by a federal decision-maker and is not expected to meet the threshold of influential or highly influential scientific information.

Respondents: PREP PREIS Grant Recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
PREIS Final Evaluation Report Template	12	1	40	480	240

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: Authorized and appropriated by Social Security Act section 513.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–16583 Filed 8–28–25; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0386]

Proposed Information Collection Activity; Office of Community Services Community Economic Development Performance Progress Report

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

ACTION: Request for public comments.

SUMMARY: The Office of Community Services (OCS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services is requesting a 3-year extension of the Community Economic Development (CED) Performance Progress Report (PPR) (Office of Management and Budget (OMB) #: 0970–0386, expiration date February 28, 2026) with revisions to support a quarterly reporting schedule. This request revises the burden estimates to reflect new reporting requirements for quarterly reporting. While the core CED PPR form remains unchanged and will still be submitted semi-annually, new awardees must now report quarterly. In alternate quarters (Q1 and Q3), they will complete a shorter version of the form with narrative updates only.

DATES: *Comments due* October 28, 2025.

ADDRESSES: 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. 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: OCS is seeking to extend the CED PPR (OMB #0970–0386), with revisions, for three years. This extension will permit OCS to continue collecting the performance progress information about projects funded through the CED Program from current and future grant recipients.

The CED PPR collects information regarding the implementation and outcomes of CED projects to support program monitoring, the provision of training and technical assistance, and the fulfillment of congressional reporting requirements. The report tracks quantitative information, including measures of job creation and project expenditures, along with narrative descriptions of project activities, challenges, and changes.

The CED PPR will continue to be administered to all active grant recipients of the CED Program. Grant recipients will complete this report based on activities completed through the second and fourth quarters of each project year.

This request revises the burden estimates to reflect new reporting requirements for quarterly reporting. The burden estimates reflect quarterly reporting for new awardees as well as a shorter response time for quarterly reporters in alternate quarters when they will only be required to complete a subset of items on the form. This request makes no changes to the current approved CED PPR form that all grant recipients will be required to complete semi-annually. The current approved CED PPR is cumulative and covers activities completed through the second and fourth quarters of each project year. For the first and third quarters of each project year, quarterly reporters will complete a subset of items to provide narrative updates on project progress.

Currently, grant recipients submit the CED PPR semi-annually. Through this request, OCS proposes to change the reporting requirements to collect information on CED project progress on a quarterly basis. This will allow OCS to monitor grant recipient progress more frequently and to support the timely provision of training and technical assistance. The reporting schedule for CED projects will be identified in the Notice of Funding Opportunity (NOFO) under which projects are funded. Currently, CED NOFOs identify a semi-annual reporting schedule. OCS anticipates that quarterly reporting requirements will be included in NOFOs beginning in federal fiscal year (FFY) 2026.

To reduce the burden for quarterly reporters, OCS will only require grant recipients to complete a subset of items from the CED PPR in the first and third quarters of each project year. The burden estimates for the subset of items are included in the annual burden estimates for the CED PPR Short Form. The CED PPR Short Form does not include the quantitative measures and focuses on narrative descriptions of project activities, challenges, and changes.

Respondents: The CED *PPR* will be completed by all CED grant recipients active during the 3-year extension. The CED PPR Short Form will be completed by grant recipients receiving awards

through an application to a NOFO requiring quarterly reporting.

Annual Burden Estimates

OCS anticipates including quarterly reporting requirements in NOFOs published in FFY 2026 and later. Because CED projects are funded for 3- to 4-year project periods, OCS anticipates that only half of active grant recipients will be required to complete the short-form during the extension period. These assumptions are reflected in the burden estimates below.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
CED PPR	79	2	1.5	237
CED PPR Short Form	48	2	0.5	48
Estimated Total Annual Burden Hours				285

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 680(a)(2), Community Services Block Grant Act, 42 U.S.C. 9921.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–16584 Filed 8–28–25; 8:45 am]

BILLING CODE 4184–27–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2654]

Amylyx Pharmaceuticals, Inc.; Withdrawal of Approval of New Drug Application for RELYVRIO (Sodium Phenylbutyrate and Taurursodiol) for Suspension, 3 Gram/Packet and 1 Gram/Packet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 gram (g)/packet and 1 g/packet, held by Amylyx Pharmaceuticals, Inc. (Amylyx), 43 Thorndike St., Cambridge, MA 02141. Amylyx has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 29, 2025.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 29, 2022, FDA approved NDA 216660 for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

On April 30, 2024, Amylyx reported to the Agency that a Phase 3 Trial of AMX0035 for Amyotrophic Lateral Sclerosis Treatment (Study A35–004, also known as PHOENIX), a global, 48-week, randomized, placebo-controlled clinical trial of sodium phenylbutyrate and taurursodiol in patients living with ALS, did not meet its prespecified primary and secondary endpoints. On September 30, 2024, Amylyx notified the Agency they planned to discontinue marketing of RELYVRIO as of October 31, 2024. On October 31, 2024, FDA requested that the applicant submit a letter to voluntarily request withdrawal of approval of RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, according to § 314.150(d) (21 CFR 314.150(d)) based on the results of the Phase 3 PHOENIX trial.

On February 28, 2025, Amylyx submitted a letter asking FDA to withdraw approval of NDA 216660 for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, according to § 314.150(d) and waiving its opportunity for a hearing. In its letter requesting withdrawal of approval, Amylyx stated that it is voluntarily requesting withdrawal based on results from the Phase 3 PHOENIX trial.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 216660 for RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of RELYVRIO (sodium phenylbutyrate and taurursodiol) for suspension, 3 g/packet and 1 g/packet, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16646 Filed 8–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1330]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submissions of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget