Supporting Statement Part A
Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits
CMS-10237, OMB 0938-0935

Note: The title of this information collection request is, "Medicare Advantage Application - Part C and 1876 Cost Plan Expansion Application Regulations under 42 CFR 422 (Subpart K) & 417.400." In this iteration we are revising the title to read, "Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits."

Background

The Balanced Budget Act of 1997 (BBA) Pub. L. 105-33, established "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) called Medicare+Choice. 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 Medicare+Choice 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 be similar to and coordinated with regulations for the MA program. The MMA changes made managed care more accessible, efficient, and attractive to beneficiaries seeking options to meet their needs.

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 FR 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.

The MA program offers several kinds of plans and health care choices which include the following:

- Coordinated Care Plans (CCPs) – A CCP is an MA plan that offers health care through an established provider network that is approved by the Centers for Medicare and Medicaid Services (CMS). There are several types of plans that are considered CCPs, including:
    - Health Maintenance Organizations (HMO)
    - Local Preferred Provider Organizations (LPPOs)
    - Regional Preferred Provider Organizations (RPPOs)
    - Special Needs Plans (SNPs)

- Medical Savings Account (MSAs) – An MSA plan is a type of MA plan that combines a high-deductible health plan with a medical savings account.

- Private Fee-For-Service (PFFS) Plans – A Medicare PFFS plan is a type of MA plan that may or may not have a network of providers. Members of a PFFS plan may see any provider who is eligible to receive payment from Medicare and agrees to accept the PFFS's terms and conditions of payment.

- Section 1876 Cost Plan – A cost contract plan is paid based on the reasonable costs incurred by delivering Medicare-covered services to plan members. Enrollees in these plans may use the cost plan's network of providers or receive their health care services through Original Medicare. CMS no longer accepts new, initial Cost Plan applications. However, an existing/approved Cost Plan can submit a service area expansion (SAE) application to expand its service area.

- Employer Group Waiver Plans (EGWPs) – The MMA provides employers and unions with a number of options for providing coverage to their Medicare –eligible members. The EGWPs can offer various health plan types such PFFS, CCPs, MSAs and RPPOs.

Applications for each of the plan types described above are included in this information collection.

This information collection includes the process for organizations wishing to provide healthcare services under MA plans. These organizations must complete an application annually (if required), file a bid, and receive final approval from CMS. The MA application process has two options for applicants that include (1) request for new MA product or (2) request for expanding the service area of an existing product. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the MA program and to make a decision related to contract award. This collection process is the only mechanism for organizations to complete the required MA application process.

Note: Organizations that wish to offer both Part C and Part D must complete a separate Part D application. CMS refers to these applicants as MA-PD applicants The Part D information collection is included under OMB control number 0938-0936 (CMS-10137).

A Justification

1. Need and Legal Basis

This clearance request is for the vital information collection process to ensure Part C applicants are in compliance with CMS requirements and the collection of data necessary to support the decision related to contract awards. As noted above, organizations wishing to provide healthcare services under MA plans must complete an application, file a bid, and receive final approval from CMS.

Collection of this information is mandated by the Code of Federal Regulations, MMA, and

CMS regulations at 42 CFR 422, subpart K, in "*Application Procedures and Contracts for Medicare Advantage Organizations*." In addition, the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) further amended titles XVII and XIX of the Social Security Act.

2. Information Users

CMS will collect and review information under the solicitation of Part C applications for the various health plan product types described in the Background section above. CMS will use the information to determine whether the applicants meet the requirements to become an MA organization and are qualified to provide a particular type of MA plan. The application consists of attestations and uploads that help CMS determine that the organization:

1. Is licensed by the State (see 42 CFR 422.501(c)(1) and 422.503(b)(2);
2. Has the management, financial, and operational capabilities to operate an MA contract (see 42 CFR 422.503(b)(4):
3. Demonstrates acceptable past performance history (see 42 CFR 422.502(b); and
4. Meets the minimum enrollment requirements to offer an MA plan (see 1857(b) and 42 CFR 422.503(b)(3).

The application process is open to all health plans that want to participate in the MA program. The application is distinct and separate from the bid process, and CMS issues a determination on the application prior to bid submissions, or before the first Monday in June.

3. 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). This is the case for both the MA initial and SAE applications.

The MA application has several sections that require the applicants to respond to attestations based upon the application type (new MA product or expanding services area for existing MA product) and health plan type (e.g., CCP, MSA, etc.). For example, when an applicant accesses HPMS to complete the application process for a new/initial MA product, the applicant would be guided through the parts of the application that need to be completed for initial applicants. Initial applicants have additional attestations than entities that currently hold contracts with CMS, such as the requirement to complete the two experience and organization history attestations.

Additionally, the application has documents referred to as "templates" which are forms that need to be downloaded from HPMS, completed by the applicant, and uploaded into HPMS.

4. Duplication of Similar Information

The MA application that is accessed via HPMS contains information essential for the operation and implementation of the MA program. It is the only standardized mechanism available to record data from organizations interested in contracting with CMS to offer an MA plan. Where possible, we have modified the standard application to auto-populate information that is captured in prior data collection and resides in HPMS. Otherwise, the form does not duplicate any information currently collected.

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 businesses from being licensed to bear risk needed to serve Medicare enrollees.

6. Less Frequent Collection

This is an annual collection. If this information were collected less frequently, CMS will have no mechanism to allow new applicants an opportunity to demonstrate that applicants meet the CMS requirements and support determination of contract awards or denials.

7. Special Circumstances

Each applicant is required to enter and maintain data in the 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 of information will be used for frequent communications during implementation of the MA organization's program. Applicants are expected to ensure the accuracy of the collected information on an ongoing basis.

8. Federal Register Notice/Outside Consultation

The 30-day notice published in the Federal Register on November 16, 2017 (82 FR 53503).

Number of Comments: CMS received comments from two respondents on the CY 2019 Part C – Medicare Advantage and 1876 Cost Plan Expansion Application. The comments and CMS responses have been included as an attachment to this package. The public comments received did not impact our application requirements or our burden estimates for the CY 2019 MA Part C application. Rather, both respondents expressed support on the removal of uploads from the CY 2019 MA Part C application.

Changes: CMS incorporated dates in the application under section 1.8. CMS considers this change non-substantive as these dates have already been announced to industry through other communications, such as HPMS emails to MA organizations and training sessions.

The 60-day notice published in the Federal Register on August 1, 2017 (82 FR 35782).

Number of Comments: CMS received comments from six respondents on the CY 2019 Part

C – Medicare Advantage and 1876 Cost Plan Expansion Application. The comments and CMS responses have been included in the 30 day PRA package. The public comments received did not impact our burden estimates for the CY 2018 MA Part C application.

Changes: CMS made the non-substantive technical/clarification changes below in the application submitted in the 30 day package in response to comments received through the 60 day comment period.

(1) 3.8 Service Area: Modified attestation 3.8.6 to read to include prosthetics, orthotics, and supplies.
(2) 5.4 D-SNP State Medicaid Agency(ies) Contract(s) - Modified section 5.4 of the application to correct the due date of the State Medicaid Agency contract.
(3) 5.5 I-SNP: Clarified the contracting requirements for in the attestation for I-SNP Individuals Residing only in Institutions.
(4) 5.13.3: Clarified the contracting requirements in the I-SNP Individuals Residing in Both Institutions and the Community Upload Document.

CMS also renamed the RPPO upload document template under section 3.8. This change is non-substantive in nature as it is a change in the naming convention only – CMS did not modify any requirements/language within the upload template.

CMS does not anticipate any impact on the CY 2019 MA application burden estimates based on the technical/clarification changes identified above. CMS believes the changes will assist applicants in enhancing their understanding of the application requirements and process.

In addition to the non-substantial changes, CMS removed three upload requirements from the application in response to comments:

(1) Medicare Part C Compliance Plan (applies to MA-only non-network organizations);
(2) Crosswalk for Part C Compliance Plan (applies to MA-only non-network organizations); and
(3) Executed banking contract (applies to MSA applicants only).

CMS anticipates a slight reduction to the 60-day burden estimate based on the removal of these upload requirements. As discussed in sections 12.2.1 and 15 below, CMS estimates a reduction of 2 hours for MA-only non-network applications (initial and SAE), and a reduction of 2 hours for MSA SAE applications based on the removal of these uploads.

CMS also found an error in the wage calculation at sections 12.1 below, Table 1. CMS inadvertently used the Median labor rate ($31.99 per hour) rather than the Mean labor rate ($33.77 per hour) for the Compliance Officer labor category. CMS corrected this labor rate error in this 30-day package, which increases the cost for the burden calculation by $1.78 per hour (see sections 12.2.2 and 15.2 below).

CMS also identified an error in the formula estimating the total hour burden for SNP SAE applications. As shown in Table 2 in section 12.2.1 below, CMS estimates that 1 SNP SAE application takes 8 hours to complete. CMS estimates a total of 84 SNP applications in CY

2019, which requires a total of 672 hours of annual burden (84*8=672). The 60-day package identified 689 hours for SNP SAE applications. Based on the corrected annual burden calculation, CMS reduced the total annual burden hours for SNP SAE applications by 17 hours.

Finally, CMS corrected the burden calculation for the government under section 14, Table 6 to align with the total burden hours identified in Table 8.

9. Payment/Gift to Respondent

While there are no gifts associated with this collection, the application is required to receive a government contract.

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, confidential or does not include an explanation of why it meets one or more of the Freedom of Information Act 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)

12.1. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). We selected the position of Compliance Officer because this position is a key contact identified by MA plans. CMS typically interacts with the Compliance Officer in matters related to the Part C/MA application after it is submitted to CMS. In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1 – BLS Labor Rate

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage

				($/hr)
Compliance Officers	13-1041	33.77	33.77	67.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because (1) fringe benefits and overhead costs vary significantly from employer to employer, and (2) because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2. Requirements and Associated Burden Estimates

Organizations wishing to provide healthcare services under Part C/MA plans must complete an application, file a bid, and receive final approval from CMS. Existing Part C/MA plans may request to expand their contracted service area by completing the SAE application.

This clearance request is for information collection of the health plan types described in the Background section of this document. The application process is open to all health plans that want to participate in the Part C/MA program.

12.2.1. Time by Application Type

In total, for CY 2019 CMS estimates that it will receive 380 applications. This would amount to 6,246 total annual hours. The estimated burden hours are based on an internal assessment of application materials that are required for submission by the applicants. The application process has two options for applicants that include (1) request for new MA product, or (2) request for expanding the service area of an existing product. If an applicant is applying for a new MA product then the application process would be longer because the required completion of attestations and potential templates that need to be completed will require more effort than an applicant that is requesting to expand their service area via the SAE application.

The chart below describes types of MA product types (as described in the Background section) that can submit applications. The chart is identifying application options in terms of initial applications and SAE applications (NOTE: No new 1876 Cost Plans can submit new applications).

Table 2 – Summary of Annual Burden Hours

Application/ Responses	Initial (CCP, PFFS-Network, MSA-Network, EGWP)	SNP Initial	PFFS (Initial-Non-network)	MSA (Initial Non-Network)	SAE (CCP, PFFS-Network, MSA-Network EGWP)	SNP SAE	PFFS (SAE-Non-network)	MSA (SAE Non-Network)	Direct EGWP	Cost Plan SAE	Summary
Expected Applications/ Responses	50	75	0	1	167	84	2	0	0	1	380
Review Instructions	1.0	1.0	0.5*	0.5	0.5	0.5	.5	.5*	0.5*	0.5	5

Application/ Responses	Initial (CCP, PFFS-Network, MSA-Network, EGWP)	SNP Initial	PFFS (Initial-Non-network)	MSA (Initial Non-Network)	SAE (CCP, PFFS-Network, MSA-Network EGWP)	SNP SAE	PFFS (SAE-Non-network)	MSA (SAE Non-Network)	Direct EGWP	Cost Plan SAE	Summary
(#of hours)											
Complete Application / Proposal (# of hours)	32.0	10.0	32.5*	32.5	17.5	7.5	20.5	23*	0.5*	17.5	138
Estimated # of hours per application / proposal	33	11	33*	33	18	8	21	23.5*	1*	18	143
Annual Burden hours	1,650	825	0	33	3,006	672	42	0	0	18	6,246

*Numbers not included in Summary column given expected workload of 0.

12.2.2. Cost by Application Type

The estimated wage burden for the MA Part C Application is $421,855 based on an estimate wage rate of $67.54/hr wage. The median cost per application is $1,216 (18 hours * $67.54 = $1,216).

Table 3 – Summary of Industry Wage Burden

Application/ Responses	Initial (CCP, PFFS-Network, MSA-Network	SNP Initial	PFFS (Initial-Non-network)	MSA (Initial)	SAE (CCP, PFFS-Network, MSA-Network	SNP SAE	PFFS (SAE-Non-network)	MSA (SAE Non-Network)	Direct EGWP	Cost Plan SAE	Total
Annual burden Hours	1,650	825	0	33	3,006	6872	42	0	0	18	6,246
Per Hour Wages	$67.54	$67.54	$67.54	$67.54	$67.54	$67.54	$67.54	$67.54	$67.54	$67.54	$67.54
Total Wage burden	$111,441	$55,720	$0	$2,228	$203,025	$45,387	$2,837	$0	$0	$1,216	$421,855

12.3. Information Collection Attachments

- Part C -Medicare Advantage and 1876 Cost Plan Expansion Application

Part C -Medicare Advantage and 1876 Cost Plan Expansion Application is submitted electronically via HPMS. CMS provides the paper version of the application in the annual Part C PRA package. The table of contents identifies the key components of the application, which are also summarized below.

(1) **General Information –** This section provides overview of the MA program, description of MA product types, description of HPMS, key due dates related to the application process;

(2) **Instructions –** This section provides general information on how to complete the application process , specific instructions related to certain health plan product types such as EGWPs, SNPs and Cost Plans, and a chart is provided that summarizes the various attestations that are required to be completed by the applicant based upon heath plan type;
(3) **Attestations –** This section has all the attestations that are utilized in the application process by both new MA product applicants and SAE applicants. The required attestations for a new MA product applicant is greater than the number of attestations required for an SAE applicant (See chart below);
(4) **Document Upload Templates –** This section has all the required templates that an applicant may need to complete based upon the type of application and /or health plan type. Currently there are 10 upload documents in this area of the application;
(5) **Appendix 1- Solicitations for Special Needs Plan (SNP) Application –** This section includes the application for applicants that want to offer a SNP. This section would be completed to reflect the type of SNP and population of beneficiaries the applicant wants to serve. Note this section also has some specific attestations and template upload documents that are required for SNP applicants;
(6) **Appendix II- Employer/union – Only Group Waiver Plans (EGWPs) MAO "800" Series –** this section is specific to EGWP applicants only. As noted above for the SNP section this section also has attestations and/or upload documents that are specific to this application type.
(7) **Appendix III- Employer/Union Direct Contract for MA –** This section has specific requirements for this health plan type that the applicant is required to complete.
(8) **Appendix IV-Medicare Cost Plan Service Area Expansion Application –** This section is required for any existing Cost Plan that wants to request an expansion in their service area. Note: no new application for Cost Plans can be submitted to CMS.

HPMS is the primary information collection vehicle through which organizations will communicate with CMS during the application process, bid submission process, ongoing operations of the MA program or Medicare Cost Plan contracts, and reporting and oversight activities.

Table 4 - Chart of Required Attestations by Application Type (non-SNP)

Attestation Section Name	Section #	Initial Applicants				Service Area Expansion				
		CCP	PFFS	RPPO	MSA	CCP	PFFS	RPPO	MSA	COST
Experience and Organizational History	3.1	X	X	X	X					
Administrative Management	3.2	X	X	X	X	X	X	X	X	X
State Licensure	3.3	X	X	X	X	X	X	X	X	X
Program Integrity	3.4	X	X	X	X					
Compliance Plan	3.5	X	X	X	X					
Key Management Staff	3.6	X	X	X	X					
Fiscal Soundness	3.7	X	X	X	X	X	X	X	X	

Attestation Section Name	Section #	Initial Applicants				Service Area Expansion				
		CCP	PFFS	RPPO	MSA	CCP	PFFS	RPPO	MSA	COST
Service Area	3.8	X	X*	X	X*	X	X*	X	X*	X
CMS Provider Participation Contracts & Agreements	3.9	X	X	X	X	X	X	X	X	X
Contracts for Administrative & Management Services	3.10	X	X	X	X	X	X	X	X	X
Quality Improvement Program	3.11	X	X	X	X					
Marketing	3.12	X	X	X	X					
Eligibility, Enrollment, and Disenrollment,	3.13	X	X	X	X					
Working Aged Membership	3.14	X	X	X	X					
Claims	3.15	X	X	X	X					
Communication between MAO and CMS	3.16	X	X	X	X					
Grievances	3.17	X	X	X	X					
Organization Determination and Appeals	3.18	X	X	X	X					
Health Insurance Portability and Accountability Act of 1996 (HIPAA)	3.19	X	X	X	X					
Continuation Area	3.20	X	X	X	X	X	X	X	X	
Part C Application Certification	3.21	X	X	X	X	X	X	X	X	X
Access to Services	3.22		X				X			
Claims Processing	3.23		X		X		X		X	
Payment Provisions	3.24		X		X		X		X	
General Administration/ Management	3.25				X				X	
Past Performance	3.26	X	X	X	X	X	X	X	X	X

**Applies to network PFFS and MSA applicants.*

13. <u>Capital Cost (Maintenance of Capital Costs)</u>

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

To derive average costs, we used data from the Office of Personnel Management's (OPM) 2017 Salary Table for the Washington-Baltimore-Northern Virginia locality (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/17Tables/html/DCB_h.aspx). The following table presents the hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 5 – Occupation-Specific OPM Labor Rates

Occupation	**Grade/Step**	**Wage ($/hr)**	**Fringe Benefit ($/hr)**	**Adjusted Hourly Wage ($/hr)**
Regional Office Account Managers/ Central Office Health Insurance Specialist	13/5	51.48	51.48	102.96
Regional Office Supervisor	14/5	60.83	60.83	121.66

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because (1) fringe benefits and overhead costs vary significantly from employer to employer, and (2) because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Our estimated cost is based on the budgeted amount for application review and estimate wages of key reviewers and support staff. Note the Part C applications are submitted by various MA plans across the country.

The primary review of the Part C applications is the responsibility of Regional Office staff which is usually at the GS 13 level with position type such as RO Account Managers. In addition, the Central Office staff (primarily in the Medicare Drug & Health Plan Contract Administration Group (MCAG) is also required to perform some portions of the Part C application review process which is usually of the GS 13 grade level and position type such as Health Insurance Specialist.

Regional Office Supervisor is requested to confirm the RO staff review decisions. The RO Supervisor is usually at the GS14 grade level.

Table 6 - Annualized Cost to Federal Government

CMS Staff	**Hour per Application**	**Application Volume**	**Total Hours**	**Hourly Rate**	**Projected Costs**	**Cost per Application**
HPMS Systems staff	4	380	1520	$102.96	$156,499	$412
Central Office Health Insurance Specialist	4	380	1520	$102.96	$156,499	$412
Regional	10	380	3800	$102.96	$391,248	$1,030

CMS Staff	Hour per Application	Application Volume	Total Hours	Hourly Rate	Projected Costs	Cost per Application
Office Account Manager						
Regional Office Supervisor	4	380	1520	$121.66	$184,923	$487
Total	**0**	**-**	**0**	**-**	**0**	**0**

15. Program or Burden Changes

There are significant changes to the burden estimates for CY 2019 when compared to CY 2018 (and prior years). These changes are:

- Increased workload volume;
- Changes in labor rates;
- Reductions in application sections and attestations;
- Reductions in application uploads; and
- Removal of burden tied to other OMB control numbers.

Table 7 provides a summary comparison burden estimates between CY 2018 and CY 2019.

Table 7 - Summary of Burden Hours Comparison CY2018 to CY2019

	CY2018 Number of Respondents	CY 2018 Estimates (hours)	CY2018 Annual Burden Hours		CY2019 Number of Respondents	CY 2019 Estimates (hours)	CY2019 Annual Burden Hours
Initial (CCP,PFFS-Network, MSA,-Network, EGWP)	41	50	2,050		50	33	1,650
SNP Initial	43	39	1,677		75	11	825
PFFS non-Network (initials)	1	35	35		0	33	0
MSA non-Network (initials)	0	0	0		1	33	33
SAE (CCP,PFFS-Network, MSA,-Network, EGWP)	113	35	3,955		167	18	3,006
SNP SAE	51	39	1,989		84	8	672
SNP Renewal Only	60	20	1,200		0	0	0
PFFS (SAE- Non-network)	0	0	0		2	21	42
MSA (SAE- Non-network)	0	0	0		0	23.5	0
Direct EGWP	0	1	0		0	1	0

Cost Plan SAE	1	35	35		1	18	18
Total	**310**	**254**	**10,941**		**0**	**0**	**0**

Table 8 below provides additional detail regarding the changes in hours between the CY 2018 and CY 2019 applications. The narrative explanation for the reduction in burden for the attestations and uploads is provided in section 15.3 through 15.5 below.

Table 8: Changes in Burden Across Attestations and Uploads

Application Type	Burden Category	2018		2019		Difference	
		Number	Hours	Number	Hours	Number	Hours
Initial CCP	**Instructions**	N/A	1	N/A	1	N/A	0
	Attestations	118	6	56	6	-62	0
	Uploads	18	43	14	26	-4	-17
	Total	**136**	**50**	**70**	**33**	**66**	**-17**
Initial SNP*	Instructions	N/A	1	N/A	1	N/A	0
	Attestations	40	2	39	2.0	-1	0
	Uploads	9	36	6	8**	-3	-28
	Total	**49**	**39**	**45**	**11**	**-4**	**-28**
Initial PFFS Non-Network	Instructions	N/A	0.5	N/A	1	N/A	+0.5
	Attestations	125	6.5	68	6	-57	-0.5
	Uploads	22	28	18	26	-4	-2
	Total	**147**	**35.0**		**33**	**-61**	**-2**
Initial MSA Non-network	Instructions	N/A	0.5	N/A	1	N/A	+0.5
	Attestations	122	6.5	65	6	-57	-0.5
	Uploads	23	28	19	26	-4	-2
	Total	**145**	**35**	**84**	**33**	**-61**	**-2**
SAE CCP*	Instructions	N/A	0.5	N/A	0.5	N/A	0
	Attestations	28	2.5	26	2.5	-2	0
	Uploads	16	32	12	15	-4	-17
	Total	**44**	**35**	**38**	**18**	**-6**	**-17**
SAE SNP	Instructions	N/A	1	N/A	0.5	N/A	0
	Attestations	22	1.5	21	1.5	-1	0
	Uploads	8	38	5	6**	-3	-32
	Total	**30**	**41**	**26**	**8**	**-4**	**-32**
SAE PFFS Non-Network	Instructions	N/A	0.5	N/A	0.5	N/A	0
	Attestations	39	N/A***	37	1.5	-2	N/A***
	Uploads	17	N/A***	16	19	-1	N/A***
	Total	**56**	**N/A*** **	**53**	**21**	**-3**	**N/A*** **
SAE MSA Non-network	Instructions	N/A	0.5	N/A	0.5	N/A	0
	Attestations	37	N/A***	34	3	-3	N/A***
	Uploads	19	N/A***	17	20	-2	N/A***
	Total	**56**	**N/A*** **	**51**	**23.5**	**-5**	**N/A*** **
SAE Cost	Instructions	N/A	0.5	N/A	0.5	N/A	0

Application Type	Burden Category	2018		2019		Difference	
		Number	Hours	Number	Hours	Number	Hours
Plan	Attestations	20	2.5	19	2.5	-1	0
	Uploads	13	32	7	15	-6	-17
	Total	**33**	**35**	**26**	**18**	**-7**	**-17**

*SNP application attestations and uploads vary slightly by application type.
**Excludes hours accounted for under CMS-10565 (OMB 0938-1296).
***Hours not estimated in prior year PRA packages.

In addition to changes to CMS's burden estimate for industry, we estimate significant reductions in Government burden estimates, which are shown in the table below.

Table 9 - Summary of Government Burden Changes: Hours Per Application

CMS Staff	CY 2018 Hours	CY 2019 Hours	Difference
HPMS Systems staff	4	4	0
Central Office Health Insurance Specialist	4	4	0
Regional Office Account Manager	20	10	-10
Regional Office Specialist HSD Review	20	0	-20
Regional Office Supervisor	4	4	0
SNP Clinical	20	0	-20
Total	**72**	**22**	**-50**

The sections below provide additional detail to support the changes described above.

15.1. Burden Changes Driven by Workload Volumes

For the CY 2018 application cycle, CMS had an approximate 50% increase in MA SAE applications. We believe this increase corresponds with increased industry preparedness regarding CMS's CY 2017 policy change regarding Health Service Delivery tables. For CY 2017 applications, CMS required SAE applicants to submit Health Service Delivery (HSD) tables for the entire provider network (both active and pending counties) that the plan was proposing to expand into with the MA SAE application. Previously, SAE applicants were only required to submit HSD tables for the pending/proposed service areas. In comparing the CY 2018 data to CYs 2015-2016, the CY 2018 application volumes align with historic volumes. CMS also had an approximate increase of 102% in MA initial applications. We believe that this increase was also due to increased industry preparedness regarding CMS's CY 2017 HSD policy change. Based on comparing the CY 2018 data to CYs 2015-2016, the CY 2018 volumes align with historic trends.

Similar to CY 2018 MA application volumes, CMS had an increase in SNP applications in CY 2018 as compared to CY 2017. CMS noted an approximate 88% increase in the number of SNP initial applications submitted in CY 2018 when compared to CY 2017, and an increase of 71% SNP SAE applications. This increase appears to correlate to the increase in MA applications. Organizations seeking SNP applications must first be qualified in the respective SNP service area through the MA application process. Therefore, initial SNP applications often have corresponding initial MA applications. CMS also sees MA SAE

applications submitted when a SNP wants to expand their service area to offer services in a new state or county.

Given the fluctuations between CY 2017 and 2018, CMS estimated the CY 2019 application workloads in Table 9 below by analyzing application receipt data from CYs 2014-2018. CMS calculated the CY 2019 workload by taking the median across these years, but excluded CY 2014 as an outlier since the initial workload volumes were significantly higher than any other year.

Table 10 - Workload Comparison: CY 2018 and CY 2019

Application/ Responses	Initial (CCP, PFFS-Network, MSA-Network EGWP)	Initial with SNP	PFFS (Initial-Non-network)	MSA (Initial Non-Network)	SAE (CCP, PFFS-Network, MSA-Network, EGWP)	SAE with SNP	SNP Renewal	PFFS (SAE-Non-network)	MSA (SAE Non-Network	Direct EGWP	Cost Plan SAE	Summary
CY 2018 Expected Applications/ Responses	41	43	1	0	113	51	60	0	0	0	1	0
CY 2019 Expected Applications/ Responses	50	75	0	1	167	84	0	2	0	0	1	0
Difference	**+9**	**+32**	**-1**	**+1**	**+54**	**+33**	**-60**	**+2**	**0**	**0**	**0**	**+70**

15.2. Burden Changes Drive by Labor Rate Adjustments

For industry burden, we have adjusted our cost estimates by using the most recent BLS wage data, as discussed in section 12.1 above. Similarly, for CMS burden, we have adjusted our cost estimates by using the most recent labor rate calculated by OPM, as discussed in section 14 above.

Table 11 - Labor Rate Comparison: CY 2018 and CY 2019

	CY 2018	**CY 2019**	**Difference**
BLS Hourly Rate	$66.52	0	+$1.02
OMB Hourly Rate – GS-13	$100.08	$102.96	+2.88
OMB Hourly Rate – GS-14	$118.26	$121.66	+2.60

15.3. Burden Changes Driven by Application Section and Attestation Reductions

CMS has reduced the number of attestations from 150 to 88 and removed two MA application sections. Many attestations were combined in order to streamline the application (e.g., CMS consolidated four grievance attestations under one attestation at section 3.18 of the application), while others were removed because they are covered in a separate OMB information collection (e.g., the removal of the Model of Care attestations

and D-SNP attestations). CMS does not estimate a significant reduction based on these changes.

We removed the Essential Hospital MA section because it is unnecessary for the purpose of qualifying an organization to have an MA or Cost Plan contract with CMS. There was no burden associated with this change given that CMS receives less than ten (10) parent organization applications per year that have the Essential Hospital attestation section. CMS also combined the Health Service Delivery (HSD) section with the Service Area section given that both relate to the service area being requested/offered under the application. CMS estimates no change in this burden as the attestations still exist in the application.

The reduction in application attestations also reduces the burden on the Government. We estimate a reduction of two (2) hours for the Regional Office Account Manager.

15.4. Burden Changes Driven by Upload Reductions

CMS removed nine (9) MA upload requirements to streamline the application and four (4) Cost Plan upload requirements.

1. CMS removed the State Licensure renewal documentation requirement for SAE applicants that are already licensed in the State. Specifically, CMS required that organizations submit evidence that the State was renewing their license as shown in the table below, extracted from the CY 2018 application.

Table 12: CY 2018 State Licensure Renewal Requirement

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: STATE LICENSURE	YES	NO	N/A
Applicant has state licensure certificate(s) in each state in which the applicant proposes to offer the managed care product that automatically renews. • If "Yes" the applicant is attesting that all applicable state licensure certificate(s) automatically renews. • If "No", the applicant is attesting that one or more of the state licensure certificate(s) does have a termination date. For states or territories whose license(s) renew after the application submission deadline, applicant agrees to (1) upload, in addition to the current license, a copy of its completed license renewal application or other documentation (e.g., invoice from payment of renewal fee; invoice from prior year for licenses which renew late in the calendar year to show when and how they renewed the previous year; emails between the applicant and the State verifying the process is being followed) to show that the renewal process is being completed in a timely			

RESPOND 'YES' OR 'NO' TO EACH OF THE FOLLOWING STATEMENTS: STATE LICENSURE	YES	NO	N/A
manner, and (2) electronically send a copy of the renewed license to the CMS Regional Office Account Manager promptly upon issuance and no later than the 31st day of December of the current calendar year. Note: If the applicant does not have a license that renews after the application submission deadline, then the applicant should respond "N/A".			

CMS believes that this documentation is unnecessary. As evidence of appropriate state licensure, CMS requires that the State complete a portion of the CMS State Certification form under section 4.4 of the application. This form requires that the state attest that the organization is licensed to offer the MA contract in the counties and states identified on the CMS State Certification form. Therefore, the requirement to submit additional evidence that the State has licensed the organization is unnecessary - CMS believes that the CMS State Certification form is sufficient to demonstrate adequate State licensure.

2. CMS removed the requirement for initial applicants to upload the Key Management Staff Organizational Chart, as CMS would not deny an application based on this information. CMS estimates a reduction of one (1) hour based on this upload removal.

3. CMS removed the upload associated with the Essential Hospital application section. There was no burden associated with this change given that CMS receives less than ten (10) parent organization applications per year that have the Essential Hospital attestation section.

4. CMS removed the Health Service Delivery (HSD) provider table upload. CMS will no longer evaluate HSD tables with the application. Rather, CMS will conduct the review of networks as part of contract operations (see the information collection *Three-Year Network Adequacy Review for Medicare Advantage Organizations CMS-10636, OMB 0938-New).* CMS estimates a reduction of six (6) hours based on the removal of this upload.

5. CMS removed the HSD facility table upload. CMS will no longer evaluate HSD tables with the application. Rather, CMS will conduct the review of networks as part of contract operations (see the information collection *Three-Year Network Adequacy Review for Medicare Advantage Organizations CMS-10636, OMB 0938-New).* CMS estimates a reduction of six (6) hours based on the removal of this upload.

6. CMS removed the Exception Request template upload. CMS will no longer evaluate network adequacy exceptions with the application. Rather, CMS will conduct the

review of networks as part of contract operations (see the information collection *Three-Year Network Adequacy Review for Medicare Advantage Organizations CMS-10636, OMB 0938-New).* CMS estimates a reduction of three (3) hours based on the removal of this upload.

7. In response to the 60-day comment period for this information collection, CMS removed two uploads requirements for MA-only non-network organizations: the compliance plan and the compliance plan matrix. Under attestation 3.5.1, CMS requires that all initial applicants respond yes or no to the following attestation: *Applicant will adhere to all compliance regulations in accordance with but not limited to 42 CFR 422.503(b)(4)(vi).* For MA-only non-network (Private Fee-for-Service and Medical Savings Account) applicants, CMS also required the organization to upload a compliance plan and compliance plan crosswalk. CMS believes that this upload requirement for the MA-only non-network plans is inconsistent with our requirements for other application types. Upon review, all applicants are held to the same standards for the compliance regulations at 42 CFR 422.503(b)(4)(vi). Therefore, CMS believes that an applicant's response to the attestation is sufficient to determine compliance for the purpose of qualifying the organization to offer an MA contract under 42 Subpart K. CMS found the compliance plan and compliance plan matrix created unnecessary burden to non-network MA-only applicants, and removed the uploads from the application. CMS believes that these uploads create unnecessary burden on industry. CMS estimates a reduction of two hours to the PFFS and MSA non-network applications based on the removal of these uploads.

8. In response to the 60-day comment period for this information collection, CMS removed the requirement for MSA organizations to upload an executed banking agreement. Upon review, CMS believes that the MSA applicant's response to attestation 3.25.6 of the application provides the necessary assurances for CMS to determine adherence to our banking requirements. Attestation 3.25.6 requires that the applicant meet the Internal Revenue Service (IRS) requirements and establish policies and procedures with its banking partner that identify services provided by the banking partner, describe how members access fund, describe how spending is tracked, and outline how claims are processed. Therefore, CMS determined that the upload of the contract with the bank to "ensure that ALL CMS direct and/or any delegated contracting requirements are included in the contract" created an unnecessary burden for MSA applicants. There is no reduction in hours because CMS inadvertently excluded the 2 hour estimate from the MSA initial applications in the 60-day package.

For Cost Plan applicants, we removed the Full Financial Risk and Budget Forecast uploads. CMS anticipates a reduction of one (1) hour based on this change.

CMS would also like to note that prior PRA packages included a burden estimate of two (2) hours for SNP SAE applicants to complete the *Health Risk Assessment: Attestation and Uploads* section. However, the *Health Risk Assessment: Attestation and Uploads* section does not apply to SAE applicants. CMS has, therefore, removed three (3) hours of burden associated with the SNP SAE application.

The reduction in application uploads also reduces the burden on the Government. We estimate a reduction of 24 hours for the Regional Office Account Manager.

15.5. Burden Changes Driven by Other OMB Information Collections

There are two sections of the application that are impacted by other OMB information collection efforts:

- Fiscal Soundness Uploads;
- Model of Care: Attestations and Uploads; and
- D-SNP State Medicaid Agency(ies) Contract(s): Attestations and Uploads.

The sections below discuss the impacts to CMS burden estimates to these sections.

15.5.1. Fiscal Soundness Uploads

For SAE CCP applicants, CMS would like to note that prior PRA packages included a full burden estimate of two hours for the financial management uploads. Unlike initial applicants, SAE applicants submit their data in the fiscal soundness module in HPMS. CMS references the information in the fiscal soundness module when reviewing an SAE applicant's attestation response. While CMS request additional information, such as financial projections and/or the most recent audited annual or quarterly financial statements to determine if the applicant is maintaining a fiscally sound operation, CMS estimates that the total hours required to upload this documentation would be less than an initial applicant, or a total burden estimate of one hour. CMS notes that the burden estimate associated with the fiscal soundness module is included under the OMB data collection *The Fiscal Soundness Reporting Requirements*, CMS-906 (OMB: 0938-0469).

15.5.2. Model of Care: Attestations and Uploads

The Affordable Care Act (ACA) PL 111-148 Section 3205(e) and Section 1859(f)(7) of the Social Security Act requires that all MA SNPs be approved by the National Committee for Quality Assurance (NCQA). Organizations submitting an initial SNP are required to respond to an attestation and submit a Model of Care (MOC) as a component of the MA application process. In the CY 2017 application, CMS removed the MOC requirement for SAE applications, estimating a burden reduction of one (1) hour.

The OMB data collection *Initial and Renewal Model of Care Submissions Off-cycle Submission of Summaries of Model of Care Changes (CMS-10565, OMB 0938-1296)* collects the burden associated with both the initial and off-cycle/SNP renewal uploads of the MOC. However, CMS did not remove the burden estimate for the MOC submission for SNP initial applications and operational SNP renewals. CMS is now removing that burden calculation with this estimate. As stated in *CMS-10565 (OMB 0938-1296)* CMS estimates six (6) hours for completing the MOC. Therefore, CMS estimates a reduction of six (6) hours to the SNP initial application and five (5) hours to the SNP SAE applications. CMS also removed the corresponding twenty hours of burden (clinical review) to the Government based on the inclusion of this burden under *CMS-10565 (OMB 0938-1296).*

15.5.3. D-SNP State Medicaid Agency(ies) Contract(s): Attestation and Uploads

An MA organization seeking to offer or currently offering a special needs plan primarily serving beneficiaries eligible for both Medicare and Medicaid (dual eligible SNPs, or D-SNPs) must have a documented relationship with the State Medicaid agency for the State in which the SNP is operating. At minimum, documented arrangements must include the means to (1) verify enrollees' eligibility for both Medicare and Medicaid, (2) identify and share information on Medicaid participation, and (3) identify Medicaid benefits which are not covered by Medicare. D-SNPs must submitted evidence of the State's approval to operate their SNP on a recurring basis, and this action occurs outside of the application process. The burden associated with establishing the document relationship/contract with the state is included in the data collection *Medicare Advantage Program and Supporting Regulations (CMS-R-267, OMB 0938-0753)*. As stated in the data collection, CMS estimates a total of 18 hours to establish a contract with the State.

In CY 2014, CMS also added a contract matrix to the application for D-SNP state contracts. CMS estimated a burden of two hours to complete this matrix.

The review of the state contract and corresponding matrix is not part of the MA or SNP application process. CMS requests and reviews this information in the summer, after the application process concludes. Since CMS does not review this information in the application, CMS is removing the *D-SNP State Medicaid Agency(ies) Contract(s): Attestation and Uploads* section from the application. CMS estimates that this removal will reduce by a total of 22 hours: 18 hours for the State contract, two (2) hours for the contract matrix, and two (2) hours for the letter of good standing.

CMS removed the corresponding four (4) hours from the Regional Office Account Manager burden estimate to the Government based on the inclusion of this burden under *CMS-10565 (OMB 0938-1296).*

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. Note this collection request is submitted annually for the Part C application.

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.