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 directed implementation of the prescription drug benefits program and revised MA program provisions by 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 4585 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 that are required 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 services under the MA and MA-PD plans must complete an application, negotiate rates and receive final approval from CMS. Certain existing MA plans may also 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 (MIPP), amended titles XVII and XIX of the Social Security Act to make various revisions to the Medicare statute intended to improve the Medicare program. However, many of these sections have an effective date of on or before 2010 that demands this justification. .

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. Cost Plans that are regulated under Section 1876 of the Social Security Act, and 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 are covering the nation (i.e., offering a plan in every region) or covering a limited number of regions. MA-PD and Cost Plan applicants 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, Cost Plan, 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

CMS has worked to improve the application process from prior years. As a result, applicants are asked to complete the application through CMS' Health Plan Management System (HPMS). This will entail clicking checkboxes, completing minor text fields electronically, and uploading certain supporting documentation. Applicants are not asked to provide any documentation by CD or hardcopy.

Technology is used in the collection, processing and storage of the data used in the application and bidding process. The paperwork burden is reduced by requesting electronic copies of the applicant submissions for review by specific CMS program areas. Specifically, the Applicant must submit the entire application and supporting documentation through HPMS.

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 Prescription Drug Benefit 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 hour 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

The final rule was published January 28, 2005.

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)

Our estimate, explained below includes a review of application instructions and the completion of the application. Based on prior years' experience CMS has estimated the number of 2010 applications based on the actual number received for 2009.

CMS estimates that respondent burden for completion of an MAO application is 33 hours per application. This estimate is based on consultations with applicants and consultants

who work with coordinated care, and Private Fee for Services plans. The respondent's burden is estimated to be 1 hour per application for the MAO ("800 series ") EGWP application and 37 hours for the Employer/Union Direct Contract PFFS MAO application. This estimate is based on consultation with applicants, employer groups and consultants who work with employer group waiver plans. For the MAO ("800 series) EGWP application, a single application is used for the various types of MA plans.

The total annual hours requested is calculated as follows:

Collections CMS- 10237 and CMS 10214 requires the following hours to complete.

1 hour x 66 (EGWP) applications from 66 respondents	=	66 annual hours
37 hours x 1 (Direct Contract Application from 1 respondent	=	37 annual hours
33 hours x 200 (applications from 200 respondents	=	6600 annual hours
Total Hours	=	6709 total annual hours.

In total 267 MA organizations to file 263 total applications. The new application permits a MA organization to offer 5 HMO-type MA plans, for instance.

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 becoming a CMS MA contract provider to offer health coverage to beneficiaries.

Annualized cost to Federal Government

The estimated cost for an average application review is $1,121.11 each application.

Plan Manager:	2 days @248/day x 200	$99,200
EGWP review	0.25 day@ 248/day x 66	6.547
EGWP Plan Manager	2 days@ 248/day x 1	496
Specialty Reviewers (in-house)	1 day @ 248 x 267	66,216
Specialty Reviewers (health services)	2 days @ 248/ day x 200	99,200
Supervisory review:	0.25 day @ 303/day x 267	20,225
Support Staff:	0.25 @ 106/day x 267	7,075
Travel for site visits		3,300
Total		**$302,259**

Total cost to the movement for applications from 267 respondents is:
Net cost to government 267@1,121.11 = **$302.259**

***** It is expected that multiple applications from individual applicants will result in minimal addition cost to the government.

3. Capital Cost (Maintenance of Capital Costs)

We do not anticipate that additional cost are incurred, 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 $302,259. This estimated cost is based on the budgeted amount for application review and support and is inclusive of wages, operational expenses (equipment, overhead, printing, and support staff), and other expenses incurred in the application effort.

15. Program or Burden Changes

The enactment of MIPPA has caused minor changes since OMB approval of the 2009 applications. Based solely on the new statute and changes it mandates to the Part C program CMS estimates they will account for approximately 35% of the requested burden hours. The remaining hours requested are because CMS received more applications and SAEs than we anticipated in our previous request. We have clarified existing instructions to update applicants about the submission process.

CMS is in the process of publishing regulations that are intened to be released as an interim final rule with comment. Many of the provisions included in MIPPA that impact the Part C program are self-implementing, meaning these provisions will go into effect without further regulatory clarification or changes to the Part C solicitations. Therefore, CMS is seeking an emergency PRA clearance to amend the Part C solicitations to reflect the new MIPPA requirements. CMS is seeking to include language from MIPPA into the Part C solicitations from section163, 164, and 165. These sections amend the

contractual requirements that Part C sponsors (applicants) must have in contracts with CMS and with any downstream or related entities performing Part C functions on the sponsor's behalf. Currently templates are provided that include language CMS expects to see in such contracts based on the statue and regulations. Failure to include these provisions in the templates will not preclude applicants from being required to have the language in the contracts upon the time they submit materials to CMS for the 2010 contract year. By including these provisions in the templates, CMS is helping applicants by clearly indicating the language that is expected in the contracts. The solicitations do not represent new policy, but rather implement the provisions that will exist in the forthcoming regulations and statue. Therefore, the material being added to the solicitation will only reflect changes made by Congress to the Medicare Advantage Program.

We request this emergency PRA clearance to be approved to accommodate the new statutorily mandated provisions under the MIPPA. The MMA requires that Part C sponsors offering Part C benefits for January 2010 be contracted with CMS for their approved service area with open enrollments beginning on November 15, 2009. Further, the MMA requires the submission of Part C benefit bids from applicant organizations by the first Monday in June of 2009 (June 1). In order to ensure appropriate due process for any applicants that may have their Part C applications denied CMS work's backwards on the calendar. CMS provides applicants with approximately 45 days to complete the application and then takes about 6 weeks to review with two opportunities of the applicants to cure any deficiencies.

In addition to the new requirements mandated by MIPPA, clarifying updates were also made to the existing language of the Part C solicitations. Such updates include date changes and incorporating the most current references in statue, regulation and CMS guidance above each section as appropriate. Lastly, clarifying instructions were added to more clearly articulate the application submission process through the Health Plan Management System (HPMS).

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

The collection of information applies only to 2010 only. A separate (revised) document will be developed for subsequent years.

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.