<u>CMS</u> PBP and Formulary CY2008
<u>Appendix A: Supporting Statement for</u>
<u>Paperwork Reduction Act Submissions</u>

<u>The Plan Benefit Package (PBP), Formulary, and Supporting Regulations Contained in 42 Code of Federal Regulation (CFR): 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, 423.251, 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</u>

Specific Instructions

A. 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 formulary file, Plan Benefit Package (PBP) software, and supporting documentation as necessary. MA and PDP organizations will generate a formulary to illustrate their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, the PBP software will be used to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. CMS uses the formulary and PBP 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 2008 through CY 2010. CMS estimates that 360 MA organizations and 90 PDP organizations will be required to submit the plan benefit package information, in CY2008. 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.

B. 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 formulary and PBP 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 formulary and PBP 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 CY2001, 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 file with guidance from CMS policy and operations groups and the solicitation of industry comment. In Appendix C, the hardcopy PBP screen prints and formulary file layout 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 health 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 MA 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 formulary and PBP 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 formulary and PBP collects the information that populates the www.medicare.gov website, *Medicare & You* Handbook and the SB, there is no need for MA or PDP 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 will now be part of the annual bidding process, where organizations are required to submit their proposed plan benefit packages (including the formulary and PBP) 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 formulary and PBP, as required by statute.

- Beneficiaries would not receive accurate, updated information via the website.

7. Special Circumstances

Organizations may be required to submit benefit data more often under certain circumstances. Each organization must submit an updated formulary and a new PBP 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

A 60-day Federal Register notice was published on June 15, 2007.

Formulary: CMS and one of its consultants first drafted the formulary submission for use during CY2006 by utilizing the vast, internal experience on the Medicare Prescription Drug Card program and by conferring with the industry on numerous occasions. The final 2008 format is included in the formulary guidelines and is published on the CMS web site. This guidance was last updated April 2, 2007.

PBP: CMS, with contractor support, prepared the initial draft of the PBP for use during CY2001 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 managed care industry, including MA and PDP organizations and Medicare managed care trade groups, to solicit comments and feedback on the PBP software. CMS 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:

- **Alpha Testing** - During the PBP/SB Alpha testing, CMS provides screen shots of the PBP software and the draft SB sentences. The Alpha testing period was held from January 9, 2007 through January 22, 2007.
- **Beta Testing** – The functional test PBP software is then distributed for the Beta testing to allow for hands-on data entry testing and SB sentence generation. CMS held the PBP/SB 2006 Beta from February 26, 2007 to March 2, 2007. This process has occurred each year since the PBP's conception.
- **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.
- **Ongoing Discussions** – As part of our daily business of assisting organizations and others, CMS has informally received comments concerning the PBP from MA organizations, trade associations, 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 operations, beneficiary education, and systems. Appendix B provides a detailed list of the changes made in the PBP software package and the formulary file for CY2008 as a result of feedback from the Medicare industry community and administrative and legislative directives.

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

9. Payments/Gifts To Respondents

There were no payments/gifts to respondents.

10. Confidentiality

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

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 Open Season. The default font color is black for 508 compliance but the font color preferences can be set so the elements used for the campaign are clearly identified in the PBP software by the red font and all other data elements are color-coded blue font.

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 formulary and PBP submission for CY2008 is 10,800 total burden hours, or 24 hours per organization.

- 450 Organization [450 = 360 Medicare Advantage + 90 Prescription Drug Plans]
- 9 plans/PBPs per organization*
- 1.5 formularies per organization*
- 4,725 total annual responses [4,725 = (450*9) + (450*1.5)]
- 2 hours to complete PBP*
- 4 hours to complete Formulary*
- 8,100 hours for industry to complete the PBPs [8,100 = 450*9*2]
- 2,700 hours for industry to complete the Formularies [2,700 = 450*1.5*4]
- 10,800 total hours for industry to complete entire submission [10,800 = 8,100 + 2,700]

An estimate of the annualized cost to the industry in burden hours for the complete submission is approximately $594,000 (10,800 hours * $55.00 per hour*).

*   Source: Estimated amounts were derived from the results of industry experience.

13. Capital Costs

There are no capital costs needed for this collection effort.

14. Cost to the Federal Government

The initial burden to the Federal government for the collection of the formulary and PBP 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 for enhance of the PBP and formulary software as well as the cost of CMS employees' time are calculated to be: **$808,279.60.** The calculations for CMS employees' hourly salary was obtained from the OPM website: http://www.opm.gov/oca/07tables/html/dcb_h.asp

PBP - Maintenance and Enhancements	$600,000
Medicare Part D Help PBP:	
1 GS-15: 1 x $51.52 x 20 hours	$1,030.40
1 GS-13: 1 x $37.06 x 20 hours	$741.20
	$1,771.60
Medicare MA Help PBP:	
2 GS-15: 2 x $51.52 x 20 hours	$2,060.80
3 GS-13: 3 x $37.06 x 20 hours	$2,223.60
	$4,284.40
TOTAL PBP COST:	**$606,056.00**
Formulary - Maintenance and Enhancements	$200,000
Medicare Part D Help FDR:	
3 GS-13: 3 x $37.06 x 20 hours	$2,223.60
TOTAL FORMULARY COST:	**$202,223.60**
Total Cost to the Government:	**$808,279.60**

15. Program Changes

There have been no changes in total burden hours from the Emergency PRA Package. To see the comprehensive list of changes from CY2007 to CY2008, please refer to the document entitled "Appendix B – PBP-Formulary CY2008 List of Changes."

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 will also be 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 third Monday of April 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 the last Monday of March. 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 2008 data in October 2007).
- *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. Similar to the website, there are quarterly updates throughout the year to capture mid-year benefit enhancements, service area expansions, and new plans.

17. Expiration Date

CMS has no objections to displaying the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C.   Collections of Information Employing Statistical Methods

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