

Supporting Statement
Data Collection and Submission of Transparency Reports and Reporting of Physician Ownership or Investment Interests

A. Background

Section 6002 of the Affordable Care Act added section 1128G to the Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid 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.

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.

CMS issued a final rule in 2013 to implement this program, which included several information collections subject to the Paperwork Reduction Act. This PRA package includes some of the collections for applicable Manufacturers and applicable GPOs (i.e., data collection and submission of information about payments or transfers of value (§ 403.904) and physician ownership and investment interests (§ 403.906).¹

¹ The final rule includes other information collections associated with (1) the registration system for applicable manufacturers and applicable GPOs (§ 403.908) and physicians and teaching hospitals (§403.908(g)(2)(b)(ii)(B)); (2) 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)); (3) 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)); (4) 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. We intend to address these collections in a future PRA package. Consistent with 5 CFR Part 1320, these provisions will not be effective until OMB approves them. If covered by the PRA, CMS will seek approval for information collections that are related to the audit/penalty/appeals process.

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 must 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. The data templates are provided in the supplemental document entitled “NPPTP Data Templates.”

Section 403.908 requires that reports must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

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 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.

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, and deter inappropriate financial relationships.

The information collected will be reported to CMS, and after a process of reviewing the data, it will be made available to the public. CMS has not yet developed the public website that will be used to display the data. However, the website will present 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 that this will enable to public to realize the benefits noted above.

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. Data is submitted in the formats defined in the *CMS NPPTP Data Templates*, which may be changed annually. 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 (AMs) and applicable GPOs. Research related transfers of value, non-research 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.

In addition, the information from the collection will be used by CMS, as required by statute, and reported publicly on a website. Data on the public site is static as of a given date. Data on the public site is refreshed at least once annually beyond the initial publication of data.

4. Duplication of Efforts

Preemption of State Laws. 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. CMS has reviewed and modeled data collection after similar information is collected by States with similar reporting programs. However, this provision preempts all State laws requiring reporting of this information, so 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 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. For example, CMS intends to utilize the CMS Enterprise Portal and User Identity Management systems to register applicable manufacturers, applicable GPOs, as well as physicians and teaching hospitals via a unified, web-based user interface. 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 for purposes of data submission to CMS, 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 statute requires that the data be collected and submitted to CMS annually.

7. Special Circumstances

None.

8. Federal Register/Outside Consultation

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 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.

The 60-day Federal Register notice published on February 8, 2013. CMS includes an appendix in which is summarizes and responds to a number of the comments raised during that comment period.

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, as noted in the data templates. 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

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.

12. Burden Estimates (Hours & Wages)

Under § 403.904, applicable manufacturers must annually report information on payments

or other transfers of value provided to covered recipients. 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 under this provision is \$71,152 per respondent on average. After year one, we estimate that the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information under this provision is \$53,364 per year, per respondent. The table that follows and the supporting assumptions explain the methodology for these estimates.

Estimated Annual Information Collection Burden*

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)****	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Adjusted ** Total Annual Cost (\$)
§§403.904 and 404.908(a)-(g) - Applicable Manufacturer Data Collection and Reporting	0938-New	1,150	1,150	1040	1,196,000	47.55	56,869,800	4,600,000***	20,285,034
				780	897,000	47.55	42,652,350	0	28,150,551
				4,160	4,784,000	26.39	126,249,760	0	41,662,421
				3,120	3,580,000	26.39	94,476,200	0	62,354,292
§§403.906 and 404.908(a)-(g) - Applicable GPO Data Collection and Reporting	0938-New	420	420	208	87,360	47.55	4,153,968	0	1,370,809
				156	65,520	47.55	3,115,476	0	2,056,214
				520	218,400	26.39	5,763,576	0	1,901,980
				390	163,800	26.39	4,322,682	0	2,852,970
Section 1128G of the Act								160,634,271	

*The Estimated Annual Information Collection Burden included in this table is for data collection and reporting of transparency reports and Reporting of physician ownership or investment interests.

**Total costs have been adjusted to account for the year 1 and 2 burden estimates and to align with OMB's 3-year approval period. Specifically, year 1 costs have been multiplied by 0.33 and year 2 costs have been doubled (years 2 and 3) and multiplied by 0.33.

***We estimate that in year 1 the infrastructure costs for applicable manufacturers will be \$10,000. This represents an average of \$4,000 for small companies (estimated to be 1000 companies) and \$50,000 for large companies (estimated to be 150 companies). We assume that the majority of these costs will be infrastructure costs, such as purchasing equipment and initial training, but assume that some costs will be required to maintain the systems. Therefore, we estimate that in year 2 and annually thereafter, applicable manufacturers will spend about \$1,000 annually to maintain their systems. For OMB's 3-year approval period the annual cost per respondent is \$4,000 (10,000 + 1,000 + 1,000/3). The annual cost for all respondents is \$4,600,000 (\$4,000 x 1,150).

****These numbers reflect year 1 and year 2 (and beyond) estimated hours for labor costs for applicable manufacturers and applicable GPOs for compliance officers and supporting staff. Specifically, for applicable manufactures: 1040 hours for compliance officer in year 1, 1780 hours for compliance officer in year 2, 4,160 hours for supporting staff in year 1, 3,120 hours for supporting staff in year 2 and for applicable GPOs: 208 hours for compliance officer in year 1, 156 hours for compliance officer in year 2, 520 hours for supporting staff in year 1, 390 hours for supporting staff in year 2

Estimated Applicable Manufacturer Burden by Process

Applicable Manufacturers									YEAR 1		YEAR 2	
Process Category	Labor Category	# of Applicable Manufacturers	FTE	Hours/FTE	TOTAL HOURS	Hourly Rate	Total per AM	Total for all AMs	Average Cost Per AM	Total Cost for All AMs	Year 2 Average Cost Per AM	Year 2 Total Cost for ALL AM
Data Collection (External to CMS)	Compliance Officer	1150	1	989	989	\$48	\$47,472	\$54,592,800	\$145,128	\$166,897,200	\$108,846	\$125,172,900
	Support Staff		2	1878	3756	\$26	\$97,656	\$112,304,400				
Data Reporting	Compliance Officer	1150	1	10	10	\$48	\$480	\$552,000	\$2,560	\$2,944,000	\$1,920	\$2,208,000
	Support Staff		2	40	80	\$26	\$2,080	\$2,392,000				
TOTAL:					4835		\$147,688		\$147,688	\$169,841,200	\$110,766	\$127,380,900

Estimated Applicable GPO Burden by Process

Applicable GPOs									YEAR 1		YEAR 2	
Process Category	Labor Category	# of Applicable GPO	FTE	Hours/FTE	TOTAL HOURS	Hourly Rate	Total per GPO	Total for all GPOs	Average Cost Per GPO	Total Cost for All GPOs	Year 2 Average Cost Per GPO	Year 2 Total Cost for ALL GPOs
Data Collection (External to CMS)	Compliance Officer	420	1	197.8	197.8	\$48	\$9,494	\$3,987,648	\$29,026	\$12,190,752	\$21,769	\$9,143,064
	Support Staff		2	375.6	751.2	\$26	\$19,531	\$8,203,104				

	Compliance Officer	420	1	10	10	\$48	\$480	\$201,600				
Data Submission	Support Staff		2	40	80	\$26	\$2,080	\$873,600	\$2,560	\$1,075,200	\$1,920	\$806,400
	TOTAL:				1039		\$31,585		\$31,586	\$13,265,952	\$23,689	\$9,949,464

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 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.
- As this is a new program, we provide estimates that reflect increased burden in the initial year. Years 2 estimates and beyond are 25% lower than year 1 due to expected higher potential costs for start-up in year 1. Cost efficiencies are assumed to reduce the out-year costs. When reporting the burden of this provision, we considered the impact in the first year of the program when applicable manufacturers and applicable GPOs must learn the reporting requirements and train their personnel, as well as build data collection and reporting systems, as well as year 2 and annually thereafter. We will revisit the accuracy of these estimates in future years.
- 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 1 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 estimate for applicable GPOs there is an 80% 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 an data to be reported under the Research data template.
- For wage rates, we used the following estimates: hourly rate for the compliance officer is \$48 and the hourly rate for support staff is \$26. According to the Bureau of Labor Statistics Occupational Employment Statistics, in May 2011 the average hourly rates for a compliance officer and booking keeping, accounting and auditing staff in the pharmaceutical and medicine manufacturing field was \$35.75 and \$19.84, 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 and \$26, respectively.

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 's and regular Applicable Manufacturers.
- The first data collection period for this regulation will be a shortened reporting cycle. However, PRA estimates assume a full year of data collection.
- Data collection and management of data collected will require 2 support staff (750 hours each) and 1 compliance officer (400 hours). 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 1 to 10 FTE employees to comply with the reporting

- requirements (we assume 2 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.

Data Submission Estimation Assumptions

- We estimate 1,150 applicable manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers) will 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 Group Purchasing Organizations (GPOs) will 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.
- 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 this in year one and 100% of applicable manufacturers will submit this in subsequent years. 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 2 support staff (40 hours each) and 1 compliance officer (10 hours). 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 1 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.

13. Capital Costs

Applicable manufacturers and applicable GPOs with a large number of reportable transfers of value will likely develop IT systems to collect and track these transfers of value. We note our estimates for those costs above.

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

The data must be tabulated for review and correction for at least 45 days prior to publication publicly, and then must be reported publicly by September 30, 2014 and June 30 each year thereafter.

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.