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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Proposed Collection; Public Comment Request; New Data Collection (ICR New) of the No Wrong Door (NWD) System Management Tool

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

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a 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 New Data Collection (ICR New) solicits comments on the information collection requirements relating to the Aging and Disability Resource Center/No Wrong Door System (ADRC/NWD). The statutory authority for ADRC/NWD is contained in Title IV of the Older Americans Act (OAA), as amended by the Older Americans Act Amendments of 2006, Public Law 109–365.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by January 2, 2019.

ADDRESSES: Submit electronic comments on the collection of information to: Ami Patel, *ami.patel@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Ami Patel.

FOR FURTHER INFORMATION CONTACT: Ami Patel at (202) 795–7376 or *ami.patel@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 of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

ACL, the Centers for Medicare and Medicaid Services (CMS), and the Veterans Health Administration (VHA) have partnered to support states' efforts in developing coordinated systems of access, or No Wrong Door (NWD) Systems, to make it easier for people to learn about and access long-term services and supports (LTSS). When seeking services and supports, individuals and caregivers often face multiple, fragmented processes that are complex and confusing. States' access systems have been built over time as programs and funding streams have been added, creating duplicative eligibility and intake processes that are difficult for individuals and their caregivers to use. To address these issues, the NWD System model supports state efforts to streamline access to LTSS options for all populations and provides the infrastructure to promote the collaboration of local service organizations, making service delivery more efficient and person-centered. Examples of coordinated efforts include processes where individuals are assessed once via a common or standardized data collection method that captures a core set of individual level data relevant for determining the range of necessary LTSS.

The federal vision for the NWD System gives states flexibility in determining how best to organize, structure and operate the various functions of their NWD System. States continue to integrate, in some cases restructure, and over time strengthen their existing programs in order to realize the joint ACL/CMS/VHA vision for a fully coordinated and integrated system of access. These efforts are supported by a variety of initiatives, including the VHA's 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 NWD System Management Tool (NWD MT) provides a platform for data collection necessary to evaluate the four primary functions of a NWD System: State Governance and Administration, Public Outreach and Coordination with Key Referral Sources, Person Centered Counseling, and Streamlined Access to Public LTSS Programs. In addition, this tool will include data collection for the VDC program to collect qualitative and quantitative data elements necessary to evaluate the impact of the VDC program. The VDC tool will track key performance measures and identify best practices and technical assistance needs.

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.

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden:

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

Fifty-six lead NWD System state and territorial agencies will respond to the NWD MT bi-annually and it will take approximately half an hour to collect the data and an additional half hour to input the data into a web-based system.

Additionally, an estimated 996 local agencies will take approximately three hours to collect the data and one hour to submit the data to their lead NWD System state agency. If all state and local agencies respond bi-annually, the national burden estimate for the NWD MT would be a total of 8,080 hours annually. This burden estimate is calculated based upon a sample of three states that tested a demonstration of the NWD MT as a part of the grantee requirements under the NWD System Implementation grant, a competitive funding opportunity funded in 2016 through 2018. Each state entity submitting data will receive local-level data from designated NWD System entities. 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.

An estimated 400 VDC program entities will respond to the VDC Tool on a monthly basis, all of which are also NWD local-level entities, for an annual burden of 2,400 hours. This burden estimate is calculated based upon information provided by a current VDC program provider testing a demonstration of the VDC tool. The NWD MT and the VDC tool have been developed to increase ease and uniformity of reporting and improve the ability of ACL to manage and analyze data.

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			10,480

Dated: October 23, 2018.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3903]

Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment; Draft 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 draft guidance for industry entitled ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs and biologics for the treatment of chronic hepatitis B virus (HBV) infection from the initial investigational new drug application (IND) through the new drug application (NDA)/biologics license application (BLA) and postmarketing phases.

DATES: Submit either electronic or written comments on the draft guidance by January 2, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2018–D–3903 for ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' 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.

- 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