(SUPPORT) for Patients and Communities Act Section 1003 Demonstration Evaluation; *Use:* Section 1003 of the SUPPORT Act authorizes the Secretary of HHS, in consultation with the Director of the Agency for Healthcare Research and Quality (AHRQ) and the Assistant Secretary for Mental Health and Substance Use from the Substance Abuse and Mental Health Services Administration (SAMHSA), to conduct a 54-month demonstration project (hereinafter, ''the Demonstration'') which is designed to increase the capacity of Medicaid providers to deliver substance use disorder (SUD) treatment and recovery services.

Section 1003 also requires an evaluation of the demonstration. The evaluation is designed to assess:

- The effectiveness of the Demonstration in increasing the capacity of providers participating under the Medicaid state plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver);
- The activities carried out under the planning grants and demonstration project;
- The extent to which participating states have achieved the stated goals; and
- The strengths and limitations of the planning grants and demonstration project.

This collection of information request is intended to satisfy the reporting requirements, defined in the statute, regarding the impact of the Demonstration. The evaluation of the Demonstration will assess the extent to which the participating states achieved the goals they established to increase substance use treatment or recovery provider capacity under the Medicaid program. This includes both the planning and post-planning periods of the demonstration, as evaluation during both phases will enable CMS and stakeholders to assess the effects of the additional support provided to states during the post-planning period, relative to the planning period only.

Primary data collection will occur in two rounds in year two and year four of the evaluation. In both rounds, data collection will consist of: (1) A survey of providers in all 15 Planning Grant states who are eligible to prescribe and/or administer either buprenorphine or methadone medication for opioid use disorder (OUD), and (2) focus groups of providers in five post-planning period states (two focus groups per state, with six to eight participants in each group) who treat SUD, including OUD.

The survey will gather information on provider experiences related to Medicaid provider enrollment, SUD service delivery, and changes in OUD medication treatment, including barriers and enablers of prescribing and dispensing.

The focus groups will examine the impact of key aspects of implementation, such as perceived burdens associated with Medicaid enrollment or MAT delivery, access to referral placements, value of state-provided TA, and benefits and unanticipated outcomes experienced by providers during the Demonstration.

Form Number: CMS–10786 (OMB control number: 0938–NEW); *Frequency:* Biennial; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 28,810; *Total Annual Responses:* 14,405; *Total Annual Hours:* 3,689. (For policy questions regarding this collection contact Melanie Brown at 410–786–1095.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.,* allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports.

In this 2021 collection of information request, we revised certain FFS, MCO, and Abbreviated MCO survey questions. While a few questions were added to the surveys to address GAO (U.S. Government Accountability Office) recommendations, other aspects of the survey changes include grammar and formatting edits. Overall, we are not revising our currently approved burden estimates.

Form Number: CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

Dated: September 21, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–20727 Filed 9–23–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Mother and Infant Home Visiting Program Evaluation (MIHOPE): Long-Term Follow-Up, Kindergarten Data Collection (MIHOPE–K) (OMB #0970–0402)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), in partnership with the Health Resources and Services Administration (HRSA), both of the U.S. Department of Health and Human Services (HHS), is proposing to extend data collection activity as part of the kindergarten phase of the Mother and Infant Home Visiting Program Evaluation Long-Term Follow-Up project (MIHOPE–K). The purpose of MIHOPE–K is to conduct a follow-up study that assesses the long-term impact of the Maternal, Infant, and

Early Childhood Home Visiting (MIECHV) Program when the participating children are in kindergarten. This **Federal Register** notice is seeking to extend data collection for the kindergarten follow-up. The original **Federal Register** notices for the MIHOPE–K data collection were titled under MIHOPE-Long-Term Follow-Up (MIHOPE–LT).

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: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This request for an extension is to complete the following data collection activities for MIHOPE–K: (1) A survey with the child's primary caregiver (who will be the mother if she is available), (2) direct assessments of child development, (3) surveys with the child's teacher, (4) a direct assessment of the caregiver, (5) videotaped interactions between the caregiver and child, (6) a caregiver website to provide current contact information, (7) state child welfare records, and (8) school records. In addition to collecting these data, the MIHOPE–K project will continue to maintain up-to-date consent forms for the collection of administrative data. Future information collection requests and related **Federal Register** notices will describe future data collection efforts for this project.

Data collected during the kindergarten follow-up study is being used to estimate the effects of MIECHV-funded programs on the following seven domains: (1) Maternal health, (2) child health, (3) child development and school performance, (4) child maltreatment, (5) parenting, (6) crime or domestic violence, and (7) family economic self-sufficiency.

Respondents: The respondents in this extension will include 1,391 families who have not yet participated in the kindergarten follow-up study activities. We have assumed that only 25 percent of respondents will complete the caregiver website. We will also obtain child welfare data from 11 MIHOPE states and school records data from state and local agencies. We have assumed that we will obtain data from 11 states and 5 local education agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Burden for previously approved, ongoing data collection					
Survey of caregivers	1,391	1	0.99	1,377	689
Direct assessments of children	1,391	1	1.33	1,850	925
Survey of the focal children's teachers	1,391	1	0.5	696	348
Direct assessments of caregivers	1,391	1	0.17	236	118
Videotaped caregiver-child interactions	2,782	1	0.25	696	348
Caregiver website	348	1	0.17	59	30
State child welfare records: data file submission	11	2	15	330	165
School records: data file submission	16	2	22.5	720	360

Estimated Total Annual Burden Hours: 2,983.

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: Social Security Act Title V 511 [42 U.S.C. 711]. As extended by the Bipartisan Budget Act of 2018 (Pub. L. 115–123) through FY22.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–20798 Filed 9–23–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0441]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cardiovascular and Renal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on