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 of covered drugs, devices, biologicals, or medical supplies (as defined at 42 C.F.R § 403.902) 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.

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 physicians and teaching hospitals (collectively called 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 2019 iteration reflects two changes proposed in the FY 2020 Physician Fee Schedule (PFS) Proposed Rule. The rule proposes adjusting the nature of payment categories and proposes standardizing data on reported products by adding a “device identifier” component for devices and medical supplies. This updated package reflects one-time burden to applicable manufacturers and applicable GPOs associated with these changes.

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 42 C.F.R. § 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.[1] According to 42 C.F.R. § 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 information needed to register in the supplemental document such as the system user guide.[2] 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 receiving during the registration process in the supplemental document entitled "Open Payments Registration Emails."

Attestation
Section 42 C.F.R § 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.

[1] 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.
[2] Open Payments User Guide for Reporting Entities Open Payments User Guide for Covered Recipients

Dispute Resolution and Corrections
Section 42 C.F.R § 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 "Open Payments Disputed Information." 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 42 C.F.R § 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 42 C.F.R § 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 42 C.F.R § 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.

The Open Payments rule is proposed to be adjusted in the FY 2020 PFS. CMS proposes updates to the nature of payment categories and standardizing 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, Section 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 February 8, 2013 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 February 8, 2013 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 February 8, 2013 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

None.

8. Federal Register/Outside Consultation

Federal Register

Serving as the 60-day notice, the proposed rule (RIN 0938-AT72, CMS-1715-P) published in the Federal Register on August 14, 2019 (84 FR 40482). The rule was filed for public inspection on July 29, 2019.

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 (Hours & Wages)

We estimate the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information according to 42 C.F.R. §§ 403.902, 403.904, 403.906, 403.908(c), 403.908(e), 403.908(g), 403.908(h), and 403.908(f). Wage rate information comes from the Bureau of Labor Statistics Occupational Employment Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates. This estimation relies on the previously approved calculation of burden hours with the addition of the new, one-time burden associated with the changes in the FY 2020 PFS.

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 42 C.F.R. §§ 403.904 and 403.906.

Estimated Total Applicable Manufacturer Burden

Burden By Action Type

	2019 Annual Hours	2020 Annual Hours	2021 Annual Hours	2022 Annual Hours
Collection	1,311,695	1,410,281	1,446,143	1,518,450
Submission	327,924	376,557	361,536	379,613
TOTAL	**1,639,618**	**1,786,838**	**1,807,679**	**1,898,063**

Burden By Payment Type

Payment Type	2019 Annual Hours	2020 Annual Hours	2021 Annual Hours	2022 Annual Hours
General	1,437,884	1,575,017	1,585,267	1,664,530
Ownership	231	242	254	267
Research	201,504	211,579	222,158	233,266
TOTAL	**1,639,618**	**1,786,838**	**1,807,679**	**1,898,063**

Estimated Total Group Purchasing Organization Burden

Burden By Action Type

	2019 Annual Hours	2020 Annual Hours	2021 Annual Hours	2022 Annual Hours
Collection	173	182	191	200
Submission	43	45	48	50
TOTAL	**216**	**227**	**238**	**250**

Burden By Payment Type

Payment Type	2019 Annual Hours	2020 Annual Hours	2021 Annual Hours	2022 Annual Hours
General	58	61	64	67
Ownership	158	166	175	183
Research	0	0	0	0
TOTAL	**216**	**227**	**238**	**250**

Estimated Applicable Manufacturer Burden by Process												
Process	**Labor**	**# of AM's**	**FTE**	**Hours / FTE**	**Total Hours**	**Hourly Rate**	**2020 Average Cost Per**	**2020 Total for all AM's**	**2021 Average Cost Per AM**	**2021 Total Cost for all AM's**	**2022 Average Cost Per AM**	**2022 Total Cost for all AM's**
General Payments												
Collection	Support Staff	1,572	2	365.87	731.75	$44.92	$32,870.10	$51,671,795	$34,513.60	$54,255,384.68	$36,239.28	$56,968,153.91
Reporting	Support Staff	1,572	2	91.47	182.94	$44.92	$8,217.52	$12,917,949	$8,628.40	$13,563,846.17	$9,059.82	$14,242,038.48
Subtotal:				**457.34**	**914.68**				**$41,087.62**	**$64,589,743.67**	**$43,142.00**	**$67,819,230.85**
Ownership Payments												
Collection	Support Staff	1,572	2	0.06	0.12	$44.92	$5.27	$8,286	$5.53	$8,700.55	$5.81	$9,135.58
Reporting	Support Staff	1,572	2	0.01	0.03	$44.92	$1.32	$2,072	$1.38	$2,175.14	$1.45	$2,283.90
Subtotal:				**0.07**	**0.15**				**$6.59**	**$10,357.80**	**$6.92**	**$10,875.69**
Research Payments												
Collection	Support Staff	1,572	2	51.27	102.55	$44.92	$4,606.39	$7,241,239	$4,836.71	$7,603,300.70	$5,078.54	$7,983,465.73
Reporting	Support Staff	1,572	2	12.82	25.64	$44.92	$1,151.60	$1,810,310	$1,209.18	$1,900,825.17	$1,269.64	$1,995,866.43
Subtotal:				**64.09**	**128.18**		**$5,757.98**	**$9,051,548.45**	**$6,045.88**	**$9,504,125.87**	**$6,348.18**	**$9,979,332.17**
Grand Total:				**521.51**	**1,043.01**		**$46,852.19**	**$73,651,649.92**	**$49,194.80**	**$77,334,232.41**	**$51,654.54**	**$81,200,944.03**

Estimated Group Purchasing Organization Burden by Process												
Process	**Labor**	**# of GPO 's**	**FTE**	**Hours / FTE**	**Total Hours**	**Hourly Rate**	**2020 Average Cost Per**	**2020 Total for all GPO's**	**2021 Average Cost Per GPO**	**2021 Total Cost for all GPO's**	**2022 Average Cost Per GPO**	**2022 Total Cost for all GPO's**
General Payments												
Collection	Support Staff	23	1	2.01	2.01	$44.92	$90.23	$2,075.30	$94.74	$2,179.07	$99.48	$2,288.02
Submission	Support Staff	23	1	0.50	0.50	$44.92	$22.56	$518.83	$23.69	$544.77	$24.87	$572.01
Subtotal:				**2.51**	**2.51**		**$112.79**	**$2,594.13**	**$118.43**	**$2,723.84**	**$124.35**	**$2,860.03**
Ownership Payments												
Collection	Support Staff	23	1	5.51	5.51	$44.92	$247.52	$5,692.86	$259.89	$5,977.50	$272.89	$6,276.38
Submission	Support Staff	23	1	1.38	1.38	$44.92	$61.88	$1,423.22	$64.97	$1,494.38	$68.22	$1,569.09
Subtotal:				**6.89**	**6.89**		**$309.39**	**$7,116.08**	**$324.86**	**$7,471.88**	**$341.11**	**$7,845.47**
Research Payments												
Collection	Support Staff	23	1	0.00	0.00	$44.92	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Submission	Support Staff	23	1	0.00	0.00	$44.92	$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:				**9.40**	**9.40**		**$422.18**	**$9,710.21**	**$443.29**	**$10,195.72**	**$465.46**	**$10,705.50**

Burden to Modify Nature of Payment Categories (FY 2020 PFS)

Process	Labor	# of AMs and GPOs	FTE	Hours / FTE	Total Hours	Hourly Rate	Total One-Time Cost for all AMs and GPOs
Burden to update collection processes for entities that expect to report a transaction with a new Nature of Payment category	Support Staff	400	1	5-30	5895	$44.92	$264,804
Subtotal:					**5,895**		**$264,804**
Burden to update submission processes and systems to account for the new Nature of Payment categories	Compliance Officer	1,600	1	1	1600	$83.70	$133,920
	Support Staff	1,600	1	2-5	6167	$44.92	$277,021
Subtotal:					**7,767**		**$410,941**
Total:					**13,662**		**$675,745**

Burden for Changes to Standardize Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies (FY 2020 PFS)

Process	Labor	# of AMs and GPOs	FTE	Hours / FTE	Total Hours	Hourly Rate	Total One-Time Cost for all AMs and GPOs
Burden to update collection & submission processes for device identifiers for entities that do not already collect them	Support Staff	450	1	20-100	24,840	$44.92	$1,115,813
Subtotal:					**24,840**		**$1,115,813**
Burden to update collection & submission processes for device identifiers for all entities which will report them	Compliance Officer	850	1	2	1,700	$83.70	$142,290.00
	Support Staff	850	1	10-40	19,400	$44.92	$871,448
Subtotal:					**21,100**		**$1,013,740**
Burden to update submission processes for device identifiers for entities which will not report them	Compliance Officer	750	1	2	1,500	$83.70	$125,550
	Support Staff	750	1	2-10	4,137	$44.92	$185,834
Subtotal:					**5,637**		**$311,384**
Total:					**51,577**		**$2,440,937**

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 $41.85 and the hourly rate for support staff is $22.46. We applied a 3 percent 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.

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 a 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. We project that reporting entities would need to update their system to incorporate the proposed new nature of payment categories. For the proposed change related to device identifiers, we estimate that approximately 850 entities (approximately 53 percent of an assumed 1,600) would need to report at least one record with a device identifier and that 450 of those entities do not already collect the device identifier.

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 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.

- 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 submission processes. For the changes to the nature of payment categories, we expect that all entities would need to make minor, one-time adjustments to their submission processes. For the proposed change related to device identifiers, we estimate that approximately 850 entities (approximately 53 percent of an assumed 1,600) would need to report at least one record with a device identifier. We also assume that the remaining 750 entities not planning to submit a device identifier would have a small amount of burden associated with updating their submission processes.

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 expanded by persons to generate, maintain, retain, or disclose or provide this information according to 42 C.F.R. §403.908(c), 403.908(e), 403.908(g), 403.908(h), and 403.908(f) is $1,290.80 per applicable manufacturer, $1,290.80 per applicable GPO, $1,852.23 per teaching hospital, and $609.53 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	2020 Total Per AM	2020 Total for all AM's	2021 Average Cost Per AM	2021 Total Cost for all AM's	2022 Average Cost Per AM	2022 Total Cost for all AM's
Registration / Recertification	Support Staff	1,572	2	0.25	0.50	$44.92	$22.46	$35,307.12	$23.58	$37,072.48	$24.76	$38,926.10
	Compliance Officer		1	0.50	0.50	$83.70	$41.85	$65,788.20	$43.94	$69,077.61	$46.14	$72,531.49
Subtotal:					**1.00**		**$64.31**	**$101,095.32**	**$67.53**	**$106,150.09**	**$70.90**	**$111,457.59**
Record Retention	Support Staff	1,572	2	0.50	1.00	$44.92	$44.92	$70,614.24	$47.17	$74,144.95	$49.52	$77,852.20
Subtotal:					**1.00**		**$44.92**	**$70,614.24**	**$47.17**	**$74,144.95**	**$49.52**	**$77,852.20**
Attestation	Compliance Officer	1,572	1	2.00	2.00	$83.70	$167.40	$263,152.80	$175.77	$276,310.44	$184.56	$290,125.96
	Support Staff		2	1.00	2.00	$44.92	$89.84	$141,228.48	$94.33	$148,289.90	$99.05	$155,704.40
Subtotal:					**4.00**		**$257.24**	**$404,381.28**	**$270.10**	**$424,600.34**	**$283.61**	**$445,830.36**
Assumptions Document	Compliance Officer	1,572	1	1.00	1.00	$83.70	$83.70	$131,576.40	$87.89	$138,155.22	$92.28	$145,062.98
	Support Staff		2	0.50	1.00	$44.92	$44.92	$70,614.24	$47.17	$74,144.95	$49.52	$77,852.20
Subtotal:					**2.00**		**$128.62**	**$202,190.64**	**$135.05**	**$212,300.17**	**$141.80**	**$222,915.18**
Dispute Resolution	Compliance Officer	1,572	1	6.19	6.19	$83.70	$517.81	$814,000.08	$543.70	$854,700.08	$570.89	$897,435.09
	Support Staff		2	3.09	6.19	$44.92	$277.90	$436,856.43	$291.79	$458,699.26	$306.38	$481,634.22
Subtotal:					**12.37**		**$795.71**	**$1,250,856.51**	**$835.50**	**$1,313,399.34**	**$877.27**	**$1,379,069.31**
TOTAL:					**20.37**		**$1,290.80**	**$2,029,137.99**	**$1,355.34**	**$2,130,594.89**	**$1,423.11**	**$2,237,124.64**

Estimated Group Purchasing Organization Burden by Process

Process	Labor	# of GPO's	FTE	Hours / FTE	Total Hours	Hourly Rate	2020 Total Per GPO	2020 Total for all GPO's	2021 Average Cost Per GPO	2021 Total Cost for all GPO's	2022 Average Cost Per GPO	2022 Total Cost for all GPO's
Registration / Recertification	Support Staff	23	1	0.50	0.50	$44.92	$22.46	$516.58	$23.58	$542.41	$24.76	$569.53
	Compliance Officer		1	0.50	0.50	$83.70	$41.85	$962.55	$43.94	$1,010.68	$46.14	$1,061.21
Subtotal:					**1.00**		**$64.31**	**$1,479.13**	**$67.53**	**$1,553.09**	**$70.90**	**$1,630.74**
Record Retention	Support Staff	23	1	1.00	1.00	$44.92	$44.92	$1,033.16	$47.17	$1,084.82	$49.52	$1,139.06
Subtotal:					**1.00**		**$44.92**	**$1,033.16**	**$47.17**	**$1,084.82**	**$49.52**	**$1,139.06**
Attestation	Compliance Officer	23	1	2.00	2.00	$83.70	$167.40	$3,850.20	$175.77	$4,042.71	$184.56	$4,244.85
	Support Staff		1	2.00	2.00	$44.92	$89.84	$2,066.32	$94.33	$2,169.64	$99.05	$2,278.12
Subtotal:					**4.00**		**$257.24**	**$5,916.52**	**$270.10**	**$6,212.35**	**$283.61**	**$6,522.96**
Assumption Document	Compliance Officer	23	1	1.00	1.00	$83.70	$83.70	$1,925.10	$87.89	$2,021.36	$92.28	$2,122.42
	Support Staff		1	1.00	1.00	$44.92	$44.92	$1,033.16	$47.17	$1,084.82	$49.52	$1,139.06
Subtotal:					**2.00**		**$128.62**	**$2,958.26**	**$135.05**	**$3,106.17**	**$141.80**	**$3,261.48**
Dispute Resolution	Compliance Officer	23	1	6.19	6.19	$83.70	$517.81	$11,909.67	$543.70	$12,505.15	$570.89	$13,130.41
	Support Staff		1	6.19	6.19	$44.92	$277.90	$6,391.67	$291.79	$6,711.25	$306.38	$7,046.81
Subtotal:					**12.37**		**$795.71**	**$18,301.34**	**$835.50**	**$19,216.40**	**$877.27**	**$20,177.22**
Total:					**20.37**		**$1,290.80**	**$29,688.41**	**$1,355.34**	**$31,172.83**	**$1,423.11**	**$32,731.47**

Estimated Physician Burden by Process

Process	Labor	# of Physician's	FTE	Hours / FTE	Total Hours	Hourly Rate	2020 Total Per Physician	2020 Total for all Physicians	2021 Average Cost Per Physician	2021 Total Cost for all Physicians	2022 Average Cost Per Physician	2022 Total Cost for all Physicians
Registration	Physician	31,897	1	0.50	0.50	$225.66	$112.83	$3,598,939	$118.47	$3,778,885.44	$124.40	$3,967,829.71
	Support Staff		1	0.50	0.50	$40.30	$20.15	$642,725	$21.16	$674,860.78	$22.22	$708,603.82
Subtotal:					**1.00**		**$132.98**	**$4,241,663.06**	**$139.63**	**$4,453,746.21**	**$146.61**	**$4,676,433.52**
Review	Physician	31,897	1	1.51	1.51	$225.66	$340.58	$10,863,453	$357.61	$11,406,625.95	$375.49	$11,976,957.25
	Support Staff		1	1.51	1.51	$40.30	$60.82	$1,940,074	$63.86	$2,037,078.02	$67.06	$2,138,931.92
Subtotal:					**3.02**		**$401.40**	**$12,803,527.59**	**$421.47**	**$13,443,703.97**	**$442.55**	**$14,115,889.17**
Dispute Resolution	Physician	31,897	1	0.28	0.28	$225.66	$63.76	$2,033,648	$66.94	$2,135,330.32	$70.29	$2,242,096.83
	Support Staff		1	0.28	0.28	$40.30	$11.39	$363,184	$11.96	$381,342.78	$12.55	$400,409.92
Subtotal:					**0.57**		**$75.14**	**$2,396,831.52**	**$78.90**	**$2,516,673.10**	**$82.84**	**$2,642,506.75**
Total:					**4.58**		**$609.53**	**$19,442,022.17**	**$640.00**	**$20,414,123.28**	**$672.00**	**$21,434,829.44**

Estimated Teaching Hospital Burden by Process

Process	Labor	# of Teaching Hospitals	FTE	Hours / FTE	Total Hours	Hourly Rate	2020 Total Per Teaching Hospital	2020 Total for all Teaching Hospitals	2021 Average Cost Per Teaching Hospital	2021 Total Cost for all Teaching Hospitals	2022 Average Cost Per Teaching Hospital	2022 Total Cost for all Teaching Hospitals
Registration	Compliance Officer	1,124	1	0.50	0.50	$65.32	$32.66	$36,710	$34.29	$38,545.33	$36.01	$40,472.60
	Support Staff		1	0.50	0.50	$40.30	$20.15	$22,649	$21.16	$23,781.03	$22.22	$24,970.08
Subtotal:					**1.00**		**$52.81**	**$59,358.44**	**$55.45**	**$62,326.36**	**$58.22**	**$65,442.68**
Review	Compliance Officer	1,124	1	11.39	11.39	$65.32	$743.88	$836,116	$781.07	$877,921.41	$820.12	$921,817.48
	Support Staff		1	11.39	11.39	$40.30	$458.94	$515,852	$481.89	$541,644.71	$505.98	$568,726.95
Subtotal:					**22.78**		**$1,202.82**	**$1,351,967.73**	**$1,262.96**	**$1,419,566.12**	**$1,326.11**	**$1,490,544.42**
Dispute Resolution	Compliance Officer	1,124	1	5.65	5.65	$65.32	$368.97	$414,717	$387.41	$435,452.51	$406.78	$457,225.14
	Support Staff		1	5.65	5.65	$40.30	$227.64	$255,865	$239.02	$268,657.94	$250.97	$282,090.83
Subtotal:					**11.30**		**$596.60**	**$670,581.38**	**$626.43**	**$704,110.45**	**$657.75**	**$739,315.97**
Total:					**35.07**		**$1,852.23**	**$2,081,907.55**	**$1,944.84**	**$2,186,002.93**	**$2,042.08**	**$2,295,303.08**

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 41.85 dollars and the hourly rate for support staff is 22.46 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 20.15 dollars, 32.66 dollars for compliance staff, and 112.83 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 lists 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 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 42 C.F.R § 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.
- Dispute 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 February 8, 2013 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 half each reviewing annual data, and approximately a total of 0.6 hours in dispute and resolution.
- 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 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.

C. Summary of Collection of Information Requirements and Burden Estimates

Annual Requirements and Burden

IC Requirements	No. Respondents	Total Responses	Burden per Response (hours)	Total Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
AM (Registration)	1,572	1,572	1	1,572	$44.92-$83.70	101,095.32
Applicable GPO (Registration)	23	23	1	23	$44.92-$83.70	1,479.13
Physicians (Registration)	31,897	31,897	1	31,897	$40.30-$225.66	4,241,663.06
Teaching Hospitals (Registration)	1,124	1,124	1	1,124	$40.30-$65.32	59,358.44
AM (Record Retention)	1,572	1,572	1	1,572	$44.92	70,614.24
Applicable GPO (Record Retention)	23	23	1	23	$44.92	1,033.16
AM (Attestation)	1,572	1,572	4	6,288	$44.92-$83.70	404,381.28
Applicable GPO (Attestation)	23	23	4	92	$44.92-$83.70	5,916.52
AM (Assumptions Document)	1,572	1,572	2	3,144	$44.92-$83.70	202,190.64
Applicable GPO (Assumptions Document)	23	23	2	46	$44.92-$83.70	2,958.26
AM Dispute Resolution and Correction	1,572	1,572	12.37	19,446	$44.92-$83.70	1,250,856.51
GPO Dispute and Resolution Correction	23	23	12.37	285	$44.92-$83.70	18,301.34
Dispute Resolution and Correction (Physicians)	31,897	31,897	3.59	114,510	$40.30-225.66	15,200,359.11
Dispute Resolution and Correction (Teaching Hospitals)	1,124	1,124	11.3	12,701	$40.30-$65.32	2,081,907
AM (Data collection and submission)	1,572	1,572	1,043.01	1,639,612	$44.92	73,651,649.92
Applicable GPO (Data collection and submission)	23	23	9.4	216	$44.92	9,710.21

Modifying Nature of Payment Categories*	400-1,600	1,600	1-30	13,662	$44.92-$83.70	675,745
Standardizing Data on Reported Products*	450-850	1,600	2-100	51,577	$44.92-$83.70	2,440,937
TOTAL	**34,616**	**78,812**	**varies**	**1,897,790**	**varies**	**100,360,798**

*These are one-time changes from the FY 2020 Physician Fee Schedule Proposed Rule

13. Capital Costs

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

14. Cost to Federal Government

Costs to CMS to implement this program include administrative costs as well as costs to procure contractor support in various functional areas including technical and business services and products. Actual expenditures will depend on results from an active procurement based on proposals received from prospective implementing contractors.

15. Changes to Burden

In this 2019 iteration, the cost estimates reflect more current salary figures and doubles all BLS wage estimates to account for fringe benefits and overhead costs. Previously we applied a 3 percent increase to account for change over time and fringe benefits. The 100% increase 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 burden estimate also includes revised figures for the estimated number of records and for the number of applicable manufacturers and applicable GPOs, teaching hospitals, and physicians to reflect current trends.

The “Summary of collection of information requirements and burden estimates” table in this 2019 iteration of this package displays the requirements across the specific groups that they pertain to. For example, registration for applicable manufacturers and applicable GPOs are listed separately, when they were previously listed together. The instruments in this package still pertain to these requirements, as described in the table below.

Instrument	**Requirements**
“Registration-Physician-Hospitals-AMs-GPOs”	Registration/Recertification
“Record Retention Requirements”	Record Retention
“Attestation and Assumptions Screen Shots”	Attestation and assumptions documents
“Review and Dispute Email Notifications”	Dispute resolution and correction

"Review and Dispute Screen Shots"	Dispute resolution and correction
"General-Research-Ownership Submission Data Elements"	Data collection and Submission
"Open Payments User Guide"	Data collection and Submission

These estimates also reflect the one-time burden associated with the changes proposed in the FY 2020 PFS proposed rule to adjust the nature of payment categories and the addition of the device identifier. This burden is outlined below and is reflected in the overall burden calculation above.

The proposed nature of payment category changes would modify the nature of payment categories and provide more options for applicable manufacturers and GPOs to capture the nature of the payment made to the covered recipient. To accommodate this change, we project that reporting entities would need to update their system to incorporate the proposed categories. We also expect that all entities would need to make minor, one-time adjustments to their submission processes.

For the proposed change related to device identifiers, we estimate that approximately 850 entities (approximately 53 percent of an assumed 1,600) would need to report at least one record with a device identifier and that 450 of those entities do not already collect the device identifier. We also assume that the remaining 750 entities not planning to submit a device identifier would have a small amount of burden associated with updating their submission processes.

These changes in the FY 2020 PFS pertain to data collected in 2021 that will be submitted in 2022. Minor adjustments to the collection materials such as the submission-mapping document will be made for versions to be used for Program Year 2021 and beyond to reflect the changes from the FY 2020 PFS proposed rule. These revised documents will be made available for review in advance of when they will be required to be used.

Burden to Modify Nature of Payment Categories

Process	Labor	# of AMs and GPOs	FTE	Hours / FTE	Total Hours	Hourly Rate	Total One-Time Cost for all AMs and GPOs
Burden to update collection processes for entities that expect to report a transaction with a new Nature of Payment category	Support Staff	400	1	5-30	5895	$44.92	$264,804
Subtotal:					**5,895**		**$264,804**
Burden to update submission processes and systems to account for the new Nature of Payment categories	Compliance Officer	1,600	1	1	1600	$83.70	$133,920
	Support Staff	1,600	1	2-5	6167	$44.92	$277,021

Subtotal:					**7,767**		**$410,941**
Total:					**13,662**		**$675,745**

Burden for Changes to Standardize Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies

Process	Labor	# of AMs and GPOs	FTE	Hours / FTE	Total Hours	Hourly Rate	Total One-Time Cost for all AMs and GPOs
Burden to update collection & submission processes for device identifiers for entities that do not already collect them	Support Staff	450	1	20-100	24,840	$44.92	$1,115,813
Subtotal:					**24,840**		**$1,115,813**
Burden to update collection & submission processes for device identifiers for all entities which will report them	Compliance Officer	850	1	2	1,700	$83.70	$142,290.00
	Support Staff	850	1	10-40	19,400	$44.92	$871,448
Subtotal:					**21,100**		**$1,013,740**
Burden to update submission processes for device identifiers for entities which will not report them	Compliance Officer	750	1	2	1,500	$83.70	$125,550
	Support Staff	750	1	2-10	4,137	$44.92	$185,834
Subtotal:					**5,637**		**$311,384**
Total:					**51,577**		**$2,440,937**

Summary of Annual Burden Estimates for Proposed Requirements

Regulation Section(s) Under Title 42 of the CFR	Respondents	Total Responses	Burden per Response (hours)	Total Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
§§ 403.902 and 403.904 ("Nature of Payment" Categories)*	400	400	5 - 30	5,895	44.92	264,804
	1,600	1,600	2 - 5	7,767	Varies	410,941
§§ 403.902 and 403.904 (Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies)**	450	450	20 - 100	24,840	44.92	1,115,813
	850	850	10 – 40	21,100	Varies	1,013,740
	750	750	2 - 10	5,637	Varies	311,384
TOTAL	1,600	4,050	varies	65,239	Varies	3,116,682

*Data Collected and Submission Hours: Burden to Modify Nature of Payment Categories (FY 2020 PFS)

** Data Collection and Submission Hours: Burden for Changes to Standardize Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies (FY 2020 PFS)

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.