

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Councils on Developmental Disabilities Annual Program Performance Report (PPR)	56	1	172	9,632
Total	56	1	172	9,632

Dated: September 26, 2017.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Revision of a Currently Approved Information Collection (OMB Approval Number 0985-0042); State Grant for Assistive Technology Program Annual Progress Report (AT APR)

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) 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 the Paperwork Reduction Act of 1995 (the PRA). This 30-day notice requests comments on the information collection requirements related to a proposed Revision of a Currently Approved Information Collection (ICR-Rev). The revision would allow ACL to continue to collect information necessary to determine grantee compliance with Section 4 of the Assistive Technology Act of 1998, as Amended (AT Act).

DATES: Submit written comments on the collection of information by November 3, 2017.

ADDRESSES: Submit written comments on the collection of information: by fax at (202) 395-5806 or by email to OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Robert Groenendaal at (202) 795-7356 or robert.groenendaal@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget

(OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or update of an existing collection of information, before submitting the collection to OMB for approval. The proposed data collection represents a revision of a currently approved information collection. In order to comply with the above requirement, ACL is requesting approval of an update of a previously approved collection, the State Grants for Assistive Technology Program Annual Progress Report (AT APR), formerly the 572 Report (0985-0042).

The AT APR is submitted annually by all State Grants for AT programs receiving formula funds under Section 4 of the Assistive Technology Act of 1998, as Amended (AT Act). The AT APR is used by ACL to assess grantees' compliance with Section 4 of the AT Act, with section 1329 of the Code of Federal Regulations, and with applicable provisions of the HHS regulations at 45 CFR part 75. The AT APR enables ACL to analyze qualitative and quantitative data to track performance outcomes and efficiency measures of the State Grants for AT programs; support budget requests; comply with the GPRA Modernization Act of 2010 (GPRAMA) reporting requirements; provide national benchmark information; and inform program development and management activities. This information collection has 3 pieces: (a) Web-based system that collects data from states; (b) performance measure survey on the access and acquisition of AT devices and services that states collect from individuals; and, (c) customer satisfaction survey that states collect from individuals on their experiences accessing and acquiring AT through the State AT program. The burden table

below identifies the data collection activities for the three surveys above as well as the estimates for record keeping and entry of aggregate data. In addition to submitting a State Plan every three years, states and outlying areas are required to submit annual progress reports on their activities. The data required for these progress reports is specified in Section 4(f) of the AT Act. The State Grants for AT program conduct the following state-level and state leadership activities: State financing, device demonstration, device loans, device reutilization, training and technical assistance, public awareness, and information and referral.

Comments in Response to the 60-Day Federal Register Notice

A 60-Day notice was published in the **Federal Register** in Vol. 82, No. 135, pg. 32710, on July 17th, 2017. ACL received one comment from the Association of Assistive Technology Act Programs (ATAP), which represents 54 State Grant for AT programs. The comment noted that the proposed changes to the currently approved information collection were developed with extensive input of those it directly impacts, the State AT Program grantees. The revision process began over two years ago and grantees had multiple opportunities to discuss and make recommendations on the proposed changes, which were reviewed during numerous meetings with ATAP membership at national conferences and during online events. There is uniform support within the ATAP membership for the revisions.

Annual Burden Estimates

The proposed State Grants for Assistive Technology Program Annual Progress Report (AT APR) may be found on the ACL Web site at: <https://www.acl.gov/about-acl/public-input>. The total estimated hour burden per respondent for the proposed AT APR will decrease from the 406 hours per respondent estimated in FY 2014 to 404 hours estimated for FY 2017, an estimated reduction of two hours per respondent or 112 in total. These are in addition to reductions made during the last information collection process. The reduction in burden is a result of a data

collection workgroup composed of State AT program staff that met with ACL on several occasions to suggest revisions to the current instrument. The workgroup identified minor changes in several sections of the instrument, including the reporting of state-level and state leadership activities. For example, AT Device Reassignment and Open-Ended Loan have been combined into a single line in “A. Recipient Table.” This update aligns the AT APR with the State Plan for AT structure and will streamline data reporting by grantees. A

separate module has been created for all the General Information for State AT programs that is consistent between the AT APR and the State Plan for AT. Data will be entered once and from that point forward only updates will be needed, which will streamline the data entry process for grantees. The Public Awareness table with numeric data has been replaced with two narrative text boxes. Numeric data reported in this section has been historically estimated with little consistency in how data is reported between grantees. With a shift

to more electronic information sharing, quantified public awareness data is difficult to report for all grantees and aggregate data is not useful. This change will allow for qualitative data that is more helpful in understanding the activities conducted. The workgroup solicited feedback from all of the grantees through face-to-face meetings and webinar presentations. The number of hours is multiplied by 56 AT State Grants programs, resulting in a total estimated hour burden of 22,624 hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Grants for AT Annual Progress Report (AT APR)	56	1	80.0	4,480
Performance Measure Surveys	56	1	54.0	3,024
Customer Satisfaction Surveys	56	1	54.0	3,024
Data Entry for the Instruments	56	1	208.0	11,648
Record Keeping Burden	56	1	8.0	448
Total	56	1	404.0	22,624

Estimated Total Annual Burden Hours: 22,624.

Dated: September 27, 2017.

Mary Lazare,
Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5624]

Agency Information Collection Activities; Proposed Collection; Comment Request; Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice

solicits comments on the content and format requirements for pregnancy and lactation labeling for human prescription drugs and biological products.

DATES: Submit either electronic or written comments on the collection of information by December 4, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 4, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 4, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 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-2017-N-5624 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Content and Format of Labeling for Human Prescription Drugs and Biological Products; Requirements for Pregnancy and Lactation Labeling.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those