



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10716 and CMS-R-262]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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>
1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
2. Call the Reports Clearance Office at (410) 786-1326.

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

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Applicable Integrated Plan Coverage Decision Letter; *Use:* The Bipartisan Budget Act (BBA) of 2018 directed the establishment of procedures to unify Medicare and Medicaid grievance and appeals procedures to the extent feasible for dual eligible special needs plans (D-SNPs) beginning in 2021. On April 16, 2019, CMS finalized rules (hereafter referred to as the April 2019 final rule) to implement these new statutory provisions.[1] As a result of these regulations, starting in 2021, a subset of full integrated dual special needs plans (FIDE SNPs) and highly integrated dual special needs plans (HIDE SNPs) will need to unify and update appeals and grievance procedures, including how enrollees are notified of their appeal rights.

Applicable integrated plans as defined at § 422.561 are required to issue form CMS-10716 when a request for either a medical service or payment covered under the Medicare or Medicaid benefit is denied in whole or in part. The notice explains why the plan denied the service or payment and informs the plan enrollees of their appeal rights.

The “Applicable Integrated Plan Coverage Decision Letter” or the “coverage decision letter”,

which will be issued as a result of an integrated organization determination under 42 CFR 422.631 when an applicable integrated plan reduces, stops, suspends, or denies, in whole or in part, a request for a service/item (including a Part B drug) or a request for payment of a service/item (including a Part B drug) the member has already received. “Applicable integrated plans,” hereinafter referred to as “plans”, are defined at 42 CFR 422.561 as FIDE SNPs or HIDE SNPs with exclusively aligned enrollment, where state policy limits the D-SNP’s membership to a Medicaid managed care plan offered by the same organization. Applicable integrated plans will issue the coverage decision letter starting in CY 2021 in place of the Notice of Denial of Medical Coverage (or Payment) (NDMCP) form (CMS-10003) as part of requirements to unify appeals and grievance processes. All other Medicare Advantage (MA) plans will continue to use the NDMCP form (CMS-10003). *Form Number:* CMS-10716 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 693; *Total Annual Responses:* 693; *Total Annual Hours:* 116. (For policy questions regarding this collection contact Marna Metcalf Akbar at 410-786-8251.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CMS Plan Benefit Package (PBP) and Formulary CY 2021; *Use:* 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 6062 of the SUPPORT Act amended section 1860D-4(e)(2) of the Act to require the adoption of transaction standards for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D plan sponsors no later than January 1, 2021. *Form Number:* CMS-R-262 (OMB control number: 0938-0763); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits institutions); *Number of Respondents:* 774; *Total Annual Responses:* 9,201; *Total Annual Hours:* 77,343. (For policy questions regarding this collection contact Joella Roland at 410-786-7638.)

Dated: April 9, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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