\$42.57 - \$81.82	\$427,647
TH Contact Field (CMS-1751-P) (AMs and GPOs)	1,588	\$46.33	\$73,574.62	3,176	\$47.72	\$151,564
TH Contact Field (CMS-1751-P) (Teaching Hospital)	-993	\$41.33	-\$41,017	-993	\$42.57	-\$42,247
Optional Annual Recertification (CMS-1751-P)	121	\$46.33	\$5,601	121	\$47.72	\$5,770
Disallowing Record Deletion Without Reason (CMS-1751-P)	0	\$46.33	\$0.00	80	\$47.72	\$3,818
Remove General Ownership Records (CMS-1751-P)	0	\$46.33	\$0.00	276	\$47.72	\$13,171
Updated Contact Information (CMS-1751-P)	15	\$46.33	\$695	15	\$47.72	\$716
Annual Survey	13	\$79.44	\$1,067	13	\$81.82	\$1,099
Total	1,918,590		\$103,449,187	1,920,534		\$106,645,434

E. Collection of Information Instruments and Instruction/Guidance Documents

Instrument	Requirements	Instrument Status
Registration-Physician-Hospitals-AMs-GPOs	Registration/Recertification	Updated based on requirements included in the 2022 Physician Fee Schedule Final Rule ⁹ .
Record Retention Requirements	Record Retention	No change
Attestation and Assumptions Screen Shots	Attestation and assumptions documents	Updated based on requirements included in the 2022 Physician Fee Schedule Final Rule.
Review_and_Dispute_Email_Notifications	Dispute resolution and correction	No change
Review and Dispute Screen Shots	Dispute resolution and correction	Updated based on requirements included in the 2022 Physician Fee Schedule Final Rule.
General-Research-Ownership Submission Data Elements	Data collection and Submission	Updated based on requirements included in the 2022 Physician Fee Schedule Final Rule.
Open Payments User Guide_for_Reporting_Entities	Data collection and Submission	Updated based on requirements included in the 2022 Physician Fee Schedule Final Rule.

13. Capital Costs

The Open Payments program has been in effect for several years. Applicable manufacturers and applicable GPOs have likely already made their investments into their IT systems. Barring significant future changes to the program, we do not anticipate any substantial additional capital costs.

14. Cost to Federal Government

It is estimated that CMS costs for managing the information collection will include around 13.5 full time employees with an average annual salary at the GS-12 step 1 level based off of Baltimore locality pay in 2020 of \$86,335 annually, increasing 5% per year for an average annual total of \$1,417,824 from 2023 to 2025. The total contract cost with a 5% per annum increase over the three years from 2023 to 2025 will be approximately \$80,032,813, meaning average cost per year is \$26,677,604.

15. Changes to Burden

Changes to burden in this package stem from three sources. The first source encompasses updates to the burden associated with the provisions recently adopted in the CY 2022 Physician Fee Schedule rule (RIN 0938-AU42, CMS-1751-P). The rule was filed for public inspection on July 13, 2021 and finalized on November 2, 2021. Second, the burden estimates included in this package are based on several adjustments to the burden calculation methodologies that had been previously used, and which now encompass the following changes: (1) the number of entities, records, and disputes were updated from 2015 to 2019; (2) the total number of estimated hours

⁸ Totals may not sum due to rounding.

⁹ The 2022 Physician Fee Schedule was published on November 19, 2021 (86 FR 64996).

for collection and reporting were corrected to remove inconsistencies in the calculations; (3) the mean hourly wage estimates were updated to BLS May 2020 National Occupational Employment and Wage Estimates; (4) dollar values were inflated to 2024 dollars; (5) the methodology to calculate the time savings for teaching hospitals due to the teaching hospital context field component of the rule change was updated and (6) new system screenshots and instructions are included in the package's Instruments. Third, in addition to these updated estimates, we are also adding an annual survey of reporting entities. We provide more information on the specific burden changes below.

a. Payment Context Field for Teaching Hospitals

The mandatory context field is a requirement for reporting entities submitting and attesting to records that are attributed to teaching hospitals only. The field will be freeform text entry. We estimate that for each applicable manufacturer and applicable group purchasing organization (GPO), the inclusion of this field for collection and reporting activities will average an additional 6 total hours. The applicable instrument for these activities is the "General-Research-Ownership Submission Data Elements". At the support staff cost per FTE of \$47.72/hr, this would increase costs by \$286.32 (6 hr x \$47.72/hr) per applicable manufacturer or applicable GPO submitting teaching hospital records. However, because we anticipate fewer disputes due to this proposed field, we believe it will decrease dispute resolution by 2 total hours for support staff at \$47.72/hr respectively, reducing costs by \$95.44 (2 hr x \$47.72/hr) per applicable manufacturer and applicable GPO. This results in a net increase in burden for each applicable manufacturer and applicable GPO submitting teaching hospital records of \$190.88 (\$286.32–\$95.44). In Program Year (PY) 2019, 794 applicable manufacturers and applicable GPOs submitted at least one teaching hospital record, meaning the increase in burden will be a total of 3,176 hours (4 hours x 794 reporting entities) at a cost of \$151,564 (3,176 x \$47.72/hr).

In addition, we estimate this requirement will reduce teaching hospital dispute resolution estimates by 0.5 hours per dispute. In CY 2019, teaching hospitals addressed 1,985 disputes. As such, we estimate a total burden reduction of 993 hours at a cost of \$42,247 (993 x \$42.57/hr).

In aggregate, we estimate an annual burden of 2,187 hours (3,176–993) at a cost of \$109,316 (\$151,564–\$42,247).

b. Optional Annual Recertification

The annual recertification is voluntary for applicable manufacturers or applicable group purchasing organizations. We approximate that 15 percent of applicable manufacturers and group purchasing organizations, or 242 reporting entities (0.15 [1,612 applicable manufacturers and applicable GPOs]) will complete and submit the optional annual recertification. We anticipate that it will be a simple check box form, which is included in the AM (Attestation) and GPO (Attestation) Annual IC Requirement and the "Attestation and Assumptions Screen Shots" Instrument in the existing. We estimate that it will take 0.5 hours at \$47.72/hr for support staff to complete and submit the recertification. In aggregate, we estimate an added annual burden of 121 hours (242 entities x 0.5 hr/response) at a cost of \$5,770 (120 hr x \$47.72/hr).

c. *Defining a Physician-Owned Distributorship (42 CFR § 403.902)*

The new definition is not subject to the PRA since it would not revise, add, or remove any collection of information requirements or burden.

d. *Disallowing Record Deletion Without Reason (§ 403.904(a)(3))*

This update to the Final Rule clarifies that entities are not permitted to delete records without reason once their timeliness, completeness, and accuracy has been attested to. In order to ensure compliance with this requirement, a freeform text dialogue box will be added to the system when records are deleted that asks the applicable manufacturer or GPO to input a reason for the deletion. This is included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) calculations and the “Open Payments User Guide” Instrument. We anticipate that this will take an average of 2 hours at \$47.72/hr to input a reason for the deletion. In aggregate, we estimate an added annual burden of 80 hours (40 applicable manufacturers or GPOs deleting records annually x 2 hr/response) at a cost of \$3,818 (80 hr * \$47.72/hr).

e. *Disallow Publication Delays of General Payments*

A very small number of general payments are delayed from publication by reporting entities every year, and these records will simply either be reported as research records instead, or not delayed at all. Therefore, we anticipate a negligible burden for this update.

f. *Short Term Loans (§ 403.902)*

This update to the Final Rule is merely a clarification of an existing requirement in regulation text. The purpose of this language is to clarify that the exemption for short-term loans from reporting requirements only applies for loans of less than 91 cumulative days per calendar year. In other words, multiple short-term loans in a calendar year would still meet reporting requirements if they add up to 91 days or greater. We do not believe this update will change reporting behavior, and therefore do not anticipate an increase in burden.

g. *Remove General Ownership Records*

Previously, the Open Payments system allowed for a reporting entity to submit either a general record with a nature of payment category of ownership, or an ownership and investment interest record. For Program Years 2015-2019, approximately 92 applicable manufacturers and GPOs reported records with the nature of payment category of ownership. Since reporting these general records as ownership records will require the addition of two additional pieces of information, we anticipate that it will take these 92 entities an additional 3 hours at \$47.72/hr to report the two extra fields. In aggregate, we estimate an added annual burden of 276 hours (92 entities x 3 hr/response) at a cost of \$13,171 (276 hr x \$47.72/hr). This is included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) burden calculations and the “Open Payments User Guide” Instrument.

h. *Updated Contact Information (§ 403.908(c)(3))*

This is a requirement for reporting entities to keep their contact information up to date with CMS. The ability to communicate with a reporting entity is important because CMS may need to contact the entity in the case of perceived issues with the records. Applicable manufacturers and applicable GPOs will only be required to update their contact information if the two contacts

provided become obsolete due to a change in the organization. This will also only apply to entities that do not have records to report for 2 years after a program year in which they reported. Therefore, we anticipate that it will only affect approximately 30 applicable manufacturers and applicable group purchasing organizations. We estimate that it will take 0.5 hours at \$47.72/hr to update the contact information. In aggregate, we estimate an added annual burden of 15 hours (30 entities x 0.5 hr/response) at a cost of \$716 (15 hr x \$47.72/hr). This is included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) burden calculation and the “Open Payments User Guide” Instrument.

i. Annual Stakeholder Survey

To increase consultation with stakeholders, we are proposing to conduct an annual digital survey of reporting entities. We calculate the estimated burden as the total number of reporting entities (AMs + GPOs: 1,612) x the survey response rate (10%) x the number of hours per respondent (5 minutes ÷ 60 = 0.0833 hours). The result is 13 hours per year. To convert the hours to a cost basis, the burden is multiplied by the hourly labor rate of the respondent (\$79.44 in 2023 and \$81.82 in 2024), which produces an estimate of \$1,067 in 2023 and \$1,099 in 2024.

j. System Changes

The following three OP system changes will improve data quality and help facilitate data validation and analysis:

System Change	Description
Add a way to track deleted records and link them to new records that are submitted.	In some cases, an entity that wishes to make a change (e.g., a covered recipient) currently must delete the old record and re-submit a new record, with no way to link the two. The system change will provide a way to link the "old" record ID to the "new" record when the entity resubmits it.
Update and Validate R&D Contact Information Fields for Reporting Entities	Entities currently use a free form text box to provide their R&D contact information. This will be replaced with specific fields for name, email, and phone number, which will be validated.
Create an 11-digit National Drug Code (NDC) file	Drug codes reported by entities are currently formatted and validated using a 10-digit NDC code file. This change will add an 11-digit NDC code file that can be used for the same purpose, but is not required.

We do not believe that these changes will increase the burden on users of the OP system.

k. Summary

Open Payments Burden Changes

Proposed Changes	Process Affected	Total Increase in Burden (Hours)	Total Decrease in Burden (Hours)	Net Change in Burden (Hours)
Teaching Hospital Contact Field	Data collection and Submission (AMs & GPOs) Dispute Resolution (THs)	3,176	-993	2,184
Optional Annual Recertification	Attestation (AMs & GPOs)	121	0	121
Defining a Physician Owned Distributorship	Registration (AMs & GPOs)	0	0	0
Disallowing Record Deletion Without Reason	Data collection and Submission (AMs & GPOs)	80	0	80
Disallowing Publication Delays of General Payments	Data collection and Submission (AMs & GPOs)	0	0	0
Short Term Loans	Data collection and Submission (AMs & GPOs)	0	0	0
Remove General Ownership Records	Data collection and Submission (AMs & GPOs)	276	0	276
Updated Contact Information	Attestation (AMs & GPOs)	15	0	15
Annual Survey	AMs, GPOs, Physicians, and Teaching Hospitals	13	0	13
System Changes		0	0	0
Total¹⁰		3,681	-993	2,689

¹⁰ This total differs from the previously estimated 1,263 additional hours for three reasons: (1) the addition of the annual survey increased the total by 13 hours; (2) the change in entity counts increased the total by 3 hours; and (3) the change in calculation for the teaching hospital context field and change in teaching hospital disputes increased the total by 1,409.

I. Burden Reconciliation

Annual Requirements and Burden

IC Requirements	No. Respondents	Total Time (hours)	Total Cost (\$)
<i>Currently Approved (Active) Burden (\$2021)</i> ¹¹	34,616	1,897,790	\$104,778,991
<i>Adjustments</i> ¹²	-583	20,055	\$1,732,553
Currently Approved Adjusted (Active) Burden (\$2024)	34,033	1,917,845	\$106,511,544
<i>Burden due to Rule Changes in CY 2022 PFS</i> ¹³	34,616	1,263	\$64,561
<i>Adjustments</i> ¹⁴	-583	1,412	\$68,229
Burden due to Rule Changes (\$2024)		2,675	\$132,790
Burden due to the Annual Survey (\$2024)		13	\$1,099
Proposed Burden (\$2024)	34,033	1,920,534	\$106,645,434
Difference between Unadjusted Approved and Proposed Burden	-583	22,744	\$1,866,443
Difference between Adjusted Approved and Proposed Burden	0	2,689	\$133,890

The table above outlines the change in annual requirements and burden between the currently approved package and this package that reflects the changes in the CY 2022 PFS as well as the addition of a short annual stakeholder survey. The changes in burden are primarily due to three factors: first, the labor rates used between the packages dropped significantly; second, the 2022 PFS added a relatively small burden to the program based on the above proposed changes to reporting requirements; and third, we used updated numbers from Program Year 2019 instead of Program Year 2015 as were used in previous packages to increase the calculations' accuracy.

16. Publication/Tabulation Dates

The data must be tabulated for review and correction for at least 45 days prior to publication, and then must be reported publicly by June 30 each year thereafter.

17. Expiration Date

The expiration date will be displayed on the first page each instrument (top, right corner).

¹¹ Registration, Attestation, Dispute Resolution and Correction, Assumptions Document and Data Retention Requirements for Open Payments (CMS-10495), March 1, 2021.

¹² Four adjustments were made to the currently approved burden: (1) the number of entities, records, and disputes were updated from 2015 to 2019; (2) the total number of estimated hours for collection and reporting were corrected to match the calculations; (3) the mean hourly wage estimates were updated to BLS May 2020 National Occupational Employment and Wage Estimates; (4) the calculation to estimate teaching hospital review hours was updated; and (5) the dollar value was inflated to show 2024 dollars for comparison with the proposed burden.

¹³ CY 2022 PFS proposed rule (CMS-1751-P, RIN 0938-AU42), July 23, 2021.

¹⁴ Adjustments were made to the burden due to rule changes that mirror the changes made to the currently approved burden: (1) the number of entities, records, and disputes were updated from 2015 to 2019; (2) the mean hourly wage estimates were updated to BLS May 2020 National Occupational Employment and Wage Estimates; (3) the calculation to estimate time savings as a result of the teaching hospital context field component of the rule change was updated; and (4) the dollar value was inflated to show 2024 dollars for comparison with the proposed burden.

