product that is in finished package form, a drug product that is not in finished package form, an active pharmaceutical ingredient, and other types of listed drugs, except for biological products or categories thereof exempted by an order under section 510(j)(3)(B) of the FD&C Act). Listed drugs subject to reporting include human drug products (including non-exempt biological products) marketed under an approved application, animal drug products marketed under an approved application, medical gases, homeopathic products, products marketed in accordance with requirements under section 505G of the FD&C Act (21 U.S.C. 355h), often referred to as over-the-counter monograph drugs, and animal drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act (21 U.S.C. 360b, 360ccc, and 360ccc–1).

This guidance finalizes the draft guidance entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act'' published on November 1, 2021 (86 FR 60249). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include changes to the recommended timeframe for report submission, as well as changes to the recommended units for the reporting of drugs that are not drug products in finished package form. These changes were made in response to public comments received and in the interest of facilitating drug amount data submission and improving data accuracy. Revisions also were made to clarify the reporting requirements applicable to registrants of listed drugs across the drug supply chain, including contract manufacturers. Further revisions were made to clarify and further detail how FDA plans to use data derived from the drug amount reporting program, including data submitted by each registrant in the drug supply chain.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 207 pertaining to registration of producers of drugs and listing of drugs in commercial distribution have been approved under OMB control number 0910–0045. The collections of information in 21 CFR parts 314 and 601 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information pertaining to notifications of discontinuance or interruption in manufacturing under 21 CFR 310.306 and 314.81(b)(3)(iii) have been approved under OMB control number 0910–0001. The collections of information relating to 21 CFR 600.81 and 600.82 have been approved under OMB control number 0910–0308. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 514.80 have been approved under OMB control number 0910–0284. The collections of information in 21 CFR 514.87 have been approved under OMB control number 0910–0659.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry,* or *https://www.regulations.gov.*

Dated: February 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02369 Filed 2–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Pediatric Mental Health Care Access Program National Impact Study

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 8, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Pediatric Mental Health Care Access Program National Impact Study, OMB No. 0915–xxxx—[New].

Abstract: This notice describes an information collection request for one of HRSA's Maternal and Child Health Bureau programs, the Pediatric Mental Health Care Access (PMHCA) Program. The PMHCA Program aims to promote behavioral health integration into pediatric primary care by supporting the development of state, regional, and tribal pediatric mental health care teleconsultation access programs. The PMHCA Program supports pediatric health professionals (HPs) [1] in their

[1] Health professionals may include but are not limited to pediatricians, family physicians,

delivery of high-quality and timely screening, assessment, treatment, and referrals for children and adolescents with behavioral health conditions through the provision of teleconsultation, care coordination support/navigation (*e.g.,* resource identification and referrals), and training and education.

The information will be collected from participants in HRSA PMHCA award recipient programs that were funded in 2021, 2022, or 2023. The 2021 and 2022 PMHCA programs are authorized by 42 U.S.C 254c–19 (Title III, § 330M of the Public Health Service Act), using funding appropriated by Section 2712 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), and the 2023 PMHCA programs are authorized by 42 U.S.C 254c–19 (§ 330M of the Public Health Service Act), as amended by section 11005 of the Bipartisan Safer Communities Act (Pub. L. 117–159). To examine the impact of the PMHCA program on children and adolescents, this data collection will use two instruments: the HP Impact Survey and the Family/Caregiver Focus Group Discussion (FGD). Additionally, family members/caregivers identified by PMHCA programs to participate in the Family/Caregiver FGD will be asked demographic questions (Family/Caregiver Demographic Questionnaire) about themselves and their child/adolescent for the purpose of FGD sampling and to inform qualitative data analyses.

Need and Proposed Use of the Information: This information is needed by HRSA to examine PMHCA program impacts on children/adolescents and their families/caregivers in order to guide future program decisions. Specifically, data collected for the PMHCA Impact Study will be used to examine changes in children's and adolescents' and their families'/caregivers' access to behavioral health care; their subsequent receipt and utilization of behavioral health care, including culturally and linguistically appropriate care; related behavioral health impacts; and monetary and societal cost-benefits. The study will examine changes over time regarding enrolled/participating HPs' practices with screening, diagnosing, treating, and referring children and adolescents with behavioral health conditions and assess their perceptions of the behavioral health impact of the PMHCA Program. Additionally, the study will deepen understanding of families'/caregivers' experiences with behavioral health care access, receipt, and utilization; satisfaction with behavioral health care services; and the impact of behavioral health services on their children/adolescents.

Likely Respondents:

- *HP Impact Survey:* Pediatricians, family physicians, physician assistants, advanced practice nurses/nurse practitioners, licensed practical nurses, registered nurses, counselors, social workers, medical assistants;
- *Family/Caregiver FGD:* Family members and caregivers who have sought and/or received behavioral health care for their child(ren)/adolescent(s); and
- *Family/Caregiver Demographic Questionnaire:* Family members and caregivers who have sought and/or received behavioral health care for their child(ren)/adolescent(s).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
HP Impact Survey	21,070	2	42,140	0.17	7,163.80
Family/Caregiver FGD	42	1	42	1.00	42
Family/Caregiver Demographic Questionnaire	270	1	270	.08	21.60
Total	21,382		42,452		7,227.40

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program Part C Early Intervention Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA expects the availability of additional funds for the RWHAP Part C Early Intervention Services (EIS) Program due to relinquishments, reductions, closeouts, and unawarded fiscal year (FY) 2023 new service area competition funds in the estimated amount of $4.2 million and intends to distribute these supplemental funds across the current cohort of RWHAP Part C EIS recipients. The amount is subject to change depending on the availability of additional funds.

FOR FURTHER INFORMATION CONTACT: CAPT Mahyar Mofidi, Director, Division of Community HIV/AIDS Programs, HIV/AIDS Bureau, Health Resources and Services Administration, at *mmofidi@hrsa.gov* or 301–443–2075.

physician assistants, advanced practice nurses/nurse practitioners, licensed practical nurses, registered nurses, counselors, social workers, medical assistants, patient care navigators.