Appendix A: Supporting Statement for Paperwork Reduction Act Submissions
CMS Plan Benefit Package (PBP) and Formulary CY 2019
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, 423.251, 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 481 MA organizations and 39 PDP organizations will be required to submit the plan benefit package information in CY 2019. 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.

This is a revision of the 60-day PRA package for the 30-day review. Changes have been made compared to the 60-day package and include additional changes to the PBP – identified in the List of Changes, a removal of a Formulary file, as well as an addition of a Formulary upload. As a result of the Formulary changes, there has been a revision of the burden estimate, and a revision to the costs to both industry and the Government. These changes are identified in more detail below, in the List of Changes, as well as in the Formulary and PBP screenshots. There were no changes to the MTMP portion of this PRA.

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.

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 files.

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.

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.

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 60-day notice published in the Federal Register on September 22, 2017 (81 FR 75406). Comments were received and are attached to this package along with our response. The majority of the comments were already received and responded to during our lessons learned over the summer, and were already being discussed by the CMS teams overseeing the program. While some of the changes ended up being made, they were NOT a direct result of the comments received from the 60-day.

The 60-day comments received by industry did not require any changes to the 30-day package.

However further CMS internal decisions did. The changes were included in the following screenshots and layouts:
Appendix_C_ Formulary_CY2019_ OTC_Record_Layout.pdf
Appendix_C_PBP_2019_ screenshots_section_a_and_upload_2017_11_17.pdf
Appendix_C_PBP_2019_ screenshots_section_b_2017_11_16.pdf
Appendix_C_PBP_2019_ screenshots_section_b_VBID_UF_2017_11_21.pdf
Appendix_C_PBP_2019_ screenshots_section_c_2017_11_16.pdf
Appendix_C_PBP_2019_ screenshots_section_d_2017_11_17.pdf
Appendix_C_PBP_2019_ screenshots_section_Rx_2017_11_17.pdf
Appendix_C_PBP_2019_ screenshots_section_Rx_VBID_2017_11_17.pdf
Appendix_C_CY2019_Formulary_Opiod Strategy Layout_final.pdf
Appendix_C_CY2019_Formulary_MED Opioid Strategy Submission.pdf

Since the PBP changes were a combination of changes that both reduced and added burden, they did not result in any net burden change for the PBP section. The changes that reduced burden included but are not limited to: adding the ability for plans to indicate benefit periods instead of writing them in the notes fields, and the removal of a question from the PBP. The changes that increased burden include but are not limited to: ability for plans to clarify benefits, and a new section for plans that include a specific benefit (note: this only affects plans to have this benefit). The changes can be found in the attached List of Changes document under the CY 2019 PBP Changes section.

However, changes to the Formulary have resulted in a net increase in burden from 30 hours per response up to 34 hours. The changes include the removal of an entire Non-Extended Day Supply (NDS) supplemental file which effectively reduced burden by 2 hours. CMS removed the Non-Extended Day Supply file based on feedback from Part D sponsors. This file contained the list of drugs that were not covered at an extended day supply (e.g., the drugs that were not covered under a 90 day supply). Part D sponsors indicated that the maintenance of this supplemental file has been operationally challenging. Additionally, CMS's review of the CY 2017 NDC files have not identified any discriminatory activities or causes for concerns. CMS has concluded the burden of maintaining this supplemental file outweighs any benefit, as such, CMS is eliminating this supplemental file for CY 2019. While the addition of the opioid upload increased burden by 6 hours, for a net increase of 4 hours. The opioid upload was added because opioid medications ("opioids") have serious risks such as addiction, overdose, and death. In response to the growing national opioid epidemic, CMS's Medicare Part D opioid overutilization policy has evolved incrementally to address prescription opioid overuse in Medicare Part D from a medication safety perspective while preserving beneficiary access to medically necessary drug regimens. The submission is a word file where the plans respond to questions regarding their P&T opioid formulary design approach, concurrent drug utilization review process, how opioids are addressed in the MTMP, their drug management process, FWA programs, overuse prevention strategies, how MA data is used to opioid utilization, commercial efforts to combat opioid crisis, lessons learned, and space where they can write other relevant information to us. The details and all questions regarding sections and summaries provided above for the opioid upload can be found in the attached List of Changes document under the Formulary Changes section as well as in the new upload file Appendix_C_CY2019_Formulary_Opiod Strategy Layout_final.

Due to the addition of the opioid upload, there is additional cost to the government for the review of the submissions. This increase is estimated to be approximately $75,000 in additional Government contractor costs.

The 30-day notice published in the Federal Register on December 29, 2017 (82 FR 61762). We received four (4) comments from one organization. The comments relate to clarifications as well as the opportunity to provide comments to CMS regarding future policy and regulatory changes. The comment has been added to this package as well as our response.

While this section of the Supporting Statement compares/contrasts the 60-day package vs. this 30-day package, section 15 (see below) compares/contrasts currently approved requirements and burden vs. this iteration's proposed requirements and burden. The changes can be found in the attached List of Changes.

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 2019 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 2019 Beta in early February 2018. 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 2018 Lessons Learned comment period was held from July 17, 2017 through July 28, 2017.
- **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 2019 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

There are no payments/gifts to respondents.

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)

Burden

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 2019 is 56,450 total burden hours, or 108.56 hours per organization.

- 520 Organization [520 = 481 Medicare Advantage + 39 Prescription Drug Plans]
- 10 plans/PBPs per organization*
- 475 Formulary submissions*
- 5,675 total annual responses [5,675 = 520*10 + 475]
- 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**
- 40,300 hours for industry to complete the PBPs [40,300 = 520*10*7.75]
- 16,150 hours for industry to complete the Formularies [16,150= 475*34]
- 56,450 total hours for industry to complete entire submission [56,450 = 40,300 + 16,150]

An estimate of the annualized cost to the industry in burden hours for the complete submission is approximately **$4,346,650.00** (56,450 hours * $77.00 per hour**).

Key
* Source: HPMS actual data
** Source: Amounts based on the results of industry survey.

Information Collection Documents

- PBP Software Screenshots
- Formulary File Record Layouts
- Crosswalk to the PBP Software and Formulary File

13. Capital Costs

There is no capital cost needed for this collection effort.

14. Cost to the Federal Government

The initial burden to the Federal government for the collection of the PBP and formulary data was borne through the development cycle as a one-time cost. The PBP and the formulary are now in maintenance mode with regard to development and enhancements. The maintenance cost and the cost to enhance of the PBP and formulary software as well as the cost of CMS employees' time are calculated to be: **$1,122,229.60.** The calculations for CMS employees' hourly salary were obtained from the OPM website: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf (effective January 2017 for the Washington-Baltimore-Arlington locality).

PBP - Maintenance and Enhancements	$639,777.00
Medicare Part D Help PBP:	
2 GS-13 (step 5): 2 x $51.48/hr x 20 hours	$2,059.20
1 GS -14 (step 5): 1 x $60.83/hr x 20 hours	$1,216.60
2 GS -15 (step 5): 2 x $71.56/hr x 10 hours	$1,431.20
Subtotal	*$4,707.00*
Medicare MA Help PBP:	
2 GS-15 (step 5): 2 x $71.56/hr x 20 hours	$2,862.40
4 GS-13 (step 5): 4 x $51.48/hr x 20 hours	$4,118.40
Subtotal	*$6,980.80*
TOTAL PBP COST:	$651,464.80
Formulary - Maintenance and Enhancements	$390,386.00

Formulary – Opioid Submission Review	$75,000
Medicare Part D Help FDR:	
3 GS-13 (step 5): 3 x $51.48/hr x 20 hours	$3,088.80
1 GS -14 (step 5): 1 x $60.83/hr x 20 hours	$1,216.60
1 GS -15 (step 5): 1 x $71.56/hr x 15 hours	$1,073.40
Subtotal	*$5,378.80*
TOTAL FORMULARY COST:	$470,764.80
Total Cost to the Government:	**$1,122,229.60**

15. Program Changes

The increase to burden is attributable to an increase in the number of actual plans submitting/PBPs per organization from 9 plans/PBP to 10 plans/PBP, along with a decrease in the number of reporting organizations from 524 to 520, as well as an increase in the number of formulary submissions from 469 formularies submitted to 475 and the addition of 4 hours due to the new opioid upload.

The number of reporting organizations decreased from 524 contracts to 520 contracts based on the most recent numbers extracted from HPMS. This number represents the total number of organizations that will submit at least one (1) PBP. Because an organization can submit a formulary that covers multiple contract numbers, only a subset of the 520 organizations will submit distinct formularies.

Cost to the government also increased as a direct result of the increased cost of maintaining and enhancing the modules, and the addition of the need to review the new opioid upload submitted by the plans.

Changes due to internal decisions based on lessons learned are reflected in the screenshots for the Formulary, PBP and the MTMP and are directly outlined, and referenced in the list of changes.

Summary of Changes

	ICR Approved on 05/08/2017	Proposed Revisions
Respondents	524	520
Responses	5,185	5,675
Time/Response	9.7	9.9
Hours	50,619	56,450

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.