

aggregate reporting only; not to be reported for each individual participant); an OMB-recommended six-point disability variable (not tied to CDC recognition and with a variable option of ‘Participant chose not to respond’); a health equity-related social determinants of health (SDOH) variable set (to assess whether there was a social needs assessment conducted; key SDOH issues identified; and whether any action was taken; not tied to CDC recognition); a Middle Eastern or North African write-in option within the current race/ethnicity variable; and two new options for the current payersource variable.

Key changes to the application data collection instrument allow for a yes/no drop-down question asking if an organization’s zip code is in an area of high social vulnerability based on the Social Vulnerability Index, which would permit an in-person organization to be fast-tracked to Preliminary

recognition status to allow the organization to apply to CMS to become an MDPP supplier; revisions to the combination delivery mode to include an option for in-person delivery with a distance learning component; and collection of a projected program start-date.

During the period of this Revision, CDC estimates receipt of approximately 200 DPRP application forms per year from new organizations. The estimated burden per one-time application response is one hour (annualized to 200 hours). In addition, CDC estimates receipt of semi-annual evaluation data submissions from the same 200 additional organizations per year, estimated at two hours per response. The total estimated average annualized evaluation burden for new respondents is 2,400 hours. This includes an estimate of the time needed to extract and compile the required data records and fields from an existing electronic

database, review the data, and enter the data via the DPRP Data Portal. CDC also has 1,500 currently recognized organizations that will continue to submit semi-annual evaluation data. These organizations are reflected in Supporting Statement B within this OMB revision.

The estimated burden per response is moderate, since the information requested for CDC recognition is routinely collected by most organizations that deliver the National DPP lifestyle change program for their own internal evaluation and possible insurance reimbursement purposes, including the MDPP benefit. Participation in the DPRP is voluntary, data are de-identified, no personally identifiable information (PII) is collected by CDC, and there are no costs to respondents other than their time. CDC is requesting a three-year approval. The total estimated annualized burden is 7,800 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Public sector organizations that deliver the National DPP lifestyle change program.	DPRP Application Form	80	1	1
	DPRP Evaluation Data	740	2	2
Private sector organizations that deliver the National DPP lifestyle change program.	DPRP Application Form	120	1	1
	DPRP Evaluation Data	1,160	2	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10434]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services.

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the “generic” clearance process. Generally, this is an expedited clearance process by which agencies may obtain OMB’s approval of

collection of information requests that are “usually voluntary, low-burden, and uncontroversial,” do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that may be submitted under that umbrella. This notice is intended to advise the public of our intent to extend OMB’s approval of our MACPro (Medicaid and CHIP Program) umbrella and all of the individual generic collection of information requests that fall under that umbrella. This notice also provides the public with general instructions for obtaining documents that are associated with such collections and for submitting comments.

DATES: Comments must be received by May 23, 2024.

ADDRESSES:

Submitting Comments: When commenting, please reference the applicable collection’s CMS ID number and/or the OMB control number (both numbers are listed below under the SUPPLEMENTARY INFORMATION caption). To be assured consideration, comments and recommendations must be

submitted in any one of the following ways and by the applicable due date:

1. Electronically. We encourage you to submit comments through the Federal eRulemaking portal at the applicable web address listed below under the SUPPLEMENTARY INFORMATION caption under “Docket Information.” If needed, instructions for submitting such comments can be found on that website.

2. By regular mail. Alternatively, you can submit written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs (OSORA), Division of Regulations Development, Attention: CMS-10434/OMB 0938-1188, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Obtaining Documents: To obtain copies of supporting statements and any related forms and supporting documents for the collections listed in this notice, please refer to the following instructions:

1. We encourage you to access the Federal eRulemaking portal at the applicable web address listed below under the SUPPLEMENTARY INFORMATION caption under “Docket Information.” If needed, follow the online instructions

for accessing the applicable docket and the documents contained therein.

FOR FURTHER INFORMATION CONTACT: For general information contact William N. Parham at 410-786-4669. For policy related questions, contact the individual listed below under the **SUPPLEMENTARY INFORMATION** caption under “Docket Information.”

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). Generally, it applies to voluntary and mandatory requirements that are related to any one or more of the following activities: the collection of information, the reporting of information, the disclose of information to a third-party, and/or recordkeeping.

While there are some exceptions (such as collections having non-substantive changes and collections requesting emergency approval) section 3506(c)(2)(A) of the PRA requires Federal agencies to publish 60- and 30-day notices in the **Federal Register** and solicit comment on each of its proposed collections of information, including: new collections, extensions of existing collections, revisions of existing collections, and reinstatements of previously approved collections before submitting such collections to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Interested parties are invited to submit comments regarding our burden estimates or any other aspect of the collection, including: the necessity and utility of the proposed information collection for the proper performance of our agency’s functions; the accuracy of burden estimates; 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. See **DATES** and **ADDRESSES** for instructions for submitting comments.

While we will review all comments received, we may choose not to post off-topic or inappropriate comments. Otherwise, all comments will be posted without edit under the applicable docket number, including any personal information that the commenter provides. Our response to such comments will be posted at [reginfo.gov](https://www.reginfo.gov) under the applicable OMB control number.

Medicaid and CHIP Program (MACPro)

At this time, MACPro is made up of the main umbrella (see collection number 1 in the following list) and nine individual generic collections of information (see collection numbers 2 through 10 in the following list). Details such as the collection’s requirements and burden estimates can be found in the collection’s supporting statement and associated materials (see **ADDRESSES** for instructions for obtaining such documents).

Docket Information

1. Title: Medicaid and CHIP Program (MACPro)

Type of Request: Revision of a currently approved collection.
CMS ID Number: CMS-10434.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0080.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0080>.

For Policy Related Questions, Contact: William N. Parham at 410-786-4669.

2. Title: Initial Application

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #1.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0081.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0081>.

For Policy Related Questions, Contact: Stephanie Bell at 410-786-0617.

3. Title: CHIP State Plan Eligibility

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #2.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0082.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0082>.

For Policy Related Questions, Contact: Stephanie Bell at 410-786-0617.

4. Title: Alternative Benefit Plans (ABPs)

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #3.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0083.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0083>.

For Policy Related Questions, Contact: Adrienne Delozier at 410-786-0278.

5. Title: Medicaid State Plan Eligibility

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #15.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0090.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0090>.

For Policy Related Questions, Contact: Suzette Seng at 410-786-4703.

6. Title: Health Home State Plan Amendment (SPA)

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #22.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0084.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0084>.

For Policy Related Questions, Contact: Mary Pat Farkas at 410-786-5731.

7. Title: Medicaid Adult and Child Core Set Measures

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #26.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0085.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0085>.

For Policy Related Questions, Contact: Virginia (Gigi) Raney at 410-786-6117.

8. Title: Maternal and Infant Health Quality

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #45.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0086.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0086>.

For Policy Related Questions, Contact: Virginia (Gigi) Raney at 410-786-6117.

9. Title: Health Home Core Sets

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS-10434 #47.
OMB Control Number: 0938-1188.
eRulemaking Docket ID Number: CMS-2023-0087.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0087>.

For Policy Related Questions, Contact: Mary Pat Farkas at 410-786-5731.

10. Title: Medicaid Extended Postpartum Coverage and Continuous Eligibility for Children

Type of Request: Extension of a currently approved collection.

CMS ID Number: CMS-10434 #77.

OMB Control Number: 0938-1188.

eRulemaking Docket ID Number: CMS-2023-0088.

Docket Web Address: <https://www.regulations.gov/docket/CMS-2023-0088>.

For Policy Related Questions, Contact: Alexa Turner at 410-786-8823.

William N. Parham, III,

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

[FR Doc. 2024-08658 Filed 4-22-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Community Services Block Grant (CSBG) Model Tribal Plan and Application (New Collection)

AGENCY: Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Community Services (OCS), Administration for Children and Families (ACF), requests an approval of the Community Services Block Grant (CSBG) Model Tribal Plan.

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 infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 677 of the CSBG Act requires Indian tribes or tribal organizations to submit an application and plan (CSBG Model Tribal Plan). The CSBG Model Tribal Plan must meet statutory requirements prior to OCS awarding CSBG tribal grant recipients with CSBG funds. Tribal grant recipients have the option to submit a detailed plan annually or biannually. Tribal grant recipients that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur. The CSBG Model Tribal Plan has been used in previous years without OMB approval. To come into compliance with the PRA, ACF is submitting the CSBG Model Tribal Plan as a new request to OMB.

Respondents: Tribal grant recipients (tribes and tribal organizations)

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
CSBG Model Tribal Plan	66	1	10	660

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: Sec. 677, Pub. L. 105-285, 112 Stat. 2742 (42 U.S.C. 9911)

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1786]

PAI Holdings, LLC DBA Pharmaceutical Associates, Inc., et al.; Withdrawal of Approval of 23 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 23, 2024.

FOR FURTHER INFORMATION CONTACT:

Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.