2009 SUPPORTING STATEMENT: CMS -10237 Medicare Advantage Master Application Automation consolidated collection for existing numbers (CMS 10117, 10118, 10119, 10135, 10136) and CMS 10214 (EGWP) remains the same as a stand alone application.

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) have been automated for the 2009 Application cycle and for MA Organizations to Offer New Medicare Advantage Employer/Union-Only Group Waiver Plans (CMS-10214).

A. Background — the nature of the collection.

We are requesting regular OMB approval for the revised and automated Medicare Advantage Master Application to meet regulatory requirements contained in 42 CFR Section 422. The applications were granted an 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-consolidated collection number is CMS-10237
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-consolidated collection number is CMS-10237

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- consolidated collection number is CMS-10237
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- MA SAE consolidated collection number is CMS-10237
Organizations may use this MA Initial application to apply for Service Area Expansion (SAE) for 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- consolidated collection number is CMS-10237
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 was reestablished under the MMA of 2003 after the BBA authority expired in 2002.

CMS-10214-EGWP collection number remains CMS-10214
An organization would use these applications to offer one of two types of MA Employer/Union-Only Group Waiver Plans (EGWPs). This includes new and existing MA Organizations (Coordinated Care Plans, PFFS plans, MSA plans and Regional PPOs) seeking to offer new "800 series" EGWP plans or new Employers/Unions seeking to contract directly with CMS to offer a PFFS MA plan to their retirees.

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 on published July 13, 2007. Public comments are attached under separate cover.

Additionally, CMS posted these documents on its own website to directly solicit industry comment (June 29, 2007 – July 20, 2007).
The public was directed to send comments to designated CMS email addresses and solicited through "open door" public conference calls with the industry.

CMS Regional Office and Central Office staffs, as well as contractor staff will be consulted to ensure the application's clarity and relevance to current managed care entities. Additional comments, minor changes, primary clarifying of the material requests was performed, prior to submission to OMB, and will be approved during the regular PRA process.

A 30-day PRA Federal Register notice was published on October 12, 2007.

Additional revisions maybe necessary as a result of comment solicitation and the incorporation into the final versions of the applications which are to be approved by OMB on December 28, 2007 and posted to CMS' website on January 14, 2007.

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-Master Application-CMS-10237

The respondent burden is estimated to be 32 hours per application. This estimate is based on consultations with applicants and consultants who work with coordinated care, Private Fee for Service plans.

CMS-SAE Application-CMS-10135-consolidated to CMS-10237

The respondent SAE burden is estimated to be included in the 32 hours per application under the Master Application automation. 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 for the MAO ("800 series") EGWP application and 37 hours for the Employer/Union Direct Contract PFFS MAO application. This estimate is based on consultations 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 (formerly CMS- 10117, 10118, 10119, 10135 and 10136) requires a total of 32 hours to complete.

1 hour X 60 (EGWP applications from 60 respondents)	= 60 annual hours
37 hours X 1 (Direct Contract application from 1 respondent)	= 37 annual hours
32 hours X 180 (applications from 180 respondents)	= 5,760 annual hours
Total Hours	= 5, 858 total annual hours

In total 241 MA organizations are estimated to file 241 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, 121.11 each application:

Plan Manager:	2 days @ 248/day x 180	$ 89, 280
EGWP review:	0 .25 day @ 248/day x 60	3, 720
EGWP Plan Manager:	2 days @ 248/day x 1	496
Specialty reviewers (in-house):	1 day @ 248/day x 241	59, 768
Specialty reviewers (health services):	2 days @ 248/day x180	89, 280
Supervisory review:	0.25 day @ 303/day x 241	18, 256
Support staff:	0.25 day @ 106/day x241 6, 387	
Travel for site visits		3, 000
Total		$270, 185

Total cost to government for applications from 241 respondents* is:
241 @$1, 121.11 = $270,185
Net cost to government = **$ 270, 185**

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

15. *Program/Burden Changes*
CMS encouraged plans to submit a Notices of Intent (NOI). The NOIs allows organizations to provide CMS an early estimate of the applications they intend to submit. NOIs will be received and entered into our Health Plan Management System (HPMS). As a result, the total burden will be increased slightly to provide a more accurate depiction of the number of applications CMS expects to receive.

Finally, for 2009 contracts awarded in September 2009; will renew annually; unless otherwise notified by CMS. Organizations holding 2008 contracts will not need to re-apply in 2009 and may continue providing services to beneficiaries unless otherwise notified by CMS.

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.