Appendix A: Supporting Statement for Paperwork Reduction Act Submissions
CMS Plan Benefit Package (PBP) and Formulary CY 2020
CMS-R-262, OMB 0938-0763

The Plan Benefit Package (PBP), Formulary, and Supporting Regulations Contained in 42 Code of Federal Regulation (CFR): 422.100, 422.101, 422.102, 422.103, 422.105, 422.106, 422.108, 422.110, 422.111, 422.112, 422.113, 422.114, 422.250, 422.252, 422.254, 422.256, 422.258, 422.262, 422.264, 422.266, 422.270, 422.300, 422.304, 422.306, 422.308, 422.310, 422.312, 422.314, 422.316, 422.318, 422.320, 422.322, 422.324, 423.100, 423.104, 423.112, 423.120, 423.124, 423.128, 423.132, 423.136,423.160, 423.251, 423.258, 423.265, 423.272, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, 423.350.

Background

Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization.

After receiving OMB clearance in spring 2000, CMS implemented the PBP as part of the Contract Year (CY) 2001 Adjusted Community Rate Proposal (ACRP) process. In addition, information collected via the PBP and formulary has been used to support the marketing material review process, the National Medicare Education Program, and other program oversight and development activities. The PBP data is used by the MA and Part D organizations in their marketing materials and by CMS to generate plan benefits data for display in the Medicare & You handbook and on the www.medicare.gov website.

CMS is requesting to continue its use of the PBP software and formulary submission for the collection of benefits and related information for CY 2019. CMS estimates that 532 MA organizations and 38 PDP organizations will be required to submit the plan benefit package information in CY 2020. This is an increase from prior years, where 481 MA organizations and 39 PDP organizations were required to submit. This increase in MA organizations has caused the burden estimate to increase. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission.

Part D eRx standards are periodically updated to take new knowledge, technology, and other considerations into account. CMS currently requires providers and dispensers to utilize the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide Version 10.6, which was approved November 12, 2008, to provide for the communication of a prescription or prescription-related information for certain named transactions. As of January 1, 2020, however, prescribers and dispensers will be required to use the NCPDP SCRIPT standard, Implementation Guide Version 2017071, which was approved July 28, 2017 to provide for the communication of prescription or prescription-related information between

prescribers and dispensers for the old named transactions and a handful of new transactions named at § 423.160(b)(2)(iv). We also currently require (under § 423.160(b)(5)) Medicare Part D plan sponsors and prescribers to convey electronic formulary and benefits information amongst themselves using either Version 1, Release 1 (Version 1.0), from October 2005, or Version 3 Release 0 (Version 3.0), from April 2012 of the National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard Implementation Guides. (For a detailed discussion of the regulatory history of eRx standards see the November 2017 proposed rule (82 FR 56437 and 56438).

Our November 30, 2018 (83 FR 62152) proposed rule (CMS-4180-P, RIN 0938-AT92) would require that each Part D plan select a real time benefit tool (RTBT) of its choosing by January 1, 2020. As discussed in sections 12 and 15, below, we are unable to fully quantify the impact of RTBT implementation due to lack of adequate data.

Section 423.120(b)(2)(vi) would implement the authority granted to CMS by section 1860D-4(b)(3)(G) of the Act to establish exceptions that would permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through prior authorization or utilization management) a particular Part D drug that is otherwise required to be included in the formulary.

For the exceptions that expand the use of prior authorization and step therapy for protected class drugs at § 423.120(b)(2)(vi)(C), the burden would consist of the time and effort for Part D sponsors to submit their formularies to CMS under the existing annual submission process. The annual submission requirements and burden are currently approved by OMB under this control number and would not impose any new or revised information collection requirements or burden.

For the exceptions related to § 423.120(b)(2)(vi)(E), for protected class drugs for which a Part D sponsor chooses to exclude from their formulary due to a price increase beyond a certain threshold, Part D sponsors would be required to submit an additional justification to CMS during the annual formulary submission process. The justification must explain why the Part D sponsor is excluding such drug from their formulary. The burden associated with this exception would consist of the time and effort put forth by Part D sponsors to prepare and submit their formularies to CMS along with the justification.

A. Justification

1. Need and Legal Basis

This information is mandated by the Social Security Act in order to collect plan bids that will establish the Medicare Advantage (Part C) and Prescription Drug (Part D) plan benefit package options to be offered to Medicare beneficiaries during the next annual open enrollment period. The Part C bid deadline (the first Monday in June) is stated at Section 1854(a)(6)(A) of the Social Security Act. The same deadline is applied to Part D bids by reference to the Part C requirement at Section 1860D-11(b)(1) of the Act and is cited in the 42 CFR references listed above. Copies of these references are provided in Appendix D.

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) requires the adoption of Part D eRx standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug

programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement eRx. However, prescribers and dispensers who electronically transmit and receive prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect. For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. of the eRx and the Prescription Drug Program February 2005 proposed rule (70 FR 6256). 4180-P proposes a requirement that each Part D plan select a real time benefit tool (RTBT) of its choosing by January 1, 2020

2. Information Users

This information is used by both CMS and the public.

CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval.

CMS uses this data to review and approve the benefit packages that the plans will offer to Medicare beneficiaries. This allows CMS to review the benefit packages in a consistent way across all submitted bids during with incredibly tight timeframes. This data is also used to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare Medicare Advantage and Prescription Drug plans.

The PBP is broken into five specific sections:

1.) Section A defines certain plan-specific data characteristics in the Plan Benefit Package (PBP). Section A consists primarily of high-level plan information, including the Contract Number, Plan ID, Plan Type, Plan Name, and Geographic Service Area of the plan. In addition, Section A allows organizations to indicate if they are offering a bid that mirrors fee-for-service cost sharing. Both MA and Part D plans must complete this section.
2.) Section B collects in-network benefit information for MA plans. This includes cost sharing, premium information, and if supplemental benefits are offered. Section B is broken into the following sections:
    a. Inpatient Hospital Services
    b. Skilled Nursing Facility (SNF)
    c. Cardiac and Pulmonary Rehabilitation Services
    d. Emergency Care/Urgently Needed Services
    e. Partial Hospitalization
    f. Home Health Services
    g. Health Care Professional Services
    h. Outpatient Procedures, Tests, Labs & Radiology Services
    i. Outpatient Services
    j. Ambulance/Transportation Services
    k. DME, Prosthetics and Medical & Diabetic Supplies
    l. Dialysis Services
    m. Other Supplemental Services
    n. Preventive and Other Defined Supplemental Services
    o. Medicare Part B Prescription (Rx) Drugs

    p. Dental
    q. Eye Exams/Eyewear
    r. Hearing Exams/Hearing Aids
    s. VBID/MA Uniformity Flexibility
    t. Prescription Drugs (ONLY for Cost Plans not offering Part D
3.) Section C collects out-of-network information, as well as information regarding the visitor/travel benefits and Point-of-Service Benefits. Only MA plans complete this section.
4.) Section D collects plan-level information. Only MA plans complete this section. This includes:
    a. Plan Deductible
    b. Maximum Enrollee Out-of-Pocket Costs
    c. Maximum Coverage for Supplemental Benefits
    d. Balance Billing (PFFS only)
    e. Medical Savings Account Information (for MSA plans only)
    f. Medicaid Covered vs. Plan Covered Cost sharing (for MMPs only)
    g. Optional Supplemental Benefit Packages.
5.) Section Rx contains all Part D information. All plans that offer Part D must complete this section. This includes:
    a. Medicare Rx Screens
    b. Pre-Initial Coverage Limit (ICL) Screens
    c. ICL Screens
    d. Gap Coverage Screens
    e. Out-of-Pocket Threshold Screens
    f. Locations and location supply Screens
    g. Rx attestations
    h. Medicare Rx Notes
    i. Section Rx VBID (only for plans offering VBID)

The formulary submission contains the following files:

1.) Formulary Submission File (required for all Part D plans offering a formulary. This file lists all Part D covered drugs offered by the plan)
2.) Formulary Over-the-Counter (OTC) Drugs File (required for any plans offering OTC drugs as part of their Part D plan)
3.) Formulary Prior Authorization (PA) File (required for any Part D plans requiring PA for any drugs on their formulary)
4.) Formulary Partial Gap Coverage File (required if there is partial tier gap coverage for the Part D plan)
5.) Formulary Free First Fill File (required if any drugs are offered for free for their first fill)
6.) Formulary Excluded Drug File (required if the Part D plan offers excluded drugs)
7.) Formulary Additional Demonstration Drug File (only required for MMP plans)
8.) Formulary Opioid Strategy Submission and Layout (required for all Part D plans)

Exact layouts of the formulary files and detailed PBP data collect can be found within the Appendix C documents.

CMS publishes beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on www.medicare.gov and the plan benefit insert in the *Medicare & You* handbook. All other information collected through the PBP follows the rules described in Section 10: Confidentiality.

Part D sponsors will use one or more electronic real-time benefit tools (RTBT) that are capable of integrating prescribers' e-Prescribing (eRx) and electronic medical record (EMR) systems to provide complete, accurate, timely, clinically appropriate, patient specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Patients must specifically consent to use of their protected health information for RTBT

3. Improved Information Technology

Since CY 2001, the Health Plan Management System (HPMS) has been utilized to upload completed benefit information during the ACRP process. Under MMA and in support of the bidding process, CMS enhanced the HPMS upload functionality to incorporate the necessary submission changes to include the formulary to supplement the plan benefit package submission.

CMS continues to improve the PBP software and formulary submission with guidance from CMS policy and operations groups and the solicitation of industry comment. In Appendix C, the hardcopy PBP screen prints and formulary submission materials are provided to illustrate a thorough overview of the tools; however, this information cannot accurately display the streamlining effect of the tools on the bidding process.

Prior experience coupled with the continued relationship with the industry for the past several years has helped to further enhance the already user-friendly nature of the plan benefit package submission process. CMS has maximized the usability of the PBP by using standardized pick lists, intelligently pre-filled data fields, and integrated online help screens.

Also, the plan benefit package data and its many outputs have served to reduce burden as it relates to the creation and publication of beneficiary education materials. The PBP serves primarily as a tool for organizations to describe and report their benefits for the upcoming contract year. The formulary supplements this information to include the drug lists associated with the plan's benefits. However, these data are also central to plan marketing and education efforts. As a result, CMS chose to take advantage of these data being collected via an electronic mechanism.

Specifically, CMS developed the PBP so that it standardizes the collection of benefits data. The formulary and PBP are both used by CMS in the comparative web application tools on www.medicare.gov that facilitate the comparison of plan choices available to beneficiaries. In addition, the PBP data is used by CMS to generate plan benefits information in the *Medicare & You* handbook. By consolidating this data reporting, CMS is able to use the information to perform numerous activities without placing additional burden on the organization.

4. Duplication of Similar Information

The information collected in the PBP and formulary is not duplicated through any other CMS effort. In fact, CMS has eliminated potential duplication by consolidating the collection of plan benefits data. The collected data are then used to support numerous activities, including the marketing material review process, the generation of plan marketing materials, and other program oversight and development activities. Because the PBP and formulary collects the

information that populates the www.medicare.gov website and in the *Medicare & You* Handbook, there is no need for organizations to complete multiple marketing data reporting activities for CMS.

The information collected in the RTBT is also not duplicated through any other CMS agency effort.

5. Small Businesses

Small businesses are not significantly affected by this collection. Where small businesses may participate in these programs, they are required to submit these same data, per statutory requirements. This software is designed to provide all participating businesses with a straightforward and efficient method for delivering these data to CMS.

6. Less Frequent Collection

Since CY 2001, CMS has collected the benefit package once a year as required by the Social Security Act. Under MMA, this collection is now part of the annual bidding process, where organizations are required to submit their proposed plan benefit packages (including the PBP and formulary) for the upcoming contract year. In the event that an organization would propose mid-year benefit enhancements to their existing plans, propose new plans, or enter the Medicare program as a new organization, the organization would be required to submit the benefit package materials during the contract year.

If this collection were not conducted or were conducted less frequently than described above, there would be adverse consequences, including but not limited to, the following:

- Organizations would not be able to increase the number of plan or enhance current plan choices available to Medicare beneficiaries.
- Organizations would not be able to make changes to the formulary that could enhance the therapeutic options or lower cost-sharing for beneficiaries.
- CMS would not be able to accurately or effectively educate Medicare beneficiaries on the plan choices available to them.
- CMS would not be able to effectively review and approve plan marketing materials.
- CMS would not be able to effectively review and approve the PBP and formulary, as required by statute.
- Beneficiaries would not receive accurate, updated plan information via the website.

7. Special Circumstances

Organizations may be required to submit benefit data more often under certain circumstances. Each organization must submit a new PBP and an updated formulary on an annual basis as part of the annual bidding process. Under certain circumstances, an organization could choose to enhance an existing plan benefit package mid-year or offer new plans, which would require a second submission. Additionally, organizations must submit any changes in their formulary prior to removing a covered Part D drug or when making any change in the preferred or tiered cost-sharing status of a covered Part D drug as required by the regulations.

8. Federal Register Notice/Outside Consultation

Federal Register

The November 30, 2018 (83 FR 62152), proposed rule (CMS-4180-P, RIN 0938-AT92) serves as the 60-day Federal Register notice.

Outside Consultation

Formulary: CMS and one of its consultants first drafted the formulary submission for use during CY 2006 by utilizing its considerable experience from the Medicare Prescription Drug Card program and by conferring with the industry on numerous occasions. CMS requests comments and feedback from the industry via a lessons learned process annually. The 2020 format is included in the formulary guidelines.

PBP: CMS, with contractor support, prepared the initial draft of the PBP for use during CY 2001 by performing extensive market research, screening, and testing. Since the initial PBP development, CMS has taken numerous opportunities to confer with representatives from the Medicare private plan industry, including MA and PDP organizations and trade groups, to solicit comments and feedback on the PBP software. CMS has also included internal users of the PBP data in these efforts. Participants included staff from each CMS Regional Office, Central Office Medicare Advantage and Prescription Drug staff, and staff from the CMS beneficiary education campaign. These comment opportunities have included the following:

- **Beta Testing** – The functional test PBP software is distributed to plans for the Beta testing to allow for hands-on data entry testing and to identify any potential bugs/defects with the software. CMS is scheduled to hold the PBP 2020 Beta in early February 2019. This process has occurred each year since the start of the PBP.
- **Lessons Learned Comments** – CMS has implemented a formal process for the electronic submission of comments and feedback through the HPMS website. The annual comment period serves as an opportunity to account for lessons learned on the PBP post production and use. The 2019 Lessons Learned comment period was held from July 9, 2018 through July 20, 2018.
- **Ongoing Discussions** – As part of our daily business of assisting organizations and others, CMS has informally received comments concerning the PBP from organizations, trade associations, Central Office, and Regional Offices.

After collecting and compiling these requests and comments during the various timeframes, CMS reviews each one and makes a determination as to whether the change should be made in the software. The CMS review team consists of the agency component areas that serve as stakeholders for the PBP, including MA and Part D policy and operations, beneficiary education, and systems. Appendix B provides a detailed list of the changes identified for the PBP software package and the formulary file for CY 2020 as a result of feedback from the Medicare private plan industry community and administrative and legislative directives.

Lastly, CMS is providing numerous instructional sessions and user instructions for the PBP and formulary submission during the upcoming months.

9. Payments/Gifts to Respondents

While there are no monetary payments or gifts to respondents, the approval of the contract for the organization is an incentive for their participation in the Medicare program.

10. Confidentiality

The information collected through the Plan Benefit Package (PBP) software is considered proprietary until the bids are approved by CMS for the upcoming contract year (September-October timeframe). After bid and contract approval, CMS publishes a subset of PBP data elements for research and analysis purposes on www.cms.gov.

Information collected through the formulary contains proprietary information, trade secret, commercial and/or financial information, therefore it is privileged, private to the extent permitted by law, and protected from disclosure. Formulary supporting documentation is considered private to the extent permitted by law and will not be disclosed to the public.

These data are protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA). Exemption 4 is provided below and is part of the HHA FOIA implementation regulation (45 CFR Section 5.65) available at: http://www.hhs.gov/foia/45cfr5.html#Subf:

> "Sec. 5.65 Exemption four: Trade secrets and confidential commercial or financial information. We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.
>
> Trade secrets. A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.
>
> Commercial or financial information. We will not disclose records whose information is "commercial or financial," is obtained from a person, and is "privileged or confidential." Information is "commercial or financial" if it relates to businesses, commerce, trade, employment, profits, or finances (including personal finances). We interpret this category broadly.
>
> Information is "obtained from a person" if HHS or another agency has obtained it from someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information. "Person" includes an individual, partnership, corporation, association, state or foreign government, or other organization. Information is not "obtained from a person" if it is generated by HHS or another federal agency. However, information is "obtained from a person" if it is provided by someone, including but not limited to an agency employee, who retains a commercial or financial interest in the information.
>
> Information is "privileged" if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.
>
> Information is "confidential" if it meets one of the following tests:
>
> Disclosure may impair the government's ability to obtain necessary information in the

future;

Disclosure would substantially harm the competitive position of the person who submitted the information;

Disclosure would impair other government interests, such as program effectiveness and compliance; or

Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.

The following questions may be relevant in analyzing whether a record meets one or more of the above tests: Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?"

This information is not published in a manner that identifies individual business decisions, unless otherwise indicated. Information provided for the CMS beneficiary education campaign (i.e., www.medicare.gov and the *Medicare & You* handbook) is published no earlier than the time frames required for the legislatively mandated annual enrollment period. The PBP software identifies for the user the specific data elements that are used for the beneficiary education campaign.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimate (Total Hours & Wages)

Wage Estimates

To derive average costs for the private sector, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Pharmacist	29-1051	58.52	58.52	117.04

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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

The estimates for “number of respondents” and “average number of responses per respondent” are based on the previous years’ bid submissions.

The estimated hour burden for the PBP and formulary submissions for CY 2020 is 65,354.5 total burden hours, or 114.66 hours per organization.

- 570 Organization (532 Medicare Advantage + 38 Prescription Drug Plans)
- 11 plans/PBPs per organization*
- 493 Formulary submissions*
- 6,763 total annual responses ([570 organizations x 11 plans/organization] + 493 submissions)
- 7.75 hours to complete gather of information, data entry, reviewing instructions, and attending training for the PBP**
- 34 hours to complete gather of information, data entry, reviewing instructions, and attending online training for the Formulary**
- 48,592.5 hours for industry to complete the PBPs (570 organizations x 11 plans/organization x 7.75 hr)
- 16,762 hours for industry to complete the Formularies (493 submissions x 34 hr)
- 65,354.5 total hours for industry to complete entire submission (48,592.5 hr + 16,762 hr)

An estimate of the annualized cost to the industry in burden hours for the complete submission is approximately $5,032,296.50 (65,354.5 hr x $77.00/hr**).

Key

* Source: HPMS actual data

** Source: Wage based on the results of industry survey of average hourly wage for individuals completing the data submissions.

Our November 30, 2018 (83 FR 62152) proposed rule (CMS-4180-P, RIN 0938-AT92) would require that that each Part D plan select a real time benefit tool (RTBT) of its choosing by January 1, 2020. As explained in more detail under section 15 (below) we are unable to fully quantify the impact of RTBT implementation due to lack of adequate data.

The use of RTBT will affect software costs; however, the production of the formulary and bid will not be changed because RTBT is being used. Consequently we are not estimating additional impact on the bid because it is not necessary.

Section 423.120(b)(2)(vi) would implement the authority granted to CMS by section 1860D-4(b)(3)(G) of the Act to establish exceptions that would permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through prior authorization or utilization management) a particular Part D drug that is otherwise required to be included in the formulary.

For the proposed exceptions that expand the use of prior authorization and step therapy for protected class drugs at § 423.120(b)(2)(vi)(C) and the exceptions for protected class drugs that are new formulations at § 423.120(b)(2)(vi)(D), the burden would consist of the time and effort for Part D sponsors to submit their formularies to CMS under the existing annual submission process. The annual submission requirements and burden are currently approved by OMB under this control number and would not impose any new or revised information collection requirements or burden.

For the proposed exceptions related to § 423.120(b)(2)(vi)(E), for protected class drugs for which a Part D sponsor chooses to exclude from their formulary due to a price increase beyond a certain threshold, Part D sponsors would be required to submit an additional justification to CMS during the annual formulary submission process. The justification must explain why the Part D sponsor is excluding such drug from their formulary. The burden associated with this exception would consist of the time and effort put forth by Part D sponsors to prepare and submit their formularies to CMS along with the justification.

While the annual formulary preparation and submission process and burden are currently approved by OMB without the need for change, we estimate that it would take an average of 10 minutes (0.167 hours) at $117.04/hr for a pharmacist to prepare and submit each justification. Because Part D sponsors already research list prices to inform the existing formulary negotiation process, we only consider the time necessary to prepare and submit the justification to CMS. We estimate that all 218 Part D plan sponsors (32 PDP parent organizations and 186 MA-PD parent organizations, based on plan year 2018 plan participation) would be subject to this requirement. In aggregate, we estimate an annual burden of 36 hours (0.167 hr x 218 sponsors) at a cost of $4,213 (36 hr x $117.04/hr).

Burden Summary

Summary of Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	**Respondents**	**Responses (per respondent)**	**Total Responses**	**Burden per Response**	**Total Annual Burden (hours)**	**Labor Cost of Reporting ($/hr)**	**Total Cost ($)**
Plan Benefit Package *423.100, 423.104, 423.112, 423.124, 423.128, 423.132, 423.136, 423.251, 423.258, 423.265, 423.272, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, and 423.350.*	570	varies	6,763	114.66 hr	65,354.5	77.00	5,032,296.50
Protected Classes *423.120*	218	1	218	0.167 hr	36	117.04	4,213
Total	570	Varies	6,981	Varies	65,390.5	Varies	5,036,509.50

Information Collection Documents

- PBP Software Screenshots (No Proposed Changes)
- Formulary File Record Layouts (No Proposed Changes)

13. Capital Costs

There is no capital cost needed for this collection effort.

14. Cost to the Federal Government

The PBP undergoes annual updates. These updates reflect system updates and help updates for both Part D and Part C. The annual updates are about $1.2 million in burden and this is the average ongoing costs. Since updates happen routinely every year, an extra update does not affect the average cost.

Consequently, we are not listing the impact on the PBP: first, as just indicated the annual $1.2 million burden (in this package) includes updates from several sources; second, we have not begun to implement these particular updates and have no way of estimating what it would cost. However, it would be incorrect to simply cite the entire PBP cost and apply it to one update

15. Program Changes

Our November 30, 2018 (83 FR 62152), proposed rule (CMS-4180-P, RIN 0938-AT92) would require that that each Part D plan select a real time benefit tool (RTBT) of its choosing by January 1, 2020. We are unable to fully quantify the impact of RTBT implementation due to lack of adequate data. We are unsure if the industry will use third party intermediaries or build their own software. As a result, we solicited comments on the RTBT proposal. However, the following illustrates a sample of the range of potential implementation costs.

Under the following scenarios plans used their own software resulting in a cost ranging from $1.05 million to $4.2 million. This cost is based on a unit of two software developers, two programmers, two physicians and two pharmacists whereby the programmers are needed to write the code while the software developers are needed for business requirements. Both physicians and pharmacists would be needed to identify clinically equivalent drugs.

We have detailed this cost in the table below. This $8,192 which is the cost per day for a unit of 8 staff is used as a factor which is multiplied by the number of days that might be needed to create the software. We informally spoke to industry and they suggested it would take half a year to 2 years. The corresponding impacts are described below

The following examples of impacts of scenarios are illustrative:

- If we assume a year of work is needed we would need $2.1 million (52 weeks x 5 days a week x $8,192 cost per day) per organization
- If we assume that 2 years of work is needed, we would double the $1-year impact with a resulting cost of $4.2 million ($2.1 million/ year x 2 years) per organization
- If we assume only 6 months are needed then half would be needed ($1.05 million or $2.1 million / 2) per organization.

In addition to the uncertainties just documented, we are uncertain on how many organizations already have RTBT and of those who do not have it, what portion will implement RTBT through their own software.

If plans were to use intermediaries, the cost could range depending on the cost per transaction, which can range from $.01/transaction for plans with large volumes to $.50/transaction for smaller plans. If we multiply this amount by the estimated 1.4 billion PDE transactions per year, which is the number based on internal CMS data, this net cost could range from $14 million year to $700,000,000/year.

In addition to the uncertainty mentioned in the previous paragraph, there is uncertainty on how many PDE events per year will benefit from RTBT; clearly this number is significantly below 1.4 billion. We are also uncertain on how many organizations would use this and thus cannot estimate the cost per organization.

Based on the above, we are not quantitatively scoring this provision.

BLS Occupation Code	Occupation Title	Mean Wages per Hour	Fringe Benefits and Overtime	Wage per Person	Number of People	Wage per Occupation	Hours per Day	Wage per Day
29-1051	Pharmacists	$58.52	$58.52	$117.04	2	$234.08	8	$1,873
29-1060	Physicians	$101.63	$101.63	$203.26	2	$406.52	8	$3,252
15-1133	Software developers system software	$53.74	$53.74	$107.48	2	$214.96	8	$1,720
15-1131	Programmers	$42.08	$42.08	$84.16	2	$168.32	8	$1,347
	Total cost per day							$8,192

The use of RTBT will affect software costs; however, the production of the formulary and bid will not be changed because RTBT is being used. Consequently we are not estimating additional impact on the bid because it is not necessary.

Section 423.120(b)(2)(vi) would implement the authority granted to CMS by section 1860D-4(b)(3)(G) of the Act to establish exceptions that would permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through prior authorization or utilization management) a particular Part D drug that is otherwise required to be included in the formulary.

For the exceptions that expand the use of prior authorization and step therapy for protected class drugs at § 423.120(b)(2)(vi)(C), the burden would consist of the time and effort for Part D sponsors to submit their formularies to CMS under the existing annual submission process. The annual submission requirements and burden are currently approved by OMB under this control number and would not impose any new or revised information collection requirements or burden.

For the exceptions related to § 423.120(b)(2)(vi)(D), for protected class drugs for which a Part D sponsor chooses to exclude from their formulary due to a price increase beyond a certain threshold, Part D sponsors would be required to submit an additional justification to CMS during the annual formulary submission process. The justification must explain why the Part D sponsor is excluding such drug from their formulary. The burden associated with this exception would consist of the time and effort put forth by Part D sponsors to prepare and submit their formularies to CMS along with the justification.

While the annual formulary preparation and submission process and burden are currently approved by OMB without the need for change, we estimate that it would take an average of 10 minutes (0.167 hours) at $117.04/hr for a pharmacist to prepare and submit each justification.

Because Part D sponsors already research list prices to inform the existing formulary negotiation process, we only consider the time necessary to prepare and submit the justification to CMS. We estimate that all 218 Part D plan sponsors (32 PDP parent organizations and 186 MA-PD parent organizations, based on plan year 2018 plan participation) would be subject to this requirement. In aggregate, we estimate an annual burden of 36 hours (0.167 hr x 218 sponsors) at a cost of $4,213 (36 hr x $117.04/hr).

The proposed rule would make no changes to our currently approved (active) PBP Software Screenshots and Formulary File Record Layouts.

The increase in burden from the previously approved package is attributable to the addition of the Protected Class Provision, which adds 36 additional hours of burden.

16. Publication and Tabulation Dates

Using the plan benefits data entry already completed by the user, the PBP software automatically generates standardized data in a consistent format that are then displayed to the public through several mechanisms, including the www.medicare.gov website and the *Medicare & You* handbook. The completed formulary is utilized to display drug benefit information on the www.medicare.gov website.

In all cases below, the organization is required to electronically submit their formulary no later than the Friday prior to the first Monday of June and the PBP no later than the first Monday of June. The organization may start developing their formulary at any time and may submit the formulary as early as mid-May. Additionally, the organization may start developing their PBP on the first Friday of April.

The following gives a description of each publication of this data:

- **CMS Website** - The formulary information and standardized benefits data from the PBP are displayed on an interactive web tool on www.medicare.gov that enables beneficiaries to compare plan benefit packages. Prior to posting, organizations are allowed to preview only their own plan benefit data. The initial posting of the benefits data for a new contract year occurs in mid-October (e.g., posting of CY 2014 data in October 2013).
- ***Medicare & You* Handbook** - CMS uses a small subset of the PBP data to generate high-level, limited plan benefits information (e.g. plan name, monthly premium, physician cost sharing) for the *Medicare & You* handbook. Organizations are provided a preview opportunity prior to printing. The initial printing of the plan benefits portion of the handbook occurs in late September to early October with the handbook being delivered to Medicare beneficiaries in October.

17. Expiration Date

CMS has no objections to displaying the expiration date. The expiration date is posted in the "about PBP" section of the PBP software and under the "OMB clearance" link of the formulary submission module in HPMS.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

Not Applicable. No statistical methods will be used in this collection effort.