Supporting Statement – Part A
Data Template for Transparency Reports and Reporting of Physician Ownership or Investment Interests (ACA Section 6002)

A. Background

Section 6002 of the Affordable Care Act requires applicable manufacturers of covered drugs, devices, biologicals and medical supplies to report annually to the Secretary all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). Section 6002 of the ACA also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities. The first reports are due on March 13, 2013 for payments and other transfers of value made, and ownership and investment interests held in CY 2012. We are proposing at section CFR 403.904 to require applicable manufacturers to report information on all payments or other transfers of value provided to covered recipients, and a document outlining the assumptions made when describing payments. We are also proposing in CFR 403.906 to require applicable manufacturers to report information regarding ownership and investment interests held by physicians or their family members, as well as any payments provided to such physicians.

B. Justification

1 . Need and Legal Basis

The Patient Protection and Affordable Care Act (ACA) was enacted on March 23, 2010 (Pub. L. 111-148). ACA amends section 1128 of the Social Security Act by adding a new subsection G to requires applicable manufacturers of drugs, devices, biologicals, 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. This data template and assumptions document is required to allow applicable manufacturers and applicable GPOs to report the information required to CMS.

2. Information Users

The information from the collection will be by CMS, as required by statute, and reported publicly on a website.

3. Use of Information Technology

The statute requires that the data be submitted electronically. We anticipate that all applications will be submitted by this means.

4. Duplication of Efforts

Similar information is collected by a few States. 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

No special considerations are given to small businesses. The same information is needed to assess the qualifications of all organizations.

6. Less Frequent Collection

The statute requires that the data be collected and submitted to CMS annually. New information will be reported during each reporting year.

7. Special Circumstances

No special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published as part of the notice of proposed rulemaking that published on December 19, 2011 (76 FR 78742).

Public input on how CMS might implement the requirements of ACA section 6002 was sought in an Open Door Forum listening session on March 24, 2011. Using this input, a Notice of Proposed Rule Making (NPRM) was drafted and will be published in the Federal Register, which proposes to amend 42 CFR, Chapter IV, Part 403 by adding Subpart I – Transparency Reports and Reporting of Physician Ownership or Investment Interests. The NPRM includes a description of the proposed information collection requirements.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

We pledge privacy to the extent allowed by law; however the vast majority of the required data is required to be reported publicly. Any proprietary data or information included in the assumption document will not be disclosed outside the Government and will not be

duplicated, used, or disclosed – in whole or in part – for any purpose other than to assess the assumptions made by applicable manufacturers and applicable GPOs. Files containing the assumptions document and other 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

No sensitive questions are part of this information collection.

12. Burden Estimates (Hours & Wages)

The burden associated with these requirements is the time and effort spent by applicable manufacturers and applicable GPOs collecting the data, and compiling reports to send to CMS. We estimate that approximately 1,150 applicable manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers), and approximately 420 applicable GPOs will submit reports.

We estimate that on average, smaller applicable manufacturers will have to dedicate 50 percent of a full time equivalent (FTE) employee (mainly in the range of zero to one), whereas larger applicable manufacturers may have to dedicate 5 to 15 FTE employees to comply with the reporting requirements (we assume 10 on average). Since there are many more small companies, we estimate that on average, 1.74 FTE employees would be needed for each applicable manufacturer in the first year (150 larger firms times 10 FTE and 1000 smaller firms times 0.5 FTE).

We anticipate it will be less burdensome for an applicable GPO to comply with these proposed reporting requirements. Applicable GPOs would have to report fewer relationships with physician owners or investors (or immediate family members), making it much easier to match ownership and investment interests to the appropriate physicians (or family members). Based on discussions with officials of some GPOs and industry observers, we estimate that it would take from 5 to 25 percent of a FTE staff member, depending on the size of the applicable GPO.

Organization	**Number of Respondents:**	**Effort Per Organization (Year 1)**	**Effort Per Organization (Year 2)**	**Total Hours (annually for three years)**
Applicable Manufacturers	1,150	1.74 FTE (70 hrs x 52 wks)	1.3 FTE (52 hrs x 52 wks)	3,460,427

Applicable GPOs	420	0.10 FTE (4 hrs x 52 wks)	0.075 FTE (3 hrs x 52 wks)	72,800

While many individuals may contribute to the data collection and reporting, we believe that majority of the work will be performed by a compliance officer. We used the annual rates for 2010 and added 33 percent for overhead and fringe benefit costs. These rates are as follows:

Labor Category	**Annual Salary**	**Annual Salary with 33% Overhead/ Fringe**
Compliance Officer (pharmaceutical and medicine manufacturing field, 2010)	$73,380	$97,595.40

For each applicable manufacturer we estimate a burden of 3,009 hours at a cost of $141,180 annually for the first three years. For applicable GPOs, estimate a burden of 173 hours as a cost of $8,100 annually for the first three years. In total, this equals $165,781,000 annually.

	Estimated Reporting Organizations	**Hours Per Reporting Organization**	**Total Cost Per Organization**	**Total Burden**
Applicable Manufacturers	1,150	3009	$141,180	$162,365,548
Applicable GPOs	410	173	$8,100	$3,415,825
Total	1570	2250	$105,600	$165,781,000

13. Capital Costs

There are no capital costs associated with preparing the application to be a qualified entity.

14. Cost to Federal Government

It is estimated that CMS costs for managing the information collection will include one full time equivalent at the GS-15 step 1 level as a manager with an annual fully loaded salary of 198,000, two full time equivalents at the GS-13 step 1 level with an annually fully loaded salary of 142,000 and $3,000,000 in contractor support, for a total of $3,482,000.

15. Changes to Burden

None, this is a new information collection.

16. Publication/Tabulation Dates

The data must be tabulated for review and correct for at least 45 days prior to publication publicly, and then must be reported publicly by September 30, 2013 and June 30 each year thereafter.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exceptions to the certification statement.