

Supporting Statement
for Registration, Attestation, Dispute & Resolution, Assumptions Document and Data
Retention Requirements for Open Payments

A. Background

Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies 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 CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS 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. CMS 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.

CMS published a final rule in 2013 to implement this program, which included several information collections subject to the Paperwork Reduction Act. This PRA package is to inform the public about information collected that is necessary for registration, attestation, dispute resolution and corrections, record retention, and submitting an assumptions document within Open Payments.

1. Registration

42 C.F.R. § 403.908(c) 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 entitled “Open Payments Registration Templates.” 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.”

2. Attestation

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.

3. Dispute Resolution and Corrections

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, including applicable manufacturers and applicable GPOs opting to submit test data, is an aspect of data collection consistent with the data collection processes and therefore covered by the Data

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.

Collection and Submission of Transparency Reports and Reporting of Physician Ownership or Investment Interest (CMS-10419) PRA package previously submitted and approved with OMB control number 0938-1173. Submission of test data is an activity we are making available which is completely voluntary on the part of interested applicable manufacturers and applicable GPOs. This will provide additional flexibility, especially in the early years of our program, for applicable manufacturers and applicable GPOs to experience system feedback and other features otherwise made available at the time of submission. We see that by providing this opportunity, there is no impact to burden estimates already provided herein.

4. Record Retention

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.

5. Assumptions Document

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.

B. 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 Act by adding a new subsection G that requires applicable manufacturers of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable 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 or other transfer of value provided to such physicians.

2. Information Users

As noted in the final rule, public reporting of the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency

will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions.

The information collected will be used by CMS to validate registration for applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors that are registering for Open Payments. Additionally, through the information collected during registration CMS will have the ability to notify physicians and teaching hospitals when applicable manufacturers and applicable GPOs submit data about them and notify applicable manufacturers and applicable GPOs when physicians and teaching hospitals are initiating disputes regarding the data that was submitted. Information collected during the dispute resolution and correction process will allow Open Payments 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. Information collected in an assumptions document submitted by an applicable manufacturer or applicable GPO will 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

Registration, attestation, dispute resolution and correction process, and submission of an assumption document will all 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.

5. Small Businesses

CMS has minimized the burden on small businesses by utilizing the CMS Enterprise Portal and User Identity Management systems to register applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors via a unified, web-based user interface. It will improve and streamline the user experience through an enterprise-level approach to the interface design. This will minimize the burden for small and large businesses for purposes registration because they will not be required to develop specialized IT systems to register for Open Payments. Additionally, CMS has minimized burden on small business by providing the Open Payments system allowing applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors to attest, submit assumptions documents and initiate disputes.

6. Less Frequent Collection

The final rule requires applicable manufacturers and applicable GPOs that are submitting data to register with CMS within 90 days of the end of the calendar year for which a report is required. Registration 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. 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. As specified in the final rule 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

The 60-day Federal Register notice for this information collection request published on July 22, 2013 (78 FR 43887).

On March 24, 2011, CMS hosted an Open Door Forum on this program. A Notice of Proposed Rule Making (NPRM), which proposed to amend 42 CFR, Chapter IV, Part 403 by adding Subpart I – Transparency Reports and Reporting of Physician Ownership or Investment Interests, was published in the Federal Register on December 19, 2011. The NPRM included a description of the proposed information collection requirements. CMS received over 300 comments on the NPRM. The final rule published in the Federal Register on February 8, 2013 incorporates and responds to this feedback. In addition, CMS conducted market research with numerous technology companies to help advise and inform CMS as to the operational approach.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

We pledge privacy to the extent allowed by law. CMS intends to seek a System of Records for the data systems involved in the program. The vast majority of the required data is required to be reported publicly. Information not required to be reported publicly will be 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

shall 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

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)

In year one, 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. §§ 403.908(c), 403.908(e), 403.908(g), 403.908(h), and 403.908(f) is \$232.50 per applicable manufacturer, \$232.50 per applicable GPO, \$ 3,531 per teaching hospital, and \$287 per physician. After year 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. §§ 403.908(c), 403.908(e), 403.908(g), 403.908(h), and 403.908(f) is \$193.50 per applicable manufacturer, \$193.50 per applicable GPO, \$ 3,526 per teaching hospital, and \$206 per physician. The table that follows and the supporting assumptions explain the methodology for these estimates.

The below charts summarizes applicable manufacturer and applicable group purchasing organizations burdens associated with registration, attestation, and submitting an assumptions document.

Applicable manufacturers									Year 1		Year 2	
Process	Labor	# of AMs	F T E	Hours /FTE	Total hours	Hourly rate	Total per AM	Total for all AMs	Average cost per AM	Total cost for all AMs	Average cost per AM	Total cost for all AMs
Registration	Support Staff	1150	2	1.5	3	\$26	\$78	\$89,700	\$78	\$89,700	\$39	\$44,850
Record Retention	Support Staff	1150	1	0.25	0.25	\$26	\$6.50	\$7,475	\$6.50	\$7,476	\$6.50	\$7,476
Attestation	Compliance Officer	1150	1	1	1	\$48	\$48	\$55,200	\$74	\$85,100	\$74	\$85,100
	Support Staff		1	1	1	\$26	\$26	\$29,900				
Assumptions document	Compliance Officer	1150	1	1	1	\$48	\$48	\$48	\$74	\$85,100	\$74	\$85,100
	Support Staff		1	1	1	\$26	\$26	\$26				
Total			6		7				\$232.50	\$267,376	\$193.50	\$222,526

Applicable GPOs									Year 1		Year 2	
Process	Labor	# of GPOs	F T E	Hours /FTE	Total hours	Hourly rate	Total per GPO	Total for all GPOs	Average cost per GPO	Total cost for all GPOs	Average cost per GPO	Total cost for all GPOs
Registration	Support Staff	420	2	1.5	3	\$26	\$78	\$32,760	\$78	\$32,760	\$39	\$16,380
Record Retention	Support Staff	420	1	0.25	0.25	\$26	\$6.50	\$2,808	\$6.50	\$2,808	\$6.50	\$2,808
Attestation	Compliance Officer	420	1	1	1	\$48	\$74	\$20,160	\$74	\$31,080	\$74	\$31,080
	Support Staff		1	1	1	\$26	\$10,920					
Assumptions Document	Compliance Officer	420	1	1	1	\$48	\$74	\$48	\$74	\$31,080	\$74	\$31,080
	Support Staff		1	1	1	\$26	\$26					
Total			6		7				\$232.50	\$97,728	\$193.50	\$81,348

The below charts summarizes physician and teaching hospital burdens associated with registration and dispute resolution and correction.

Physicians (includes physician owners and investors)									Year 1		Year 2	
Process	Labor	# of physicians	F T E	Hours /FTE	Total hours	Hourly rate	Total per physician	Total for all physicians	Average cost per physician	Total cost for all physicians	Average cost per physician	Total cost for all physicians
Registration	Physician	224,425	1	0.25	0.25	\$137	\$40	\$8,977,000	\$40	\$8,977,000	\$20	\$4,488,500
	Physician support staff		1	0.25	0.25	\$22						
Dispute resolution and Correction	Physician	224,425	1	1	1	\$137	\$137	\$30,746,225	\$247	\$55,432,975	\$185	\$31,139,015
	Physician support staff		1	5	5	\$22	\$110					
Total			4		6.5				\$287	\$64,409,975	\$206	\$31,627,515

Teaching Hospitals									Year 1		Year 2	
Process	Labor	# of THs	F T E	Hours /FTE	Total hours	Hourly rate	Total per TH	Total for all THs	Average cost per TH	Total cost for all THs	Average cost per TH	Total cost for all THs
Registration	Support Staff	1,162	2	0.25	0.5	\$22	\$11	\$12,782	\$11	\$12,782	\$6	\$6,972
Dispute resolution and Correction	Compliance officer	1,162	1	40	40	\$44	\$1,760	\$2,045,120	\$3,520	\$4,090,240	\$3,520	\$4,090,240
	Support staff		1	80	80	\$22	\$1,760	\$2,045,120				
Total			4		120.5				\$3,531	\$4,103,022	\$3,526	\$4,091,212

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 48 dollars and the hourly rate for support staff is 26 dollars. According to the Bureau of Labor Statistics Occupational Employment Statistics, in May 2011 the average hourly rates for a compliance officer and book keeping, accounting, and auditing staff in the pharmaceutical and medicine manufacturing field was 35.75 and 19.84 dollars, respectively. We applied a 33 percent increase to this amount to account for change over time and fringe benefits, making the total hourly compensation 48 dollars and 26 dollars, respectively.
- For physicians and teaching hospital support staff wage rates, we used the following estimates: hourly rate for support staff at 22 dollars for physicians support staff, 44 dollars for teaching hospital support staff, and 137 for physicians. According to the Bureau of Labor Statistics Occupational Employment Statistics the average hourly rate for support staff for a physician is 16.35 dollars, 16.22 dollars for a teaching hospital, and 103.32 dollars for a physician. We applied a 33 percent increase to this amount to account for change overtime and fringe benefits, making the total hourly compensation 22 dollars, 44 dollars, and 137 dollars, respectively.
- We estimate 1,150 applicable manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers) will register in order to submit data. We based these estimates on the number of manufacturers reporting in states with similar transparency provisions, as well as, the number of manufacturers registered with FDA. The number of drug manufacturers is based on reporting in Massachusetts, Minnesota, and Vermont, whereas the number of device manufacturers is based on reporting in Massachusetts and Vermont, since Minnesota does not require device manufacturers to report. Because the state laws have higher payment thresholds and are specific to the physicians in the state, we estimated that the number of manufacturers reporting would be greater under section 1128G of the Act, so we increased the state reporting numbers by 50 percent. For device manufacturers, we also used data from the FDA to identify the total number of manufacturers to use as a ceiling for our estimate; combining the two data sources we increased the state reporting numbers by 75 percent.
- We estimate 420 GPOs will register in order to submit data. The definition of GPO includes some physician owned distributorships (PODs). However, we did rely on a recent report by the Senate Finance Committee which identified 20 states with multiple PODs and more than 40 PODs in California. When we extrapolate these estimates to the national level, taking into account the disproportionately higher number in California, we estimate that there are approximately 260 PODs currently in the U.S. We further estimate that there are an additional 160 GPOs, which have some form of physician ownership or investment. This is based on a review of what little literature exists and discussions with knowledgeable persons. Our research found that there are approximately 800 GPOs and that approximately 20 percent of GPOs have at least one physician owner or investor.
- We estimate about 224,425 physicians will 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. According to the Bureau of Labor Statistics Occupations Outlook Handbook, we estimate that there may be as many as 897,700 physicians. However, we believe that not all physicians will have relationships with applicable manufacturers or applicable GPOs. Based on feedback we received from stakeholders during rulemaking we estimate that less than 50 percent of the physicians have transaction with industry, which reduces our universe of affected physicians to approximately 448,850. Additionally, we assumed based on stakeholder feedback many physicians maintain relationships with applicable manufacturers that are relatively insignificant from a financial point of view. Therefore, we estimate only 50 percent of the remaining 448,850 physicians will review Open Payments report reducing the number of physicians registering to approximately 224,425.

- There are approximately 1,162 teaching hospitals expected to register for Open Payments in year 1. 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.
- As this is a new program, we provide estimates that reflect increased burden for registration in the initial year. Year two estimates are 50 percent lower than year one due to registration is completed once in year one and then validated in following years.

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 Resolution and Correction 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 resolution and data correction requires two support staff (20 days for eight hours, which is 160 hours each) and the compliance officer (five days for eight hours, which is 40 hours).
- We estimate a teaching hospital compliance officer will need hours 40 hours to review data. In addition, we estimate a teaching hospital will utilize 80 hours of administrative supporting staff at teaching hospitals to maintain the records. The role of the compliance officer will be review and oversight, while the administrative supporting staff will conduct the recordkeeping. In the final rule, we estimated the supporting staffs such as bookkeeping, accounting, and auditing would perform the tasks while the compliance officer would oversee the review process.
- We estimate that only 50 percent of the approximately 448,850 physicians will review reported information. This reduces the number of physicians we estimate to be involved in the dispute resolution and correction process to 224,425. This information is based from stakeholders expressing that many physicians maintain relationships with applicable manufacturers and applicable GPOs that are relatively insignificant from a financial point of view, so we estimate that many physician will not devote any time in reviewing the aggregated reports from CMS.
- We estimate for year 2 that there would be a further reduction in the number of physicians choosing to review the data because they would be familiar with the type of information on the database, so we reduced the number of physicians reviewing by another 25 percent, to 168,319. We also reduced the amount of time it would take the physicians choosing to review the information, since we believe they will be familiar with the review, correction and dispute process. We estimate in year 2 a physician will spend approximately 0.75 hours reviewing data and physician support staff will spend approximately 3.75 hours reviewing data.
- We estimate that the vast majority of teaching hospitals would have at least one financial relationship with an applicable manufacturer, so we did not apply any adjustments to the number of teaching hospitals. We also estimate that there will not be a reduction in the number of teaching hospitals that review the information after the first year because teaching hospitals probably have more complex financial relationships.

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.

Assumptions Document Estimations 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 or applicable GPOs to submit this information. For the purposes of analysis, we estimate that 100 percent of applicable manufacturers and applicable GPOs will submit this in year one and 100 percent of applicable manufacturers and applicable GPOs will submit this in subsequent years. We assume that all entities will submit an assumptions document, which will take one hour to prepare (compliance officer) and one hour to submit (support staff). We expect preparation of this document to essentially occur in conjunction with data collection.

13. Capital Costs

CMS is responsible for all costs to create a CMS Enterprise Portal and User Identity Management systems to register applicable manufacturers, applicable GPOs, covered recipients and physician owners and investor via a unified, web-based user interface. Applicable manufacturers, applicable GPOs, physicians, and teaching hospitals will not incur any costs to create a system for registration. Additionally, CMS is responsible for all costs to create an Open Payments system that will provide a platform for attestation, initiating dispute, submitting corrected data, and submitting an assumptions document.

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

None, this is a new information collection.

16. Publication/Tabulation Dates

Information collected during registration that is necessary to identify the entity that is submitting data or identify the covered recipients and physician owners or investors that have data reported about them will be reported publicly by September 2014, and June 30 each year thereafter. Data that is disputed and not resolved will be marked as disputed and available for public viewing.

17. Expiration Date

CMS does not seek an exemption from the requirement to display the expiration date for this

collection.

18. Certification Statement

There are no exceptions to the certification statement.