



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-262 and CMS-10662]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

*Contents*

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-R-262 Contract Year 2021 Plan Benefit Package (PBP) Software and Formulary Submission  
CMS-10662 Administrative Simplification HIPAA Compliance Review

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### *Information Collection*

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Contract Year 2021 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* 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.

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. *Form Number:* CMS-R-262 (OMB control number: 0938-0763); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 672; *Total Annual Responses:* 7,264; *Total Annual Hours:* 67,368. (For policy questions regarding this collection contact Kristy L. Holtje at 410-786-2209.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Administrative Simplification HIPAA Compliance Review; *Use:* The authority for administering and enforcing compliance with the Administrative Simplification non-privacy Health Insurance Portability and Accountability Act (HIPAA) rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). (68 FR 60694 Part F, October 23, 2003) 45 CFR 160.308 states, “that the Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable administrative simplification provisions.” These reviews are conducted at the discretion of the Secretary. Title 45 CFR 160.310 requires that a covered entity provide records and compliance reports to the Secretary in cooperation with a compliance review. Title 45 CFR 160.310 provides that a covered entity must permit HHS, or its delegated entity, access during normal business hours to its facilities, books, records, and other

information, and other information necessary to determine compliance, but also provides that if the Secretary determines that “exigent circumstances exist, such as when documents may be hidden or destroyed,” the covered entity must permit access at any time without notice.

The purpose of this collection is to retrieve information necessary to conduct a compliance review as described in CMS-0014-N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), Program Management National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS-10662 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 425. (For policy questions regarding this collection contact Cecily Austin at 410-786-0895.)

**Dated:** October 1, 2019.

**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**

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