

for the revised form. One commenter suggested that we change the list of AT devices. After consideration of the comment, AIDD will modify the list of AT devices while retaining the majority of the original categories. One commenter suggested we delay the data collection for one year to allow grantees time to prepare. While this may be optimal, two other tools are expiring in

2019. Therefore, AIDD will proceed with using this data collection in 2019.

Issues of the scope, content, availability of data, format, and clarity of instructions for the One PPR have been discussed with all of the P&A systems through focus groups, work groups, and in conferences organized on behalf of Administration on Intellectual and Developmental Disabilities by the National Disability Rights Network

(NDRN). The format is based on the efforts of these focus groups, work groups, and conferences.

The proposed form(s) may be found on the ACL website at: <https://www.acl.gov/about-acl/public-input>.

#### Estimated Program Burden

The annual burden on this form is estimated as 7,296 annual burden hours.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
One Protection and Advocacy Annual Program Performance Report .....	57	1	128	7,296

Dated: March 13, 2019.

**Lance Robertson,**

*Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; No Wrong Door (NWD) System Management Tool

**AGENCY:** Administration for Community Living (ACL), 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 by the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to ACL's Aging and Disability Resource Center/No Wrong Door System (ADRC/NWD) New Data Collection (ICR New).

**DATES:** Submit written comments on the collection of information by April 18, 2019.

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

(a) email to: [OIRA\\_submission@omb.eop.gov](mailto: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:** Joseph Lugo at [joseph.lugo@acl.hhs.gov](mailto:joseph.lugo@acl.hhs.gov) or 202-795-7391.

**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 NWD System Management Tool (NWD MT) provides a platform documenting key elements that are necessary to evaluate the progress of the NWD System model and to understand and document the extent to which a state's NWD System is streamlining and coordinating access to LTSS through four core functions of State Governance and Administration, Public Outreach and Coordination with Key Referral Sources, Person-Centered Counseling, and Streamlined Eligibility for Public Programs.

In addition, this tool will include data collection for the Veteran Directed Care (VDC) program, an evidence-based self-directed program where person-centered counselors from aging and disability network agencies within a state's NWD System provide facilitated assessment and care planning, arrange fiscal management services and provide ongoing counseling and support to Veterans, their families and caregivers. The VDC too will collect qualitative and

quantitative data elements necessary to evaluate the impact of the VDC program.

The NWD MT and the VDC tool will enable ACL and its partners to collect and analyze data elements necessary to assess the progress of the NWD System model, track performance measures, and identify gaps and best practices. These tools have been designed in close collaboration with states and are intended to simplify grant reporting requirements to reduce burden on local and state entities and will provide a consistent, streamlined and coordinated statewide approach to help states govern their NWD System and manage their programs efficiently.

#### Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on November 2, 2018, Volume 83, Number 213, pp. 55186-55187. Three emails were received with comments.

In addition to the public comments, feedback on the tools were sought from the following:

- ACL Performance and Evaluation subject matter experts.
- VHA and CMS subject matter experts.
- Subject-matter experts at state agencies representing Aging, Intellectual/Developmental Disabilities, Physical Disabilities, and Medicaid.
- Grantee focus groups and workgroups (with fewer than 9 participants).

ACL's response to the comments received are noted in the table below:

Data collection form	Comment	ACL response
<i>NWD Management Tool</i> .....	I understand that although not required, health information shared solution models that are multi-state adoptable is key to the NWD system, tracking, and monitoring systems of the I/DD care and services. Please feel free to share this correspondence with team members/stakeholders whom we can speak with in regards to furthering contact with regarding healthcare technology expansion within the I/DD industry.	ACL appreciates the commenter's views on healthcare technology and I/DD care and services, however ACL finds this comment to be unrelated to the proposed data collection tools.
<i>NWD Management Tool</i> .....	In State Level Question 5 and Local Level Question 1 related to funding of the NWD System, it is unclear if the dollars and percentages to be reported are actual dollars or if that can include in-kind contributions. One of the choices in those two reporting tables under Federal Funding is "Other ACL Programs" which references Assistive Technology. A State/Territory AT Program could make an in-kind contribution to the state or local level NWD system, <i>e.g.</i> , they could provide a refurbished AT device allowing an individual to remain in their home as part of their reuse program (state level AT Act activity) or they could provide training on AT for NWD staff/partners (state leadership AT activity). It is highly unlikely there would be actual Section 4 AT Act dollars being provided to the NWD state system budget as the NWD System functions as outlined for these data points are not authorized activities for use of Section 4 funds under the AT Act. It would be helpful to clarify if in-kind contributions are or are not to be reported in both of these tables.	ACL appreciates this comment and fully understands the authorizations of Section 4 AT Act dollars. The State Level question 5 and Local Level Question 1 are meant to capture actual expenditures and dollars supporting NWD System functions, not in-kind contributions. Therefore, in response to this comment, ACL proposes to edit these questions for clarification and remove Assistive Technology as an example under "Other ACL Programs."
<i>NWD Management Tool</i> .....	The level of detail proposed is tremendous, with no permanent federal funding source for the programs. The number of divisions within Nebraska DHHS & Nebraska Veterans Administration will require significant coordination. If the information remains as proposed, I would suggest a long lead time in collection requirements. Or parceled out requests and the ability for each division to address their area of expertise.	ACL appreciates this comment and understands that states and aging and disability network agencies will need support ( <i>e.g.</i> , training, grant funding, etc.) before beginning the data collection. The state's NWD Lead Agency will determine which state and local partners would contribute to the data collection. Various agencies and divisions may prepare for data submission in phases, as determined by the state.

The proposed form(s) may be found on the ACL website at: <https://www.acl.gov/about-acl/public-input>.

#### Estimated Program Burden

ACL estimates the burden of this collection of information as 112 hours

for state level staff, 7,968 hours for local agency staff and 2,400 hours for VDC program providers for a total of 10,480 hours. This burden estimate is calculated based upon a sample of states and program providers testing the NWD

MT and VDC Tool. The estimated response burden includes time to review the instructions, gather existing information, and complete and review the data entries in a web-based system.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
NWD Management Tool data collection and entry—State Level .....	56	2	1.0	112
NWD Management Tool data collection and entry—Local Level .....	996	2	4.0	7,968
Veteran Directed Care Tool .....	400	12	0.5	2,400
Total: .....	1,452	6,904	.....	10,480

Dated: March 13, 2019.

**Lance Robertson,**

*Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-0549]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Use of Symbols in Labeling—Glossary to Support the Use of Symbols in 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 product labeling regulations to explicitly allow for the optional inclusion of graphical representations of information, or symbols, in labeling (including labels) without adjacent explanatory text (referred to in this document as “stand-alone symbols”) if certain requirements are met.

**DATES:** Submit either electronic or written comments on the collection of information by May 20, 2019.

**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 May 20, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 2019. 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-2019-N-0549 for “Use of Symbols in Labeling.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **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 for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.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 of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice