Supporting Statement for Applications for
Prescription Drug Plans, Medicare Advantage Organizations, Cost Plans, PACE, 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 established 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 ensure 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, PACE, and EGWP Plan applicants. The collected information will be used by CMS to: (1) ensure 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, completing some minor text fields electronically, and uploading certain supporting documentation. Applicants are not asked to provide any documentation by CD or hardcopy.

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 entire application and supporting documentation through HPMS.

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, PACE, and Service Area Expansion applications (See attachments One through Five).

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) ensure that applicants meet CMS requirements, (2) to support determination of contract awards.

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 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 ensure the accuracy of the collected information on an ongoing basis.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on July 13, 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 11,890 hours. The overall estimated hour burden has decreased from the emergency approval CMS received in January 2007 for the 2008 applications from 28,122 hours to 11,890 hours. CMS had increased the expected hours for the 2008 applications due to the large number of Notices of Intent to apply that were received for the 2008 contract year; however, the volume of organizations that actually submitted applications for 2008 was quite less. As a result, CMS has estimated the number of 2009 applicants based on the actual numbers received for 2008. The estimated wage burden for the Prescription Drug Applications is $653,882 which is a decrease from the $1,546,696 estimate for the 2008 applications. 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, PACE,

EGWP Plan, and SAE applicants by excluding the collection of information that is collected in other CMS programs. Attachments 1-5 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 within HPMS and reduces the burden hours of completing each of these sections from one hour to 15 minutes. In addition, the ability to complete the entire application in HPMS reduces burden hours for producing CDs and hard copy materials. 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 11,890 hours or 7,738 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 2009 based on the number of 2008 applications received by CMS.

Table 1

Summary of Hour Burden by Type of Applicant and Process

	Hours Estimate								
Activity (expected volume)	**PDP** 10	**MA-PD** 160	**Cost Plans** 0	**PACE** 3	**Direct EGWP** 3	**800 Series Only EGWP** 10	**EGWP** 77	**SAE** 190	**Total Hours**
Review of Instructions	20	320	0	6	6	20	154	190	716
Complete Application	399	5,680	0	39	106	353	154	4,443	11,174
Total All	**419**	**6,000**	**0**	**45**	**112**	**373**	**308**	**4,633**	**11,890**

Table 2

Summary of Wage Burden by Type of Applicant and Process

	Wages Estimate								
Activity	**PDP**	**MA-PD**	**Cost Plans**	**PACE**	**Direct EGWP**	**800 Series Only EGWP**	**EGWP**	**SAE**	**Total Wages**
Review of Instructions	1,100	17,600	0	330	330	1,100	8,470	10,450	39,380
Complete Application	21,945	312,400	0	2,145	5,816	19,388	8,470	244,338	614,502
Total All	23,045	330,000	0	2,475	6,146	20,488	16,940	254,788	653,882

Table 3

Summary of Burden Hours by Type of Application

Type of Part D Application	2008 (hours) Final Emergency justification estimates	2009 (hours) Estimates
PDP	41.50	39.50
MA-PD	39.50	37.50
Cost Plan	39.00	37.25
PACE	13.20	15
Direct EGWP	39.25	37.25
800 Series Only EGWP	39.25	37.25
EGWP	5.00	4
SAE	25.00	24

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

There have been minor changes since the 60-day posting of the 2009 Draft Part D applications and the final approval of the 2008 Part D applications. Based mainly off of comments received, CMS either consolidated or deleted some attestations that were either repetitive or would have led to increasing the burden on Part D sponsors after the application process (increase new reporting requirements). Additionally, new instructions were added to the 2009 Draft Part D applications that provide applicants with the option to use two different software vendors to generate certain documentation related to the Part D applications. In prior years there has only been one software vendor available to produce pharmacy access reports. As a result of a comment received, CMS was

made aware of a new vendor that produces the same quality pharmacy access reports.

Prior to the final approval of the 2008 Part D applications, CMS issued the 2008 Part D Call Letter and provided further additional guidance through the release of several chapters of the Medicare Prescription Drug Benefit Manual. These documents should improve applicants' ability to assess their own eligibility and fit for the Medicare Part D program. CMS has continued to invest resources to streamline and automate the Part D application process. For the 2008 contract year, applicants completed a portion of the application electronically and for the first time in 2009 the entire application will be submitted electronically. This will reduce the paperwork and burden hours significantly for applicants. Since the employer group applications are based off of the general Part D applications for the 2009 contract year, CMS will consolidate the direct employer group applications into the general Part D applications. As a result there will be less stand-alone employer group applications in the overall Paperwork Reduction Act package from 2008. Lastly, CMS revised the burden hours for the 2008 contract year based on the large number of notices of intent to apply that were received in November 2007. While this provided a basis to determine workload, the actual amount of applications received by CMS was much lower. As a result, CMS is not expecting to receive the same volume as anticipated for the 2008 contract year.

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

This collection of information applies to 2009 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 Part D Application Requirements Waived or Modified for Employer/Union-Only Group Waiver Plan (EGWP) Applicants

Part D Regulation	Type of EGWP Applicant Waiver or Modification Applies To	Application Requirement(s) Description	Waiver/Modification
42 CFR 423.104(b)	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Enrollment: Applicant will permit the enrollment of all Medicare beneficiaries that reside in the service area.	The requirement to enroll all beneficiaries residing in service area is waived for all EGWP applicants. Enrollment in these plans is restricted to the employer/union plan sponsor's retirees.
42 CFR 423.120(a)(1)	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Retail Pharmacy Access: Applicant agrees to meet the "TRICARE" retail pharmacy access standards defined in 42 CFR 423.120(a).	EGWP applicants are required to submit retail pharmacy access for review in the same manner as individual plans but are not held to the same "TRICARE" measurement standards as individual plans. EGWPs are required to attest that their retail networks are sufficient to meet the needs of its retiree population, and that CMS reserves the right to review the adequacy of the networks and potentially require expanded access.
42 CFR 423.50(a)	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Prior Review and Approval of Dissemination Materials: Applicant must submit all marketing/dissemination materials for CMS prior review and approval.	EGWP applicants are waived from the requirement for prior review and approval requirements of beneficiary dissemination materials. EGWPs must provide informational copies of dissemination materials to CMS at time of use in accordance with the specific requirements that apply to these applicants.
42 CFR 423.128; Medicare Marketing Guidelines	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Timing of Certain Dissemination Materials: Annual Notice of Change (ANOC) Summary of Benefits (SB), and Formulary Materials must be mailed to beneficiaries by October 31st of each year (15 days before annual coordinated election period).	These rules have been modified for all EGWP applicants when the employer or union sponsor has an open enrollment period that does not correspond with Medicare's annual open coordinated election period. In these cases, the materials must be sent at least 15 days before the beginning of the employer or union sponsor's annual open enrollment period.

Part D Regulation	Type of EGWP Applicant Waiver or Modification Applies To	Application Requirement(s) Description	Waiver/Modification
42 CFR 423.128(d)(2)	"800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Internet Website: Applicants are required to provide specific Information via an Internet website.	The requirement to post "800 Series" plan information on the Applicant's internet plan website has been waived. These plans are not open to general enrollment and the posting of this information usually takes place on a separate website or on a website provided by the employer or union group plan sponsor.
42 CFR 423.48	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	CMS Reporting Requirements Re: Information About Part D: Applicants are required to submit certain information to CMS such as pricing and pharmacy network information to be publicly reported to beneficiaries on www.medicare.gov to make informed enrollment decisions.	These requirements have been waived for all EGWPs. These plans are not open to general enrollment and thus this information would be inapplicable and confusing to Medicare beneficiaries.
42 CFR 423.265	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Part D Bid Submission: All applicants are required to submit a Part D bid and to receive approval from CMS for the bid.	The requirement to submit a Part D bid (i.e., Bid Pricing Tool) has been waived for all Part D EGWPs beginning in 2008.
42 CFR 423.293(a)	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Premium Withholding Requirements: All applicants are required to allow beneficiaries to request premium withholding from their Social Security check.	The requirement to offer premium withholding to beneficiaries has been waived for all EGWPs. This option is not available to any EGWP enrollees.
42 CFR 423.34	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Auto and Facilitated Enrollment Requirements: Part D applicants must accept auto and facilitated enrollments.	These requirements are waived for all EGWPs. These plans do not receive auto or facilitated enrollments.

Part D Regulation	Type of EGWP Applicant Waiver or Modification Applies To	Application Requirement(s) Description	Waiver/Modification
Medicare Marketing Guidelines	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Part D Beneficiary Customer Service Call Center Requirements: Applicants are required to comply with certain beneficiary customer service call center hour and performance requirements.	These service call center hours and performance requirements are waived for all EGWP applicants. EGWPs must provide beneficiary customer call center services during normal business hours. CMS may require expanded call center hours in the event of beneficiary complaints or for other reasons to ensure hours are sufficient to meet the needs of beneficiaries.
42 CFR 423.401(a)(1); 423.504(b)(2); 422.400(a); 422.503(b)(2)	Direct Contract PDP Direct Contract MA-PD	Licensure and Financial Solvency: Applicant must be licensed under State law as a risk bearing entity eligible to offer health benefits coverage in each State in which the benefits are offered.	Direct Contract EGWPs are not required to be licensed as they are providing benefits solely to their retirees. However, in exchange for the waiver of licensing requirements, Direct Contract EGWPs are required to meet certain ongoing Part C and/or Part D financial solvency and capital adequacy requirements. These requirements demonstrate that the entity's fiscal soundness is commensurate with its financial risk and that through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered.
42 CFR 423.504(b)(4)(i)-(iii)	Direct Contract PDP Direct Contract MA-PD	Administrative and Management Requirements: Applicant must comply with certain administrative and management requirements.	These requirements have been waived for all Direct Contract EGWPs that meet certain requirements. A waiver applies when the Applicant is subject to other administrative and management requirements such as ERISA fiduciary standards or other similar state or federal standards.

Part D Regulation	Type of EGWP Applicant Waiver or Modification Applies To	Application Requirement(s) Description	Waiver/Modification
42 CFR 423.514(a)	Direct Contract PDP Direct Contract MA-PD	Reporting Requirements to the Public and Enrollees: Applicants are required to report certain information to CMS, to the public and to enrollees (such as the cost of their operations or financial statements).	This requirement to report to the public and enrollees is waived for Direct Contract EGWPs under certain circumstances. To avoid imposing additional and possible conflicting public disclosure obligations, CMS modified these reporting requirements for Direct EGWPs to allow information to be reported to enrollees and to the general public to the extent required by other law (e.g., ERISA or securities laws) or by contract.
42 CFR 423.4	Direct Contract PDP	Non-Governmental Entity Requirement: Governmental entities are not permitted to be PDP Sponsors	This prohibition is waived for Direct Contract PDPs so that governmental entities (state and local governments and municipalities) may apply to sponsor a PDP for their retirees.

Attachment 4

Summary of PDP Application Requirements Waived for PACE Prescription Drug Applicants

PART D WAIVERS

CMS is authorized to grant waivers of Part D program requirements where such a requirement conflicts with or duplicates a PACE requirement, or where granting such a waiver would improve the PACE Organization's coordination of PACE and Part D benefits. The following waivers are in effect for all PACE organizations.

Summary of Medicare Part D Regulatory Requirements Waived for PACE Organizations

Part D Regulation	**Regulatory Requirement(s) Description**
423.44	Involuntary disenrollment
423.48	Information about Part D
423.50	Approval of marketing materials and enrollment forms
423.104(g)(1)	Access to negotiated prices
423.112	Establishment of PDP service areas
423.120(a)	Access to covered Part D drugs
423.120(c)	Use of standardized technology
423.124	Out-of-network access to covered Part D drugs at out-of-network pharmacies
423.128	Dissemination of Part D plan information
423.132	Public disclosure of pharmaceutical prices for equivalent drugs
423.136	Privacy, confidentiality, and accuracy of enrollee records
423.153(a)-423.153(d)	Drug utilization management, quality assurance, and medication therapy management programs (MTMPs)
423.156	Consumer satisfaction surveys
423.162	Quality Improvement organization activities
423.265(b) ***Note: Automatic waiver applies to new or potential organizations that are not operational by the June deadline.*** ***Those organizations with effective program agreements must submit a Part D waiver request in the event they are unable to meet the June deadline.***	Part D bid submission deadline
423.401(a)(1)	Licensure
423.420	Solvency standards for non-licensed entities
423.462	Medicare secondary payer procedures
423.464(c)	Coordination of benefits and user fees
423.464(f)(2) and 423.464(f)(4)	Coordination with other prescription drug coverage
423.502(b)(1)(i-ii)	Documentation of State licensure or Federal waiver
423.504(b)(2-3), 423.504(b)(4)(i-v) and (vi)(A-E), and 423.504(d) ***Note: Organizations are required to abide by 423.504(b)(4)(vi)(F-H), 423.504(b)(5), 423.504(c), and 423.504(e)***	Conditions necessary to contract as a Part D plan sponsor
423.505(a-c) and 423.505(e-i) ***Note: Organizations are required to abide by 423.505(d and j)***	Contract provisions

Part D Regulation	**Regulatory Requirement(s)** **Description**
423.505(k)(6) ***Note: Organizations are required to abide by 423.505(k)(1-5)***	Certification for purposes of price compare
423.506(a)-(b) ***Note: Organizations are required to abide by 423.506(c)-(e)***	Effective date and term of contract
423.512 – 423.514	Contracting terms
423.551-423.552	Change of ownership or leasing of facilities during term of contract
423.560-423.638	Grievances, coverage determinations, and appeals
N/A	A PDP sponsor is required to be a nongovernmental entity

Attachment 5
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.