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.

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 enacted the prescription drug benefits program and revised MA program provisions with a required implementation date of 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 458,5 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.

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 (MIPPA) amended titles XVII and XIX of the Social Security Act to improve the Medicare program.

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.

1876 Cost Plan SAE

The Cost plan application is based on Section 1876 of Title XVIII of the Social Security Act and applicable regulations and Title XIII of the Public Health Services Act and the applicable regulations.

Any current 1876 Cost Plan Contractor that wants to expand its Medicare cost-based contract with CMS under Section 1876 of the Social Security Act, as amended by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) and subsequent legislation can complete the service area expansion application. 1876 Cost plans under section 1876 of the Social Security Act

2. Information Users

The information will be collected under the solicitation of Part C application from MA, EGWP Plan, and Cost 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

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

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Federal Register Notices & Comments

60 Day Notice: Volume 77 Page number 40064 Publication date 07-06-2012 Number of Comments: 35

30 Day Notice: Volume Page number Publication date

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)

CMS estimates that respondent burden for completion of an MA Initial application is 37 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.

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 21,581 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)	0.5	0.5	0.5	0	0.5	0.5	0	0.5	0.5	3.5
Complete Application/Proposal (# of hours)	36.5	34.5	32.5	0	41.5	41.5	20	0.5	34.5	241.5
Overall # of hours per application /proposal	37	35	33	0	42	42	20	1	35	245
Annual Burden hours	2442	210	6336	0	10038	2520	0	0	35	21,581

*Number represents # of expected SNP proposals

Table 2
Total Wage burden by Application

The estimated wage burden for the MA Part C Application is $1,186,955 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	2442	210	6336	0	10038	2520	0	0	35	21,581
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	$134,310	$11,550	$348,480	0	$552,090	$138,600	$0	$0	$1,925	$1,186,955

Table 3
Summary of Burden Hours Comparison CY2013 to CY2014

The overall annual burden hours increased 8,285 hours (CY2014 Burden hours-CY2013 Burden hours). The overall number of expected respondents has increased by 188.

	CY 2013 Number of Respondents	**CY 2013 Estimates (hours)**	**CY2013 Annual Burden Hours**	**CY 2014 Number of Respondents**	**CY 2014 Estimates (hours)**	**CY2014 Annual Burden Hours**
MA (initials)	30	40	1200	66	37	2442
PFFS non-network	5	35	175	6	35	210
SAE	150	35	5250	192	33	6336
MSA	0	0	0	2	0	0
SNP with MA	80	40	3200	239	42	10038
SNP with SAE	60	40	2400	60	42	2520
SNP Only	50	20	1000	0	20	0
Direct EGWP	1	1	1	0	1	0
800 Series* only	0	0	0	0	0	0
Cost Plan SAE	2	35	70	1	35	35
Total	**378**	**246**	**13296**	**566**	**245**	**21581**

*For CY2014, EGW P 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.

Table 4
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

**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

Increase Burden Hours per Special Needs Plan (SNP) application:

For CY2014, CMS added one (1) new matrix to facilitate the contract review process for Fully-Integrated Dual Eligible (FIDE) Special Needs Plans (SNPs). This need to collect information to determine if a D-SNP qualifies as a FIDE SNP is not a new requirement this year. FIDE SNPs were created by Congress in Section 3205 of the Affordable Care Act (ACA), which was designed to promote the full integration and coordination of Medicare and Medicaid benefits for dual eligibles by a single managed care organization. D-SNPs that qualify for FIDE designation may qualify for benefits such as marketing exceptions, and the frailty adjuster payment.

Last year, which was the first year D-SNPS were evaluated for FIDE determination, all of the SNP Medicare Improvements for Patients and Providers Act (MIPPA) State Medicaid Agency Contracts (SMACs) were simultaneously reviewed for both MIPPA compliance and FIDE determination (under 42 CFR 422.2) because all MAOs offering D-SNPS were required to submit SMACs if they wished to operate in 2013. As such, all health plans, even

those that did not apply for FIDE SNP status, were evaluated to determine whether or not they met FIDE SNP status. This resulted in confusion for plans that did not intend to be reviewed for FIDE status (and were subsequently sent letters from CMS informing them that they did not qualify.)

In order to remedy this issue this year, rather than review all D-SNP SMACs to determine whether they meet the requirements at 422.2 for FIDE status, we are only going to review those D-SNPs that specifically request (through an attestation in the application) to be evaluated for FIDE qualification. This year we have added the matrix to the application in order to facilitate this process for reviewers as it indicates where in their State Medicaid Agency Contract(s) D-SNPs describe how they meet the requirements at 422.2.

Revisions were also made to the End Stage Renal Disease (ESRD) Waiver to ensure the collection of required information from SNPs applying for this waiver. An additional two (2) hours of burden was added to the SNP Medicare Advantage (MA) and SNP Service Area Expansion (SAE) applications.

Decrease Burden Hours per Init ia l and SAE MA application:

CMS removed the Tiering of Medical Benefits template and attestation that requested that Medicare Advantage Organizations (MAOs) describe how enrollees will have equal access to specified tiered medical benefits. Twelve (12) hours of burden was removed from the initial MA applications as reflected in the 60-day PRA package.

Key management position descriptions and resumes are not requested in the CY 2014 Part C MA Application; therefore, an additional one (1) hour of burden was removed from the initial MA applications.

Applicants who received a Part C application approval, initial, or SAE, from CMS during one or both of the two most recent application review cycles will no longer be required to upload the administrative contract upload document. Two (2) hours of burden was removed from the initial and SAE MA applications. This will represent an estimated
20% of applicants who will be exempt from this requirement.

Increase in Overall Burden of Hours and Respondents:

Although there was a reduction in burden as mentioned in the decreased burden section of this document, the overall burden hours increased because of the increase in the expected number of respondents and the addition of the SNP matrix and upload document. An internal assessment of the number of respondents resulted in a higher projection for CY 2014.

Table 5

Summary of Changes for Increased Burden Hours

Change Impacting Burden Hours	Purpose of Change	Total Burden Hours
Increase of respondents in CY2014	The number of anticipated respondents was increased to reflect a more accurate estimate of MA, PFFS, SAE, MSA, and MA-SNP applications in CY 2014. The average number of applications received in previous contract years was calculated and found to be greater than previously reported. The overall number of expected respondents increased by 188 when compared to CY 2013 (see Comparison Table #3). The increase in 5 of 10 applications is reflected below. MA +36 PFFS +1 SAE +42 MSA +2 MA-SNP +159	21,581 (Overall burden hours increased 8,285 hours primarily due to the increase in respondents – See Comparison Table #3)
Addition of D-SNP FIDE SNP Matrix for SNPs	This document was added to aid in determining if the D-SNP qualifies as a FIDE SNP during the contract review. An increase of 2 hours was added to the SNP applications (MA and SAE) as determined by CO SMEs. The addition of 1 hour increased the annual MA-SNP burden 239 hours and the SNP SAE burden 60 hours. However, the increase in respondents (+159) significantly impacts the overall burden hours.	299 239 (MA-SNP) 60 (SNP SAE)

Update ESRD Waiver Request Upload Document	This waiver was updated to improve the ESRD Waiver request upload document to collect more complete information from SNPs applying for ESRD Waivers. Specifically, the document now requests information on care coordination, additional services, delegation, and health services delivery. An additional 2 hours was added to the SNP applications (MA and SAE) as determined by CO SMEs. The addition of 1 hour increased the annual MA-SNP burden 239 hours and the SNP SAE burden 60 hours. However, the increase in respondents (+159) significantly impacts the overall burden hours. As per table #3, the total burden hours decreased from 246 to 245. The respondents increased by approximately half (188) of the previous year's total number of respondents, which proportionately increased the total annual burden hours.	299 239 (MA-SNP) 60 (SNP SAE)

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.

C. Collection of Information Employing Statistical Methods

There has been no statistical method employed in this collection.