Supporting Statement Part-A
Solicitation for Applications for Medicare Prescription Drug Plan 2025 Contracts
(CMS-10137, OMB 0938-0936)

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), on March 23, 2010 by the enactment of the Patient Protection and Affordable Care Act and on March 30, 2010 by the enactment the Health Care and Education Reconciliation Act of 2010 (collectively the Affordable Care Act).

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.

In this package iteration, the only changes to the 2025 Application were technical changes related to dates and clarification of instructions.

There was no change in the estimated hours per applicant it will take to complete 2025 applications compared to 2024.

We estimate that we will receive about 54 more applicants for 2025 than we actually received for 2024, with an estimated 274.50 hour increase in the time burden compared to the actual burden for 2024. The estimate is based on a 5-year average of applications received and is significantly higher than the actual number of applications received for 2024 because there were an unusually low number of applications received for 2024.

We are requesting a Revision approval from Office of Management and Budget (OMB) for CMS-10137 with small changes in substance and burden hours per applicant.

A. 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, Program of All-Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards.

3. Use of Information Technology

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.

4. Duplication of Efforts

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.

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

CMS is currently required by statute to provide an opportunity for organizations to apply for new or expanded contracts annually, so CMS cannot reduce the frequency of this 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 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 60-day notice published in the Federal Register (88 FR 41404) on June 26, 2023, and the comment period closed on August 25, 2023. CMS did not receive comments during the 60-day comment period. CMS provided clarification on when past performance deficiencies are issued.

The 30-day notice published in the Federal Register (88 FR 62087) on September 8, 2024.

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 Estimates (Hours & Costs)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Compliance Officers	13-1041	37.01	37.01	74.02

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

Requirements and Associated Burden Estimates

Tables 1 and 2 provide an estimate of the total hours and costs by activity related to the application processes, including organizations that complete the Notice of Intent to Apply but do not submit an application. The time for reviewing the instructions and completing the NOIA is separated from time for completing the application. Many more organizations do the former than the latter, as indicated in Tables 3 and 4.

Table 1
Summary of Time Estimates (Hours) by Type of Applicant and Process

Activity	PDP	MA-PD	Cost Plans	Direct EGWP	800 Series Only EGWP	SAE	PACE	Total Hours
Review of Instructions*	15	261	0	0	2	507	10	795
Complete Application	23.61	541.60	0	0	7.54	430.85	40.09	1,043.68
Total	**38.61**	**802.60**	**0**	**0**	**9.54**	**937.85**	**50.09**	**1,838.68**

***** Includes organizations that complete a Notice of Intent to Apply but do not file an application.

Table 2
Summary of Labor Cost Estimates by Type of Applicant and Process (based on an adjusted wage of $74.02/hr)

Activity	PDP	MA-PD	Cost Plans	Direct EGWP	800 Series Only EGWP	SAE	PACE	Labor Costs
Review of Instructions*	1,110.30	19,319.22	$0	$0	$148.04	$37,528.14	$740.20	$58,845.90
Complete Application	$1,747.46	$40,088.95	$0	$0	$557.81	$31,891.70	$2,967.63	$77,253.55
Total	**$2,857.76**	**$59,408.17**	**$0**	**$0**	**$705.85**	**$69,419.84**	**$3,707.83**	**$136,099.45**

***** Includes organizations that complete a Notice of Intent to Apply but do not file an application.

Table 3 provides an estimate of the total hours for applicants who we anticipate will complete the application. Table 4 provides an estimate of the total hours for organizations that we anticipate will file a Notice of Intent to Apply (and thus incur burden in reviewing instructions, etc.) but ultimately do not complete the application. 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.

Table 3
Summary of Time (Hours per Application) by Type of Application For Applicants who Complete the Application
(Includes Both Review of Instructions and Completion of Application)

Type of Part D Application	2025 Burden per Applicant (rounded to nearest quarter hour)	2025 Estimated Number of Applicants
PDP Initial Applications*	9.54	3
MA-PD Initial Applications	6.43	100
Cost Plan Initial Applications	6.36	0
Direct EGWP Initial Applications	10.54	0
800 Series Only EGWP Initial Applications	9.54	1
Service Area Expansions (All Contract Types)	3.36	319
PACE Applications	5.01	10

* Includes time to review instructions (1 hour) and time to complete an application to request state licensure (1 hour). Because CMS does not anticipate anyone requesting a waiver, this hour is deducted from the estimates of total time all organizations will take to complete the collection.

Table 4
Summary of Time (Hours per Notice of Intent) to Apply for Entities that Submit Notices but Do Not File Applications
(Includes only Review of Instructions)

Type of Part D Application	2025 Burden per Entity (rounded to nearest quarter hour)	2025 Estimated Number of Entities Not Completing Applications
PDP Initial Applications	1	12
MA-PD Initial Applications	1	161
Cost Plan Initial Applications	1	0
Direct EGWP Initial Applications	1	0
800 Series Only EGWP Initial Applications	1	1
Service Area Expansions (All Contract Types)	1	188
PACE Applications	1	0

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 time for completing the prescription drug applications is 1,839.68 hours for 433 applicants. PACE applicants complete the Medicare Part D Application for New PACE Organizations. All others complete the Solicitation for Applications for Medicare Prescription Drug Plan 2025 Contracts.

Annual Burden Summary (Totals)

Number of Respondents: 795 (includes 362 organizations that submit a Notice of Intent to Apply but do not file applications)
Number of Responses: 433 (includes only those organizations that submit applications)
Hours: 1,839.68
Cost: $136,099.4

Information Collection Attachments

Solicitation for Applications for Medicare Prescription Drug Plan 2025 Contracts

Medicare Part D Application for New PACE Organizations, 2024 Contract Year

Supporting Statement Attachments (by Application Type)

The following Attachments provide summaries of requirements that are waived in the Part D application for certain types of applicants. Everyone else has to fulfill everything. The title of the attachment indicates the type of application.

Please note that the PDP and PACE applications are listed above under *Information Collection Attachments*.

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

Attachment 2: Summary of Part D Application Requirements Fulfilled under Part C for Cost Plan Prescription Drug Applicants

Attachment 3: Summary of Part D Application Requirements Waived or Modified for Employer/Union-Only Group Waiver Plan (EGWP) Applicants

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, and support staff), and other expenses incurred in the application effort. Due to increased efficiencies in the application review process, the cost to the Federal Government remains unchanged from 2024.

15. Changes to Burden

The burden per applicant stayed the same for the 2025 application cycle. On average, we anticipate that it will take each applicant 7.25 hours to complete their application. the same as for 2024.

Overall, the estimated time for completing the prescription drug applications is 1,838.68 hours. This is a **22.1 hour** decrease from the estimate of 1,860.78 hours for the 2024 prescription drug application. However, the *actual* number of 2024 applicants was much lower than anticipated and, so the burden for the number of applications received for 2024 was 1,542.69 hours, 318.09 hours less than the estimated burden for 2024.

Burden Changes: Time Estimates (Hours) by Type of Applicant and Process

Activity	PDP	MA-PD	Cost Plans	Direct EGWP	800 Series Only EGWP	SAE	PACE	Total Hours
2024 (in approved PRA package)	49.14	880.76	0	0	10.54	870.25	50.09	1,860.78
2025 (projected)	38.61	802.60	0	0	9.54	937.85	50.09	1,839.68
DIFFERENCE	**-10.53**	**-78.16**	**0**	**0**	**1.00**	**67.60**	**0.0**	**22.1**

Burden Changes: Labor Cost Estimates by Type of Applicant and Process

Activity	PDP	MA-PD	Cost Plans	Direct EGWP	800 Series Only EGWP	SAE	PACE	Labor Costs
2024*	$3,582.59	$64,207.10	$0	$0	$768.07	$63,441.23	$3,651.73	$135,650.71
2025**	$2,857.76	$59,408.17	$0	$0	$705.85	$69,419.84	$3,707.83	$136,099.45
DIFFERENCE	-$724.83	-$4,798.93	$0	$0	-$62.22	$5,978.61	$56.10	$448.74

*Based on a 2021 BLS adjusted wage of $72.90/hr.
**Based on a 2022 BLS adjusted wage of $74.02/hr (see Wages).

The overall estimated paperwork burden is increased for PDP, MA-PD, Cost Plan, EGWP Plan, PACE, and SAE applicants increased because of the increase in the estimated number of applicants. The hourly burden per applicant has increased by .01 hours for applicants.

Summary of Time (Hours per Application) by Type of Application For Applicants who Complete the Application

(Includes Both Review of Instructions and Completion of Application)

Type of Part D Application	2024 Burden Estimates per Applicant	2024 Estimated Number of Applicants	**2025 Burden Estimates per Applicant**	**2025 Estimated Number of Applicants**
PDP Initial Applications*	9.54	4	9.54	3
MA-PD Initial Applications	6.43	110	6.43	100
Cost Plan Initial Applications	6.36	0	6.36	0
Direct EGWP Initial Applications	10.54	0	10.54	0
800 Series Only EGWP Initial Applications	9.54	1	9.54	1
Service Area Expansions (All Contract Types)	3.36	300	3.36	319
PACE Applications	5.01	10	5.01	10

*Includes time to review instructions (1 hour) and time to complete an application to request state licensure (1 hour). Because CMS does not anticipate anyone requesting a waiver, this hour is deducted from the estimates of total time all organizations will take to complete the collection.

Summary of Time (Hours per Notice of Intent) to Apply for Entities that Submit Notices but Do Not File Applications

(Includes only Review of Instructions)

Type of Part D Application	**2024 Burden Estimates per Entity**	**2024 Estimated Number of Entities Not Completing Applications**	**2025 Burden Estimates per Entity**	**2025 Estimated Number of Entities Not Completing Applications**
PDP Initial Applications	1	15	1	12
MA-PD Initial Applications	1	175	1	161
Cost Plan Initial Applications	1	0	1	0
Direct EGWP Initial Applications	1	0	1	0
800 Series Only EGWP Initial Applications	1	2	1	1
Service Area Expansions (All Contract Types)	1	166	1	188
PACE Applications	1	0	1	0

Based on more recent BLS wage data, we have also increased our wage estimate by $1.12/hr (from $72.90/hr to $74.02/hr).

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

CMS will display the expiration date and OMB control number on the cover of the print application guidance, as indicated in the document to be posted.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There have been no statistical methods employed in this collection.