Supporting Statement for Applications for Medicare Advantage Organizations, Employer Group Waiver Plans, and Service Area Expansions to Provide Part C Benefits as defined in Part 422 of 42 C.F. R.

A Background

The Balanced Budget Act of 1997 (BBA) Pub. L. 105-33, established a new "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)).which provided for a Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the Original Medicare Program or an M+C plan, if one was offered where he or she lived.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Pub. L. 108-173 was enacted on December 8, 2003. The MMA established the Medicare Prescription Drug Benefit Program (Part D) and made revisions to the provisions of Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice. The MMA directed that important aspects of the new Medicare Prescription Drug Benefit Program under Part D by similar to and coordinated with regulations for the MA program.

The MMA also enacted the prescription drug benefits program and revised MA program provisions with a required implementation date of January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 CFR 4194 through 458,5 respectively. Many of the provisions relating to applications, marketing, contracts and the new bidding process for the MA program became effective on March 22, 2005, 60 days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. As we have gained more experience with the MA and the Part D programs, we are revising areas of both programs. Many of these revisions clarify existing polices or codify current guidance.

Coverage for the prescription drug benefit is provided through contracted prescription drug plans or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost plans under section 1876 of the Social Security Act and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit.

Organizations wishing to provide healthcare services under MA and/or MA-PD plans must complete an application, file a bid, and receive final approval from CMS. Existing

MA plans may expand their contracted area by completing the Service Area Expansion (SAE) application.

B Justification

1. Need and Legal Basis

Collection of this information is mandated in {Part C of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) in Subpart K of 42 CRF 422 entitled "*Contracts with Medicare Advantage Organizations*."

In addition, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), amended titles XVII and XIX of the Social Security Act to make various revisions to the Medicare statute intended to improve the Medicare program. Changes made to the 2011 Part C MA applications including: the addition of two new attestation statements related to broker/agent oversight and new Model of Care and Reporting requirements for Special Needs Plans (SNPs). In addition, CMS is streamlining the process for submitting and assessing provider network adequacy (health service delivery).

In general, coverage for the prescription drug benefit is provided through prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) organizations that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA-CCPs) either must offer a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA-PFFS) may choose to offer a Part D benefit. Employer Group Plans may also provide Part D benefits. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Applicants may offer either a MA or an MA-PD plan with service area covering the nation (i.e., offering a plan in every region) or covering a limited number of regions. MA-PD may offer local plans.

Regional MA plans may be offered in 26 MA regions. The MMA requires that each region have at least two Medicare prescription plans from which to choose, and at least one of those must be an MA-PD.

This clearance request is for the information collected to ensure applicant compliance with CMS requirements and to gather data used to support determination of contract awards.

1876 Cost Plan SAE

The Cost plan application is based on Section 1876 of Title XVIII of the Social Security Act and the applicable regulations and Title XIII of the Public Health Services Act and the applicable regulations.

Any current Cost Plan Contractor that wants to expand its Medicare cost-based contract with CMS under Section 1876 of the Social Security Act, as amended by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) and subsequent legislation can complete the application.

2. Information Users

The information will be collected under the solicitation of proposals from MA-PD, and EGWP Plan applicants. The collection information will be used by CMS to: (1) ensure that applicants meet CMS requirements, (2) support the determination of contract awards.

Participation in all Programs is voluntary in nature. Only organizations that are interested in participating in the program will respond to the solicitation. MA-PDs that voluntarily participate in the Part C program must submit a Part D application and successful bid.

3. Improved Information Technology

In the application process, technology is used in the collection, processing and storage of the data. Specifically, the Applicant must submit the entire application and supporting documentation through CMS' Health Plan Management System (HPMS). This means that the application submission is 100% electronic.

For the 2012 Application process, CMS is using technology to streamline Cost Plan application. The Cost plan application is being added as an appendix to this MA application.

4. Duplication of Similar Information

This form does not duplicate any information currently collected. It contains information essential for the operation and implementation of the Medicare Advantage program. It is the only standardized mechanism available to record data from organizations interested in contracting with CMS.

As possible, for Medicare Advantage Organizations (MAOs) we have modified the standard application to accommodate information that is captured in prior data collection. However, because of the MIPPA provision we are estimating an additional burden of hours to our previous estimate.

5. Small Business

The collection of information will have a minimal impact on small businesses or other small organizational entities since the applicants must possess an insurance license and be able to accept risk. Generally, state statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the MAO benefit package.

6. Less Frequent Collection

If this information is not collected, CMS will have no mechanism to: (1) ensure that applicants meet the CMS requirements, and (2) support determination of contract awards.

7. Special Circumstances

Each applicant is required to enter and maintain data in the CMS Health Plan Management System (HPMS). Prompt entry and ongoing maintenance of these data in HPMS will facilitate the tracing of the applicant's application throughout the review process. If the applicant is awarded a contract after negotiation, the collection information will be used for frequent communications during implementation of the Medicare Advantage Organizations Program. Applicants are expected to ensure the accuracy of the collected information on an ongoing basis.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on June 11, 2010; five comments were received.

9. Payment/Gift To Respondent

There are no payments or gifts associated with this collection.

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, only information within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the Applicant, and which includes an explanation of how it meets one of the expectations specified n 45 CFR Part 5, will be protected from release by CMS under 5 U.S.C.§552(b)(4). Information not labeled as trades secret, privileged, or confidential or not including an explanation of why it meets one or more of the FOIA exceptions in 45 CFR Part 5 will not be withheld from release under 5 U.S. C. § 552(b)(4).

11. Sensitive Questions

Other than, the labeled information noted above in section 10, there are no sensitive questions included in the information request.

12. Burden Estimate (Total Hours & Wages)

CMS estimates that respondent burden for completion of an MA application without a SNP proposal is 35 hours per application. CMS estimates the respondent burden for completion of a MA application with SNP proposal is 40 hours. CMS estimates the respondent burden for completion of an EGWP Direct application is 35 hours per application. CMS estimates the respondent burden for completion of a MAO "800 series" application is 22 hours per application. These estimates are based on consultation with applicants, employer groups, and consultants who work with employer group waiver plans, special needs plans, coordinated care plans and PFFS plans.

The total annual hours requested is calculated as follows:

Note: The 1876 Cost plan SAE application is being added to OMB 0938-0935. CMS believes by added this application to this package gives applicants a one stop application process.

.

Table 1
Summary of Hours Burden by Type of Applicant and Process

In total, CMS estimates 870 MA organizations to file 870 applications/responses. This would amount to 15696 total annual hours.

Activity	**CCP**	**PFFS**	**SAE**	**MSA**	**MA wth SNP**	**SAE with SNP**	**SNP only**	**Direct EGWP**	**800 Series EGWP**	**Cost Plan SAE**	**Summary**
Expected Applications/ Responses	30	30	170	**0**	65	50	500	1	22	2	870
Review Instructions	2 hrs	2 hrs	2 hrs	0 hrs	2 hrs	2hrs	.5hrs	4 hrs	.5 hrs	2 hrs	17
Complete Application	33 hrs	33 hrs	31 hrs	0 hrs	33hrs	31hrs	0hrs	29 hrs	.5 hrs	31hrs	221.5
SNP Sections	-	-			6	6	6				18
Hours per application (from table 1)	35	35	33	0	41	39	6.5	33	1	33	256.5
Annual Burden hours	1050	1050	5610	0	2665	1950	3250	33	22	66	15696

Table 2
Total Wage burden by Application

The estimated wage burden for the MA Part C Application is $933,075 based on an estimate wage rate of $55.00 per hour wage

Application type	**CCP**	**PFFS**	**SAE**	**MSA**	**MA with SNP**	**SAE with SNP**	**SNP only**	**Direct EGWP**	**800 Series EGWP**	**Cost Plan SAE**	**Total**
Annual burden Hours	1050	1050	5610	0	2665	1950	3250	33	22	66	15696
Hourly Wages.	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00
Total Wage burden	$57,750	$57,750	$308,550	$	$220,000	$107,250	$178,750	$1,815	$1,210	$3,630	$ 933,075

Table 3
Summary of Burden Hours Comparison CY2011 to CY2012

The overall burden hour increase is 6149 hours (CY2012 Burden hours-CY2011 Burden hours). The overall number of expected respondents has increased by 579. For CY2012, the number of respondents and hours for SAE with SNP, SNP only and Cost Plan SAEs has been added.

	CY2011 Number of Respondents	**2011 (hours) Estimates**	**CY2011 Annual Burden Hours**		**Number of Respondents**	**2012 (hours) Estimates**	**CY2012 Annual Burden Hours**
MA	160(CCP,PFFS, &SAE)	33	5280		30	35	1050
PFFS					30	35	1050
SAE					170	33	5610
MSA					0	0	0
MA SNP	108	39	4212		65	41	2665
SAE SNP					50	39	1950
SNP Only					500	6.5	3250
Direct EGWP	1	33	33		1	33	33
800 Series only	22	1	22		22	1	22
Cost Plan SAE	-	-	-		2	33	66
Total	**291**		**9547**		**870**		**15696**

Estimate of total annual cost burden to respondents from collection of information – (a) total capital and start-up cost; (b) total operation and maintenance

Not applicable. The entities that apply are ongoing health organizations that voluntarily elect to pursue a CMS MA contract to offer health coverage to beneficiaries.

13. Capital Cost (Maintenance of Capital Costs)

We do not anticipate additional capital cost. CMS requirements do not require the acquisition of new systems or the development of new technology to complete the application. CMS anticipates that all qualified applicants maintain systems for maintenance of their pharmacy network contracts, pharmacy benefits, and financial records.

System requirements for submitting HPMS applicant information are minimal. MAO's will need the following access to HPMS: (1) Internet or Medicare Data Communications Network (MDCN) connectivity, (2) use of Microsoft Internet Explorer web browser (version 5.1 or higher) with 128-bits encryption and (3) a CMS-issued user ID and password with access rights to HPMS for each user within the MAO organization who

will require such access. CMS anticipates that all qualified applicants meet these system requirements and will not incur additional capital costs.

14. Cost to Federal Government

The estimated cost for preparation, review, and evaluation of the managed-care organization application is $3,307. This estimated cost is based on the budgeted amount for application review and estimate wages of key reviewers and support staff.
Annualized cost to Federal Government

Systems staff (HPMS	4 hours x $50.00/hr x 870 applications	$174,000
SME (MCAG)	4 hours x $50.00/hr x 870 applications	$174,000
RO Acct. Manager	20 hours x $50.00/hr x 870 applications	$870,000
RO Sp. Review (HSD)	20 hours x $50.00/hr x 870 applications	$870,000
RO Supervisor	4 hours x $50.00/hr x 870 applications	$174,000
SNP Clinical	20 hours x $50.00/hr x 615 applications	$615,000
Total		$2,877,000

The estimated approximated cost for per application review is $3,307 ($2,877,000 divided by 870 applications).

15. Program or Burden Changes

Increase in Respondents

For contract year 2012, CMS expects a slight increase in initial applicants and SAE applications based on CY 2011 application submissions, and a major increase in the number SNP proposal submission.

Increase Burden of Hours:

An additional 2 hours of burden was added to the base MA application. This increase stems from changes in regulations at 42 CFR 422 with regards to the compliance plans and quality improvement plans. CMS made an internal decision to have organizations' submit its compliance plan and quality improvement program plans as a part of the application process. CMS believes having this information will help us evaluation an organization understanding of the MA programs and an organization readiness to serve beneficiaries as a MA contractor. CMS has also made an internal decision to have MA contractors that are currently

offering a SNP product to complete and submit a SNP proposal. CMS believes having this information will help us better evaluate the quality of health care being offered across all SNP programs.

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

CMS is not requesting an exemption from displaying the expiration date.

18. Certification Statement

There are not exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There has been no statistical method employed in this collection.