Supporting Statement for Applications for
Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans
to Provide Part C Benefits as defined in Part 417 & 422 of 42 C.F. R.
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 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 making revisions to both programs, to clarify existing polices or codify current guidance.

A JUSTIFICATION

1. Need and Legal Basis

Collection of this information is mandated by the CFR, MMA and CMS regulations at 42 CFR 422, subpart K, in "*Contracts with 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

The 60-day Federal Register notice published on June 28, 2013 (78 FR 38926). We received a total of 11 comment letters. After sorting through each letter we received a total of 115 individual comments from different organizations. A summary of the comments and our response have been added to this PRA package.

Subsequent to the publication of the 60-day FR notice, the 30-day notice's PRA package has been revised. A new attestation that was added to Section 3.11 of the application was broken out into two separate attestations. After internal review we decided that it was bad practice to ask the applicant to attest to two things in one attestation since a "NO" response might mean that the organization can only attest to one of the two things or it might mean that it can't attest to either.

While there is an increase in burden hours from the 2014 contract year (CY) by +1,374, the 30-day package's revision to section 3.11 of the application does not increase our burden estimate.

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 52 hours per application. CMS estimates the respondent burden for completing a Special Needs Plan Proposal (SNP) is 42 hours. CMS estimates the respondent burden for completion of an EGWP Direct application is 1 hour per application. These estimates are based on an internal assessment of the application materials and have been increased for CY2015.

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 22,955 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	4

Complete Application/Proposal (# of hours)	51.0	34.5	34.5	0	41.5	41.5	20	0.5	34.5	258
Overall # of hours per application /proposal	52	35	35	0	42	42	20	1	35	262
Annual Burden hours	3432	210	6720	0	10038	2520	0	0	35	22,955

*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 $1,262,525 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	3432	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	$188,760	$11,550	$369,600	0	$552,090	$138,600	$0	$0	$1,925	$1,262,525

Table 3
Summary of Burden Hours Comparison CY2014 to CY2015

The overall annual burden hours for CY2015 increased +1,374 hours from CY2014. The overall number of expected respondents remains the same for CY2015.

	CY 2014 Number of Respondents	**CY 2014 Estimates (hours)**	**CY2014Annual Burden Hours**		**CY 2015 Number of Respondents**	**CY 2015 Estimates (hours)**	**CY2015Annual Burden Hours**
MA (initials)	66	37	2442		66	52	3432
PFFS non-network	6	35	210		6	35	210
SAE	192	33	6336		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**	**245**	**21581**		**566**	**262**	**22955**

*For CY2015, 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. 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 the 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

While there is an increase in burden hours from the 2014 contract year (CY) by +1,374, the 30-day package's revision to section 3.11 of the application does not increase our burden estimate. The change is described below.

PART C -MEDICARE ADVANTAGE and 1876 COST PLAN EXPANSION APPLICATION:

Based on current internal review of the CY2014 burden estimates we are revising them for CY2015. Specifically, an additional 15 hours of burden was added to complete the Initial CCP, PFFS network, EGWP application and an additional 2 hours of burden was added to complete the SAE CCP, PFFS network, EGWP applications. The increase in burden in not due to any statutory changes, regulatory changes or public comments. Instead the increase reflects a more realistic timeframe on how long it takes an applicant to complete the applications mentioned above.

CY2015 changes to application:

1. CMS added new attestations to section 3.1. Waiver request will need to be completed if the applicant attests "no" to the new attestation (section 3.1 #3).
2. CMS added attestations after the 60 day comment period for section 3.11. Attestations are related to admitting privileges of contracted providers at contracted facilities and pertaining to delivery of transplant services.

CY2015 changes to application after 60 day comment period by:

1. Removing Section IV of Partial County Justification referring to Provider Network Assessment for partial counties because this section no longer applies due to the HPMS automated review of partial county networks.
2. Removing Section 4.14 Partial County Network Assessment Table because this table no longer applies due to the HPMS automated review of partial county networks.

PART C -MEDICARE ADVANTAGE and 1876 COST PLAN EXPANSION APPLICATION-Appendix 1 Special Needs Plan Proposal:

1.) Removing the upload requirement for the D-SNP State Medicaid Agency Contract Negotiation Status Document from the application.
2.) Removing attestation #6, "Provide the State Medicaid contract begin date, under the D-SNP State Medicaid Agency Contracts Attestation section."
3.) Removing attestation #7, "Provide the State Medicaid contract end date, under the D-SNP State Medicaid Agency Contracts Attestation section."

4.) Removing attestation #8, “Does the applicant want the State Medicaid Agency Contract to be reviewed to determine if it qualifies as a FIDE SNP for the contract period(s) identified in numbers 6 and 7”, as it similar to Attestation #2 which says “Applicant wishes the contract with the State Medicaid Agency(ies) to be reviewed to determine if it qualifies as a fully integrated dual eligible SNP (FIDE).”
5.) Removing approximately 240 attestations from the Model of Care section.

All of these changes to Appendix 1 Special Needs Plan Proposal decrease burden by approximately 1 hour.

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.