

Supporting Statement Part A
Solicitation for Applications for Medicare Prescription Drug Plan 2023 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 re-designating 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 2023 Application were technical changes related to dates and clarification of instructions and the addition of two attestations to clarify application requirements.

There was a slight increase of .03 hours (from 7.20 to 7.23 hours) in the estimated hours per applicant it will take to complete 2023 applications compared to 2022 applications. This increase is due to the addition of two attestations for initial applicants.

We estimate that we will receive about 43 fewer applicants for 2023 than we actually received for 2022, with an estimated 514.96-hour reduction in the time burden compared to the actual burden for 2022. The estimate is based on a 5-year average of applications received and is significantly lower than the actual number of applications received for 2022 because there were an unusually high number of applications received for 2022.

We are requesting a Revision approval from Office of Management and Budget (OMB) for CMS-10137.

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 on June 23, 2021 (86 FR 32935). We received comments from one Part D sponsor.

The commenter had several comments related to the form of the Part D application and to the way CMS's electronic system of record, HPMS, operates. In response to one comment, CMS added language to the *Organization Background and Structure* document in Appendix IX of the Part D application, clarifying that required organizational charts could be provided as part of that document or as separate document uploads in the application. The commenter also requested that CMS allow Part D attestation responses to be copied from one application to another, as is permitted for parts of the MA application, but CMS declined to allow this for 2023 because attestation answers are supposed to be specific to the type of application being filed by a given organization. The commenter also asked that CMS provide a version of the application with redline changes from the previous year's application and CMS agreed to consider this for the final application posting, although CMS noted that the PRA process provides this information annually as well.

The commenter also had a number of comments about HPMS operations and the MA application that were out of scope for this collection. CMS has provided these comments to the appropriate component for consideration.

CMS made the minor addition noted above in the *Organization Background and Structure* document in response to these comments. CMS made other minor adjustments, including deleting an obsolete element in the *Compliance Program Crosswalk* in Appendix XVIII and updating the years for which data must be provided when requesting convenient access and any willing pharmacy waivers on pages 46 and 47 of the application, as part of its review of the application.

To assist CMS in assessing new PDP applicants' compliance with the experience requirements in 42 CFR § 423.504(b)(9), CMS also updated the *Organization Background and Structure* document to request new PDP applicants to provide the number of covered lives they provided health insurance and/or prescription drug coverage to in 2020 and 2021. This does not add to the burden on applicants and allows CMS to better assess whether an organization has the required two years of experienced offering health insurance and/or prescription drug coverage.

The 30-day notice published in the Federal Register 10/26/2021 (86 FR 59165).

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 2020 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 | 36.35 | 36.35 | 72.70 |

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 | Direct | 800 Series | SAE | PACE | Total Hours |
|----------|-----|-------|------|--------|------------|-----|------|-------------|
|----------|-----|-------|------|--------|------------|-----|------|-------------|

| | | | Plans | EGWP | Only EGWP | | | |
|-------------------------|--------------|---------------|----------|----------|--------------|---------------|--------------|-----------------|
| Review of Instructions* | 17 | 271 | 0 | 0 | 3 | 415 | 10 | 716 |
| Complete Application | 30.06 | 577.37 | 0 | 0 | 7.52 | 345.15 | 39.89 | 999.99 |
| Total | 47.06 | 848.37 | 0 | 0 | 10.52 | 760.15 | 49.89 | 1,715.99 |

* 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 \$72.70/hr)**

| Activity | PDP | MA-PD | Cost Plans | Direct EGWP | 800 Series Only EGWP | SAE | PACE | Labor Costs |
|-------------------------|-------------------|--------------------|------------|-------------|----------------------|--------------------|-------------------|---------------------|
| Review of Instructions* | \$1,235.90 | \$19,701.70 | \$0 | \$0 | \$218.10 | \$30,170.50 | \$727.00 | \$52,053.20 |
| Complete Application | \$2,185.64 | \$41,974.65 | \$0 | \$0 | \$546.41 | \$25,092.41 | \$2,900.17 | \$72,699.28 |
| Total | \$3,421.54 | \$61,676.35 | \$0 | \$0 | \$764.51 | \$55,262.91 | \$3,627.17 | \$124,752.48 |

* 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 | 2023 Burden per Applicant (rounded to nearest quarter hour) | 2023 Estimated Number of Applicants |
|----------------------------|---|-------------------------------------|
| PDP Initial Applications* | 9.52 | 4 |
| MA-PD Initial Applications | 6.41 | 107 |

| | | |
|--|-------|-----|
| Cost Plan Initial Applications | 6.34 | 0 |
| Direct EGWP Initial Applications | 10.52 | 0 |
| 800 Series Only EGWP Initial Applications | 9.52 | 1 |
| Service Area Expansions (All Contract Types) | 3.34 | 260 |
| PACE Applications | 4.99 | 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 | 2023 Burden per Entity (rounded to nearest quarter hour) | 2023 Estimated Number of Entities Not Completing Applications |
|--|---|--|
| PDP Initial Applications | 1 | 13 |
| MA-PD Initial Applications | 1 | 164 |
| Cost Plan Initial Applications | 1 | 0 |
| Direct EGWP Initial Applications | 1 | 0 |
| 800 Series Only EGWP Initial Applications | 1 | 2 |
| Service Area Expansions (All Contract Types) | 1 | 155 |
| 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

1,715.99 hours for 382 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 2023 Contracts.

Annual Burden Summary (Totals)

Number of Respondents: 716 (includes 334 organizations that submit a Notice of Intent to Apply but do not file applications)
Number of Responses: 382 (includes only those organizations that submit applications)
Hours: 1,715.99
Cost: \$124,752.47

Information Collection Attachments

Solicitation for Applications for Medicare Prescription Drug Plan 2023 Contracts

Medicare Part D Application for New PACE Organizations, 2022 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 2022.

15. Changes to Burden

The burden per applicant increased slightly, by .03 hours (approximately 2 minutes) since the 2022 application cycle. On average, we anticipate that it will take each applicant 7.23 hours to complete their application, compared to 7.20 for 2022 (this represents an average of the number of hours spent on the application by each type of applicant).

There were two substantive changes to the application for 2023. One attestation was added for an organization to verify that they are organized under the laws of a state. Another attestation was split into two attestations, so organizations can verify separately whether they are affected by the restrictions in 42 CFR §423.509 or the restrictions in 42 CFR §§ 423.507, 423.508, or 423.510. This added .04 hours (approximately 2 minutes) to the time it takes to complete an initial application.

Overall, the estimated time for completing the prescription drug applications is 1,715.99 hours. This is a **166.44 hour** increase from the estimate of 1,549.55 hours for the 2022 prescription drug application. However, the *actual* number of 2022 applicants was much higher than anticipated and, so the burden for the number of applications received for 2022 was 1,719.66, hours, 170.11 hours more than the estimated burden for 2022.

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

| | | | | | | | | |
|--|--|--|--|--|-----|--|--|--|
| | | | | | 800 | | | |
|--|--|--|--|--|-----|--|--|--|

| Activity | PDP | MA-PD | Cost Plans | Direct EGWP | Series Only EGWP | SAE | PACE | Total Hours |
|--------------------------------|--------------|--------------|------------|-------------|------------------|--------------|----------|---------------|
| 2022 (in approved PRA package) | 47.90 | 781.88 | 0 | 0 | 9.48 | 660.40 | 49.89 | 1549.55 |
| 2023 | 47.06 | 848.37 | 0 | 0 | 10.52 | 760.15 | 49.89 | 1,715.99 |
| DIFFERENCE | -0.84 | 66.49 | 0 | 0 | 0.04 | 99.75 | 0 | 164.44 |

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 |
|-------------------|----------------|-----------------|------------|-------------|----------------------|-----------------|--------------|------------------|
| 2022* | 3,356.14 | 54,778.81 | 0 | 0 | 663.89 | 46,267,27 | 3,495.46 | 108,561.57 |
| 2023** | 3,421.54 | 61,676.35 | 0 | 0 | 764.51 | 55,262,91 | 3,627.17 | 124,752.48 |
| DIFFERENCE | -923.26 | 8,705.54 | 0 | 0 | 3.23 | 4,211.64 | 16.97 | 12,014.11 |

*Based on a 2019 BLS adjusted wage of \$70.06/hr.

**Based on a 2020 BLS adjusted wage of \$72.70/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 and the addition of two attestations for initial applicants. The hourly burden per applicant has increased by .04 hours for initial 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 | 2022 Burden Estimates per Applicant | 2022 Estimated Number of Applicants | 2023 Burden Estimates per Applicant | 2023 Estimated Number of Applicants |
|--------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| PDP Initial Applications* | 9.48 | 4 | 9.52 | 4 |
| MA-PD Initial Applications | 6.37 | 98 | 6.41 | 107 |
| Cost Plan Initial Applications | 6.30 | 0 | 6.34 | 0 |
| Direct EGWP Initial | 10.48 | 0 | 10.52 | 0 |

| | | | | |
|--|------|-----|-------|-----|
| Applications | | | | |
| 800 Series Only EGWP Initial Applications | 9.48 | 1 | 10.52 | 1 |
| Service Area Expansions (All Contract Types) | 3.34 | 218 | 3.34 | 260 |
| PACE Applications | 4.99 | 10 | 4.99 | 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 | 2022 Burden Estimates per Entity | 2022 Estimated Number of Entities Not Completing Applications | 2023 Burden Estimates per Entity | 2023 Estimated Number of Entities Not Completing Applications |
|-----------------------------------|---|--|---|--|
| PDP Initial Applications | 1 | 14 | 1 | 13 |
| MA-PD Initial Applications | 1 | 159 | 1 | 164 |
| Cost Plan Initial Applications | 1 | 0 | 1 | 0 |
| Direct EGWP Initial Applications | 1 | 0 | 1 | 0 |
| 800 Series Only EGWP Initial | 1 | 1 | 1 | 2 |
| Service Area Expansions (All | 1 | 153 | 1 | 155 |
| PACE Applications | 1 | 0 | 1 | 0 |

Based on more recent BLS wage data, we have also increased our wage estimate by \$2.64/hr (from \$70.06/hr to \$72.70/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.