

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. The SUPPORT Act included a provision which omits non-physician practitioners from these burden calculations (see Public Law No: 115-271 (10/24/2018) Sec. 6111).

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. This package does not contain any substantial burden changes from the previous version.

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 provide the information needed to register in more detail in the system user guide, which is in the supplemental document of this package³. 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

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 The Open Payments User Guide for Reporting Entities can be found at <https://www.cms.gov/files/document/open-payments-user-guide-reporting-entities.pdf>. The Open Payments User Guide for Covered Recipients can be found at <https://www.cms.gov/files/document/open-payments-user-guide-covered-recipients.pdf>.

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 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 and Audits

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, though the newly added covered recipient types were excluded from Paperwork Reduction Act burden estimates⁴. 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. CMS also added an annual voluntary survey distributed to registered entities via email.

2. Information Users

As noted in the February 8, 2013, final rule, public reporting of the extent and nature of

⁴ See Public Law No: 115-271 (10/24/2018) Sec. 6111(c). “(c) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to this section or the amendments made by this section.”

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. 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 assumption 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://openpaymentsdata.cms.gov>), 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.
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7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register on 08/18/2025 (90 FR 40073). No comments were received during the comment period.

The 30-day Federal Register notice published in the Federal Register on 11/20/2025 (90 FR 52406)

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. CMS also has the availability of an annual digital survey of stakeholders that solicits 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 2023 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 2023 wage figures will increase by 3 percent annually to produce the estimates for 2025 – 2028.

Adjusted Hourly Wage by Occupation (Current \$)

Occupation Title	Occ. code	2025	2026	2027	2028
Bookkeeping, Accounting, and Auditing Clerks	43-3031	\$52.57	\$55.20	\$57.96	\$60.85
Compliance Officer	13-1041	\$85.00	\$89.25	\$93.72	\$98.40
Office and Administrative Support Workers, All Other	43-9199	\$49.41	\$51.88	\$54.48	\$57.20
Anesthesiologist	29-1211	\$137.11	\$143.96	\$151.16	\$158.72
Family Medicine Physicians	29-1215	\$359.88	\$377.87	\$396.77	\$416.60
General Internal Medicine Physicians	29-1216	\$255.27	\$268.04	\$281.44	\$295.51
Obstetrician and Gynecologists	29-1218	\$260.21	\$273.22	\$286.88	\$301.23
Pediatricians, General	29-1221	\$295.40	\$310.17	\$325.68	\$341.97
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	\$218.23	\$229.14	\$240.60	\$252.63
Psychiatrists	29-1223	\$232.01	\$243.61	\$255.79	\$268.58
Surgeons, Except Ophthalmologists	29-1248	\$272.38	\$286.00	\$300.30	\$315.32
Physicians*	Average of 29-*	\$270.02	\$283.52	\$297.70	\$312.58

In Program Year (PY) 2023, there were 1,768 applicable manufacturers that submitted and attested data, and there were 20 GPOs that submitted and attested data. In 2023, AM's and GPO's reported data for 636,802 physicians. We estimate that 5%, or 31,840 physicians, will annually register 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 because this action is entirely voluntary. 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 Payments⁵. As of reporting year end for 2023, there were records for 1,227 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 2023 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 2023)

Entity Type	PY 2023
Applicable Manufacturers (AMs)	1,786
Group Purchasing Organizations (GPOs)	20
Total Physicians with Reported Data	636,802
Physicians Registered to Review Information (5% of Total)	31,840
Teaching Hospitals	1,227

Count of Records (CY 2023)

Record Type	AM Records (CY 2023)	GPO Records (CY 2023)
General	9,637,574	492
Ownership	2,013	2,010
Research	1,438,623	0
Total	11,078,210	2,502

This estimation is a modified iteration of the previously approved calculation of burden hours. 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.

⁵ Note that non-physician practitioners are also reportable but are excluded for the purposes of PRA burden calculation due to their addition by the SUPPORT Act of 2018. Non-physician practitioners are defined as physician assistants, nurse practitioners, clinical nurse specialist, certified nurse midwives, and certified registered nurse anesthetists (42 CFR 403.902).

Total Estimated Applicable Manufacturer Burden (Hours)

	Labor	FTEs per AM	2025		2026		2027		2028	
			Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE
Burden by Action Type										
Collection	Support Staff	2	1,495,589	423	1,540,457	436	1,586,671	449	1,634,271	462
Reporting	Support Staff	2	373,972	106	385,191	109	396,746	112	408,649	116
Total Hours			1,869,561	529	1,925,648	545	1,983,417	561	2,042,920	578
Burden by Payment Type										
General	Support Staff	2	1,614,966	457	1,663,415	470	1,713,317	485	1,764,717	499
Ownership	Support Staff	2	222	0.1	229	0.1	236	0.1	243	0.1
Research	Support Staff	2	254,373	72	262,004	74	269,864	76	277,960	79
Total Hours			1,869,561	529	1,925,648	545	1,983,417	561	2,042,920	578

*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	2025		2026		2027		2028	
			Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE
Burden by Action Type										
Collection	Support Staff	1	221	0	228	11	235	12	242	12
Reporting	Support Staff	1	66	11	68	3	70	3	72	4
Total Hours			287	11	296	15	305	15	314	16
Burden by Payment Type										
General	Support Staff	1	65	11	67	3	69	3	71	4
Ownership	Support Staff	1	222	0	229	11	236	12	243	12
Research	Support Staff	1	0	0	0	0	0	0	0	0
Total Hours			287	11	296	15	305	15	314	16

*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	2026		2027		2028	
		Total Per AM	Total - All AMs	Total Per AM	Total - All AMs	Total Per AM	Total - All AMs
General Payments							
Collection	1,768	\$41,542	\$73,447,118	\$44,928	\$79,433,058	\$48,590	\$85,906,852
Reporting	1,768	\$10,388	\$18,366,001	\$11,235	\$19,862,831	\$12,150	\$21,481,651
Subtotal		\$51,930	\$91,813,119	\$56,163	\$99,295,889	\$60,740	\$107,388,504
Ownership Payments							
Collection	1,768	\$6	\$10,118	\$6	\$10,942	\$7	\$11,834
Reporting	1,768	\$1	\$2,529	\$2	\$2,736	\$2	\$2,958
Subtotal		\$7	\$12,647	\$8	\$13,678	\$8	\$14,792
Research Payments							
Collection	1,768	\$6,544	\$11,569,153	\$7,077	\$12,512,039	\$7,654	\$13,531,770
Reporting	1,768	\$1,636	\$2,892,288	\$1,769	\$3,128,010	\$1,913	\$3,382,942
Subtotal		\$8,180	\$14,461,441	\$8,846	\$15,640,048	\$9,567	\$16,914,712
Total		\$60,117	\$106,287,207	\$65,017	\$114,949,615	\$70,316	\$124,318,008

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

Process	# of GPOs	2026		2027		2028	
		Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs
General Payments							
Collection	20	\$124	\$2,473	\$134	\$2,674	\$145	\$2,892
Reporting	20	\$61	\$1,221	\$66	\$1,321	\$71	\$1,429
Subtotal		\$185	\$3,694	\$200	\$3,995	\$216	\$4,321
Ownership Payments							
Collection	20	\$505	\$10,103	\$546	\$10,926	\$591	\$11,816
Reporting	20	\$126	\$2,526	\$137	\$2,731	\$148	\$2,954
Subtotal		\$631	\$12,628	\$683	\$13,657	\$739	\$14,770
Research Payments							
Collection	20	\$0	\$0	\$0	\$0	\$0	\$0
Reporting	20	\$0	\$0	\$0	\$0	\$0	\$0
Subtotal		\$0	\$0	\$0	\$0	\$0	\$0
Total		\$816	\$16,322	\$883	\$17,653	\$955	\$19,091

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 these types of companies have 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 as this has been a consistent trend.
- For wage rates, we used the following estimates, based on the BLS May 2023 National Occupational Employment and Wage Estimates: hourly rate for the compliance officer is \$38.55 and the hourly rate for support staff is \$22.41. After doubling to account for fringe and overhead, we also applied an annual 3 percent increase to account for inflation 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.

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.
- We assume the final step of attestation was completed by AMs and GPOs, as this is done for the vast majority of records (99.4% in Program Year 2023).

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

Annually for 2026, 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 \$65,017 per applicable manufacturer, \$760 per applicable GPO, \$254 per teaching hospital, and \$319 per physician in 2026 and \$65,017 per applicable manufacturer, \$804 per applicable GPO, \$273 per teaching hospital, and \$340 per physician in 2027. The tables that follow and the supporting assumptions explain the methodology for these estimates.

Estimated Applicable Manufacturer Burden by Process (Hours)

Process	Labor	FTEs per AM	2025		2026		2027		2028	
			Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE
Registration / Recertification										
Registration - Support	Support Staff	2	884	0.3	884	0.3	884	0.3	884	0.3
Registration - Confirm	Compliance	1	884	0.5	884	0.5	884	0.5	884	0.5
Subtotal			1,768	0.8	1,768	0.8	1,768	0.8	1,768	0.8
Retention										
Retention	Support Staff	2	1,768	0.5	1,768	0.5	1,768	0.5	1,768	0.5
Subtotal			1,768	0.5	1,768	0.5	1,768	0.5	1,768	0.5
Attestation										
Attestation - Compliance	Compliance	1	3,536	2.0	3,536	2.0	3,536	2.0	3,536	2.0
Attestation - Support	Support Staff	2	3,681	1.0	3,681	1.0	3,681	1.0	3,681	1.0
Subtotal			7,217	3.0	7,217	3.0	7,217	3.0	7,217	3.0
Assumption										
Assumption - Compliance	Compliance	1	1,768	1.0	1,768	1.0	1,768	1.0	1,768	1.0
Assumption - Support	Support Staff	2	1,768	0.5	1,768	0.5	1,768	0.5	1,768	0.5
Subtotal			3,536	1.5	3,536	1.5	3,536	1.5	3,536	1.5
Dispute Resolution										
Dispute - Compliance	Compliance	1	1,240	0.7	1,277	0.7	1,315	0.7	1,355	0.8
Dispute - Support	Support Staff	2	1,240	0.4	1,277	0.4	1,315	0.4	1,355	0.4
Subtotal			2,480	1.1	2,554	1.1	2,631	1.1	2,710	1.1
Total			16,769	6.8	16,843	6.9	16,920	6.9	16,999	6.9

*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)

Process	Labor	FTEs per GPO	2025		2026		2027		2028	
			Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE
Registration / Recertification										
Registration - Support	Support Staff	1	10	0.5	10	0.5	10	0.5	10	0.5
Registration - Confirm	Compliance	1	10	0.5	10	0.5	10	0.5	10	0.5
Subtotal			20	1	20	1	20	1	20	1
Retention										
Retention	Support Staff	1	20	1.0	20	1.0	20	1.0	20	1.0
Subtotal			20	1	20	1	20	1	20	1
Attestation										
Attestation - Compliance	Compliance	1	40	2.0	40	2.0	40	2.0	40	2.0
Attestation - Support	Support Staff	1	44	2.2	44	2.2	44	2.2	44	2.2
Subtotal			84	4	84	4	84	4	84	4
Assumption										
Assumption - Compliance	Compliance	1	20	1.0	20	1.0	20	1.0	20	1.0
Assumption - Support	Support Staff	1	20	1.0	20	1.0	20	1.0	20	1.0
Subtotal			40	2	40	2	40	2	40	2
Dispute Resolution										
Dispute - Compliance	Compliance	1	25.3	1.3	26.1	1.3	26.8	1.3	27.6	1.4
Dispute - Support	Support Staff	1	25.3	1.3	26.1	1.3	26.8	1.3	27.6	1.4
Subtotal			50.6	2.5	52.1	2.6	53.7	2.7	55.3	2.8
Total			215	10.7	216	10.8	218	10.9	219	11.0

*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)

Process	Labor	FTEs per Physician	2025		2026		2027		2028	
			Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE
Registration										
Registration - Confirm	Physician	1	15,972	0.5	15,972	0.5	15,972	0.5	15,972	0.5
Registration - Support	Support Staff	1	15,972	0.5	15,972	0.5	15,972	0.5	15,972	0.5
Subtotal			31,944	1.0	31,944	1.0	31,944	1.0	31,944	1.0
Review										
Review - Physician	Physician	1	12,920	0.4	13,307	0.4	13,706	0.4	14,118	0.4
Review - Support	Support Staff	1	12,920	0.4	13,307	0.4	13,706	0.4	14,118	0.4
Subtotal			25,839	0.8	26,614	0.8	27,413	0.9	28,235	0.9
Dispute										
Dispute - Physician	Physician	1	1,092	0.0	1,124	0.0	1,158	0.0	1,193	0.0
Dispute - Support	Support Staff	1	1,092	0.0	1,124	0.0	1,158	0.0	1,193	0.0
Subtotal			2,183	0.1	2,249	0.1	2,316	0.1	2,386	0.1
Total			59,967	1.9	60,808	1.9	61,673	1.9	62,565	2.0

*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	2025		2026		2027		2028	
			Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE	Total Hours	Hours per FTE

Registration										
Registration - Confirm	Compliance	1	614	0.5	614	0.5	614	0.5	614	0.5
Registration - Support	Support Staff	1	614	0.5	614	0.5	614	0.5	614	0.5
Subtotal			1,227	1.0	1,227	1.0	1,227	1.0	1,227	1.0
Review										
Review - Compliance Officer	Compliance	1	375	0.3	386	0.3	398	0.3	410	0.3
Review - Support	Support Staff	1	375	0.3	386	0.3	398	0.3	410	0.3
Subtotal			750	0.6	772	0.6	796	0.6	820	0.7
Dispute Resolution										
Dispute - Compliance Officer	Compliance	1	1,439	1.2	1,482	1.2	1,526	1.2	1,572	1.3
Dispute - Support	Support Staff	1	719	0.6	741	0.6	763	0.6	786	0.6
Subtotal			2,158	1.8	2,223	1.8	2,289	1.9	2,358	1.9
Total			4,135	3.4	4,222	3.4	4,312	3.5	4,404	3.6

*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	Labor	FTEs	# of	2026	2027	2028
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		per AM	AMs	Hours per AM	Hours per FTE	Hourly Rate	Total Per AM	Total - All AMs	Hours per AM	Hours per FTE	Hourly Rate	Total Per AM	Total - All AMs	Hours per AM	Hours per FTE	Hourly Rate	Total Per AM	Total - All AMs
General Payments																		
Collection	Support Staff	2	1,768	753	376	\$55.20	\$41,542	\$73,447,118	775	388	\$57.96	\$44,928	\$79,433,058	798	399	\$60.85	\$48,590	\$85,906,852
Reporting	Support Staff	2	1,768	188	94	\$55.20	\$10,388	\$18,366,001	194	97	\$57.96	\$11,235	\$19,862,831	200	100	\$60.85	\$12,150	\$21,481,651
Subtotal				941	470		\$51,930	\$91,813,119	969	485		\$56,163	\$99,295,889	998	499		\$60,740	\$107,388,504
Ownership Payments																		
Collection	Support Staff	2	1,768	0.1	0.1	\$55.20	\$6	\$10,118	0.1	0.1	\$57.96	\$6	\$10,942	0.1	0.1	\$60.85	\$7	\$11,834
Reporting	Support Staff	2	1,768	0.0	0.0	\$55.20	\$1	\$2,529	0.0	0.0	\$57.96	\$2	\$2,736	0.0	0.0	\$60.85	\$2	\$2,958
Subtotal				0.1	0.1		\$7	\$12,647	0.1	0.1		\$8	\$13,678	0.1	0.1		\$8	\$14,792
Research Payments																		
Collection	Support Staff	2	1,768	119	59	\$55.20	\$6,544	\$11,569,153	122	61	\$57.96	\$7,077	\$12,512,039	126	63	\$60.85	\$7,654	\$13,531,770
Reporting	Support Staff	2	1,768	30	15	\$55.20	\$1,636	\$2,892,288	31	15	\$57.96	\$1,769	\$3,128,010	31	16	\$60.85	\$1,913	\$3,382,942
Subtotal				148	74		\$8,180	\$14,461,441	153	76		\$8,846	\$15,640,048	157	79		\$9,567	\$16,914,712
Total				1,089	545		\$60,117	\$106,287,207	1,122	561		\$65,017	\$114,949,615	1,155	577.7		\$70,316	\$124,318,008
Total Hours				1,925,648					1,983,417					2,042,920				

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

Process	# of GPOs	2025		2026		2027		2028	
		Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs	Total Per GPO	Total - All GPOs

Registration / Recertification									
Registration - Support	20	\$26	\$526	\$28	\$552	\$29	\$580	\$30	\$609
Registration - Confirm	20	\$43	\$850	\$45	\$893	\$47	\$937	\$49	\$984
Subtotal		\$69	\$1,376	\$72	\$1,444	\$76	\$1,517	\$80	\$1,593
Retention									
Retention	20	\$53	\$1,051	\$55	\$1,104	\$58	\$1,159	\$61	\$1,217
Subtotal		\$53	\$1,051	\$55	\$1,104	\$58	\$1,159	\$61	\$1,217
Attestation									
Attestation - Compliance	20	\$170	\$3,400	\$179	\$3,570	\$187	\$3,749	\$197	\$3,936
Attestation - Support	20	\$116	\$2,313	\$121	\$2,429	\$128	\$2,550	\$134	\$2,678
Subtotal		\$286	\$5,713	\$300	\$5,999	\$315	\$6,299	\$331	\$6,614
Assumption									
Assumption - Compliance	20	\$85	\$1,700	\$89	\$1,785	\$94	\$1,874	\$98	\$1,968
Assumption - Support	20	\$53	\$1,051	\$55	\$1,104	\$58	\$1,159	\$61	\$1,217
Subtotal		\$138	\$2,751	\$144	\$2,889	\$152	\$3,033	\$159	\$3,185
Dispute									
Dispute Resolution - Compliance	20	\$108	\$2,151	\$116	\$2,326	\$126	\$2,516	\$136	\$2,721
Dispute Resolution - Support	20	\$67	\$1,330	\$72	\$1,438	\$78	\$1,556	\$84	\$1,683
Subtotal		\$174	\$3,481	\$188	\$3,765	\$204	\$4,071	\$220	\$4,403
Total		\$719	\$14,372	\$760	\$15,201	\$804	\$16,079	\$851	\$17,011

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

Process	# of Physicians	2025		2026		2027		2028	
		Total Per	Total - All Phys	Total Per	Total - All Phys	Total Per	Total - All Phys	Total Per	Total - All Phys

		Phys		Phys		Phys		Phys	
Registration									
Registration - Confirm	31,944	\$135	\$4,312,838	\$142	\$4,528,480	\$149	\$4,754,904	\$156	\$4,992,649
Registration - Support	31,944	\$25	\$789,251	\$26	\$828,714	\$27	\$870,149	\$29	\$913,657
Subtotal		\$160	\$5,102,089	\$168	\$5,357,194	\$176	\$5,625,053	\$185	\$5,906,306
Review									
Review - Physician	31,944	\$109	\$3,488,562	\$118	\$3,772,880	\$128	\$4,080,369	\$138	\$4,412,919
Review - Support	31,944	\$20	\$638,408	\$22	\$690,438	\$23	\$746,709	\$25	\$807,566
Subtotal		\$129	\$4,126,970	\$140	\$4,463,318	\$151	\$4,827,079	\$163	\$5,220,485
Dispute									
Dispute - Physician	31,944	\$9	\$294,773	\$10	\$318,797	\$11	\$344,779	\$12	\$372,879
Dispute - Support	31,944	\$2	\$53,944	\$2	\$58,340	\$2	\$63,095	\$2	\$68,237
Subtotal		\$11	\$348,717	\$12	\$377,137	\$13	\$407,874	\$14	\$441,116
Total		\$300	\$9,577,776	\$319	\$10,197,649	\$340	\$10,860,006	\$362	\$11,567,907

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

Process	# of Hospitals	2025		2026		2027		2028	
		Total Per Hosp	Total - All Hosps	Total Per Hosp	Total - All Hosps	Total Per Hosp	Total - All Hosps	Total Per Hosp	Total - All Hosps
Registration									
Registration - Confirm	1,227	\$43	\$52,149	\$45	\$54,757	\$47	\$57,494	\$49	\$60,369
Registration - Support	1,227	\$25	\$30,316	\$26	\$31,831	\$27	\$33,423	\$29	\$35,094
Subtotal		\$67	\$82,465	\$71	\$86,588	\$74	\$90,917	\$78	\$95,463
Review									
Review - Compliance	1,227	\$26	\$31,875	\$28	\$34,472	\$30	\$37,282	\$33	\$40,320
Review - Support	1,227	\$15	\$18,529	\$16	\$20,040	\$18	\$21,673	\$19	\$23,439
Subtotal		\$41	\$50,404	\$44	\$54,512	\$48	\$58,955	\$52	\$63,760
Dispute									
Dispute - Compliance	1,227	\$100	\$122,283	\$108	\$132,249	\$117	\$143,028	\$126	\$154,684
Dispute - Support	1,227	\$29	\$35,543	\$31	\$38,440	\$34	\$41,573	\$37	\$44,961
Subtotal		\$129	\$157,826	\$139	\$170,689	\$150	\$184,600	\$163	\$199,645
Total		\$237	\$290,695	\$254	\$311,789	\$273	\$334,472	\$292	\$358,868

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 2023 National Occupational Employment and Wage Estimates: hourly rate for the compliance officer is \$38.55 and the hourly rate for support staff is \$22.41. After doubling to account for fringe and overhead, we applied an annual 5 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 2023 National Occupational Employment and Wage Estimates: hourly rate for support staff is \$22.41, hourly rate for compliance staff is \$38.55, and hourly rate for physicians is \$122.46. After doubling to account for fringe and overhead, we applied an annual 5 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.
- We are adjusting the time per record to reflect improvements in information tracking and processing technology, system enhancements, and industry consolidation, that has occurred since the initial package over a decade ago.
- Note that burden estimates for advanced nurse covered recipients are not included in this ICR per the SUPPORT Act of 2018.

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 date 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 1% of the 14,613,027 physician records are reviewed ($14,613,027 \times 1\% = 146,130$). We estimate that each record will take 5 minutes for a physician to review. In total, 12,173 hours will be spent on physicians' review of records ($668,008 \times 0.0833$ hours). This equates to approximately .2 hours per physician ($12,173 \div 1,029$ physicians involved in the review process). We assume one support staff will assist every physician, dedicating another .2 hours each to review records.
- We assume that 5% of the 169,660 hospital records are reviewed ($169,660 \times 5\% = 8,483$). We estimate that each record will take 5 minutes total for a compliance officer and support staff to review. In total, 707 hours will be spent on teaching hospitals' review of records ($8,483 \times 0.0833$ hours). This equates to approximately 0.58 hours per teaching hospital ($707 \div 1,227$ hospitals). We assume one support staff will assist every compliance officer, each dedicating .058 hours to review records.
- These assumptions have been adjusted to reflect the lower number of covered recipient

reviews that have been conducted as the program has continued.

- 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).
- We estimate that AMs will address 98% of disputes or 2,337 disputes and GPOs will address 2% of disputes or 48 disputes.⁶ We estimate that each dispute will take a compliance officer 0.5 hours. In total, compliance officers at AMs will spend 1,669 hours on disputes (2,337 x 0.5 hours) and compliance officers for GPOs will spend 12 hours on disputes (24 x 0.5 hours). This equates to approximately .94 hours per AM (1,669 ÷ 1,768 AMs) and 0.6 hours per GPO (12 ÷ 20 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 2023, physicians were involved in 1,029 disputes.⁷ We estimate that each dispute will take a physician 1 hour. In total, physicians will spend 1,029 hours on disputes (1,029 x 1 hour). This equates to approximately 0.03 hours per physician (1,029 ÷ 31,944 physicians involved in the dispute process). One support staff will assist every physician, dedicating another 0.03 hours each to complete the dispute and resolution process.
- In PY 2023, teaching hospitals were involved in 1,356 disputes.⁸ We estimate that each dispute will take a hospital compliance officer 1 hour. In total, these compliance officers will spend 1,356 hours on disputes (1,356 x 1 hour). This equates to approximately 1.1 hours per hospital compliance officer (1,356 ÷ 1,227 hospitals). One support staff will assist every compliance officer, dedicating another 1.1 hours each to complete the dispute and resolution process.

C. Annual Stakeholder Survey

To increase consultation with stakeholders, we have also implemented 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.

Estimation Assumptions

- 10% of the entities that receive the survey will respond.
- Covered recipients will not be included as participants in this annual survey.

⁶ These counts include only resolved disputes.

⁷ This includes all disputes, resolved and unresolved.

⁸ This includes all disputes, resolved and unresolved.

- It will take a Compliance Officer 5 minutes (or 0.0833 hours) to complete the five-question survey.
- The hourly wage rate of the survey respondent is doubled to account for fringe and overhead.

Estimates

We calculate the estimated burden as the total number of reporting entities (AMs + GPOs = 1,788) x the survey response rate (10%) x the number of hours per respondent (5 minutes ÷ 60 = 0.0833 hours). The result is 15 hours per year. To convert the hours to a cost basis, the burden is multiplied by the hourly labor rate of the compliance officer respondent (\$77.10 in 2025 and \$80.96 in 2026), which produces an estimate of \$1,157 for 2025 and \$1,214 for 2026.

A. Summary of Annual Collection of Information Requirements and Burden Estimates

IC Requirements	Total Time (2025)	Labor Cost (\$/hr) (2025)	Total Cost (\$) (2025)	Total Time (2026)	Labor Cost (\$/hr) (2026)	Total Cost (\$) (2026)
AM (Data collection and submission)	1,869,561	\$52.57	\$98,277,584.18	1,925,648	\$55.20	\$106,287,207.3
GPO (Data collection and submission)	287	\$52.57	\$15,092.36	296	\$55.20	\$16,322.4
AM (Registration)	1,768	\$52.57 - \$85.00	\$121,612	1,768	\$55.20 - \$89.25	\$127,692.4
GPO (Registration)	20	\$52.57 - \$85.00	\$1,376	20	\$55.20 - \$89.25	\$1,444.5
Physicians (Registration)	31,944	\$49.41 - \$270.02	\$5,102,089	31,944	\$51.88 - \$283.52	\$5,357,193.7
Teaching Hospitals (Registration)	1,227	\$49.41 - \$85.00	\$82,465	1,227	\$51.88 - \$89.25	\$86,587.9
AM (Record Retention)	1,768	\$52.57	\$92,938.81	1,768	\$55.20	\$97,585.8
GPO (Record Retention)	20	\$52.57	\$1,051.34	20	\$55.20	\$1,103.9
AM (Attestation)	7,217	\$52.57 - \$85.00	\$494,075	7,217	\$55.20 - \$89.25	\$518,778.6
GPO (Attestation)	84	\$52.57 - \$85.00	\$5,713	84	\$55.20 - \$89.25	\$5,998.7
AM (Assumptions Document)	3,536	\$52.57 - \$85.00	\$243,224	3,536	\$55.20 - \$89.25	\$255,384.9
GPO (Assumptions Document)	40	\$52.57 - \$85.00	\$2,751	40	\$55.20 - \$89.25	\$2,889.0
AM (Dispute Resolution and Correction)	2,480	\$52.57 - \$85.00	\$170,562	2,554	\$55.20 - \$89.25	\$184,462.9
GPO (Dispute and Resolution Correction)	51	\$52.57 - \$85.00	\$3,481	52	\$55.20 - \$89.25	\$3,764.5
Physicians (Dispute Resolution and Correction)	2,183	\$49.41 - \$270.02	\$348,717	2,249	\$51.88 - \$283.52	\$377,137.4
Hospitals (Dispute and Resolution Correction)	2,158	\$49.41 - \$85.00	\$157,826	2,223	\$51.88 - \$89.25	\$170,689.2
Physicians (Review)	25,839	\$49.41 - \$270.02	\$4,126,970	26,614	\$51.88 - \$283.52	\$4,463,318.1
Hospitals (Review)	750	\$49.41 - \$85.00	\$50,404	772	\$51.88 - \$89.25	\$54,512
Annual Survey	15	\$85.00	\$1,267	15	\$89.25	\$1,330
Total	1,950,948		\$109,299,198	2,008,047		\$118,013,403

B. Collection of Information Instruments and Instruction/Guidance Documents

Instrument	Requirements	Instrument Status
Registration-Physician-Hospitals-AMs-GPOs	Registration/Recertification	No change, latest version included.
Record Retention Requirements	Record Retention	No change, latest version included.
Attestation and Assumptions Screen Shots	Attestation and assumptions documents	No change, latest version included.
Review_and_Dispute_Email_Notifications	Dispute resolution and correction	No change, latest version included.

Review and Dispute Screen Shots	Dispute resolution and correction	No change, latest version included.
General-Research-Ownership Submission Data Elements	Data collection and Submission	No change, latest version included.
Open Payments User Guide_for_Reporting_Entities	Data collection and Submission	No change, latest version included.

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 10 full time employees with an average annual salary at the GS-12 step 1 level based off of Baltimore locality pay in 2025 of \$101,401 annually, increasing 3% per year for an average annual total of \$1,076,077 from 2026 to 2028. The total contract cost with a 3% per annum increase over the three years from 2026 to 2028 will be approximately \$54,509,325, meaning average cost per year is \$18,169,775.

15. Changes to Burden

Changes to burden 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 Program Year 2019 to Program Year 2023; (2) the total number of estimated hours for the mean hourly wage estimates were updated to BLS May 2023 National Occupational Employment and Wage Estimates. No burden-impacting updates to the system or program have been implemented since the previous iteration of this package.

B. Burden Reconciliation

Annual Requirements and Burden

IC Requirements	No. Respondents	Total Time (hours)	Total Cost (\$)
Currently Approved (Active) Burden (\$2024)	34,033	1,946,034	\$106,645,434
Proposed Burden (\$2025)	34,959	1,950,948	\$109,299,198
Difference	926	4,914	\$2,653,764

a. 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.

b. Expiration Date

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

