

Background

Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (the Act), which requires applicable manufacturers 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. 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.

This 2021 iteration reflects five changes proposed in the CY 2022 Physician Fee Schedule (PFS) Proposed Rule (CMS-1751-P, RIN: 0938-AU42). The rule proposes to clarify existing Open Payments requirements, as well as add provisions that program stakeholders have requested and we agree would improve the quality of the data. We propose the following revisions effective for data collection beginning in CY 2023 and reporting in CY 2024: (1) adding a mandatory payment context field for records to teaching hospitals; (2) adding the option to recertify annually even when no records are being reported; (3) disallowing record deletions without a substantiated reason; (4) requiring entities to update their contact information; and (5) removing the option to

¹ Currently “covered recipients” include physicians and teaching hospitals. Beginning with data required to be submitted on or after January 1, 2022, the definition of a covered recipient will also include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives.

submit and attest to general payment records with an “Ownership” Nature of Payment category. We believe these changes will all have minimal burden, but will increase the usability of the data, address concerns we have heard from stakeholders, and give reporting entities sufficient time to prepare for changes to their data collection and reporting procedures.

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.

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](#)

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 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.

2. Information Users

As noted in the February 8, 2013, final rule, public reporting of the extent and nature of relationships between physicians, teaching hospitals, 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 sixty-four million records totaling more than forty-three 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. 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 physician or teaching hospital. Additional transfers of value to the same physician or teaching hospital 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 will provide easy access to data for internal, operational, and technical considerations including streamlined tools for registration and data submission. It will improve and streamline the user experience through an enterprise-level approach to the interface design.

Small businesses, which may have fewer payments, etc. to report, will have the option to input their data manually for data submission. This will provide flexibility for small businesses because they will not be required to develop specialized IT systems to submit required data to CMS. Larger firms will be 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. The final rule 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.
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. Additionally, physicians and teaching hospitals 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

Federal Register

Serving as the 60-day notice, the CY 2022 PFS proposed rule (CMS-1751-P, RIN 0938-AU42) filed for public inspection on July 13, 2021 and published in the Federal Register on July 23, 2021 (86 FR 39104). Public comments must be received no later than 5 p.m. on September 13, 2021.

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.

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 physicians and the financial relationships of physicians and their families. While we are sensitive to the privacy concerns of physicians and their families, this reporting is required by statute. During the 45-day review period, physicians 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. 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.

This estimation relies on the previously approved calculation of burden hours. However, 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.

The sections below summarize applicable manufacturer and applicable group purchasing organizations burdens associated with data collection and submission, registration, attestation, and submitting an assumptions document.

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				
Burden by Action Type				
	2021	2022	2023	2024
	# of Hours	# of Hours	# of Hours	# of Hours
Collection	1,378,288	1,447,202	1,519,562	1,595,540
Reporting	344,573	361,802	379,892	398,887
TOTAL	1,722,861	1,809,004	1,899,454	1,994,427
Burden by Payment Type				
	2020	2021	2022	2023
	# of Hours	# of Hours	# of Hours	# of Hours
General	1,509,778	1,585,267	1,664,530	1,747,757
Ownership	243	256	268	282
Research	212,840	223,481	234,656	246,388
TOTAL	1,722,861	1,809,004	1,899,454	1,994,427
Total Estimated Group Purchasing Organization Burden				
Burden by Action Type				
	2021	2022	2023	2024
	# of Hours	# of Hours	# of Hours	# of Hours
Collection	182	191	200	210
Reporting	46	49	51	54
TOTAL	228	239	251	264
Burden by Payment Type				
	2021	2022	2023	2024
	# of Hours	# of Hours	# of Hours	# of Hours
General	61	64	67	70
Ownership	167	176	184	194
Research	0	0	0	0

TOTAL	228	239	251	264
--------------	------------	------------	------------	------------

Estimated Applicable Manufacturer Burden by Process

Process	Labor	# of AM's	FTE	Hours / FTE	Total Hours	Hourly Rate (Base +100%)	2021 Average Cost Per AM	2021 Total for all AM's	2022 Average Cost Per AM	2022 Total Cost for all AM's	2023 Average Cost Per AM	2023 Total Cost for all AM's
General Payments												
Collection	Support Staff	1,572	2	384.17	768.33	\$43.67	\$33,554.72	\$52,748,024	\$34,561.36	\$54,330,464.95	\$35,598.21	\$55,960,378.89
Reporting	Support Staff	1,572	2	96.04	192.08	\$43.67	\$8,388.68	\$13,187,006	\$8,640.34	\$13,582,616.24	\$8,899.55	\$13,990,094.72
Subtotal:				480.21	960.42		\$41,943.40	\$65,935,030.28	\$43,201.71	\$67,913,081.18	\$44,497.76	\$69,950,473.62
Ownership Payments												
Collection	Support Staff	1,572	2	0.06	0.12	\$43.67	\$5.38	\$8,458	\$5.54	\$8,711.54	\$5.71	\$8,972.89
Reporting	Support Staff	1,572	2	0.02	0.03	\$43.67	\$1.38	\$2,175	\$1.43	\$2,240.24	\$1.47	\$2,307.45
Subtotal:				0.08	0.15		\$6.76	\$10,632.80	\$6.97	\$10,951.79	\$7.18	\$11,280.34
Research Payments												
Collection	Support Staff	1,572	2	54.16	108.32	\$43.67	\$4,730.34	\$7,436,102	\$4,872.25	\$7,659,184.78	\$5,018.42	\$7,888,960.33
Reporting	Support Staff	1,572	2	13.54	27.08	\$43.67	\$1,182.59	\$1,859,025	\$1,218.06	\$1,914,796.20	\$1,254.61	\$1,972,240.08
Subtotal:				67.70	135.39		\$5,912.93	\$9,295,127.17	\$6,090.32	\$9,573,980.98	\$6,273.03	\$9,861,200.41
Grand Total:				547.98	1,095.97		\$47,863.10	\$75,240,790.24	\$49,298.99	\$77,498,013.95	\$50,777.96	\$79,822,954.37

Estimated Group Purchasing Organization Burden by Process												
Process	Labor	# of GPO's	FTE	Hours / FTE	Total Hours	Hourly Rate (Base + 100%)	2021 Average Cost Per GPO	2021 Total for all GPO's	2022 Average Cost Per GPO	2022 Total Cost for all GPO's	2023 Average Cost Per GPO	2023 Total Cost for all GPO's
General Payments												
Collection	Support Staff	23	1	2.11	2.11	\$43.67	\$94.85	\$2,181.63	\$97.70	\$2,247.08	\$94.85	\$2,181.63
Submission	Support Staff	23	1	0.53	0.53	\$43.67	\$23.71	\$545.41	\$24.42	\$561.77	\$23.71	\$545.41
Subtotal:				2.64	2.64		\$118.57	\$2,727.04	\$122.12	\$2,808.85	\$118.57	\$2,727.04
Ownership Payments												
Collection	Support Staff	23	1	5.79	5.79	\$43.67	\$260.24	\$5,985.63	\$268.05	\$6,165.19	\$260.24	\$5,985.63
Submission	Support Staff	23	1	1.49	1.49	\$43.67	\$66.92	\$1,539.25	\$68.93	\$1,585.43	\$66.92	\$1,539.25
Subtotal:				7.27	7.27		\$327.17	\$7,524.88	\$336.98	\$7,750.62	\$327.17	\$7,524.88
Research Payments												
Collection	Support Staff	23	1	0.00	0.00	\$43.67	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Submission	Support Staff	23	1	0.00	0.00	\$43.67	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Subtotal:				0.00	0.00		\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Grand Total:				9.91	9.91		\$445.74	\$10,251.92	\$459.11	\$10,559.48	\$445.74	\$10,251.92

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 estimate that on average, smaller applicable manufacturers will have to dedicate 25 percent of an FTE employee (mainly in the range of zero to 50 percent), whereas larger applicable manufacturers may have to dedicate one to 10 FTE employees to comply with the reporting requirements (we assume two FTEs on average). Furthermore, we estimated that reporting activities will be conducted by the managerial staff and supporting staffs, the compliance or similar level of staffs will oversee the reporting activities, which will largely be supported by staff involved with bookkeeping, accounting and auditing.
- 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: hourly rate for the compliance officer is \$36.35 and the hourly rate for support staff is \$22.20. We applied a 3 percent increase to this amount 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.
- Data collection and management of data collected will require two support staff and one compliance officer. We are assuming multiple support staff for bookkeeping accounting, and auditing. We estimate that, for year 1, on average, smaller applicable manufacturers will have to dedicate 25 percent of an FTE employee (mainly in the range of zero to 50 percent), whereas larger applicable manufacturers may have to dedicate one to 10 FTE employees to comply with the reporting requirements (we assume two FTEs on average).
- We estimated that reporting activities will be conducted by the managerial staff and supporting staff: the compliance or similar level of staffs will oversee the reporting activities, which will largely be performed by staff involved with bookkeeping, accounting and auditing.

- 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 the last approved package, we have not incorporated those numbers into this package.

Data Submission Estimation Assumptions

- In 2015 there were 1,572 applicable manufacturers that submitted data, and there were 23 GPO's that submitted data and we maintain this data submission estimate in this updated package.
- 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 would be attestation.
- 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 assume that all entities will submit an assumptions document which will take 1 hour to prepare (compliance officer) and 1 hour to submit (support staff). We expect preparation of this document to essentially occur in conjunction with data collection.
- 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 PRA we have not assumed a difference in burden depending on which type of data is being submitted.
- Data submission requires two support staff and one compliance officer. We estimate that, for year 1, on average, smaller applicable manufacturers will have to dedicate 25 percent of an FTE employee (mainly in the range of zero to 50 percent), whereas larger applicable manufacturers may have to dedicate one to 10 FTE employees to comply with the reporting requirements (we assume 2 FTEs on average). Furthermore, we estimated that reporting activities will be conducted by the managerial staff and supporting staffs, the compliance or similar level of staffs will oversee the reporting activities, which will largely be supported by staff involved with bookkeeping, accounting and auditing.

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 \$1,289.33 per applicable manufacturer, \$1,289.33 per applicable GPO, \$1,961.99 per teaching hospital, and \$637.06 per physician. The tables that follow and the supporting assumptions explain the methodology for these estimates.

Estimated Applicable Manufacturer Burden by Process

Process	Labor	# of AM's	FTE	Hours / FTE	Total Hours	Hourly Rate	2021	2021	2022	2022	2023	2023
							Total Per AM	Total for all AM's	Average Cost Per AM	Total Cost for all AM's	Average Cost Per AM	Total Cost for all AM's
Registration / Recertification	Support Staff	1,572	2	0.25	0.50	\$43.67	\$21.84	\$34,326.19	\$22.49	\$35,355.98	\$23.17	\$36,416.66
	Compliance Officer		1	0.50	0.50	\$74.88	\$37.44	\$58,856.47	\$38.56	\$60,622.16	\$39.72	\$62,440.82
Subtotal:					1.00		\$59.28	\$93,182.66	\$61.05	\$95,978.14	\$62.89	\$98,857.48
Record Retention	Support Staff	1,572	2	0.50	1.00	\$43.67	\$43.67	\$68,652.38	\$44.98	\$70,711.96	\$46.33	\$72,833.31
Subtotal:					1.00		\$43.67	\$68,652.38	\$44.98	\$70,711.96	\$46.33	\$72,833.31
Attestation	Compliance Officer	1,572	1	2.00	2.00	\$74.88	\$149.77	\$235,446.18	\$154.27	\$242,509.57	\$158.90	\$249,784.86
	Support Staff		2	1.00	2.00	\$43.67	\$87.35	\$137,316.62	\$89.97	\$141,436.12	\$92.67	\$145,679.20
Subtotal:					4.00		\$237.13	\$372,762.80	\$244.24	\$383,945.68	\$251.57	\$395,464.06
Assumption Document	Compliance Officer	1,572	1	1.00	1.00	\$74.88	\$74.88	\$117,712.93	\$77.13	\$121,244.32	\$79.44	\$124,881.65
	Support Staff		2	0.50	1.00	\$43.67	\$43.67	\$68,652.38	\$44.98	\$70,711.96	\$46.33	\$72,833.31
Subtotal:					2.00		\$118.55	\$186,365.32	\$122.11	\$191,956.28	\$125.77	\$197,714.96
Dispute Resolution	Compliance Officer	1,572	1	6.19	6.19	\$74.88	\$463.25	\$728,233.45	\$477.15	\$750,080.46	\$491.46	\$772,582.87
	Support Staff		2	3.09	6.19	\$43.67	\$270.18	\$424,719.37	\$284.50	\$437,460.95	\$293.03	\$450,584.78
Subtotal:					12.37		\$733.43	\$1,152,952.82	\$761.65	\$1,187,541.41	\$784.50	\$1,223,167.65
TOTAL:					20.37		\$1,192.06	\$1,873,915.98	\$1,234.03	\$1,930,133.46	\$1,271.06	\$1,988,037.47

Estimated Group Purchasing Organization Burden by Process

Process	Labor	# of GPO's	FTE	Hours / FTE	Total Hours	Hourly Rate	2021	2021	2022	2022	2023	2023
							Total Per GPO	Total for all GPO's	Average Cost Per GPO	Total Cost for all GPO's	Average Cost Per GPO	Total Cost for all GPO's
Registration / Recertification	Support Staff	23	1	0.50	0.50	\$43.67	\$21.84	\$502.23	\$22.49	\$517.29	\$23.17	\$532.81

	Compliance Officer	1	0.50	0.50	\$74.88	\$37.44	\$861.13	\$38.56	\$886.97	\$39.72	\$913.57	
Subtotal:				1.00		\$59.28	\$1,363.36	\$61.05	\$1,404.26	\$62.89	\$1,446.39	
Record Retention	Support Staff	23	1	1.00	1.00	\$43.67	\$43.67	\$1,004.46	\$44.98	\$1,034.59	\$46.33	\$1,065.63
Subtotal:				1.00		\$43.67	\$1,004.46	\$44.98	\$1,034.59	\$46.33	\$1,065.63	
Attestation	Compliance Officer	23	1	2.00	2.00	\$74.88	\$149.77	\$3,444.82	\$154.27	\$3,548.17	\$158.90	\$3,654.61
	Support Staff	1	2.00	2.00	\$43.67	\$87.35	\$2,009.09	\$89.97	\$2,069.36	\$92.67	\$2,131.44	
Subtotal:				4.00		\$237.13	\$5,453.91	\$244.24	\$5,617.53	\$251.57	\$5,786.05	
Assumption Document	Compliance Officer	23	1	1.00	1.00	\$74.88	\$74.88	\$1,722.26	\$77.13	\$1,773.93	\$79.44	\$1,827.15
	Support Staff	1	1.00	1.00	\$43.67	\$43.67	\$1,004.46	\$44.98	\$1,034.59	\$46.33	\$1,065.63	
Subtotal:				2.00		\$118.55	\$2,726.72	\$122.11	\$2,808.52	\$125.77	\$2,892.78	
Dispute Resolution	Compliance Officer	23	1	6.19	6.19	\$74.88	\$463.25	\$10,654.82	\$477.15	\$10,974.46	\$491.46	\$11,303.69
	Support Staff	1	6.19	6.19	\$43.67	\$270.18	\$6,214.09	\$278.28	\$6,400.51	\$286.63	\$6,592.53	
Subtotal:				12.37		\$733.43	\$16,868.90	\$755.43	\$17,374.97	\$778.10	\$17,896.22	
Total:				20.37		\$1,192.06	\$27,417.35	\$1,227.82	\$28,239.87	\$1,264.65	\$29,087.06	

Estimated Physician Burden by Process

Process	Labor	# of Physician's	FT E	Hours / FTE	Total Hours	Hourly Rate	2021	2021	2022	2022	2023	2023
							Total Per Physician	Total for all Physicians	Average Cost Per Physician	Total Cost for all Physicians	Average Cost Per Physician	Total Cost for all Physicians
Registration	Physician	31,897	1	0.50	0.50	\$216.75	\$108.38	\$3,456,888	\$111.63	\$3,560,595.06	\$114.98	\$3,667,412.91
	Support Staff		1	0.50	0.50	\$38.95	\$19.48	\$621,267	\$20.06	\$639,905.46	\$20.66	\$659,102.63
Subtotal:					1.00		\$127.85	\$4,078,155.85	\$131.69	\$4,200,500.52	\$135.64	\$4,326,515.54
Review	Physician	31,897	1	1.51	1.51	\$216.75	\$327.14	\$10,434,673	\$336.95	\$10,747,712.98	\$347.06	\$11,070,144.37
	Support Staff		1	1.51	1.51	\$38.95	\$58.79	\$1,875,306	\$60.56	\$1,931,564.84	\$62.37	\$1,989,511.78
Subtotal:					3.02		\$385.93	\$12,309,978.46	\$397.51	\$12,679,277.82	\$409.43	\$13,059,656.15
Dispute Resolution	Physician	31,897	1	0.28	0.28	\$216.75	\$61.24	\$1,953,380	\$63.08	\$2,011,981.23	\$64.97	\$2,072,340.67
	Support Staff		1	0.28	0.28	\$38.95	\$11.01	\$351,059	\$11.34	\$361,590.62	\$11.68	\$372,438.34
Subtotal:					0.57		\$72.25	\$2,304,438.69	\$74.41	\$2,373,571.85	\$76.65	\$2,444,779.01
Total:					4.58		\$586.03	\$18,692,573.00	\$603.61	\$19,253,350.19	\$621.72	\$19,830,950.70

Estimated Teaching Hospital Burden by Process

Process	Labor	# of Teaching Hospitals	FT E	Hours / FTE	Total Hours	Hourly Rate	2021 Total Per Teaching Hospital	2021 Total for all Teaching Hospitals	2022 Average Cost Per Teaching Hospital	2022 Total Cost for all Teaching Hospitals	2023 Average Cost Per Teaching Hospital	2023 Total Cost for all Teaching Hospitals
Registration	Compliance Officer	1,124	1	0.50	0.50	\$74.88	\$37.44	\$42,083	\$38.56	\$43,345.62	\$39.72	\$44,645.98
	Support Staff		1	0.50	0.50	\$38.95	\$19.48	\$21,892	\$20.06	\$22,549.26	\$20.66	\$23,225.74
Subtotal:					1.00		\$56.92	\$63,975.61	\$58.63	\$65,894.88	\$60.38	\$67,871.72
Review	Compliance Officer	1,124	1	11.39	11.39	\$74.88	\$852.76	\$958,499	\$878.34	\$987,254.28	\$904.69	\$1,016,871.90
	Support Staff		1	11.39	11.39	\$38.95	\$443.62	\$498,631	\$456.93	\$513,589.50	\$470.64	\$528,997.19
Subtotal:					22.78		\$1,296.38	\$1,457,129.88	\$1,335.27	\$1,500,843.78	\$1,375.33	\$1,545,869.09
Dispute Resolution	Compliance Officer	1,124	1	5.65	5.65	\$74.88	\$422.97	\$475,419	\$435.66	\$489,682.05	\$448.73	\$504,372.51
	Support Staff		1	5.65	5.65	\$38.95	\$220.04	\$247,323	\$226.64	\$254,742.44	\$233.44	\$262,384.71
Subtotal:					11.30		\$643.01	\$722,742.22	\$662.30	\$744,424.49	\$682.17	\$766,757.23
Total:					35.07		\$1,996.31	\$2,243,847.71	\$2,056.19	\$2,311,163.14	\$2,117.88	\$2,380,498.04

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: hourly rate for the compliance officer is 36.35 dollars and the hourly rate for support staff is 22.20 dollars. We applied a 3 percent annual increase to this amount to account for change over time.
- 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.
- For physicians and teaching hospital support staff wage rates, we used the following estimates: hourly rate for support staff at 18.91 dollars, 36.35 dollars for compliance staff, and 105.22 for physicians. We applied a 3 annual percent increase to this amount 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.
- In 2015 we had 1,572 Applicable Manufacturers report data to the Open Payments portal and we maintain this estimate in this updated package.
- In 2015 we had 23 GPO's submit data to the Open Payments portal. The definition of GPO includes some physician owned distributorships (PODs) and we maintain this estimate in this updated package.
- We estimate 31,897 physicians register in order to review data submitted about them. Physicians are defined in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, optometrists and licensed chiropractors, for purposes of Open Payments. In 2015 AM's and GPO's have reported data for 629,647 physicians and we maintain this estimate in this updated package. However, we believe that not all physicians will have relationships with applicable manufacturers or applicable GPOs.
- As of reporting year end for 2015 there were records for 1,124 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.

Registration Estimation Assumptions

- We assume two FTEs per applicable manufacturer and applicable GPO will participate in the registration process. Additionally, we assume one physician

and one FTE will participate to register physicians and two FTEs for teaching hospitals will participate to register a teaching hospital.

Attestation Estimation Assumptions

- We estimate two FTEs per applicable manufacturer and applicable GPO will participate in the attestation process. We assume applicable manufacturer's or applicable GPO's support staff will assist the compliance officer, which can be Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other 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).

Dispute and Resolution Estimation Assumptions

- We estimate 30 percent of applicable manufacturers and applicable group purchasing organizations will need to resolve at least one dispute, initiated by a physician or teaching hospital, which may require correction, based on CMS market research.
- We estimate that resolution and data correction for applicable manufacturers and group purchasing organizations requires two support staff (6.19 hours total) and the compliance officer (6.19 hours total).
- We estimate a teaching hospital compliance officer will need hours 11.39 hours to review data. In addition, we estimate a teaching hospital will utilize 11.39 hours of administrative supporting staff at teaching hospitals to maintain the records. The role of the compliance officer will be review and oversight, while the administrative supporting staff will conduct the recordkeeping. In the final rule, we estimated the supporting staffs such as bookkeeping, accounting, and auditing would perform the tasks while the compliance officer would oversee the review process.
- We estimate 31,897 physicians registered to review reported information despite records for 629,649 physicians. This reduces the number of physicians we estimate to be involved in the dispute resolution and correction process to roughly 5% of the total industry. This information is based from records to date, so we estimate that many physicians will not devote any time in reviewing the aggregated reports from CMS. Therefore, we estimate that physicians and their support staff that do review their records will spend approximately an hour and a half each reviewing annual data, and approximately a total of 0.6 hours reviewing dispute and resolution materials.
- We estimate that the vast majority of teaching hospitals would have at least one financial relationship with an applicable manufacturer, so we expect one Compliance Officer and one Support Staff employee to spend nearly 11.5 hours each reviewing reported information. We also estimate that these two resources will each spend around 5.65 hours reviewing materials for the dispute and resolution process (for a total of 11.3 hours).

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. We assume one FTE per applicable manufacturer and applicable GPO is necessary for this process.

CY 2022 Physician Fee Schedule NPRM (RIN 0938-AU42, CMS-1751-P)

a. Payment Context Field for Teaching Hospitals

The proposed mandatory context field is a new 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 in the current PRA package is the “General-Research-Ownership Submission Data Elements”. At the support staff cost per FTE of \$42.40/hr, this would increase costs by \$254.40 (6 hr x \$42.40/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 \$42.40/hr respectively, reducing costs by \$84.80 (2 hr x \$42.40/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 \$169.60 (\$254.40 - \$84.80). 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 \$134,662.40 (3,176 x \$42.40/hr).

In addition, we estimate this proposal would reduce teaching hospital dispute resolution estimates by 2 hours per support staff FTE at \$37.82/hr or \$75.64 (2 hr x \$37.82/hr) per teaching hospital with records attributed to them. In PY 2019, 1,202 hospitals had record attributed to them, so for teaching hospitals we estimate a total burden reduction of 2,404 hours at a cost of \$90,919.28 (2,404 x \$75.64/hr).

In aggregate, we estimate an annual burden of 772 hours (3,176 - 2,404) at a cost of \$43,743.12 (\$134,662.40 - \$90,919.28).

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 240 reporting entities (0.15 [1,595 applicable manufacturers and applicable GPOs]) will complete and submit the proposed optional annual recertification. We anticipate that it will be a simple check box form to be included in the AM (Attestation) and GPO (Attestation) Annual IC Requirement and the “Attestation and Assumptions Screen Shots” Instrument in the existing PRA package. We estimate that it would take 0.5 hours at \$42.40/hr for support staff to complete and submit the recertification. In aggregate, we estimate an added annual burden of 120 hours (240 entities x 0.5 hr/response) at a cost of \$5,088 (120 hr x

\$42.40/hr).

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

The proposed 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 proposal 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 would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the “Open Payments User Guide” Instrument in the existing PRA package. We anticipate that this would take an average of 2 hours at \$42.40/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 \$3,392 (80 hr * \$42.40/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 proposal.

f. Short Term Loans (§ 403.902)

This proposal 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 proposal will change reporting behavior, and therefore do not anticipate an increase in burden.

g. Remove General Ownership Records

Currently the Open Payments system allows 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 \$42.40/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 \$11,702 (276 hr x \$42.40/hr). This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the “Open Payments User Guide” Instrument in the existing PRA package.

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

This proposal creates 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 would take 0.5 hours at \$42.40/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 \$636 (15 hr x \$42.40/hr). This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the “Open Payments User Guide” Instrument in the existing PRA package.

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

IC Requirements	No. Respondents	Total Responses	Burden per Response (hours)	Total Time (hours)	Labor Cost (\$/hr)	Total Cost (\$)
AM (Registration)	1,572	1,572	1	1,572	43.67 - 74.88	93,183
Applicable GPO (Registration)	23	23	1	23	43.67 - 74.88	1,363
Physicians (Registration)	31,897	31,897	1	31,897	38.95 - 210.44	4,078,156
Teaching Hospitals (Registration)	1,124	1,124	1	1,124	37.82 - 72.70	63,976
AM (Record Retention)	1,572	1,572	1	1,572	43.67	68,652
Applicable GPO (Record Retention)	23	23	1	23	43.67	1,004
AM (Attestation)	1,572	1,572	4	6,288	43.67 - 74.88	372,763
Applicable GPO (Attestation)	23	23	4	92	43.67 - 74.88	5,454
AM (Assumptions Document)	1,572	1,572	2	3,144	43.67 - 74.88	186,365
Applicable GPO (Assumptions Document)	23	23	2	46	43.67 - 74.88	2,727
AM Dispute Resolution and Correction	1,572	1,572	12.37	19,446	43.67 - 74.88	1,152,953
GPO Dispute and Resolution Correction	23	23	12.37	285	43.67 - 74.88	16,869
Dispute Resolution and Correction (Physicians)	31,897	31,897	3.59	114,510	38.95 - 210.44	14,614,417
Dispute Resolution and Correction (Teaching Hospitals)	1,124	1,124	11.3	12,701	38.95 - 72.70	2,179,872
AM (Data collection and submission)	1,572	1,572	1,043.01	1,639,612	43.67	75,240,790
Applicable GPO (Data collection and	23	23	9.4	216	43.67	9,953

submission)						
Teaching Hospital Contact Field (CMS-1751-P)	794 (AM and applicable GPO)	794	4	3,176	42.40	134,662
	1,202 (teaching hospitals)	(1,202)	(2)	(2,404)	42.40	(90,919)
Optional Annual Recertification (CMS-1751-P)	240	240	0.5	120	42.40	5,088
Disallowing Record Deletion Without Reason (CMS-1751-P)	40	40	2	80	42.40	3,392
Remove General Ownership Records (CMS-1751-P)	92	92	3	276	42.40	11,702
Updated Contact Information (CMS-1751-P)	30	30	0.5	15	42.40	636
TOTAL	34,616	75,606	varies	1,833,814	varies	98,153,058

D. Collection of information Instruments and Instruction/Guidance Documents

Instrument	Requirements	Instrument Status
Registration-Physician-Hospitals-AMs-GPOs	Registration/Recertification	No change
Record Retention Requirements	Record Retention	No change
Attestation and Assumptions Screen Shots	Attestation and assumptions documents	No change at this time. When ready, the proposed changes will be made available to the public for review/comment via the Federal Register.
Review and Dispute Email Notifications	Dispute resolution and correction	No change
Review and Dispute Screen Shots	Dispute resolution and correction	No change
General-Research-Ownership Submission Data Elements	Data collection and Submission	No change at this time. When ready, the proposed changes will be made available to the public for review/comment via the Federal Register.
Open Payments User Guide	Data collection and Submission	No change at this time. When ready, the proposed changes will be made available to the public for review/comment via the Federal Register.

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 a total of \$3,674,310 over three years. The total contract cost with a 5% per annum increase over three years will be approximately \$65,461,043. Total cost for three years is \$69,135,353, meaning average cost per year is \$23,045,117.

15. Changes to Burden

The following proposed changes were included in the CY 2022 Physician Fee Schedule rule (RIN 0938-AU42, CMS-1751-P) that published in the Federal Register on July 23, 2021 (86 FR 39104). The rule filed for public inspection on July 13, 2021.

a. Payment Context Field for Teaching Hospitals

The proposed mandatory context field is a new 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 in the current PRA package is the “General-Research-Ownership Submission Data Elements”. At the support staff cost per FTE of \$42.40/hr, this would increase costs by \$254.40 (6 hr x \$42.40/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 \$42.40/hr respectively, reducing costs by \$84.80 (2 hr x \$42.40/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 \$169.60 (\$254.40 - \$84.80). 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 \$42.40/hr or a total of \$134,662.40 (3,176 x \$42.40).

In addition, we estimate this proposal would reduce teaching hospital dispute resolution estimates by 2 hours per support staff FTE at \$37.82/hr or \$75.64 (2 hr x \$37.82/hr) per teaching hospital with records attributed to them. In PY 2019, 1,202 hospitals had record attributed to them, so for teaching hospitals we estimate a total burden reduction of 2,404 hours at a cost of \$90,919.28 (2,404 x \$75.64).

In aggregate, we estimate an annual burden of 772 hours (3,176 - 2,404) at a cost of \$43,743.12 (\$134,662.40 - \$90,919.28).

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 240 reporting entities (0.15 [1,595 applicable manufacturers and applicable GPOs]) will complete and submit the proposed optional annual recertification. We anticipate that it will be a simple check box form to be included in the AM (Attestation) and GPO (Attestation) Annual IC Requirement and the “Attestation and Assumptions Screen Shots” Instrument in the existing PRA package. We estimate that it would take 0.5 hours at \$42.40/hr for support staff to complete and submit the recertification. In aggregate, we estimate an added annual burden of 120 hours (240 entities x 0.5 hr/response) at a cost of \$5,088 (120 hr x \$42.40/hr).

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

The proposed 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 proposal 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 would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the “Open Payments User Guide” Instrument in the existing PRA package. We anticipate that this would take an average of 2 hours at \$42.40/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 \$3,392 (80 hr * \$42.40/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 proposal.

f. Short Term Loans (§ 403.902)

This proposal 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 proposal will change reporting behavior, and therefore do not anticipate an increase in burden.

g. Remove General Ownership Records

Currently the Open Payments system allows 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 \$42.40/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 \$11,702 (276 hr x \$42.40/hr). This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the “Open Payments User Guide” Instrument in the existing PRA package.

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

This proposal creates 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 would take 0.5 hours at \$42.40/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 \$636 (15 hr x \$42.40/hr). This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the “Open Payments User Guide” Instrument in the existing PRA package.

i. Summary

Open Payments Burden Changes

IC Requirements		Total Increase in Burden (Hours)	Total Decrease in Burden (Hours)	Total (Hours)
Dispute Resolution and Correction (Teaching Hospitals)	Teaching Hospital Contact Field	3,176 (794 reporting entities x 4 hr)	(2,404)(1,202 hospitals x -2 hr)	+772
AM (Attestation), Applicable GPO (Attestation)	Optional Annual Recertification	120 (240 entities x 0.5 hr)	0	+120
AM (Registration), Applicable GPO (Registration)	Defining a Physician Owned Distributorship	0	0	0
AM (Data collection and submission), Applicable GPO (Data collection and submission)	Disallowing Record Deletion Without Reason	80 (40 applicable manufacturers or GPOs deleting records annually x 2 hr)	0	+80
AM (Data collection and submission), Applicable GPO (Data collection and submission)	Disallow Publication Delays of General Payments	0	0	0
AM (Data collection and submission), Applicable GPO (Data collection and submission)	Short Term Loans	0	0	0
AM (Data collection and submission), Applicable GPO (Data collection and submission)	Remove General Ownership Records	276 (92 entities x 3 hr)	0	+276
AM (Attestation), Applicable GPO (Attestation)	Updated Contact Information	15 (30 entities x 0.5 hr)	0	+15
				+1,263

Burden Reconciliation

Annual Requirements and Burden

IC Requirements	No. Respondents	Total Responses	Burden per Response (hours)	Total Time (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
Currently Approved (Active) Burden	34,616	78,812	varies	1,897,790	varies	97,244,116
Proposed Burden (see section 12, above)	34,616	75,606	varies	1,833,814	varies	98,153,058

Correction*	n/a	n/a	n/a	65,239	n/a	n/a
DIFFERENCE	0	0	varies	+1,263	varies	+908,942

*Section 12 of our active Supporting Statement estimates total time of 1,897,790 hours. The correct total should be 1,832,551, a difference of 65,239 hours.

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. The changes in burden are primarily due to two factors: first, the labor rates used between the packages dropped significantly; and second, the 2022 PFS added a relatively small burden to the program based on the above proposed changes to reporting requirements.

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).

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.