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"). The MMA was amended on July 15, 2008 by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

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."*

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 PDPs that offer drug-only coverage, or through 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.

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 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' online 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 offset 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 electronically 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 decreases the estimated hour burden for MAO and Cost Plan applicants by an estimated 2 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 new or expanding 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. Applicants are expected to ensure the accuracy of the collected information on an ongoing basis.

8. Federal Register Notice/Outside Consultation

The final rule was published January 28, 2005. Below is a table that identifies each of the subsequent publications of regulations related to the Part D program.

Additional Part D Regulations Since 2006

Reference	Title	Date Published
CMS-4124-FC	Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes	December 5, 2007
CMS-0016-F and CMS-0018-F	Medicare Programs; Standards for E-Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)	April 7, 2008
CMS-4133-F	Medicare Program; Weighting Methodology Used to Calculate the Low-Income Benchmark Amount	April 3, 2008, corrected April 17, 2008
CMS-4130-F	Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit	April 15, 2008
CMS-4119-F	Medicare Program; Medicare Part D Claims Data	May 28, 2008
CMS-4138-IFC	Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs	September 18, 2008
CMS-4131-F	Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions	September 18, 2008
CMS-4138-IFC2	Medicare Program; Revision to the Medicare Advantage and Prescription Drug Benefit Programs: Clarification of Compensation Plans	November 10, 2008
CMS-4131-FC	Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions	January 12, 2009
CMS-4138-IFC4	Medicare Programs; Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies	January 16, 2009
CMS-4085-F	Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs	April 15, 2010

The 60-day notice for public comment began on June 11, 2010. Four comments on the Part D Applications were received by CMS.

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) update

Tables 1 and 2 provide an estimate of the total hours and costs by activity related to the application processes. Our estimates include the review of application instructions, and completion of the application. The completion of the application encompasses completing attestations and uploading supporting documentation. Overall, the estimated hour burden for completion of the prescription drug applications is 3,576 hours. This is a decrease from the 2011 prescription drug applications. Based on prior years' experience CMS has determined that the estimated the number of 2012 applicants should be adjusted to properly reflect the vastly different number of organizations that submit Notices of Intent to Apply (NOIA) to become a Part D sponsor from the number of organizations that submit applications (see section 15 for further detail). . The estimated wage burden for the Prescription Drug Applications is $196,680 and estimates of overall wages were calculated by assuming a $55.00 per hour wage rate. CMS kept the hour wage rate constant from 2011 calculations.

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 are collected electronically within HPMS and reduce the burden hours of completing each of these sections in paper from one hour to 15 minutes. The most substantial portion of the application remains the documentation of pharmacy networks for use by Medicare beneficiaries. We estimate that completion of the entire pharmacy network section of the applications requires 33% of the total 3,576 hours or 1,170 hours. The estimated number of hours required to document pharmacy networks for each type of applicant is

20 hours. Table 3 provides a summary of the estimated number of hours to complete each type of Part D application for 2012.

Table 1
Summary of Hour Burden by Type of Applicant and Process

	Hours Estimate								
Activity	**PDP**	**MA-PD**	**Cost Plans**	**PACE**	**Direct EGWP**	**800 Series Only EGWP**	**EGWP**	**SAE**	**Total Hours**
Review of Instructions	28	266	0	6	16	10	100	300	726
Complete Application	101	1314.25	0	36.75	30	76	100	1192	2,850
Total All	**129**	**1580.25**	**0**	**42.75**	**46**	**86**	**200**	**1492**	**3,576**

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	1540	14,630	0	330	880	550	5,500	16,500	39,930
Complete Application	5555	72,284	0	2021	1,650	4,180	5,500	65,560	156,750
Total All	**7,095**	**86,914**	**0**	**2,351**	**2,530**	**4,730**	**11,000**	**82,060**	**196,680**

Table 3
Summary of Burden Hours by Type of Application

Type of Part D Application	**2011 (hours) Estimates**	**2012 (hours) Estimates**
PDP	40.00	24.50
MA-PD	38.00	22.75
Cost Plan	37.75	22.25
PACE	15.25	17.50
Direct EGWP	39.25	24.25
800 Series Only EGWP	39.25	24.25
EGWP	6.25	6.25
SAE	25.25	9.00

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 approximately $140,000.00. 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

CMS reduced the burden hours to complete the Part D applications for several reasons identified below.

In prior years, CMS has estimated total burden hours based on a number of applicants that submit NOIA to the Part D program. Since the inception of the program, the number of NOIAs received does not reflect the number of actual applications that are submitted to CMS. Typically, CMS receives significantly fewer Part D applications compared to the NOIAs. As a result for the 2012 applications, CMS based the burden hours to submit the NOIAs and review the overall application instructions on the number of organizations that typically complete the NOIA; however, the burden hours were reduced to complete the actual Part D application to reflect the number of organizations that typically submit applications. To demonstrate the difference between NOIAs received and the Part D applications received for the 2009 Contract Year CMS received 880 notices of intent to apply and received 384 Part D applications. For the 2010 Contract Year CMS received 1135 notices of intent to apply and received 244 Part D applications.

In addition to changing the burden hour calculation to more accurately reflect the appropriate number of applicants, the estimated burden hours for existing questions and the re-evaluation of the need for certain documentation within the applications has caused an overall decrease in the total burden hours for each of the Part D applications. Specifically, attestation tables related to key Part D functions, general pharmacy access and the compliance plan that are duplicative of required supporting documentation were deleted. Supporting documentation related to past and present legal actions that are not considered in the evaluation of whether an organization is qualified to contract as a Part D sponsor were removed.

In another effort to reduce the burden on organizations to complete the Part D applications, CMS is

automating the retail pharmacy access section of the application. The pharmacy access section of the applications accounts for the most burden. In prior years, organizations had to provide an access report that reflected each organization's retail pharmacy access in the urban, suburban, and rural parts of their service area. To relieve the burden of generating this report, CMS has automated the process. Beginning with the 2012 applications, applying organizations will provide their contracted retail pharmacy list (a document that is already required) and CMS will calculate the access levels. Applying organizations no longer need to generate or submit an access report.

The enactment of the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010, and the issuance of a new regulation have generated minor additions and clarifications to the Part D applications for 2012. General attestations were added to several sections that reflect statutory language from the Patient Protection and Affordable Care Act (PPACA).

CMS does not expect that the changes from PPACA and the new regulation will increase the burden hours when combined with the deletions and automation improvements made to the applications. The burden hours represent the time it takes for an applicant to complete the Part D solicitation and not the time that applicants spend drafting and negotiating contracts with downstream and related entities to perform key Part D functions on their behalf.

Clarifying updates were also made to the existing language of the Part D solicitations. Such updates include date changes and incorporating the most current references in statute, regulation and CMS guidance above each section as appropriate.

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

This collection of information applies to contract years 2012-2014.

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 42 CFR §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 owned and operated by Applicant.
42CFR §423.34 42 CFR §423.36 42 CFR §423.38 42 CFR §423.42	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

Part D Regulation	Regulatory Requirement(s) Description	Basis for Waiver
42 CFR §423.44		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 §423.272(b)(3)(i)	Direct Contract PDP Direct Contract MA-PD "800 Series" PDP "800 Series" MAO "800 Series" Cost PD	Meaningful Differences: All Applicants are required to submit plan offerings that represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures.	The requirement to have meaningful differences in plan offerings by the sponsor in the service area has been waived for all EGWPs.
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.
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.

Part D Regulation	Type of EGWP Applicant Waiver or Modification Applies To	Application Requirement(s) Description	Waiver/Modification
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**
42 CFR §423.44	Involuntary disenrollment
42 CFR §423.48	Information about Part D
42 CFR §423.50	Approval of marketing materials and enrollment forms
42 CFR §423.104(g)(1)	Access to negotiated prices
42 CFR §423.112	Establishment of PDP service areas
42 CFR §423.120(a)	Access to covered Part D drugs
42 CFR §423.120(c)	Use of standardized technology
42 CFR §423.124	Out-of-network access to covered Part D drugs at out-of-network pharmacies
42 CFR §423.128	Dissemination of Part D plan information
42 CFR §423.132	Public disclosure of pharmaceutical prices for equivalent drugs
42 CFR §423.136	Privacy, confidentiality, and accuracy of enrollee records
42 CFR §423.153(a)- 42 CFR §423.153(d)	Drug utilization management, quality assurance, and medication therapy management programs (MTMPs)
42 CFR §423.156	Consumer satisfaction surveys
42 CFR §423.159(c), 42 CFR §423.160(a)	Electronic prescribing
42 CFR §423.162	Quality Improvement organization activities
42 CFR §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
42 CFR §423.401(a)(1)	Licensure
42 CFR §423.420	Solvency standards for non-licensed entities
42 CFR §423.462	Medicare secondary payer procedures
42 CFR §423.464(c)	Coordination of benefits and user fees
42 CFR §423.464(f)(2) and 42 CFR §423.464(f)(4)	Coordination with other prescription drug coverage
42 CFR §423.502(b)(1)(i-ii)	Documentation of State licensure or Federal waiver
42 CFR §423.504(b)(2-3), 42 CFR §423.504(b)(4)(i-v) and (vi)(A-E), and 42 CFR §423.504(d) ***Note: Organizations are required to abide by 42 CFR §423.504(b)(4)(vi)(F-H), 42 CFR §423.504(b)(5), 42 CFR §423.504(c), and 42 CFR §423.504(e)***	Conditions necessary to contract as a Part D plan sponsor

Part D Regulation	**Regulatory Requirement(s)** **Description**
42 CFR §423.505(a-c) and 42 CFR §423.505(e-i) ***Note: Organizations are required to abide by 42 CFR §423.505(dand j)***	Contract provisions
42 CFR §423.505(k)(6) ***Note: Organizations are required to abide by 42 CFR §423.505(k)(1-5)***	Certification for purposes of price compare
42 CFR §423.506(a)-(b) ***Note: Organizations are required to abide by 423.506(c)-(e)***	Effective date and term of contract
42 CFR §423.512 – 42 CFR §423.514	Contracting terms
42 CFR §423.551-42 CFR §423.552	Change of ownership or leasing of facilities during term of contract
42 CFR §423.560-42 CFR §423.638	Grievances, coverage determinations, and appeals
N/A	A PDP sponsor is required to be a nongovernmental entity

Attachment 5
Summary of Part D Application Requirements Needed for
All Service Area Expansion Applicants

Note: SAE 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 2011. 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.