Report. Due to the market sensitive nature of PDE data, external uses of the data are subject to significant limitations. However, CMS does analyze the data on a regular basis to determine drug cost and utilization patterns in order to inform programmatic changes and to develop informed policy in the Part D program. *Form Number:* CMS–10174 (OMB control number: 0938–0982); *Frequency:* Monthly; *Affected Public:* Private Sector, Federal Government; *Number of Respondents:* 856; *Total Annual Responses:* 1,499,064,780; *Total Annual Hours:* 62,918. (For policy questions regarding this collection contact Shelly Winston at (443) 934–3621.)

Dated: July 12, 2023.

William N. Parham, III,

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

[FR Doc. 2023–15061 Filed 7–14–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Mother and Infant Home Visiting Program Evaluation: Long-Term Follow-Up, Third Grade Data Collection (Office of Management and Budget #0970–0402)

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

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), in partnership with the Health Resources and Services Administration, both of the U.S. Department of Health and Human Services (HHS), is proposing to collect data as part of the elementary school phase of the Mother and Infant Home Visiting Program Evaluation (MIHOPE). MIHOPE is a longitudinal study of the effects of Maternal, Infant, and Early Childhood Home Visiting (MIECHV)-funded home visiting on child and family outcomes. The purpose of the MIHOPE Long-Term Follow-Up, Third grade (MIHOPE–3G) data collection, which will focus on children when they are in approximately third grade, is to assess the long-term effects of MIECHV-funded home visiting on families and children when participating children are in elementary school.

DATES: *Comments due within 30 days of publication. The Office of Management and Budget* (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 *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: To date, MIHOPE has been collecting data through the time children in the study were in approximately kindergarten. The currently approved materials under this OMB number include those for the kindergarten follow-up. The kindergarten direct data collection with study participants is complete, but some administrative data are still being collected from states and local education agencies.

This request is to complete administrative data collection for the kindergarten follow-up and to conduct the following data collection activities for MIHOPE–3G: (1) child welfare records data collection from states and (2) school records data collection from states and local education agencies. Future information collection requests and related **Federal Register** notices will describe future data collection efforts for this project.

Data collected during the third grade 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: For MIHOPE–3G, we will seek to obtain child welfare data from 11 states and school records data from up to 48 states and local education agencies. This data will be collected for 4,105 families who are currently participating in MIHOPE.

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)
Remaining Burden for Kindergarten Follow-up					
State and local education agency school records: data file submission	8	1	15.6	125	42
State child welfare records: data file submission	5	1	8.4	42	14
New Request for MIHOPE–3G					
State and local education agency school records: data file submission	48	2	33.75	3,240	1,080
State child welfare records: data file submission	11	[a] 2.1	21.43	495	165

Estimated Total Annual Burden Hours: 1,301.

Note: The 2.1 responses is a weighted average that reflects that the study team expects to collect 2 data extracts from 10 states and 3 data extracts from 1 state.

Authority: Social Security Act Title V 511 [42 U.S.C. 711]. As amended by Section 6101 of the Consolidated Appropriations Act, 2023 (Public Law 117–328).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–15075 Filed 7–14–23; 8:45 am]

BILLING CODE 4184–74–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; 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 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: 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.

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: 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 (Public Law 117–103).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–15016 Filed 7–14–23; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2607]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ELEVIDYS (delandistrogene moxeparvovec-rokl), manufactured by Sarepta Therapeutics, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.