

DATES: Comments must be received by April 29, 2024.

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 <https://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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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-10882 The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents.

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents; *Use:* Sections 1860D-2(b)(2)(E)(v)(II)-(IV) of the Act state the requirements for Part D sponsors and MA organizations in implementing the program, which include the processes for outreach to enrollees identified as likely to benefit, election, and termination. Subsection II states that any Part D enrollee may elect into the program prior to (aa) or during (bb) the plan year. Subsection III details that PDP sponsors and MA organizations must have a mechanism in place to inform enrollees that they are likely to benefit from electing into the program at the point of sale (POS). Subsection IV(aa) states that plans must terminate a beneficiary’s participation in the program when the beneficiary fails to pay the amounts owed under this program.

CMS has developed the six materials in the attached package as model notices in order to provide standardized and consistent language for potential and active program participants, regardless of which Part D plan they may be enrolled in. CMS will require Part D plans to disseminate these notices, as appropriate, to Part D enrollees to fulfill the requirements of the Sections 1860D-2(b)(2)(E)(v)(II)-(IV) of the Act. *Form Number:* CMS-10882 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private, Federal Government, Business or other for profits, Not-for-profits institutions; *Number of Respondents:* 1,065; *Total Annual Responses:* 3,195; *Total Annual Hours:* 127,800. (For policy questions regarding this collection contact Michael Brown at (872) 287-1370 or michael.brown3@cms.hhs.gov.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-04302 Filed 2-28-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Clearance for the Comprehensive Child Welfare Information System (CCWIS) Technical Assistance and Review Process (Office of Management and Budget #: 0970-0568)

AGENCY: Children’s Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children’s Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is requesting a 3-year extension of the Generic Clearance for the Comprehensive Child Welfare Information System (CCWIS) Technical Assistance (TA) and Review Process, (OMB #0970-0568, expiration 4/30/2024) and all approved information collections under this generic. There are no changes requested to the terms of the umbrella generic or to the currently approved information collections.

DATES: Comments due within 60 days of publication. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing info_collection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The CCWIS Technical Assistance and Review information collection includes two components.

The CCWIS Assessment Review (CAR) Process.

TA tools for title IV-E agencies to self-assess their conformity to CCWIS project and design requirements at 45 CFR 1355.52-3; The CCWIS requirements at 45 CFR 1355.55 require the review, assessment, and inspection of the planning, design, development, installation, operation, and maintenance of each CCWIS project on a continuing basis. The Advance Planning Document (APD) regulations at 45 CFR 95.621 require periodic reviews of state and local agency methods and practices to ensure information systems, including CCWIS, are utilized for purposes

consistent with proper and efficient administration.
This request is for an extension with no changes to the umbrella generic and

all currently approved information collections, which can be found here: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202311-0970-010.

Respondents: Title IV–E agencies under the Social Security Act.

Annual Burden Estimates

ANNUAL BURDEN—CURRENTLY APPROVED INFORMATION COLLECTIONS

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
CCWIS Self-Assessment—Administration	55	1	10	550
CCWIS Self-Assessment—Adoption	55	1	10	550
CCWIS Self-Assessment—Case Management	55	1	10	550
CCWIS Self-Assessment—Foster Care and Service Provider Management	55	1	10	550
CCWIS Self-Assessment—Intake	55	1	10	550
CCWIS Self-Assessment—Investigation	55	1	10	550
CCWIS Self-Assessment: Child Welfare Contributing Agency (CWCA)	55	1	10	550
CCWIS Self-Assessment: Data Exchanges	55	1	10	550
CCWIS Self-Assessment: Data Quality	55	1	10	550
CCWIS Self-Assessment: Design Requirements	55	1	24	1,320
CCWIS Self-Assessment: Financial	55	1	10	550
CCWIS Self-Assessment: Reporting	55	1	10	550
CCWIS Self-Assessment: Security	55	1	10	550
CCWIS Self-Assessment: Title IV–E Foster Care Maintenance Eligibility	55	1	10	550
CCWIS Self-Assessment: User Experience	55	1	10	550
Total Annual Burden for Currently Approved Generics:	9,020

ANNUAL BURDEN—POTENTIAL ADDITIONAL INFORMATION COLLECTION REQUESTS

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Future Tools to be developed	55	5	10	2,750

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 5 U.S.C. 301; 42 U.S.C. 470, 620 *et seq.*, 622(b), 629(b)(a), 652(b), 654A, 670 *et seq.*, 671(a), 1302, and 1396a(a).

Mary C. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2024-04264 Filed 2-28-24; 8:45 am]

BILLING CODE 4184-25-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2022-E-2261, FDA-2022-E-2262, and FDA-2022-E-2263]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVNAR-20

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for PREVNAR-20 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are

incorrect may submit either electronic or written comments and ask for a redetermination by April 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 27, 2024. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,