Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
	54	1	1	54
Total	54	1	1	54

Dated: October 15, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–23468 Filed 10–22–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Alzheimer's and Dementia Program Data Reporting Tool (ADP–DRT); OMB #0985–0022

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the Information Collection tools for information collection requirements related to Alzheimer's and Dementia Program Data Reporting Tool (ADP–DRT).

DATES: Submit written comments on the collection of information by 11:59 p.m. (EST) or postmarked by November 23, 2020.

ADDRESSES: Submit written comments on the collection of information by:

(a) Email to: *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Erin Long. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201 Attention: Erin Long Phone: 202–795–7389 *Erin.Long@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Older American's Act requires ACL to evaluate ''demonstration projects that support the objectives of this Act, including activities to bring effective demonstration projects to scale with a prioritization of projects that address the needs of underserved populations, and promote partnerships among aging services, community-based organizations, and Medicare and Medicaid providers, plans, and health (including public health) systems. (Section 201 (42 U.S.C. 3011) Sec. 127. Research and Evaluation). To fulfill the evaluation requirements and allow for optimal federal and state-level management of ACL's Alzheimer's Disease Program, specific information must be collected from grantees.

The current reporting tool is set to expire December 30, 2020. The Alzheimer's and Dementia Program (ADP) Project Officer has reviewed the current data collection procedures to ensure the acceptability of these items as appropriate and thorough evaluation of the program, while minimizing burden for grantees. The result of this process is the proposed modifications to the existing data collection tool. ACL is aware that different grantees have different data collection capabilities. Following the approval of the modified data collection tool, ACL will work with its grantees to offer regular training to ensure minimal burden.

Comments in Response to the 60-Day Federal Register Notice

ACL published both a 60-day and 30-day **Federal Register** Notice in the **Federal Register** soliciting public comments on this revision request. The 60-day FRN published on July 20, 2020 in volume 85 No. 137 pages 43241–43242. ACL received comments from one individual.

Comments on Proposed Collection: Alzheimer's and Dementia Program Data Reporting Tool (ADP–DRT) OMB #0985–0022.

General

It would be helpful if the explanation of categories and definitions for all data elements were part of this information collection (*i.e.,* PRA process). It is difficult to comment on estimated burden and utility of the information collection when the information being collected hasn't been fully explained. Also, definitions and data elements should be synchronized or crosswalked to those in the American Community Survey or another national collection to facilitate analyses across data collections.

PLWD & CG Served

CG data points—It is important to get a more fulsome profile of the caregivers to assess the impact caregiving has on their lives, their families, and those they care for. Understanding this data collection may not be for this purpose, a few extra data points could shed help expand the CG profile: employment status, # of chronic diseases, # of people cared for, # recent traumas experienced (*e.g.,* emotional, physical, etc.), etc.

There are sections on race and ethnicity. It's not clear what is meant by ''Minority Status'' or why it's needed. This section should be deleted to reduce burden.

Living arrangement—This section describes who the PLWD lives with but doesn't identify where the person is living. It would be helpful to know whether these individuals are living in a private home setting, an institutional setting such as a nursing home, supportive housing, or if they are experiencing homelessness. It would also be helpful to know where they are receiving most of their care—*i.e.,* in the home or outside of the home. Where people are receiving their care is relevant to the workforce and services needed to support them.

Professionals Trained

The note at the bottom states that ''Persons trained should not include . . . . Caregivers . . .'' but there are caregivers who are trained and licensed and some family caregivers who receive stipends from Medicaid and other programs. It's not clear if they would be excluded. Also, in the middle of the sheet there's a section on ''Total Units of Direct Service Delivered.'' How does

this relate to Professionals Trained? This heading may belong to the last worksheet.

Services & Expenditures

Assuming that grantees can accurately report these totals if they have more granular data, there wouldn't be much more burden added if grantees reported the details behind ''Total Units of Direct Service Delivered.'' This should be broken out by service/expenditure type. Also, there should be separate column for PLWD and for CG. As noted previously, direct services for PLWD should be separated from direct services for the CG to get a better understanding the impact AD caregiving on family members.

The proposed data collection tools may be found on the ACL website for review at *https://nadrc.acl.gov/node/226*.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Local Program Site	180	2	3.03	1,090.8
Grantee	90	2	6.93	1,247.4
Total				2,338.2

Dated: October 15, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–23472 Filed 10–22–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4212]

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.'' This guidance explains that FDA intends to extend the delay in enforcement described in the guidance entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy,'' published in the **Federal Register** on September 24, 2019 (the 2019 Compliance Policy), which relates to Drug Supply Chain Security Act (DSCSA) provisions requiring wholesale distributors to verify the product identifier prior to further distributing returned product beginning on November 27, 2019. In addition, this guidance announces FDA's intended enforcement policy with respect to DSCSA provisions requiring dispensers to verify the product identifier for suspect or illegitimate product in the dispenser's possession or control beginning on November 27, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on October 23, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–4212 for ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available