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.

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 2011 Application process, CMS is using technology to streamline the process for submitting and assessing provider network adequacy (health service delivery) per the following explanation:

> Applicants will be demonstrating network adequacy through an automated review process and revised Health Service Delivery Tables (HSD). Detailed instructions on how to complete each of the required HSD Tables will be available in a separate file along with the HSD Table templates. Detailed HSD instructions and table templates will be available in the MA Download file in HPMS.
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> As part of the application module in the Health Plan Management System (HPMS), CMS will be providing applicants with an automated tool for submitting network information via revised and automated HSD tables. The revised tables will then be reviewed automatically against default adequacy measures for each required provider type in each county. This new process will permit applicants to determine if they have achieved network adequacy before completing the submission of their application. Further, CMS will make these default values known prior to the opening of the application module. As such, applicants will see the values (providers and facilities of each required type in each county) that CMS requires before the application module opens. Applicants that believe that CMS defaults values for a given provider type in a given county are not in line with local patterns of care may seek an exception, in which case the applicant will submit required information to support the exceptions request and HSD review will occur manually by a CMS reviewer as it has in the past. Applicants that submit HSD tables that 'clear' CMS's default values will still be required to submit signed contracts and other documents that demonstrate the accuracy of the HSD tables submission. Applicants may still be determined to have network deficiencies even if they 'pass' the automated review.
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> CMS intends to provide training to applicants on the new automated system, the new HSD tables, and the default values for determining network adequacy before the application module opens, and expects to annually post the

default values for determining network adequacy in November of each year, prior to the last date for submitting the Notice of Intent to Apply.

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

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Federal Register Notices & Comments
60 Day Notice:

Volume 74 Page number 30574 Publication date 6/26/2009

Six comments were received.

30 Day Notice:
Volume 74 Page number 50799 Publication date 10/01/2009

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 33 hours per application. CMS estimates the respondent burden for completion of a MA application with SNP proposal is 39 hours. CMS estimates the respondent burden for completion of an EGWP Direct application is 33 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: In an effort to streamline the application process, CMS Collection 10214 (EGWP Applications) is no longer a separate collection under OMB 0938-0935. Collection is 10214 has been combined with Collection CMS- 10237 under OMB 0938-0935. CMS believes that the streamlining of these applications will reduce confusion and burden for those applicants seeking to apply solely in the employer market or in both individual and employer markets.

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

In total, CMS estimates 291 MA organizations to file 291 applications/responses. This would amount to 9547 total annual hours.

Activity	**CCP**	**PFFS**	**SAE**	**MSA**	**MA wth SNP**	**Direct EGWP**	**800 Series EGWP**	**Summary**
Expected Applications/ Responses	20	40	100	**0**	**108**	**1**	22	291
Review Instructions	2 hrs	2 hrs	2 hrs	**0 hrs**	**2 hrs**	**4 hrs**	.5	12.5
Complete Application	31 hrs	31 hrs	31 hrs	0 hrs	31	29 hrs	.5	153.5
SNP Sections	-	-			6			6
Hours per application (from table 1)	33	33	33	0	39	33	1	172
Annual Burden hours	660	1320	3300	0	4212	33	22	9547

Table 2
Total Wage burden by Application

The estimated wage burden for the MA Part C Application is $525,085 based on an estimate wage rate of $55.00 per hour wage

Application type	**CCP**	**PFFS**	**SAE**	**MSA**	**MA with SNP**	**Direct EGWP**	**800 Series EGWP**	**Total**
Annual burden Hours	660	1320	3300	0	4212	33	22	9547
Hourly Wages.	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00
Total Wage burden	$36,300	$72,600	$ 181,500	$ -	$231,660	$1,815	$1,210	$525,085.00

Table 3
Summary of Burden Hours Comparison CY2010 to CY2011

The overall burden hour increase is 3057 hours (CY2011 Burden hours-CY2010 Burden hours). The overall number of expected respondents has increased by 24. In CY 2010 PRA package the burden hours for the MA-SNP was omitted. For CY2011, the number of respondents and hours to complete the MA application with SNP has been broken out.

	CY2010 Number of Respondents	**2010 (hours) Estimates**	**CY2010 Annual Burden Hours**		**Number of Respondents**	**2011 (hours) Estimates**	**CY2011 Annual Burden Hours**
MA	240	27	6435		160 (CCP,PFFS, &SAE)	33	5280
MA SNP	4	-0	-0		108	39	4212
Direct EGWP	1	33	33		1	33	33
800 Series only	22	1	22		22	1	22
Total	**267**		**6490**		**291**		**9547**

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 $2,971.00. 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 291 applications	$58,200
SME (MCAG)	4 hours x $50.00/hr x 291 applications	$58,200
RO Acct. Manager	20 hours x $50.00/hr x 291 applications	$291,000
RO Sp. Review (HSD)	20 hours x $50.00/hr x 291 applications	$291,000
RO Supervisor	4 hours x $50.00/hr x 291 applications	$58,200
SNP Clinical	20 hours x $50.00/hr x 108 applications	$108,000
Total		$864,600

The estimated approximated cost for per application review is $2,971.13($864,600 divided by 291 applications).

15. Program or Burden Changes

Increase in Respondents

For contract year 2011 and subsequent contract years, MIPPA requires that non-employer/union sponsored PFFS plans that are operating in a "network area" must meet the access requirements described in section 1852(d)(4)(B) of the Act through contracts with providers. Due to this new MIPPA requirement, CMS does envision a slight increase in the number of respondents in order to comply with this new provision.

Increase Burden of Hours:

1. An additional 6 hours of burden was added to the base each MA application. This increase stems from the enactment of MIPPA, the American Recovery and Reinvestment Act of 2009 (ARRA) and internal feedback that generated additions and clarification to the Part C application for 2011. CMS clarified attestations, added 2 forms to the application, redesigned the HSD forms, and clarified all instructions to support organizations in completing the application. New attestations were added to existing sections to address MIPPA required

agent/broker issues and to address Health Information Technology requirements imposed by ARRA.

2. CMS included an additional increase of 6 hours to complete the MA with SNP application due to the new MIPPA requirement that states that all SNPs must have in place an evidenced-based model of care with appropriate networks of providers and specialists. In addition to the collection, analysis, and reporting of HEDIS and Structure and Process measures, MIPPA also requires that SNPs evaluate their care management system within their internal performance improvement program. CMS made changes to the SNP proposal to support applicants in meeting the MIPPA requirements.

The additional 6 hours account for the following 3 filings, requiring 2 hours each:

- Completing the attestations and uploading the documents required in the 2011 SNP Proposal.
- Prepare and upload an overall care management plan that describes policies, procedures, and systems to implement the model of care;
- Prepare and upload an overall quality improvement program that describes the internal performance improvement activities and how the MAO will meet the external required reporting submissions such as HEDIS measures and Part C monitoring elements.

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.