Appendix A: Supporting Statement Part A
CY 2016 Plan Benefit Package (PBP), Formulary, and Supporting Regulations
CMS-R-262, OCN 0938-0763

Supporting Regulations Contained in 42 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, and 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. For instance, the PBP software automatically generates the standardized sentences for the Summary of Benefits (SB) by using the plan benefit package data entered into the PBP software by the organization's user. These standardized sentences are used by the MA organizations in their SB 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 2016 through CY 2018. CMS estimates that 549 MA organizations and 49 PDP organizations will be required to submit the plan benefit package information in CY 2016. 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.

A. Justification

1. Need and Legal Basis

This information is mandated by the Social Security Act and is cited in the 42 CFR references listed above. Copies of these references are provided in Appendix D.

2. Information Users

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 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. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information. 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 automatically generates the standardized sentences for the SB by using the plan benefit package data already entered into the software by the organization user. These standardized sentences are used by the organization in their SB

marketing materials. The formulary and SB 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. Finally, 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. Also, the SB standardization, resulting from the PBP, has provided organizations with a more timely marketing approval turnaround since these organizations now know precisely the language that will be approved prior to submission.

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, *Medicare & You* Handbook and the SB, 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.

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 Federal Register notice published on September 26, 2014 (79 FR 57931). Comments were received and are attached to this package along with our response.

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 2016 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 SB sentence generation. CMS is schedule to hold the PBP/SB 2016 Beta in early February 2015. 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/SB post production and use. The 2015 Lessons Learned comment period was held from July 14, 2014 through July 25, 2014.
- **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/SB, 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 2016 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.
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> 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.
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> 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.
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> 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)

The estimated hour burden for the PBP and formulary submissions for CY 2016 is 56,410.5 total burden hours, or 94.33 hours per organization.

- 598 Organization [598 = 549 Medicare Advantage + 49 Prescription Drug Plans]
- 9 plans/PBPs per organization*
- 400 Formulary submissions*
- 5,872 total annual responses [5,872 = 598*9 + 490]

- 7.75 hours to complete gather of information, data entry, reviewing instructions, and attending training for the PBP**
- 30 hours to complete gather of information, data entry, reviewing instructions, and attending online training for the Formulary**
- 41,710.5 hours for industry to complete the PBPs [41,710.5 = 598*9*7.75]
- 14,700 hours for industry to complete the Formularies [14,700 = 490*30]
- 56,410.5 total hours for industry to complete entire submission [53,710.5= 41,710.5 + 14,700]

An estimate of the annualized cost to the industry in burden hours for the complete submission is approximately **$4,343,608.50** (56,410.5 hours * $77.00 per hour**).

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

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: **$849,059.75.** The calculations for CMS employees' hourly salary were obtained from the OPM website: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB_h.pdf.

PBP - Maintenance and Enhancements	$560,000
Medicare Part D Help PBP:	
2 GS-13: 2 x $43.09 x 20 hours	$1,723.60
1 GS -14: 1 x $50.92 x 20 hours	$1018.40
2 GS -15: 2 x $59.89 x 10 hours	$1197.80
	$3,939.80
Medicare MA Help PBP:	
2 GS-15: 2 x $59.89 x 20 hours	$2,395.60
4 GS-13: 4 x $43.09 x 20 hours	$3,447.20
	$5,842.80
TOTAL PBP COST:	**$569,782.60**
Formulary - Maintenance and Enhancements	$274,775
Medicare Part D Help FDR:	

3 GS-13: 3 x $43.09 x 20 hours	$2,585.40
1 GS -14: 1 x $50.92 x 20 hours	$1018.40
1 GS -15: 1 x $59.89 x 15 hours	$898.35
	$4,502.15
TOTAL FORMULARY COST:	**$279,277.15**
Total Cost to the Government:	**$849,059.75**

15. Program Changes

The minimal change to burden is attributable to an increase in the number of formulary submissions as well as a decrease in the number of reporting organizations Additionally the Cost to the Government decreased due to efficiencies gained in the development of the modules. This results in a net decrease of overall burden to industry, but an increase to burden to the individual entities.

The number of reporting organizations decreased from 652 contracts to 598 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 598 organizations will submit distinct formularies.

16. Publication and Tabulation Dates

Using the plan benefits data entry already completed by the user, the PBP software automatically generates standardized sentences that are then displayed to the public through several mechanisms, including the SB marketing material, 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:

- **SB Marketing Material** - The PBP generates a standardized SB for each plan benefit package offered by an organization. The organization is then required to produce a hardcopy version of the SB for its plan members. The organization can begin developing their hardcopy SB as soon as their PBP is completed. CMS will begin reviewing their hard copy SB after the PBP is submitted.
- **CMS Website** - The formulary information and standardized SB sentences generated by 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.

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.