

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

## **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.<sup>1</sup> 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.

This iteration incorporates one update to the collection of information associated with the Open Payments program: (1) adjusted burden estimates. This update reflects five changes adopted in the CY 2022 Physician Fee Schedule (PFS) final rule (CMS-1751-F, RIN: 0938-AU42). The rule clarifies existing Open Payments requirements, as well as adds provisions that program stakeholders have requested and we agree will improve the quality of the data. The new provisions will be implemented for data collection in 2023 and reporting in 2024. They include:

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<sup>1</sup> 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.

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

We believe the new provisions will all have minimal burden, but will increase the usability of the data and address concerns we have heard from stakeholders.

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.

## **A. JUSTIFICATION**

### **1. Need and Legal Basis**

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

The final rule (February 8, 2013; 78 FR 9468; RIN 0938-AR33) implementing Section 1128G of the Social Security Act includes other information collections associated with (1) data collection and submission (§§ 403.904 and 403.906), (2) the registration system for applicable

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

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

In 2021, CMS finalized (CMS-1751-F, RIN: 0938-AU42) 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 publications delays for general payment records; clarifying the exception for short-term loans; and removing the option to submit and attest to general payment records with an “Ownership” Nature of Payment category.

## **2. Information Users**

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

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

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

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

### **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.<sup>2</sup> 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,<sup>3</sup> 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

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<sup>2</sup> 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.

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

applicable GPO is required to attest that the information reported is timely, accurate, and complete to best of his or her knowledge and belief.

### **Dispute Resolution and Corrections**

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

### **3. Use of Information Technology**

The Open Payments statute (Section 1128G of the Social Security Act) requires that the data be submitted electronically. Data may be submitted through an interactive online interface or through a bulk data submission in Character Separated Values (CSV) format. Providing two data submission options helps reduce burden on covered entities as the entity can assess their circumstances and choose the least costly way to report: e.g., entities with a large number of

transactions can implement systems that allow them to report in bulk – reducing the costs that would otherwise be required to enter their transactions one-by-one in the interactive online interface.

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

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

#### **4. Duplication of Efforts**

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

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

#### **5. Small Businesses**

CMS has minimized the burden on small businesses by using the CMS Enterprise Portal. This provides easy access to data for internal, operational, and technical considerations, including streamlined tools for registration and data submission. It improves and streamlines the user experience through an enterprise-level approach to the interface design.

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

#### **6. Less Frequent Collection**

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

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

## 7. **Special Circumstances**

There are no special circumstances.

## 8. **Federal Register/Outside Consultation**

### *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 were received and are responded to in an attachment to this collection of information request.

The CY 2022 PFS final rule (CMS-1751-F, RIN 0938-AU42) published in the Federal Register on November 19, 2021 (86 FR 64996).

### *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](mailto:openpayments@cms.hhs.gov) / 1-855-326-8366 / TTY Line: 1-844-649-2766) and Open Payments Compliance ([opcompliance@cms.hhs.gov](mailto:opcompliance@cms.hhs.gov)).

### **9. Payments/Gifts to Respondents**

There are no payments/gifts to respondents.

### **10. Confidentiality**

We pledge privacy to the extent allowed by law. Our “Open Payments System” (System Number: 09-70-0507) (June 5 2014; 79 FR 32547) contains information about the following categories of individuals covered by the Open Payments program: (1) physicians and authorized representatives of physicians and teaching hospitals and, (2) any applicable manufacturers and applicable GPO system users. The vast majority of the required data is required to be reported publicly, as noted in the data templates.

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

### **11. Sensitive Questions**

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

### **12. Burden Estimates**

We estimate the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information according to §§ 403.902, 403.904, 403.906, and 403.908(c), (e), (g), (h), and (f). We utilize data from the U.S Bureau of Labor Statistics (BLS) to derive average costs for all estimates of salary in establishing the information collection requirements. Mean salary estimates are based on the BLS May 2020 National Occupational Employment and Wage Estimates ([https://www.bls.gov/oes/current/oes\\_nat.htm](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.

#### **Adjusted Hourly Wage by Occupation**

Occupation Title	Occ. code	BLS Mean	Adjusted
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		Wage (\$/hr)	Wage (\$/hr)
Bookkeeping, Accounting, and Auditing Clerks	43-3031	21.20	42.40
Compliance Officer	13-1041	36.35	72.70
Office and Administrative Support Workers, All Other	43-9199	18.91	37.82
Physicians	Average of the following occupations	108.66	217.32
Anesthesiologist	29-1211	60.45	120.90
Family Medicine Physicians	29-1215	130.50	261.00
General Internal Medicine Physicians	29-1216	103.06	206.12
Obstetricians and Gynecologists	29-1218	101.42	202.84
Pediatricians, General	29-1221	114.96	229.92
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	88.74	177.48
Psychiatrists	29-1223	105.22	210.44
Surgeons, Except Ophthalmologists	29-1248	104.38	208.76

In 2015, there were 1,572 applicable manufacturers that submitted data, and there were 23 GPOs that submitted data. AMs and GPOs have reported data for 629,649 physicians. We estimate that just 5.0658%, or 31,897 physicians, registered to review reported information. This information is based on records to date, so we estimate that many physicians will not devote any time in reviewing the aggregated reports from CMS. Physicians are defined in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, optometrists, and licensed chiropractors for the purposes of Open Payments. In 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. The record counts for AMs and GPOs 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

Entity Type	Count of Entities
Applicable Manufacturers (AMs)	1,572
Group Purchasing Organizations (GPOs)	23
<i>Total Physicians with Reported Data</i>	629,649
Physicians Registered to Review Information (5% of Total)	31,897
Teaching Hospitals	1,124

### Count of Records

Record Type	AM Records	GPO Records
General	12,078,225	485
Ownership	2,905	1,996
Research	1,015,579	0
<b>Total</b>	<b>13,096,709</b>	<b>2,481</b>

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

The sections below present the estimated time and cost burdens. Section A summarizes the active burdens associated with data collection and submission, registration, attestation, record retention, dispute and resolution, and submitting an assumptions document. Estimates are presented by entity type (AMs, GPOs, physicians, and teaching hospitals) as applicable. Section B presents the estimated changes to the burdens due to the CY 2022 Physician Fee Schedule (PFS) final rule (CMS-1751-F, RIN: 0938-AU42). Section C consolidates the estimates from Section A and Section B, and presents an estimate of the total proposed burden.

#### ***A. Summary of Active Burden Estimates***

##### ***A1. Active Burden Estimates for Data Collection & Submission (Hours and Wages)***

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

**Total Estimated Applicable Manufacturer Burden (Hours)**

<b>Record Type</b>	<b>Total Hours</b>	<b>Hours Per AM</b>	<b>FTE Needed</b>	<b>Hours Per FTE</b>
<b>Collection</b>				
General	1,207,823	768.3	2	384.2
Ownership	194	0.12	2	0.06
Research	169,263	107.7	2	53.8
<b>Reporting</b>				
General	303,564	193.1	2	96.6
Ownership	50	0.03	2	0.02
Research	42,316	26.9	2	13.5

**Total Estimated Applicable Group Purchasing Organization Burden (Hours)**

<b>Record Type</b>	<b>Total Hours</b>	<b>Hours Per GPO</b>	<b>FTE Needed</b>	<b>Hours Per FTE</b>
<b>Collection</b>				
General	49	2.1	1	2.1
Ownership	133	5.8	1	5.8
Research	0	0	0	0
<b>Reporting</b>				
General	12	0.5	1	0.5
Ownership	34	1.5	1	1.5
Research	0	0	0	0

**Estimated Applicable Manufacturer Burden by Process<sup>4</sup>**

Process	Labor	# of AMs	FTE*	Hours / FTE	Total Hours	Hourly Rate	Average Cost Per AM	Total for all AMs
<b>General Payments</b>								
Collection	Support Staff	1,572	2	384	768	\$42.40	\$32,577	\$51,211,674
Reporting	Support Staff	1,572	2	96	192	\$42.40	\$8,188	\$12,871,103
<b>Subtotal</b>				<b>480</b>	<b>960</b>		<b>\$40,765</b>	<b>\$64,082,777</b>
<b>Ownership Payments</b>								
Collection	Support Staff	1,572	2	0.06	0.12	\$42.40	\$5	\$8,211
Reporting	Support Staff	1,572	2	0.02	0.03	\$42.40	\$1	\$2,112
<b>Subtotal</b>				<b>0.08</b>	<b>0.15</b>		<b>\$7</b>	<b>\$10,323</b>
<b>Research Payments</b>								
Collection	Support Staff	1,572	2	54	108	\$42.40	\$4,565	\$7,176,758
Reporting	Support Staff	1,572	2	14	27	\$42.40	\$1,141	\$1,794,190
<b>Subtotal</b>				<b>68</b>	<b>135</b>		<b>\$5,707</b>	<b>\$8,970,948</b>
<b>Grand Total</b>				<b>548</b>	<b>1,096</b>		<b>\$46,478</b>	<b>\$73,064,048</b>

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

<sup>4</sup> All totals may not sum due to rounding.

**Estimated Group Purchasing Organization Burden by Process<sup>5</sup>**

Process	Labor	# of GPOs	FTE*	Hours / FTE	Total Hours	Hourly Rate	Average Cost Per GPO	Total for all GPOs
<b>General Payments</b>								
Collection	Support Staff	23	1	2.1	2.1	\$42.40	\$89	\$2,056
Reporting	Support Staff	23	1	0.5	0.5	\$42.40	\$22	\$517
<b>Subtotal</b>				<b>2.6</b>	<b>2.6</b>		<b>\$112</b>	<b>\$2,573</b>
<b>Ownership Payments</b>								
Collection	Support Staff	23	1	5.8	5.8	\$42.40	\$245	\$5,642
Reporting	Support Staff	23	1	1.5	1.5	\$42.40	\$63	\$1,451
<b>Subtotal</b>				<b>7.3</b>	<b>7.3</b>		<b>\$308</b>	<b>\$7,093</b>
<b>Research Payments</b>								
Collection	Support Staff	23	1	0.0	0.0	\$42.40	\$0	\$0
Reporting	Support Staff	23	1	0.0	0.0	\$42.40	\$0	\$0
<b>Subtotal</b>				<b>0.0</b>	<b>0.0</b>		<b>\$0</b>	<b>\$0</b>
<b>Grand Total</b>				<b>9.9</b>	<b>9.9</b>		<b>\$420</b>	<b>\$9,666</b>

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

<sup>5</sup> All totals may not sum due to rounding.

### *General Estimation Assumptions*

- The burden associated with these requirements is the time and effort spent by applicable manufacturers and applicable GPOs collecting the data, compiling reports, and submitting and re-submitting data to send to CMS. The assumptions, when applicable, generally utilize an upward estimation model to provide the likely maximum estimate. We realize that this may provide an estimate which may be higher than what is actually encountered through operational and procedural factors and capabilities which may help to minimize burden for various activities. Although the initial rule included a downward adjustment to reflect the potential time savings accrued through ability to query CMS and receive guidance on low cost methods of compliance, we did not adjust these estimates in the same fashion to remain consistent with our overall assumption regarding estimation.
- We assume that, on average, AMs will utilize two employees to comply with data collection and reporting requirements, whereas GPOs will utilize one employee. Furthermore, we assumed that these data collection and reporting activities will largely be conducted by supporting staff involved with bookkeeping, accounting and auditing. Estimated hours per employee are derived from the assumed number of employees and the estimated hours per entity needed to comply with the requirements.
- We estimate for applicable GPOs there is a significant reduction in burden over an applicable manufacturer since we believe companies will have fewer relationships with physician owners or investors (or immediate family members) and fewer transfers of value per physician. This will make it much easier for applicable GPOs to match ownership and investment interests to the appropriate physicians (or family members). Furthermore, we do not anticipate that GPOs will have any data to be reported under the Research data template.
- For wage rates, we used the following estimates, based on the BLS May 2020 National Occupational Employment and Wage Estimates. The total hourly labor cost for support staff is \$21.20. After doubling to account for fringe and overhead, the resulting total hourly labor cost is \$42.40.

### *Data Collection Estimation Assumptions*

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

### *Data Submission Estimation Assumptions*

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

### ***A2. Active Burden Estimates for 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 \$1,157 per applicable manufacturer, \$1,157 per applicable GPO, \$1,938 per teaching hospital, and \$585 per physician. The tables that follow and the supporting assumptions explain the methodology for these estimates.

**Estimated Applicable Manufacturer Burden by Process<sup>6</sup>**

Process	Labor	# of AMs	FTE*	Hours / FTE	Total Hours	Hourly Rate	Average Cost Per AM	Total for all AMs
<b>Registration / Recertification</b>								
Registration	Support Staff	1,572	2.0	0.25	0.5	\$42.40	\$21	\$33,326
Registration	Compliance Officer	1,572	1.0	0.5	0.5	\$72.70	\$36	\$57,142
<b>Subtotal</b>					<b>1.0</b>		<b>\$58</b>	<b>\$90,469</b>
<b>Retention</b>								
Retention	Support Staff	1,572	2.0	0.5	1.0	\$42.40	\$42	\$66,653
<b>Subtotal</b>					<b>1.0</b>		<b>\$42</b>	<b>\$66,653</b>
<b>Attestation</b>								
Attestation	Compliance Officer	1,572	1.0	2.0	2.0	\$72.70	\$145	\$228,591
Attestation	Support Staff	1,572	2.0	1.0	2.0	\$42.40	\$85	\$133,319
<b>Subtotal</b>					<b>4.0</b>		<b>\$230</b>	<b>\$361,909</b>
<b>Assumption</b>								
Assumption	Compliance Officer	1,572	1.0	1.0	1.0	\$72.70	\$73	\$114,284
Assumption	Support Staff	1,572	2.0	0.5	1.0	\$42.40	\$42	\$66,653
<b>Subtotal</b>					<b>2.0</b>		<b>\$115</b>	<b>\$180,937</b>
<b>Dispute Resolution</b>								
Dispute	Compliance Officer	1,572	1.0	6.2	6.2	\$72.70	\$450	\$707,023
Dispute	Support Staff	1,572	2.0	3.1	6.2	\$42.40	\$262	\$412,349
<b>Subtotal</b>					<b>12.4</b>		<b>\$712</b>	<b>\$1,119,372</b>
<b>Grand Total</b>					<b>20.4</b>		<b>\$1,157</b>	<b>\$1,819,340</b>

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

**Estimated Group Purchasing Organization Burden by Process<sup>7</sup>**

Process	Labor	# of GPOs	FTE*	Hours / FTE	Total Hours	Hourly Rate	Average Cost Per GPOs	Total for all GPOs
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<sup>6</sup> All totals may not sum due to rounding.

<sup>7</sup> All totals may not sum due to rounding.

<b>Registration / Recertification</b>								
Registration	Support Staff	23	1.0	0.5	0.5	\$42.40	\$21	\$488
Registration	Compliance Officer	23	1.0	0.5	0.5	\$72.70	\$36	\$836
<b>Subtotal</b>					<b>1.0</b>		<b>\$58</b>	<b>\$1,324</b>
<b>Retention</b>								
Retention	Support Staff	23	1.0	1.0	1.0	\$42.40	\$42	\$975
<b>Subtotal</b>					<b>1.0</b>		<b>\$42</b>	<b>\$975</b>
<b>Attestation</b>								
Attestation	Compliance Officer	23	1.0	2.0	2.0	\$72.70	\$145	\$3,345
Attestation	Support Staff	23	1.0	2.0	2.0	\$42.40	\$85	\$1,951
<b>Subtotal</b>					<b>4.0</b>		<b>\$230</b>	<b>\$5,295</b>
<b>Assumption</b>								
Assumption	Compliance Officer	23	1.0	1.0	1.0	\$72.70	\$73	\$1,672
Assumption	Support Staff	23	1.0	1.0	1.0	\$42.40	\$42	\$975
<b>Subtotal</b>					<b>2.0</b>		<b>\$115</b>	<b>\$2,647</b>
<b>Dispute Resolution</b>								
Dispute	Compliance Officer	23	1.0	6.2	6.2	\$72.70	\$450	\$10,344
Dispute	Support Staff	23	1.0	6.2	6.2	\$42.40	\$262	\$6,033
<b>Subtotal</b>					<b>12.4</b>		<b>\$712</b>	<b>\$16,378</b>
<b>Grand Total</b>					<b>20.4</b>		<b>\$1,157</b>	<b>\$26,619</b>

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

**Estimated Physician Burden by Process<sup>8</sup>**

<b>Process</b>	<b>Labor</b>	<b># of Physicians</b>	<b>FTE*</b>	<b>Hours / FTE</b>	<b>Total Hours</b>	<b>Hourly Rate</b>	<b>Total Per Physician</b>	<b>Total for all Physicians</b>
<b>Registration / Recertification</b>								
Registration	Physician	31,897	1.0	0.5	0.5	\$217	\$109	\$3,465,928
Registration	Support Staff	31,897	1.0	0.5	0.5	\$38	\$19	\$603,172
<b>Subtotal</b>					<b>1.0</b>		<b>\$128</b>	<b>\$4,069,100</b>
<b>Review</b>								
Review	Physician	31,897	1.0	1.5	1.5	\$217	\$328	\$10,461,959
Review	Support Staff	31,897	1.0	1.5	1.5	\$38	\$57	\$1,820,685
<b>Subtotal</b>					<b>3.0</b>		<b>\$385</b>	<b>\$12,282,644</b>
<b>Dispute Resolution</b>								
Dispute	Physician	31,897	1.0	0.3	0.3	\$217	\$61	\$1,958,488
Dispute	Support Staff	31,897	1.0	0.3	0.3	\$38	\$11	\$340,834
<b>Subtotal</b>					<b>0.6</b>		<b>\$72</b>	<b>\$2,299,322</b>
<b>Grand Total</b>					<b>4.6</b>		<b>\$585</b>	<b>\$18,651,066</b>

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

<sup>8</sup> All totals may not sum due to rounding.

### Estimated Teaching Hospital Burden by Process<sup>9</sup>

Process	Labor	# of THs	FTE*	Hours / FTE	Hours/TH	Hourly Rate	Total Per TH	Total for all THs
<b>Registration / Recertification</b>								
Registration	Compliance Officer	1,202	1.0	0.5	0.5	\$72.70	\$36	\$43,693
Registration	Support Staff	1,202	1.0	0.5	0.5	\$37.82	\$19	\$22,730
<b>Subtotal</b>		1,202			<b>1.0</b>		<b>\$55</b>	<b>\$66,423</b>
<b>Review</b>								
Review	Compliance Officer	1,202	1.0	11.4	11.4	\$72.70	\$828	\$995,160
Review	Support Staff	1,202	1.0	11.4	11.4	\$37.82	\$431	\$517,702
<b>Subtotal</b>		1,202			<b>22.8</b>		<b>\$1,259</b>	<b>\$1,512,862</b>
<b>Dispute Resolution</b>								
Dispute	Compliance Officer	1,202	1.0	5.7	5.7	\$72.70	\$411	\$493,603
Dispute	Support Staff	1,202	1.0	5.7	5.7	\$37.82	\$214	\$256,782
<b>Subtotal</b>		1,202			<b>11.3</b>		<b>\$624</b>	<b>\$750,385</b>
<b>Grand Total</b>		1,202			<b>35.1</b>		<b>\$1,938</b>	<b>\$2,329,669</b>

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

<sup>9</sup> All totals may not sum due to rounding.

### *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.
- We assume that support staff for AMs and GPOs most closely align with the “Bookkeeping, Accounting, and Auditing Clerks” occupation. For applicable manufacturers and applicable GPOs staff wage rates, we used the following estimates, based on the BLS May 2020 National Occupational Employment and Wage Estimates: hourly rate for the compliance officer is \$36.35 and the hourly rate for support staff is \$21.20. After doubling to account for fringe and overhead, the resulting total hourly labor costs are \$72.70 for compliance officers and \$42.40 for support staff.
- We assume that support staff for AMs and GPOs most closely align with the “Office and Administrative Support Workers” occupation. For physicians and teaching hospital staff wage rates, we used the following estimates, based on the BLS May 2020 National Occupational Employment and Wage Estimates: hourly rate for support staff is \$18.91, hourly rate for compliance staff is \$36.35, and hourly rate for physicians is \$108.66. After doubling to account for fringe and overhead, the resulting total hourly labor costs are \$37.82 for support staff, \$72.70 for compliance officers, and \$217.32 for physicians.
- Note that burden estimates for advanced nurse covered recipients are not included in this ICR.

### *Registration Estimation Assumptions*

- We assume three full-time employees (FTEs) per applicable manufacturer and two FTEs per applicable GPO will participate in the registration process. Additionally, we assume one physician and one support staff (i.e., 2 FTEs) 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. For AMs, the 30 minutes from support staff will be split between two support staff, dedicating 15 minutes each to the registration process.

### *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. This will be completed entirely by two support staff at AMs and one support staff at GPOs.

#### *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 compliance officer to attest that the applicable manufacturer met one of the reporting limitations outlined in § 403.904(b).
- We estimate that it will take 4 hours for each AM and GPO to complete this process. This will include 2 hours of time from support staff and 2 hours of time from a compliance officer.

#### *Assumptions Document Estimation Assumptions*

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

#### *Review, Dispute, and Resolution Estimation Assumptions*

- We assume that 5% of the 11,553,797 physician records are reviewed ( $11,553,797 \times 5\% = 577,689$ ). We estimate that each record will take 5 minutes for a physician to review. In total, 48,140 hours will be spent on physicians' review of records ( $577,689 \times 0.0833$  hours). This equates to approximately 1.5 hours per physician ( $48,140 \div 31,897$  physicians involved in the review process). We assume one support staff will assist every physician, dedicating another 1.5 hours each to review records. Based on analyses of prior data, we assume physicians will be involved in 9,012 disputes. We estimate that each dispute will take a physician 1 hour. In total, physicians will spend 9,012 hours on disputes ( $9,012 \times 1$  hour). This equates to approximately 0.28 hours per physician ( $9,012 \div 31,897$  physicians involved in the dispute process). One support staff will assist every physician, dedicating another 0.28 hours each to complete the dispute and resolution

process. In total, each physician will spend 1.8 hours reviewing records and completing the dispute process and the support staff will spend 1.8 will spend 1.8 hours reviewing records and completing the dispute process.

- We assume that 50% of the 921,622 hospital records are reviewed and disputed ( $921,622 \times 50\% = 460,811$ ). We estimate that each record will take 5 minutes total for a compliance officer and support staff to review and complete the dispute resolution process. In total, 38,401 hours will be spent on teaching hospitals' review of records and dispute process ( $460,811 \times 0.0833$  hours). This equates to approximately 34 hours per teaching hospital ( $38,401 \div 1,124$  hospitals). We assume one support staff will assist every compliance officer, each dedicating 17 hours to review records and complete the dispute process. We assume two thirds of these 17 hours (11.33 hours) will be dedicated to the review process and one third of these hours (5.67 hours) will be dedicated to dispute resolution.
- AMs and GPOs addressed 19,735 disputes, of which we assume 19,450, or 99%, are addressed by AMs.<sup>10</sup> We estimate that each dispute will take a compliance officer 0.5 hours. In total, compliance officers at AMs will spend 9,725 hours on disputes ( $19,450 \times 0.5$  hours) and compliance officers for GPOs will spend 142 hour on disputes ( $284 \times 0.5$  hours). This equates to approximately 6.2 hours per AM ( $9,725 \div 1,572$  AMs) and 6.2 hours per GPO ( $142 \div 23$  GPOs). We assume two support staff will assist every compliance officer at AMs, dedicating another 3.1 hour each to complete the dispute process. At GPOs, one support staff will assist every compliance officer, dedicating another 6.2 hours each to complete the dispute process.

## ***B. Changes to Burden***

Changes to burden in this package are due to updates to the burden associated with the provisions recently adopted in the CY 2022 Physician Fee Schedule rule (RIN 0938-AU42, CMS-1751-F). The rule was filed for public inspection on July 13, 2021 and finalized on November 19, 2021. As discussed below, provisions in the rule clarify existing Open Payments requirements, as well as adds provisions that program stakeholders have requested and we agree will improve the quality of the data.

### ***a. Payment Context Field for Teaching Hospitals***

The mandatory context field is a requirement for reporting entities submitting and attesting to records that are attributed to teaching hospitals only. The field will be freeform text entry. We estimate that for each applicable manufacturer and applicable group purchasing organization (GPO), the inclusion of this field for collection and reporting activities will average an additional 6 total hours. The applicable instrument for these activities is the "General-Research-Ownership Submission Data Elements". At the support staff cost per FTE of \$42.40/hr, this would increase costs by \$254.40 ( $6 \text{ hr} \times \$42.40/\text{hr}$ ) 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 ( $2 \text{ hr} \times \$42.40/\text{hr}$ ) 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

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<sup>10</sup> 99% is based on the ratio of total AMs (1,572) to total GPOs (23).

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). It is assumed that 99% of the burden would fall on AMs and just 1% of the burden would fall on GPOs.

In addition, we estimate this proposal would reduce teaching hospital dispute resolution estimates by two hours per support staff FTE at \$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, we estimate a total burden reduction for teaching hospitals 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 optional annual recertification. We anticipate that it will be a simple check box form, which is included in the AM (Attestation) and GPO (Attestation) Annual IC Requirement and the “Attestation and Assumptions Screen Shots” Instrument in the existing. We estimate that it will take 0.5 hours at \$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 new definition is not subject to the PRA since it would not revise, add, or remove any collection of information requirements or burden.

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

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

**f. Short Term Loans (§ 403.902)**

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

**g. Remove General Ownership Records**

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

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

This is a requirement for reporting entities to keep their contact information up to date with CMS. The ability to communicate with a reporting entity is important because CMS may need to contact the entity in the case of perceived issues with the records. Applicable manufacturers and applicable GPOs will only be required to update their contact information if the two contacts provided become obsolete due to a change in the organization. This will also only apply to entities that do not have records to report for 2 years after a program year in which they reported. Therefore, we anticipate that it will only affect approximately 30 applicable manufacturers and applicable group purchasing organizations. We estimate that it will take 0.5 hours at \$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 is included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) burden calculation and the “Open Payments User Guide” Instrument.

**i. Summary**

The following table summarizes the burden changes associated with the eight provisions that were in the final rule.

### Open Payments Burden Changes by Provision

<b>Rule Provision (CMS-1751-F)</b>	<b>Process Affected</b>	<b>Total Increase in Time (Hours)</b>	<b>Total Decrease in Time (Hours)</b>	<b>Net Change in Time (Hours)</b>
<b>Teaching Hospital Context Field</b>	Data collection and Submission (AMs & GPOs) Dispute Resolution (THs)	3,176	-2,404	+772
<b>Optional Annual Recertification</b>	Attestation (AMs & GPOs)	120	0	+120
<b>Defining a Physician Owned Distributorship</b>	Registration (AMs & GPOs)	0	0	0
<b>Disallowing Record Deletion Without Reason</b>	Data collection and Submission (AMs & GPOs)	80	0	+80
<b>Disallowing Publication Delays of General Payments</b>	Data collection and Submission (AMs & GPOs)	0	0	0
<b>Short Term Loans</b>	Data collection and Submission (AMs & GPOs)	0	0	0
<b>Remove General Ownership Records</b>	Data collection and Submission (AMs & GPOs)	276	0	+276
<b>Updated Contact Information</b>	Attestation (AMs & GPOs)	15	0	+15
<b>Total</b>		<b>3,667</b>	<b>-2,404</b>	<b>+1,263</b>

The next table provides detail on the burden changes by IC requirement.

### Estimated Burden Changes by IC Requirement

IC Requirements	Rule Changes (CMS-1751-F)	No. Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost (\$/hr)	Total Cost (\$)
	TH Context Field	786	786	4	3,144	42.40	133,306
	Disallowing Record Deletion Without Reason	35	35	2	70	42.40	2,968
	Remove General Ownership Records	80	80	3	240	42.40	10,176
<i>Subtotal</i>		<i>Varies</i>	<i>901</i>	<i>Varies</i>	<i>3,454</i>	<i>42.40</i>	<i>146,450</i>
	TH Context Field	8	8	4	32	42.40	1,357
	Disallowing Record Deletion Without Reason	5	5	2	10	42.40	424
	Remove General Ownership Records	12	12	3	36	42.40	1,526
<i>Subtotal</i>		<i>Varies</i>	<i>25</i>	<i>Varies</i>	<i>78</i>	<i>42.40</i>	<i>3,307</i>
	Optional Annual Recertification	230	230	0.5	115	42.40	4,876
	Updated Contact Information	25	25	0.5	12.5	42.40	530
<i>Subtotal</i>		<i>Varies</i>	<i>255</i>	<i>0.5</i>	<i>127.5</i>	<i>42.40</i>	<i>5,406</i>
	Optional Annual Recertification	10	10	0.5	5	42.40	212
	Updated Contact Information	5	5	0.5	2.5	42.40	106
<i>Subtotal</i>		<i>Varies</i>	<i>15</i>	<i>0.5</i>	<i>7.5</i>	<i>42.40</i>	<i>318</i>
TH (Dispute and Resolution Correction)	TH Context Field	1,202	1,202	-2	-2,404	37.82	-90,919
<b>TOTAL</b>		<b>Varies</b>	<b>2,398</b>	<b>Varies</b>	<b>1,263</b>	<b>Varies</b>	<b>64,562</b>

**c. Summary of Annual Collection of Information Requirements and Burden Estimates<sup>11</sup>**

The table below estimates the total time and financial burden for each requirement and each entity.

#### Burden Estimates by IC Requirement

<sup>11</sup> Totals may not sum due to rounding.

IC Requirement	No. Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost (\$/hr)	Total Cost (\$)
AM (Registration)	1,572	1,572	1	1,572	\$42.40 - \$72.70	\$90,469
GPO (Registration)	23	23	1	23	\$42.40 - \$72.70	\$1,324
Physicians (Registration)	31,897	31,897	1	31,897	\$36.35 - \$216.75	\$4,069,100
TH (Registration)	1,202	1,202	1	1,202	\$36.35 - \$72.70	\$66,423
AM (Record Retention)	1,572	1,572	1	1,572	\$42.40	\$66,653
GPO (Record Retention)	23	23	1	23	\$42.40	\$975
AM (Assumptions Document)	1,572	1,572	2	3,144	\$42.40 - \$72.70	\$180,937
GPO (Assumptions Document)	23	23	2	46	\$42.40 - \$72.70	\$2,647
AM (Dispute Resolution and Correction)	1,572	1,572	12.4	19,446	\$42.40 - \$72.70	\$1,119,372
GPO (Dispute and Resolution Correction)	23	23	12.4	285	\$42.40 - \$72.70	\$16,378
Physicians (Review, Dispute Resolution and Correction)	31,897	31,897	3.6	114,510	\$36.35 - \$216.75	\$14,581,966
<b>CMS-1751-F Related Collections</b>						
AM (Data collection and submission)	1,572	1,572	1,096	1,723,208	\$42.40	\$73,064,048
CMS-1751-F: AM (Data collection and submission)	Varies	901	Varies	3,454	\$42.40	\$146,450
<i>Subtotal: AM (Data collection and submission)</i>	<i>Varies</i>	<i>2,473</i>	<i>Varies</i>	<i>1,726,662</i>	<i>\$42.40</i>	<i>\$73,210,498</i>
GPO (Data collection and submission)	23	23	9.9	228	\$42.40	\$9,666
CMS-1751-F: GPO (Data collection and submission)	Varies	25	Varies	78	\$42.40	\$3,307
<i>Subtotal: GPO (Data collection and submission)</i>	<i>Varies</i>	<i>48</i>	<i>Varies</i>	<i>306</i>	<i>\$42.40</i>	<i>\$12,973</i>
AM (Attestation)	1,572	1,572	4	6,288	\$42.40 - \$72.70	\$361,909
CMS-1751-F: AM (Attestation)	255	255	0.5	127.5	\$42.40	\$5,406
<i>Subtotal: AM (Attestation)</i>	<i>Varies</i>	<i>1,827</i>	<i>Varies</i>	<i>6,416</i>	<i>\$42.40 - \$72.70</i>	<i>\$367,315</i>
GPO (Attestation)	23	23	4	92	\$42.40 - \$72.70	\$5,295
CMS-1751-F: GPO (Attestation)	15	15	0.5	7.5	\$42.40	\$318
<i>Subtotal: GPO (Attestation)</i>	<i>Varies</i>	<i>38</i>	<i>Varies</i>	<i>100</i>	<i>\$42.40 - \$72.70</i>	<i>\$5,613</i>
TH (Review, Dispute Resolution and Correction)	1,202	2,404	Varies	40,956	\$36.35 - \$72.70	\$2,263,247
CMS-1751-F: TH (Review, Dispute Resolution and Correction)	1,202	1,202	-2	-2,404	\$37.82	-\$90,919
<i>Subtotal: TH (Review,</i>	<i>1,202</i>	<i>2,404</i>	<i>Varies</i>	<i>38,552</i>	<i>\$36.35 -</i>	<i>\$2,172,328</i>

<i>Dispute Resolution and Correction)</i>					\$72.70	
<b>TOTAL</b>	<b>34,694*</b>	<b>78,166</b>	<b>Varies</b>	<b>1,945,755</b>	<b>Varies</b>	<b>\$95,964,970</b>

\*This figure represents 1,572 AMs, 23 GPOs, 31,897 Physicians, and 1,202 THs.

### 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 table compares the currently approved burden to the new burden to highlight the differences due to the rule change and to corrections to estimates of the active burden. The currently approved burden is 1,897,790 hours. However, there were several calculation errors in the model used to develop that estimate; for example, for teaching hospitals involved in review and dispute resolution, the formula for total hours reported included hours only for the dispute activity and inadvertently excluded hours for the review process. The correct total hours for the active burden should be 1,944,492, a difference of 46,702 hours. In addition, there were errors in several of the wages rates used to develop the currently approved burden estimates, which partially explains the large difference infca the total cost figures. For example, the wage rate used for a Compliance Office (occ code 13-1041) was over 13 percent higher than the actual value reported by BLS. The number of respondents has been updated to reflect an increase in the number of teaching hospitals. The total number of responses for the active burden has also been corrected; the correction is needed for two reasons. First, the summary table in Section 12.C of Supporting Statement A incorrectly reported the total number of responses as 78,812 when it should have been 75,612 (a difference of 3,200); this was due to an error in the summation formula. Second, the increase in the number of teaching hospitals adds responses that need to be accounted for.

#### **Annual Requirements and Burden Reconciliation**

<b>IC Requirements</b>	<b>No. Respondents</b>	<b>Total Responses</b>	<b>Time per Response (hours)</b>	<b>Total Time (hours)</b>	<b>Labor Cost (\$/hr)</b>	<b>Total Cost</b>
Currently Approved (Active) Burden <sup>12</sup>	34,616	78,812	varies	1,897,790	varies	\$104,778,991

Correction	78	-3,044	n/a	+46,702	n/a	-\$8,878,583
<i>Subtotal</i>	<i>34,694</i>	<i>75,768</i>	<i>varies</i>	<i>1,944,492</i>	<i>varies</i>	<i>\$95,900,408</i>
Rule Changes	0	+ 2,398	varies	+ 1,263	varies	+ \$64,562
Total Proposed Burden	34,616	78,166	varies	1,945,755	varies	\$95,964,970

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).

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<sup>12</sup> ICR Reference No.: 202102-0938-019.