Supporting Statement for Applications for
Prescription Drug Plans, Medicare Advantage Organizations, Cost Plans, Employer Group Waiver Plans, and Service Area Expansions to
Provide Part D Benefits as defined in
Part 423 of 42 C.F.R.

A. Background

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the voluntary Prescription Drug Benefit Program ("Part D").

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

B. Justification

1. Need and Legal Basis

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled "*Application Procedures and Contracts with PDP Sponsors.*"

The Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965. The addition of outpatient drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. Effective January 1, 2006, the Part D program establishes an optional prescription drug benefit for individuals who are entitled to Medicare Part A or enrolled in Part B.

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 coverage (MA-PD plans). PDPs must offer a

basic drug benefit. Medicare Advantage Coordinated Care Plans (MA-CCPs) must offer either 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 a Part D benefit. Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Plans may also provide a Part D benefit. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Applicants may offer either a PDP or MA-PD plan with a service area covering the nation (i.e., offering a plan in every region) or covering a limited number of regions. MA-PD and Cost Plan applicants may offer local plans.

There are 34 PDP regions and 26 MA regions in which PDPs or regional MA-PDs may be offered respectively. The MMA requires that each region have at least two Medicare prescription drug plans from which to choose, and at least one of those must be a PDP. In regions where the required minimum number of plan choices is not available, the MMA requires CMS to contract with Fallback Plans. Fallback Plans must satisfy the same requirements as PDPs, but will receive reimbursement from CMS on a cost rather than a risk basis.

Requirements for contracting with Part D Sponsors are defined in Part 423 of 42 C.F.R.

This clearance request is for the information collected to insure applicant compliance with CMS requirements and to gather data used to support determination of contract awards.

2. Information Users

The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, and EGWP Plan applicants. The collected information will be used by CMS to: (1) insure that applicants meet CMS requirements, (2) support the determination of contract awards.

Participation in the Part D program 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

CMS has worked to improve the application process from prior years. As a result, applicants are asked to complete the application through CMS' Health Plan Management System (HPMS). This will entail clicking checkboxes and completing some minor text fields electronically. Applicants are asked to provide a total of two (2) hard copies of the supporting documentation.

Technology is used in the collection, processing and storage of the data used in the application and bidding process. The paperwork burden is reduced by requesting electronic copies of the applicant submissions for review by specific CMS program areas. Specifically the Applicant must submit the written application and supporting documentation electronically using CD-ROMs. This will support the review of the application by different CMS components.

4. Duplication of Similar Information

This form does not duplicate any information currently collected. It contains information essential to the operation and implementation of The Medicare Prescription Drug Benefit program. It is the only standardized mechanism available to record data from organizations interested in contracting with CMS.

As possible, for Medicare Advantage Organizations (MAOs) and Cost Plans, we have modified the standard PDP application to accommodate information that is captured in prior data collection. Removing the duplication of data collection decreased the estimated hour burden for MAO and Cost Plan applicants by an estimated 11 hours per applicant. Five matrices are attached that summarize duplicative data collection or areas where requirements were waived in the Medicare Advantage, Section 1876 Cost Plan, Employer Waiver Group Plan, and Service Area Expansion applications (See attachments One through Four).

5. Small Businesses

The collection of information will have a minimal impact on small businesses or other small organizational entities since the applicants must possess an insurance license and be able to accept risk. Generally, state statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the pharmacy benefits required in the Medicare Prescription Drug Benefit Program.

6. Less Frequent Collection

If this information is not collected CMS will have no mechanism to: (1) insure that applicants meet CMS requirements, (2) to support determination of contract awards.

7. Special Circumstances

Each applicant is required to enter and maintain requested data in the CMS Health Plan Management System (HPMS). Prompt entry and ongoing maintenance of these data in HPMS will facilitate the tracking of the applicant's application throughout the review process. If the applicant is awarded a contract after negotiation, the collected information will be used for frequent communications during implementation of the Prescription Drug Benefit Program. Applicants are expected to insure the accuracy of the collected information on an ongoing basis.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice published March 23, 2007.

The final rule was published January 28, 2005.

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 exceptions specified in 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 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)

Tables 1 and 2 provide an estimate of the total hours and costs by activity related to the application process. Our estimates include the review of application instructions, and completion of the application. Overall, the estimated hour burden for completion of the prescription drug applications is 28,122 hours. The overall estimated hour burden has actually increased from the 5,316 hours estimated for the emergency approval that CMS received in January. The increase is the direct result of the large number of Notices of Intent to apply for the 2008 contract year which were received by CMS in late December 2006. CMS originally estimated 151 Part D applicants for the 2008 contract year and instead received 857 notices of intent to apply. One reason for the increased interest in 2008 applicants is due to the statute allowing for local preferred provider organizations to enter the Part D market for the first time in 2008 (see Section 15 for further detail). As a result of the increase in the number of estimated applicants, the estimated wage burden for the Prescription Drug Applications is $1,546,696, which has increased from the $292,366 approved for the emergency clearance. Estimates of overall wages were calculated by assuming a $55.00 per hour wage rate.

As discussed in Item 4 above, the paperwork burden is reduced for MA-PD, Cost Plan, EGWP Plan, and SAE applicants by excluding the collection of information that is collected in other CMS programs. Attachments 1-4 provide detail on the sections of the PDP application that are not included in other applications.

Generally, a large portion of the applications are simple attestations and require minimal documentation (i.e., check Yes or No). These attestations will all be collected electronically this year within HPMS and reduces the burden hours of completing each of these sections from one hour to 15 minutes. The most substantial portion of the application is documentation of pharmacy networks for use by Medicare beneficiaries. We estimate that completion of the entire pharmacy network section of the applications requires 65% of the total 28,122 hours or 18,279 hours. The estimated number of hours required to document pharmacy networks for each type of applicant is 21 hours. Table 3 provides a summary of the estimated number of hours to complete each type of Part D application for 2008 based on the Notices of Intent to apply received in December compared to the original emergency justification request for 2008.

Table 1

Summary of Hour Burden by Type of Applicant and Process

	Hours Estimate							
Activity (expected volume)	**PDP** 34	**MA-PD** 510	**Cost Plans** 0	**Direct EGWP** 3	**800 Series Only EGWP** 10	**EGWP** 77	**SAE** 250	**Total Hours**
Review of Instructions	68	1,020	0	6	20	154	250	1518
Complete Application	1,343	18,615	0	112	366	231	5,938	26,604
Total All	**1,411**	**19,635**	**0**	**118**	**386**	**385**	**6,188**	**28,122**

Table 2

Summary of Wage Burden by Type of Applicant and Process

	Wages Estimate							
Activity	**PDP**	**MA-PD**	**Cost Plans**	**Direct EGWP**	**800 Series Only EGWP**	**EGWP**	**SAE**	**Total Wages**
Review of Instructions	3,740	56,100	0	330	1,100	8,470	13,750	83,490
Complete Application	73,865	1,023,825	0	6,146	20,103	12,705	326,563	1,463,206
Total All	77,605	1,079,925	0	6,476	21,203	21,175	340,313	1,546,696

Table 3

Summary of Burden Hours by Type of Application

Type of Part D Application	2008 (hours) Emergency justification estimates	2008 (hours) Notices of Intent to Apply estimates
PDP	42.75	41.50
MA-PD	40.75	39.50
Cost Plan	40.25	39.00
Direct EGWP	40.50	39.25
800 Series Only EGWP	40.50	39.25
EGWP	6.00	5.00
SAE	25.75	25.00

13. Capital Costs (Maintenance of Capital Costs)

We do not anticipate that additional capital costs are incurred. CMS requirements do not require the acquisition of new systems or the development of new technology to complete the application. CMS anticipates that all qualified applicants maintain systems for maintenance of their pharmacy network contracts, pharmacy benefits, and financial records.

System requirements for submitting HPMS applicant information are minimal. PDPs will need the following to access HPMS: (1) Internet **or** Medicare Data Communications Network (MDCN) connectivity, (2) use of a Microsoft Internet Explorer web browser (version 5.1 or higher) with 128-bit encryption, and (3) a CMS-issued user ID and password with access rights to HPMS for each user within the PDP organization who will require such access. CMS anticipates that all qualified applicants meet these systems requirements and will not incur additional capital costs.

14. Cost to Federal Government

The estimated cost for preparation, review, and evaluation of the prescription drug applications is $100,800.00. This estimated cost is based on the budgeted amount for application review and support and is inclusive of wages, operational expenses (equipment, overhead, printing, and support staff), and other expenses incurred in the application effort.

15. Program or Burden Changes

Several things have occurred since the emergency approval of the 2008 Part D applications. Subsequent to OMB granting the emergency approval of the Part D applications, the Part C applications were reviewed by OMB. As a result of this review, the major program change that has occurred in Part D applications was that CMS removed several attestations related to HIPAA, bids and privacy to address OMB concerns. This program change slightly reduced the number of burden hours it would take an applicant to complete a Part D application. When these attestations were removed, CMS issued public notices to the pending applicants and reposted the Part D solicitations. In December, CMS requested all 2008 pending applicants to submit a Notice of Intent to Apply. These notices allowed CMS to better monitor potential workload and ensure that each applicant would have a pending contract number to complete the HPMS portion of the Part D application.

The large amount of Notices of Intent to apply is the main reason for the burden change. Part of the reason for the large increase in estimated applicants is related to a provision in the Medicare Modernization Act. The statute prohibited local preferred provider organizations from participating in the Part D program for 2006 and 2007. As a result, the 2008 contract year is the first time that these types of organizations may apply to participate as Part D sponsors.

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

This collection of information applies to 2008 only. A separate (revised) document will be developed for subsequent years.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There have been no statistical methods employed in this collection.

Attachment 1
Summary of Medicare Part D Regulatory Requirements Waived for
Medicare Advantage Prescription Drug (MA-PD) Applicants

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
42 CFR 423 Subpart I, excepting 42 CFR 423.440 **(which concerns Federal preemption of State law and prohibition of State premium taxes**)	Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards.	Duplicative of MA Organization requirements for licensure and solvency under 42 CFR 422.6 (i); 42 CFR 422.400; and 42 CFR 422.501).
42 CFR 423.153(b) &(d) ***Waiver applies to MA-PFFS only***	Utilization Management - Applicant must have a cost effective utilization management system.	Waiver stated in regulations at 42 CFR §423.153 (e) excuses MA PFFS organizations from meeting the utilization management requirements specified in 423.153 (b).
42 CFR 423.153(b) &(d) ***Waiver applies to MA-PFFS only***	Medication Therapy Management Program – Applicant must have a program to manage medication therapy to optimize outcomes, reduce adverse drug interactions.	Waiver stated in regulations at 42 CFR §423.153 (e) excuses MA PFFS organizations from meeting Medication Therapy Management Program requirements specified in 42 CFR §423.155.
42 CFR 423.112 (a)	Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region.	Conflicts with MA regulations (42 CFR 422.2) that allow MA organizations to offer local MA plans (i.e., plans that serve less than an entire state).
42 CFR 423.120 (a) (7)(i) ***Waiver applies only to MA-PDs that operate their own pharmacies***	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards.	Waiver stated in regulations at 42 CFR 423.120(a)(7) (i) excuses from the CMS convenient access standards those MA organizations that administer their Part D benefit through pharmacies owned by the MA organization if that organization's pharmacy network access is comparable to the CMS convenient access standards .
42 CFR 423.120(a) (7)(ii) ***Waiver applies to MA-PFFS plan that provides access through all pharmacies.***	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS convenient access standards	Waiver stated in regulations at 42 CFR §423.120 (a) (7) (ii). excuses from the CMS convenient access standards those MA-PFFS organizations that offer a qualified prescription drug coverage, and provide plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of the requirements for qualified prescription drug coverage.
42 CFR 423.120(a) (8)(i) **Waiver applies only to MA-PDs that operate their own pharmacies**	Pharmacy Network – Applicant must offer its Part D benefit through any willing pharmacy that agrees to meet reasonable and relevant standard network terms and conditions.	Waiver promotes the coordination of Parts C and D benefits. Excuses from CMS any willing pharmacy requirement those MA organizations that administer their Part D benefit through pharmacies owned by the MA organization and dispense at least 98% of all prescriptions through pharmacies

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
		owned and operated by Applicant.
42CFR 423.34 42 CFR 423.36 42 CFR 423.38 42 CFR 423.42 42 CFR 423.44	Enrollment and Eligibility – Applicant agrees to accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements.	Duplicative of MA requirements under 42 CFR 422 Subpart B - Eligibility, Election, and Enrollment. MA organizations will conduct enrollment and determine eligibility consistent with MA program requirements. These requirements mirror those stated in the Part D regulation
42 CFR 423.514(b) and (c)	Reporting Requirements – Applicant must report information concerning significant business transactions.	Duplicative of MA requirements for reporting significant transactions under 42 CFR 422.500 and 42 CFR 422.516(b) and (c) and requirements for providing annual financial statements.
42 CFR 423.514(e)	Reporting Requirements – Applicant must notify CMS of any loans or any other special arrangements it makes with contractors, subcontractors, and related entities.	Duplicative of MA requirement for reporting loans or special arrangements under 42 CFR 422.516(e).
42 CFR 423.512	Experience and Capabilities – Applicant must reach the minimum enrollment standard within the first year it offers a Part D benefit.	Conflicts with MA regulation that permits three years to achieve the minimum enrollment level.

Attachment 2

Summary of PDP Application Requirements Fulfilled under Part C for Cost Plan Prescription Drug Applicants

Part D Regulation Waived	Regulatory Requirement(s) Description	Basis and Rationale
42 CFR 423 Subpart I, excepting 42 CFR 423.440 (which concerns Federal preemption of State law and prohibition of State premium taxes)	Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards.	Duplicative of Cost Plan requirements for licensure and solvency under 42 CFR §417.404 (General requirements) and 42 CFR 417.407 (Requirements for a Competitive Medical Plan (CMP)). All Cost Plans are State licensed in some manner or have authority to offer a Cost Plan in all states in which they operate.
42 CFR 423.112 (a)	Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region.	Conflicts with Cost Plan regulations (42 CFR 417.1) defining the service area for HMOs and CMPs offering Medicare reasonable Cost Plans.
42 CFR 423.120(a)(3) ***Waiver applies only to Cost contractors that operate their own pharmacies***	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS standards for convenient access.	Waiver stated in regulations at 42 CFR 423.120(a)(7)(i) excuses from the CMS standards for convenient access those Cost contractors that administer their Part D benefit through pharmacies owned by the Cost contractor if that organization's pharmacy network access is comparable to the CMS convenient access standards . *{Note: Applicants will be expected to provide comparable information in the application for organizational pharmacies}*
42 CFR 423.120(a)(8)(i) ***Waiver applies only to Cost contractors that operate their own pharmacies***	Pharmacy Network – Applicant must offer its Part D benefit through any willing pharmacy that agrees to meet reasonable and relevant standard network terms and conditions.	Waiver promotes the coordination of Parts C and D benefits. Excuses from CMS any willing pharmacy requirement those Cost contractors that administer their Part D benefit through pharmacies owned by the Cost contractor and dispense at least 98% of all prescriptions through pharmacies owned and operated by Applicant.

Attachment 3
Summary of PDP Application Requirements Waived for
Direct Employer Group Waiver Plan (Direct EGWP) Applicants

Part D Regulation	PDP Application Section	Application Requirement(s) Description	Basis and Rationale
42 CFR 423.104(b)	**3.5 A 3,4,5,7**	Enrollment- Applicant will enroll all Medicare beneficiaries in the area that they reside.	Direct EGWPs are waived of these requirements as they only enroll their retirees and they cover retirees nationwide.
42 CFR 423.120(a)	**3.4.1 A**	Pharmacy Access- Applicant agrees to meet the standards of convenient access defined in 42 CFR 423.120(a)	Applicant is only providing coverage to its retirees. Applicant will sign an attestation that the networks are sufficient to meet the needs of its retiree population, and CMS reserves the right to review the adequacy of the networks and potentially require expanded access.
42 CFR 423.50(a); 423.128	**3.10 A 1 (modified), 2 (If applicant is eligible for the waiver)**	Disclosure and Dissemination Requirements- Applicant will be required to comply with the Regulations outlined in 42 CFR 423.50(a) and 423.128.	Those Applicants that are subject to alternative standard (e.g., ERISA) do not need to comply with these standards as they are duplicative. All other applicants not subject to alternative disclosure requirements must comply with the Medicare Guidelines as outlined under the regulations.
42 CFR 423.112 (a)	**3.3 A 1, 2 3.5 A 3**	Service Area Requirements- Applicant will offer a PDP in at least one PDP region and will provide coverage to the entire region.	Direct EGWPs are not selling a product in the individual market, and have a national service area to cover retirees wherever they may reside.
42 CFR 423.401(a)(1); 42 CFR 23.504(b)(2); 42 CFR 423.420	**3.1.4 A, B, C, D; Appendix IX**	Licensure and Solvency-A PDP generally must be licensed in at least one state as a risk-bearing entity to contract with CMS. If waived, certain financial solvency standards must be met	Direct EGWPs are not insurance companies—they are employers and are providing only providing coverage—they are not selling a product. Direct EGWPs must submit necessary documentation that demonstrates they meet certain financial solvency standards and fiscal soundness commensurate with financial risk as outlined in Appendix VII of the Direct EGWP solicitation.
42 CFR 423.504(b)(4)(i)-(iii); 42 CFR 423.504(b)(iv)-(v); 1860D-41(a)(13)	**3.1.2 A (2, 7, 8); 3.1.2 A (4, 5, 6) (if eligible for waiver).**	Management and Operation Requirements: Applicant must comply with Medicare Management and administrative arrangements.	Direct EGWPs may be subject to other standards governing management and operations and it would be duplicative to impose Medicare standards on Applicant. Applicant must attest it is subject to ERISA or fiduciary requirements. Sections 3.1.2 A2, A7, and A8 will be met addressed in Appendix VII of the Direct EGWP solicitation. If the entity is not subject to other standards governing management and operations, then the

Part D Regulation	PDP Application Section	Application Requirement(s) Description	Basis and Rationale
			entity must comply with Medicare management and operation policies.
42 CFR 423.514 (a)	**3.13 A21**	Public Reporting- The entity will submit pricing and pharmacy network information to be publicly reported to Medicare.gov.	These entities are not selling a productive in the individual market and their information would be more confusing to the public if reported as individuals cannot enroll in these plans.

Attachment 4
Summary of PDP Application Requirements Needed for
Service Area Expansion Applicants

Note: SEA Applicants are currently under contract with CMS for the Part D benefit. CMS is only requesting the sections identified below for the service area not under contract with CMS for 2006. The remaining application sections are reviewed through the contract renewal process.	
Application Section	**Rationale**
Contract Number	SAE will be expanding regions covered under an existing CMS contract number.
Service Area	Provided to identify the new service area/region that Part D sponsor is seeking to cover.
Licensure and Solvency	For those Part D sponsors operating a PDP, state licensure and solvency requirements will need to be met for the new service area/region.
Pharmacy Access	Part D sponsors will need to meet the pharmacy access requirements for the new service area/region.
Certification	Part D sponsors will need to have an authorized representative submit a signed certification to ensure that submission meets CMS requirements.