SUPPORTING STATEMENT: CMS -10117, 10118, 10119, 10135, 10136, 10214

MEDICARE ADVANTAGE APPLICATION FOR COORDINATED CARE PLANS (CMS-10117); MEDICARE ADVANTAGE APPLICATION FOR PRIVATE FEE-FOR-SERVICE PLANS (CMS-10118); MEDICARE ADVANTAGE APPLICATION FOR REGIONAL PPO PLANS(CMS-10119); MEDICARE ADVANTAGE APPLICATION FOR SERVICE AREA EXPANSION FOR COORDINATED CARE and PRIVATE FEE-FOR-SERVICE PLANS (CMS-10135); AND MEDICARE ADVANTAGE APPLICATION FOR MEDICAL SAVINGS ACCOUNT PLANS (CMS-10136) AND APPLICATION FOR MA ORGANIZATIONS TO OFFER NEW EMPLOYER GROUP WAIVER PLANS (CMS-10214).

A. Background — the nature of the collection.

We are requesting regular OMB approval for the revised Medicare Advantage Program Applications to meet regulatory requirements contained in 42 CFR Section 422. The applications were granted an emergency approval under 0938-0935.

In enacting Title II of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Public Law 108-173), the Congress initiated a major Federal effort to modernize Medicare managed care.

Through this initiative, the Congress changed the name of Medicare's managed care program to the Medicare Advantage (MA) Program, making some fundamental changes while retaining other key features of the Medicare + Choice program which it replaced. The new features of the MA program were intended to encourage organizations to offer a greater selection of health plan options for Medicare beneficiaries. In implementing the MA Program, the Centers for Medicare & Medicaid Services (CMS) developed separate application formats to allow it to ensure that organizations were in compliance with the requirements for the different plan types introduced under MA and to provide potential applicants with efficient application vehicles. These application types are as follows:

CMS-10117

Organizations that may use this MA Coordinated Care Plan Initial application are: Health Maintenance Organizations (HMOs); State Licensed Provider-Sponsored Organizations (PSOs), and other State licensed risk-bearing entities eligible to offer health benefits coverage. Preferred Non-state licensed Provider Sponsored Organizations (PSOs) are not eligible to apply to offer MA Coordinated Care Plans. Regional Preferred Provider Organizations (Regional PPO), Private Fee-For-Service (PFFS), and Medical Savings Account (MSA) plans may not use this application. PFFS, Regional PPO, and MSA plans must use the applications specific to that type of MA plan.

CMS-10118

An organization may use this MA Initial PFFS application to apply / to enter into an MA PFFS agreement with CMS. The MA Program has given PFFS plans the option of adding a Prescription Drug Benefit.

CMS-10119
An organization may use this MA Initial application to seek / to become a Regional PPO, providing Medicare covered services throughout various regions established under the MA Program. The Regional PPO plan type was one of the program changes enacted under the MMA of 2003.

CMS-10135
Organizations that may use this MA Service Area Expansion (SAE) application are HMOs; State Licensed PSOs; PPOs and other State licensed risk-bearing entities eligible to offer Medicare health benefits coverage and who already have an approved coordinated care plan contract with CMS. PFFS plans and MSA plans may also use this application to request an expansion of their service area. Regional PPO plans may not use this application.

CMS-10136
An organization would use this application to apply / to enter into a MA MSA plan contract with CMS. The MSA plan option was initially created under the Balanced Balance Budget Act of 1997 (BBA) and reestablished under the under the MMA of 2003 after the BBA authority expired in 2002.

CMS-10214
An organization would use this application to offer "800-series" Employer/Union-only Group Waiver Plans of the same plan type (CCP, PFFS, MSA, or RPPO) under an existing or new contract number for non-group MA plans.

B. Justification

1. *Need and Legal Basis*
   An entity seeking a contract as an MA organization must be able to provide Medicare's basic benefits plus meet the organizational requirements set out in regulations at 42 CFR Part 422. An applicant must demonstrate that it can meet the benefit and other requirements within the specific geographic area it is requesting.

   The application forms are designed to give Federal staff the information they need about the health plan to determine compliance with Federal regulations at 42 CFR Part 422 in an efficient manner. The cited regulations outline the MA application process that begins with submission of an application in the form and manner that the Secretary provides. The regulatory requirements are incorporated into the MA applications that are being submitted with this paperwork package.

2. *How, by whom, and for what purpose is the information is to be used? Actual use the agency has made of the information received from the current collection.*
   The MA application forms will be used by Federal staff to determine whether an entity is eligible to enter into a contract to provide services to Medicare beneficiaries.

3. *The use of technological collection techniques.*

The applications are in Microsoft Word format and supporting tables are in Microsoft Excel format. In the narrative sections of the forms, the user fills in responses to questions and fills in the cells on formulated tables. The text in these electronic files is marked so that pagination is automatic and the user can automatically generate a table of contents. Required tables to be inserted into the application documents are saved in separate electronic files to facilitate completion. This simplifies application preparation because the user does not need to retypes either questions nor table formats, but simply adds their text to the existing templates or formats provided. Technical instructions are included in the beginning of the applications.

4. *Efforts to identify duplication.*
Each application is unique to the type of organization applying and CMS must evaluate all information related to regulatory requirements. Specific information about each MA organization is not collected or available in any form other than through this application form.

For networks of health plan organizations operated by one "parent" company, CMS has streamlined the process to avoid requiring each subsidiary to submit identical information if all use certain systems that are essentially the same, New submissions from the related entities can rely on materials previously submitted from others in the network. Another example of how CMS further streamlines the application process is for those seeking to expand their approved service areas. These entities are required to submit only a narrow range of information going to their licensure and provider access requirements if other required information remained the same as in their earlier submissions.

5. *Impact on small businesses or other small entities.*
Each organization desiring an MA contract or expansion must complete the application as a one-time submission and adhere to the annual renewal process. There is no difference for small or larger businesses.

6. *Consequence if the collection is not conducted or is conducted less frequently.*
Not applicable. Each organization desiring a MA contract or expansion must complete the application as a one-time submission. Service area expansions are on an event basis.

7. *Special circumstances causing information collection to be conducted, as listed.*
The only circumstance that applies here is confidentiality; see B.10.below for response.

8. *Federal Register Notice/Outside Consultation*

A 60-day Federal Register notice was published March 30, 2007.

Additionally, CMS posted these documents on its own website to directly solicit industry comment (December 1, 2006 – December 8, 2006). The public was directed to send comments to designated CMS email addresses and solicited through "open door" public conference calls with the industry. Additional revisions resulted from the comment solicitation and were incorporated into the final versions of the applications; which was

approved by OMB on January 31, 2007 and posted to CMS' website on January 31, 2007.

CMS Regional Office and Central Office staffs, as well as contractor staff were consulted to ensure the application's clarity and relevance to current managed care entities. All additional comments, minor changes, primary clarification of the material requests were performed, submitted to OMB, and was approved during the emergency PRA process.

A 14-day PRA Federal Register notice was published on December 8, 2006.

9. *Any payment or gift to respondents, other than remuneration of contractors or grantees.*
There are no gifts or payments from CMS to applicants.

10. *Assurance of confidentiality to respondents and the basis for the assurance*

MA regulations at 42 CFR 422.501(e) address disclosure of application information under the Freedom of Information Act by saying that

> [a]n applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material "privileged" and include a concise explanation of the applicability of an exception described in 45 CFR Part 5.

The applications require submission of financial information, which is of a confidential nature. The data is necessary to evaluate applicants' bids. Section 1854 of the Social Security Act and 42 CFR Part 422 Subpart F enables CMS to require that MA organizations submit bids that estimate costs associated with the MA plans they intend to offer. Potential applicants are apprised of the regulations and the statutes relating to compliance with the Freedom of Information Act.

11. *Justification for any questions of a sensitive nature.*
No data is collected dealing with sensitive areas such as religious beliefs, sexual behavior, or other matters commonly of a private nature.

12. *Estimates of the hour burden of the collection of information.*

CMS-10117

The respondent burden is estimated to be 38 hours per application. This estimate is based on consultations with applicants and consultants who work with coordinated care plans.

CMS-10118

The respondent burden is estimated to be 38 hours per application. This estimate is based on consultations with applicants and consultants who work with Private Fee for Service plans.

CMS-10119

The respondent's burden is estimated to be 38 hours per application. This estimate is based on consultations with applicants and consultants who work with coordinated care plans.

CMS-10135-

The respondent's burden is estimated to be 25 hours per application. This estimate is based on consultations with applicants and consultants who work with coordinated care plans.

CMS-10136

The respondent's burden is estimated to be 38 hours per application. This estimate is based on consultations with applicants and consultants who work with coordinated care plans.

CMS-10214

The respondent's burden is estimated to be 1 hour per application. This estimate is based on consultations with applicants, employer groups, and consultants who work with employer group waiver plans.

A single application will permit an MA organization to offer multiple EGWP plans of the same type.

The total annual hours requested is calculated as follows:

Collections 10117, 10118, 10119, and 10136 require a total of 38 hours each to complete. Collection 10135 requires 25 hours to complete.

1 hour X 40 (EGWP applications from 40 respondents)	= 40 annual hours
38 hours X 80 (applications from 80 respondents)	=3,040 annual hours
25 hours X 100 (applications from 100 respondents)	=2,500 annual hours
Total Hours	=5,580 total annual hours

In total 220 MA organizations are estimated to file 220 total applications. Some MA organizations will need to file more than one MA application where; for instance when offering more than one type of MA plan, both HMO and PFFS plans. A single application will permit a MA organization to offer multiple MA plans of the same type. A single application will permit a MA organization to offer 5 HMO-type MA plans, for instance.

13. *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.

14. *Annualized cost to federal government*
The estimated cost for an average application review is $1,220.61 each application:

Plan Manager:	2 days @ 248/day x 180	$ 89,280
EGWP Plan Manager:	1 day @ 248/day x 40 9,920	
Specialty reviewers (in-house):	1 day @ 248/day x 220	54,560
Specialty reviewers (health services):	2 days @ 248/day x180	89,280
Supervisory review:	0.25 day @ 303/day x220	16,665
Support staff:	0.25 day @ 106/day x220	5,830
Travel for site visits		3,000
Total		$268,535

Total cost to government for applications from 220 respondents* is:
220 @1,220.61= $268,535
Net cost to government = **$ 268, 535.00**

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

15. *Program/Burden Changes*
No changes from the prior approved collection.

16. *Plans for publication.*
Not applicable. The application forms are used for determining compliance with regulations, not for data collection.

17. *Reasons for not displaying the OMB approval expiration date*
We are not seeking this exemption.