

Supporting Statement Part A
Data Collection and Submission of Transparency Reports and Reporting of
Physician Ownership or Investment Interests
CMS-10419, OCN 0938-1173

Terms of Clearance

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) 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.

CMS addressed these collections in the PRA package titled “Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments” under OMB control number 0938-1237 (CMS-10495).

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.

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 is revision to Transparency Reports and Reporting of Physician Ownership and Investment Interests, OMB control number: 0938-1173, which 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).

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.

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.

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 Open Payments Submissions Data Mapping document 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 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.

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

Serving as the 60-day Federal Register notice, this package's proposed rule published on July 11, 2014 (79 FR 40317, RIN 0938-AS12, CMS-1612-P). No comments were received.

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.

For year one, we estimated the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide this information under this provision is \$147,766 per applicable manufacturer and \$31,658 per applicable GPO.

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 \$110,325 per year, per applicable manufacturer and \$23,743 per applicable GPO.

The following tables and the supporting assumptions explain the methodology for these estimates.

Estimated Applicable Manufacturer Burden by Process

	2013 (year 1)	2014-2015 (year 2)*	2016**			
	Total Hours (annual)	Total Hours (annual)	Respondents	Number of Responses (per year)	Time (per response)	Total Hours (annual)
Collection	4,874,500	3,655,875	1,150	1	3,179	3,655,850
Reporting	103,500	77,625			68	78,200
TOTAL	4,978,000 (Approved)	3,733,500	1,150	1	3,247	3,734,050

Annualized burden: $(3,733,500 + 3,733,500 + 3,734,050)/3 = 3,733,683$ hr

Estimated Applicable Group Purchasing Organization Burden by Process

	2013 (year 1)	2014-2015 (year 2)*	2016**			
	Total Hours (annual)	Total Hours (annual)	Respondents	Number of Responses (per year)	Time (per response)	Total Hours (annual)
Collection	217,140	162,855	420	1	388.75	163,275
Reporting	37,800	28,350			68	28,560

TOTAL	254,800 (Approved)	191,205	420	1	456.75	191,835
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Annualized burden: $(191,205 + 191,205 + 191,835)/3 = 191,415$ hr

*Year 2 burden hours reflect a 25% decrease as discussed in the General Estimation Assumptions section

**2016 reflects a burden increase for data collection 2016

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.

Estimates provided 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 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 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 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 \$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 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.

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 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.

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

Templates

The current approved package contains three, (1) general (non-research), (2) research, and (3) ownership and investment interest templates, which outlined the data collected by manufacturers and submitted to the Open Payments' system. Please note that this 2014 iteration contains one document which includes all the data elements collected by manufacturers and submitted to the Open Payments' system. The document is still separated by each category, general, research, and ownership and investment interests, however, the public will be able to see all the data elements submitted to the Open Payments' system.

Changes Associated with Final Rule (November 13, 2014; 79 FR 67547, RIN 0938-AS12, CMS-1612-FC)

Applicable manufacturers and applicable GPOs must report the marketed name and therapeutic area or product category of covered drugs, devices, biologicals and medical supplies. The amendment has a non-measurable effect on current burden estimates since the manufacturers and GPOs are already required to report the marketed name for drugs and biologicals and report the marketed name, therapeutic area or product category for devices and medical supplies. Removing 42 CFR 403.904(g) will require applicable manufacturers and applicable GPOs to report all payments or other transfers of value provided as compensation for speaking at a continuing education program. We estimate that it will take 1.0 hour to report payments or other transfers of value to CMS which were provided to physician at a continuing education program. Additionally, applicable manufacturers and applicable GPOs are required to report the form of payment or other transfer of value as: cash or cash equivalent, in-kind items or services, stock, stock option, or any other ownership investment. We estimate it will take 0.5 hours to revise an applicable manufacturer or applicable GPO's reporting system to report the form of payment.

According to changes associated with November 13, 2014, final rule this package is requesting 1,725 additional burden hours for applicable manufactures and 630 additional burden hours for applicable GPOs to complete data collection in 2015 for data reporting in 2017. .

Amending 42 CFR § 403.904(d)(3) increased the data reporting burden by 0.5 hour support staff for both applicable manufacturers and applicable GPOs. Removing § 403.904(g) increased the data collection burden by 1.0 hour support staff for both applicable manufactures and applicable GPOs. There are estimated 1,150 applicable manufacturers and 420 applicable GPOs, therefore increasing the total burden for both applicable manufacturers and applicable GPOs by 2,355 hours [(1,150 x 1.5) + (420 x 1.5)].

Additional Changes

Consistent with the July 26, 2013, Terms of Clearance this package is removing requirements/burden (5,226,920 hr) that are now approved under OMB control number 0938-1237 (CMS-10495).

The requirements/burden approved under OMB control number 0938-1173 account for 4,978,000 requirements/burden hours for all applicable manufacturers and 254,800 requirements/burden hours for all applicable GPOs.

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.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.