Supporting Statement – Part A
Medicare Parts C and D Universal Audit Guide

A. Background

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 C.F.R. Parts 422 and 423 Medicare Part D plan sponsors and Medicare Advantage organizations (MAOs) are required to comply with all Medicare Parts C and D program requirements. The explosive growth of these sponsoring organizations has forced CMS to update its current auditing strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy will reflect a move away from routine audits to more targeted, data-driven and risk-based audits. We will produce a performance profile of MAOs and Part D sponsors based upon reported data and comparative data across all MAOs and Part D sponsors and will target organizations that demonstrate poor performance.1 We will also focus on high-risk areas that have the greatest potential for beneficiary harm. In addition to this risk-based approach, there will be some degree of random selection. The goal of the audits will be earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors and MAOs.

To accomplish these goals, we have combined all Part C and Part D audit elements into one universal guide which will also promote consistency, effectiveness and reduce financial and time burdens for both CMS and Medicare-contracting entities. The Medicare Part C & D Universal Audit Guide listed in this instrument will be posted on HPMS. Plans have access to HMPS and can (and in fact do) download the Guide at their convenience. Therefore, because the Guide is available to plans on an ongoing basis we do not actually send this Guide with the audit request.

The Part C instrument originally received OMB approval October 16, 2006. The Part D audit instrument received OMB approval on November 1, 2008.

B. Justification

1 . Need and Legal Basis

Section 1857(d) of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 C.F.R §422.502(d) states that CMS must oversee a Medicare Advantage (MA) organization's continued compliance with the requirements for a MA organization.

Section 1860D-12 of the Act, added by MMA and implementing regulations at 42 C.F.R. §423.503(d) states that CMS must oversee a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

1 Reported data and comparative data include, but are not limited to, information collected via CMS reporting requirements (OMB control number 0938-0992) and CMS application requirements (OMB control number 0938-0935 and 0938-0936).

2. Information Users

Data will be used by CMS Regional Office staff, CMS' Center for Drug and Health Plan Choice (CPC), and CMS' Program Compliance and Oversight Group (PCOG). If outliers or other data anomalies are detected, Regional Offices will work in collaboration with PCOG and other divisions within CMS for follow-up and resolution. CMS has also contracted with an outside vendor (Booze Allen Hamilton) to assist in the administration of auditing sponsoring organizations.

3. Use of Information Technology

Sponsoring organizations are able to produce approximately 70% of requested information from their internal systems. The remaining 30% is produced by CMS via our internal systems. Of the 70% produced by the sponsoring organization, approximately 90% of plan produced information is provided electronically by burning it to a CD or DVD. The remaining 10% is either mailed in hardcopy to CMS in advance of the audit or provided while CMS is onsite at the sponsoring organizations location during the audit. CMS is able to obtain the remaining 30% via our internal systems and there is no level of effort required on the part of the sponsoring organizations.

The Health Plan Management System (HPMS) is the current conduit by which organizations submit many sources of audit materials such as bids and other ongoing updates to CMS. CMS and its subcontractors, in turn, communicate to sponsoring organizations regarding this information. HPMS therefore is already a familiar tool to organizations to navigate through the auditing requirements. Additionally, as access to HPMS must be granted to each user, and is protected by individual login and password, electronic signatures are unnecessary.

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

This collection does not impose a significant impact on small businesses and other entities.

6. Less Frequent Collection

42 C.F.R. 423 Subpart K and 422 Subpart J of the final rule stipulate CMS must oversee a sponsoring organization's continued compliance with CMS requirements. Less frequent collection of the data from sponsoring organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, compliance and auditing activities around the Part C and D Medicare benefits and could result in an increased potential for harm to Medicare beneficiaries.

7. Special Circumstances

42 CFR §§460.190 – 460.192 require CMS to perform an audit of PACE organizations annually for the first three contract years and biannually thereafter.

42 C.F.R. §422.504(d) and §423.505(d) stipulates records are to be maintained for 10 years.

CMS could potentially require clarification around submitted data, and therefore CMS may need to contact Medicare Part D plan sponsors and Medicare Advantage organizations within 30 days of data submission.

8. Federal Register/Outside Consultation

The original Part C audit guide was reviewed by the industry, including trade groups, Medicare Advantage plans, and independent consultants, and was approved by OMB in October 2006. In the development of the Part D Audit guide, we worked closely with subject matter experts covering each of the functional areas forming the basis for the 14 chapters of the guide. An independent consultant was contracted to assist in capturing all new MMA and CMS policy requirements when revising the Part D Audit Guide.

The proposed audit tool for 2010 combines these previously reviewed audit elements for Parts C and D.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents associated with this information collection request.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies. CMS will keep information private to the extent permitted by law.

11. Sensitive Questions

CMS will adhere to all statutes, regulations, and agency policies. No sensitive questions regarding sexual behavior and attitudes, religious beliefs, and other similar matters commonly considered private.

12. Burden Estimates (Hours & Wages)

Anticipated staff needed for collecting data and their estimated hourly rate follow:

- program director $ 66
- compliance officer 82

• lead analyst	50
• quality assurance specialist	33
• information technology specialist	39
• 2 clerical/administrative assistants	25 ea.
• Lead claims analyst	37
Total	$ 357

Taking the average of the above rates, we estimate an average hourly rate of $44.62.

Broadbased Audits

Based on our audit strategy, for each sponsoring organization we estimate an average of 80 hours for administrative and systemic work to assemble the requested information, 39.5 hours to review the information for completeness and 30 minutes to submit the information to CMS. This is a total of approximately 120 hours for each sponsoring organization. The average number of parent organizations that will receive a broad based audit annually is 75. This number includes Medicare Part C and D sponsoring organizations, plus all PACE organizations.

Focused Audits

Based on our audit strategy, for each sponsoring organization we estimate an average of 40 hours for administrative and systemic work to assemble the requested information, 19.5 hours to review the information for completeness and 30 minutes to submit the information to CMS. This is a total of approximately 60 hours for each sponsoring organization but this estimate may be less based on the elements selected for audit. The average number of parent organizations subject to a focused audit annually is 120. Although some parent organizations may be subject to multiple focused audits. So for purposes of the burden estimate, we estimate that approximately 250 focused audits will be performed on 120 parent organizations.

Calculation of Total Audit Hours & Approximate Cost

Some of the parent organizations mentioned above may receive both a broad-based and a focused audit, however, we have simply added the 75 parent organizations mentioned under the broad-based and the 120 parent organizations mentioned under the focused audits to come up with a total of 195 parent organizations subject to audit annually. The average number of hours per parent organization is roughly 124. Please note the below estimates include all aspects of the audit process including time to gather information, travel costs, meetings, presentations, interviews, and entrance/exit conferences.

Total audit hours (195 x 124)	=	24,180
Average hourly wage	=	$44.62 per hour
Total Cost of Collection Effort	=	$1,078,912

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

The cost to the Federal Government associated with this collection is outlined below:

1 CMS GS-14 employees average hourly wage = $36 for 40 hours: $1,440
4 CMS GS-13 employees average hourly wage = $43 for 120 hours: $20,640
2 CMS GS-12 employees average hourly wage = $51 for 120 hours: $12,240

Total CMS employee wages $34,320 plus administrative costs (paper, shipping, postage, copying, and office supplies) of approximately $50 equals a total cost to the Federal Government of approximately $34,370.

15. Changes to Burden

The change in burden is due to the following:

1) Our audit approach in 2010 will target sponsoring organizations at their parent organization level. While parent organizations often consist of multiple contracts, we believe that by targeting these entities at their parent organization level, as opposed to an individual contract level, audits will be more efficient as many of these contracts share the same platforms. This strategy is a less burdensome approach for both the sponsoring organization and CMS.

2) Our audit approach allows sponsoring organizations to submit requested information electronically, eliminating the burden of printing, copying and mailing paper documentation.

3) The combining of all Part C and D guides into one universal audit instrument allows for a more streamlined and efficient audit approach.

We estimate the above changes to our audit strategy will reduce the amount of burden to the sponsoring organization by 50% when compared to prior burden estimates under past collection packages which listed Part C & Part D separately. We believe this decrease can be attributed to:

- combining the Part C and D guides into one universal audit instrument (10% decrease);
- moving away from routine audits to more targeted, data-driven and risk-based audits (20% decrease);
- targeting sponsoring organizations at their parent organization level (10% decrease); and
- implementing the use of electronic information (10% decrease).

16. Publication/Tabulation Dates

This is a collection that has been used and is being revised to account for the changes that have been required by regulation and operational policy. This is a coverage benefit for Medicare beneficiaries and the collection of these data for Medicare Parts C and D will continue indefinitely.

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.

C. Collections of Information Employing Statistical Methods

Not applicable. The information collection does not employ statistical methods.