

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Territories	One-time Addition of Diseases and Data Elements.	5	1	2	10
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
Freely Associated States	One-time Addition of Diseases and Data Elements.	3	1	2	6
Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (DMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements.	2	1	2	4
Total	18,354

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Evaluation of LifeSet (OMB #0970–0577)

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

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services is proposing additional information collection activities to assess the implementation of LifeSet, a program that provides services and supports to young adults ages 17 to 21 with previous child welfare involvement. Current data collection activities are approved under this same Office of Management and Budget (OMB) #: 0970–0577.

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 OPREinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed information collection activities are part of the second phase of a study that intends to assess the impact and implementation of LifeSet, a program that provides services and supports to young adults ages 17 to 21 with previous child welfare involvement. The program aims to support young adults in their transition from foster care to independent living in the areas of education, employment and earnings, housing and economic well-being, social support, well-being, health and

safety, and criminal involvement. It focuses on helping young adults identify and achieve their goals while developing the skills necessary for independent living.

The evaluation is part of a larger project to help ACF build the evidence base in child welfare through rigorous evaluation of programs, practices, and policies. The activities and products from this project will contribute to evidence building in child welfare and help to determine the effectiveness of a program for youth formerly in foster care on young adult outcomes.

The implementation study will collect information through video conferences and site visits to the participating program and child welfare agency. Data collection activities for the implementation study began, as previously approved by OMB. Additional protocols are proposed as part of the implementation study. Proposed information collection activities include interviews and focus groups with administrators and staff from the program developer, child welfare agency, and program providers; online survey of program staff; interviews with youth who participated in the program; and focus groups with youth who participated in the program and who received services as usual.

Respondents: Program participants, young adults receiving services as usual, agency and program administrators and staff, other program stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Respondents	Number of respondents (total over request period)	Number of responses per respondent (total over period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Burden for previously approved, ongoing data collection						
Baseline Youth Survey	Youth Formerly in Foster Care.	470	1	0.6	282	141
Administrative data file	Agency and Program Staff	12	1	5	60	30
Burden for newly requested information collection						
Site Visit 3 Interview Guide for Administrators.	Child Welfare Agency Administrators. Licensed LifeSet Experts Provider Agency Administrators LifeSet Developer Administrators	22	1	1	22	11
Site Visit 3 Focus Group Guide for Staff.	LifeSet Specialists LifeSet Team Supervisors .. Child Welfare Agency Caseworkers.	28	1	1.5	42	21
LifeSet Specialist Survey	LifeSet Specialists	16	1	.3	5	2.5
Interview Guide for Youth ...	LifeSet Program Youth	12	1	1	12	6
Focus Group Guide for Youth.	LifeSet Program Youth Services As Usual Youth	64	1	1.5	96	48
Screening Recruitment Phone Call Script.	LifeSet Program Youth Services As Usual Youth Services As Usual Youth	90	1	0.25	22.5	11

Estimated Total Annual Burden Hours: 270.5.

Authority: 42 U.S.C. 677.

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2673]

Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing our preliminary assessment that certain types of naloxone hydrochloride (“naloxone”) drug products may be approvable as safe and effective for nonprescription use. It is our preliminary opinion at this time that naloxone nasal spray up to 4 milligrams (mg), and naloxone autoinjector for intramuscular (IM) or

subcutaneous (SC) use up to 2 mg, have the potential to be safe and effective for use as directed in nonprescription drug labeling without the supervision of a healthcare practitioner. We believe the prescription requirement for these naloxone products might not be necessary for the protection of the public health. However, we need additional data such as product-specific data on the nonprescription user interface design, including packaging and labeling, to make a conclusive determination in this respect. The Federal Food, Drug, and Cosmetic Act (FD&C Act) does not permit the simultaneous marketing of the same drug with the same active ingredient as both a prescription and nonprescription product, absent a clinically meaningful difference between them. Therefore, if and when FDA has sufficient data to support approval of a nonprescription naloxone product (e.g., through submission and approval of an application for a nonprescription naloxone product or a supplemental application to switch an FDA-approved naloxone product from prescription to nonprescription status), currently marketed naloxone products labeled as “Rx only” with no clinically meaningful difference from the approved nonprescription products will be considered misbranded.

DATES: Either electronic or written comments on the notice must be submitted by January 17, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 17, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or