Supporting Statement Part A
Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits as defined in 42 CFR Parts 417 & 422
CMS-10237, OCN 0938-0935

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)) called Medicare+Choice (M+C). 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 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 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 4,585 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 making revisions to both programs, to clarify existing polices or codify current guidance.

A Justification

1. <u>Need and Legal Basis</u>

Collection of this information is mandated by the CFR, MMA and CMS regulations at 42 CFR 422, subpart K, in “*Application Procedures and Contracts for Medicare Advantage Organizations*.” In addition, MIPPA further amended titles XVII and XIX of the Social Security Act.

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 products (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 enrollees 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.

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 request to expand their contracted service area by completing the Service Area Expansion (SAE) application. Applicants may offer a local MA plan in a county, a portion of a county (i.e., a partial county) or multiple counties. Applicants may offer a MA regional plan in one or more of the 26 MA regions.

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.

Section 1876 Cost Plan SAE

The Cost plan application is based on Section 1876 of Title XVIII of the Act, as amended by Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), and Title XIII of the Public Health Services Act and applicable regulations.

Any current 1876 Cost Plan Contractor that wants to expand its Medicare cost-based contract with CMS under Section 1876 of the Act can complete the service area expansion application.

2. Information Users

The information will be collected under the solicitation of Part C applications from MA, EGWP Plan, and Cost Plan applicants and 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, applicants must submit the entire application and supporting documentation through CMS' Health Plan Management System (HPMS). The application submission is 100% electronic.

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. Where possible, we have modified the standard application to accommodate information that is captured in prior data collection and resides in (HPMS).
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5. Small Business

The collection of information will have a minimal impact on small businesses since applicants must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small business from being licensed to bear risk needed to serve Medicare enrollees.

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 or denials.

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 the 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

Federal Register Notices & Comments

60 Day Notice: Volume 79 Page number 40105 Publication date July 11, 2014 Public Comments Yes (attached to PRA package along with our response to the comments)

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 trade 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 Initial application is 47 hours per application. CMS estimates the respondent burden for completing a Special Needs Plan Proposal (SNP) is 42 hours. These estimates are based on an internal assessment of the application materials. There is a five hour decrease in burden estimates from the 2015 contract year (CY).

The total annual hours requested is calculated as follows:

Table 1

Summary of Hours Burden by Type of Applicant and Process

In total, CMS estimates that it will receive 566 applications/responses. This would amount to 22,625 total annual hours.

Application/ Responses	Initial (CCP,PFFS-Network, EGWP)	PFFS (Initial-Non-network)	SAE (CCP, PFFS-Network, EGWP)	MSA	Initial with SNP	SAE with SNP	SNP only	Direct EGWP	Cost Plan SAE	Summary
Expected Applications/ Responses	66	6	192	**2**	239*	60*	0	0	1	566
Review Instructions (#of hours)	1.0	0.5	0.5	0	0.5	0.5	0	0.5	0.5	3.5
Complete Application/Proposal (# of hours)	46.0	34.5	34.5	0	41.5	41.5	20	0.5	34.5	246.5
Overall # of hours per application /proposal	47	35	35	0	42	42	20	1	35	257
Annual Burden hours	3102	210	6720	0	10038	2520	0	0	35	22,6255

*Represents the number of expected SNP proposals

Table 2

Total Wage burden by Application

The estimated wage burden for the MA Part C Application is $1,244,375 based on an estimate wage rate of $55.00 per hour wage.

Application/ Responses	Initial (CCP, PFFS-Network, EGWP)	PFFS (Initial-Non-network)	SAE (CCP, PFFS-Network, EGWP)	MSA	MA with SNP	SAE with SNP	SNP only	Direct EGWP	Cost Plan SAE	Total
Annual burden Hours	3102	210	6720	0	10038	2520	0	0	35	22,955
Hourly Wages.	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00	$55.00
Total Wage burden	$170,610	$11,550	$369,600	0	$552,090	$138,600	$0	$0	$1,925	$1,244,375

Table 3
Summary of Burden Hours Comparison CY2015 to CY2016

The overall annual burden hours decreased (CY2015 Burden hours-CY2016 Burden hours). The overall number of expected respondents remains the same for CY2016.

	CY 2015 Number of Respondents	CY 2015 Estimates (hours)	CY2015 Annual Burden Hours		CY 2016 Number of Respondents	CY 2016 Estimates (hours)	Y2016 Annual Burden Hours
MA (initials)	66	52	3432		66	47	3102
PFFS non-network	6	35	210		6	35	210
SAE	192	35	6720		192	35	6720
MSA	2	0	0		2	0	0
SNP with MA	239	42	10038		239	42	10038
SNP with SAE	60	42	2520		60	42	2520
SNP Only	0	20	0		0	20	0
Direct EGWP	0	1	0		0	1	0
800 Series* only	0	0	0		0	0	0
Cost Plan SAE	1	35	35		1	35	35
Total	**566**	**262**	**22955**		**566**	**257**	**22625**

*For CY2016, EGWP 800 series only are included in the CCP and SAE

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 costs. CMS requirements do not require the acquisition of new systems or the development of new technology to complete the application.

System requirements for submitting HPMS applicant information are minimal. Medicare Advantage Organization's (MAOs) 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's 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 each MAO's application is $3,128. 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 566 applications	$113,200
SME (MCAG)	4 hours x $50.00/hr x 566 applications	$113,200
RO Acct. Manager**	20 hours x $50.00/hr x 566 applications	$566,000
RO Sp. Review** (HSD)	20 hours x $50.00/hr x 566 applications	$566,000
RO Supervisor**	4 hours x $50.00/hr x 566 applications	$113,200
SNP Clinical	20 hours x $50.00/hr x 299 applications	$299,000
Total		$1,770,600

**These individuals do not review SNP-only responses

The estimated approximated cost per application review is $3,128 ($1,770,600 divided by 566 applications).

15. Program or Burden Changes

There is a decrease in burden hours for 2016 as described below (decreased by 4.5 hours):
CMS removed the following upload requirements in section 3.9 CMS Provider Participation Contracts & Agreements and 3.10 Contracts for Administrative & Management Services. The upload requirements were removed from section 3.9 because CMS will no longer request a sample of Provider Participation Contracts & Agreements

for review. CMS will still require applicants to complete the attestations in this section. CMS continues to hold the MAO responsible for the compliance of its providers and subcontractors with all contractual, legal, regulatory, and operational obligations.
The upload requirements were removed from section 3.10 because CMS will no longer be reviewing Contracts for Administrative and Management Services. This applies only to the Part C review of application materials. The Part D application review process will continue to review these documents in its review of administrative and management services. CMS also removed attestation #5 under section 3.10 because it related to the upload requirements that are now removed.

HSD tables, instructions and exceptions process: Slight decrease in burden as we removed the requirement for the applicants to record the CMS certification number (CCN) on the MA facility table. The HSD Instructions document was revised to no longer include instructions on obtaining the CCN number. Decrease in burden .5 hours.

Total decrease in burden 5 hours.

Currently approved Initial Application hr	3,432
Revised Initial Application hr	-3,102
Program Change	-330 hr

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 no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There has been no statistical method employed in this collection.