

Name of grant recipient that has funds to be returned for reallocation	Preliminary amount available for reallocation ¹
Seneca Nation of Indians	20,244
South Puget Intertribal Planning Agency	739
Spirit Lake Nation	287,077
Standing Rock Sioux Tribe	396,242
Thlopthocco Tribal Town	9,446
Turtle Mountain Band of Chippewa Indians	2,376,042
United Keetoowah Band of Cherokee Indians	272,128
Ute Indian Tribe	1,672
Yankton Sioux Tribe	244,986
Total	21,985,238

¹ Preliminary funds for reallocation consist of the funds in excess of LIHEAP's 10 percent carryover cap that (1) 73 recipients indicated on the FFRs or reported on the CRRs as unobligated; or (2) amounted to 100 percent of regular funds or IJA funds for the 3 recipients that failed to submit the associated FFRs and their CRRs.

If funds are reallocated, then grant recipients may use them for any purpose authorized under LIHEAP and must add these funds to their total LIHEAP funds payable for FFY 2023 for purposes of calculating statutory caps on administrative costs, carryover, Assurance 16 activities, and weatherization assistance.

Additionally, all recipients of these funds must (1) ensure that they are included in the amounts on Lines 1.1 of their FFY 2023 CRRs; (2) reconcile these funds, to the extent that they received them, on a separate FFR; and (3) record, on their FFY 2023 Household Reports, households that receive benefits at least partly from these funds. State recipients must also ensure that these funds are included in the Grantee Survey sections of their FFY 2023 LIHEAP Performance Data Forms.

Statutory Authority: 42 U.S.C. 8626(b).

Karen D. Shields,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Title V State Sexual Risk Avoidance Education (Office of Management and Budget #0970-0551)

AGENCY: Family and Youth Services Bureau, Administration for Children

and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Family and Youth Services Bureau (FYSB) within the Administration on Children, Youth and Families (ACYF) is accepting mandatory formula grant applications and State plans from States and Territories for the development of and implementation for Title V State Sexual Risk Avoidance Education (SRAE) Program. The Title V State SRAE Notice of Funding Opportunity (NOFO) sets forth the application requirements for recipients. This request is to extend Office of Management and Budget (OMB) approval of the request for information. No changes are proposed.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION: The Title V SRAE Program has mandatory, formula allotments for State and Territories to apply. The application process is for States and Territories to submit and for ACYF/FYSB to collect an application, State plan, and semi-annual performance progress reports.

Purpose and Use of the Information Collection

The application and State plans will offer information about the proposed State project and it will be used as the primary basis to determine whether or not the project meets the minimum requirements of the NOFO for the grant award.

The Performance Progress Reports are collected semi-annually and will inform the monitoring of the grantees' program design, program evaluation, management improvement, service quality and compliance with agreed upon goals. ACYF/FYSB will use the information to assure effective service delivery for program participants. Finally, the data from this collection will be used to report outcomes and efficiencies and will provide valuable information to policy makers and key stakeholders in the development of program and research efforts.

Respondents: Thirty-eight States and nine Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands, and Palau.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Applications	47	1	24	1,128
State Plans	47	1	40	1,880
Performance Progress Reports	47	2	16	1,504

Estimated Total Annual Burden Hours: 4,512.

Authority: Section 510 of the Social Security Act (42 U.S.C. 710), as amended by section 50502 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) and extended by Division CC, title III, section 303 of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103).

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA–2023–N–0001]

Advancing the Development of Pediatric Therapeutics on Drug Dosing in Pediatric Patients With Renal Impairment; Public Workshop

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Advancing the Development of Pediatric Therapeutics (ADEPT 8) on Drug Dosing in Pediatric Patients With Renal Impairment.” The purpose of the public workshop is to discuss the current landscape of drug dosing in pediatric patients with renal impairment, understand the gaps in knowledge, and consider innovative approaches to improve the current paradigm for dosing in pediatric patients with renal impairment.

DATES: The public workshop will be held on November 30, 2023, and December 1, 2023, from 9 a.m. to 5 p.m. eastern time each day. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus Great Room and online. Entrance for the registered public workshop participants (non-FDA employees) is through

Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>.

FOR FURTHER INFORMATION CONTACT: Julie Levin, Office of New Drugs Public Meeting Support, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6481, Silver Spring, MD 20993–0002, 202–567–7565, ONDPublicMTGSupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The pharmacokinetics of drugs excreted by the kidneys may be altered by renal (kidney) impairment, requiring dosing adjustments. However, the majority of drugs that are predominantly renally excreted and have dosage recommendations for adults with renal impairment lack dose adjustment recommendations for pediatric patients with renal impairment. This is largely due to the lack of generation of pharmacokinetic data in pediatric patients with renal impairment, which is attributable to both the ethical and the practical limitations of conducting dedicated renal impairment studies in pediatric patients, as well as the exclusion of pediatric patients with renal impairment from most clinical efficacy and safety studies. For drugs that are renally cleared, exposures can be impacted by both the maturation of kidney function and the renal impairment due to kidney disease.

II. Topics for Discussion at the Public Workshop

The main objective of the “Advancing the Development of Pediatric Therapeutics (ADEPT 8) on Drug Dosing in Pediatric Patients With Renal Impairment” workshop is to discuss current approaches to classifying renal impairment in the pediatric population, identify data gaps, and explore scientifically supported approaches and methods for providing information on dosing adjustment. The workshop will specifically focus on measurements of renal function, extrapolation of adult data, and approaches to generating clinical trial data to assess the impact of

renal impairment on the pharmacokinetics of drugs in pediatric patients. In addition, the workshop will allow for an open dialogue around the use of these approaches among regulators, industry, academia, and patient organizations.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://www.eventbrite.com/e/adept-8-pediatric-renal-impairment-workshop-tickets-687423571407>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by November 15, 2023, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Julie Levin at ONDPublicMTGSupport@fda.hhs.gov no later than November 15, 2023.

Streaming Webcast of the Public Workshop: This public workshop will also be via Zoom. A link will be provided via email to registered participants. If you have never attended a Zoom event before, test your internet connection by joining a test meeting at <https://zoom.us/test>. FDA has verified the website addresses in this document, as of the date this document is published in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that when a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.