

under Section 1862(a)(1)(A) of the ACT. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat MR. *Form Number:* CMS-10531 (OMB control number: 0938-1274); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 8,649; *Total Annual Responses:* 34,596; *Total Annual Hours:* 12,974. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

2. *Title of Information Collection:* Healthcare Fraud Prevention Partnership (HFPP) Data Sharing and Information Exchange; *Type of Information Collection Request:* Revision; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a-7c(a)(2)) authorizes the Secretary and the Attorney General to consult, and arrange for the sharing of data with, representatives of health plans for purposes of establishing a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. The result of this authority has been the establishment of the HFPP. The HFPP was officially established by a Charter in the fall of 2012 and signed by HHS Secretary Sibelius and US Attorney General Holder. In December 2020, President Trump signed into law H.R.133—Consolidated Appropriations Act, 2021, which amended Section 1128C(a) of the Social Security Act (42 U.S.C. 1320a-7c(a)) providing explicit statutory authority for the Healthcare Fraud Prevention Partnership including the potential expansion of the public-private partnership analyses.

Data sharing within the HFPP primarily focuses on conducting studies for the purpose of combatting fraud, waste, and abuse. These studies are intended to target specific vulnerabilities within the payment systems in both the public and private healthcare sectors. The HFPP and its committees design and develop studies in coordination with the TTP. The core function of the TTP is to manage and execute the HFPP studies within the HFPP. *Form Number:* CMS-10501 (OMB control number: 0938-1251); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 28; *Number of Responses:* 28; *Total Annual Hours:* 120. (For questions regarding this collection, contact Marnie Dorsey at (410-786-5942).

Dated: September 21, 2021.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10786 and CMS-R-153]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 November 23, 2021.

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' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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-10786 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act Section 1003 Demonstration Evaluation

CMS-R-153 Medicaid Drug Use Review (DUR) Program

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:* Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment

(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.

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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