

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 900 local agencies will take approximately two

hours to collect and submit the data to their lead NWD System state agency. There may be several lead NWD System state and territorial agencies who will be submitting on behalf of their local agencies. Therefore, the approximate burden for the local level agencies may be thirty minutes less than anticipated. If all state and local agencies respond bi-annually, the national burden estimate for the NWD MT would be a total of 3,712 hours annually. This burden estimate is calculated based upon a sample of ADRC/NWD grantees. 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 275 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 1,650 hours. This burden estimate is calculated based upon information provided by current VDC program providers testing an abbreviated version 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	900	2	2.0	3,600
Veteran Directed Care Tool	275	12	0.5	1,650
Total	1,231	5,362

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000, Protection and Advocacy Systems To Expand the Public Health Workforce

Title: Expanding the Public Health Workforce within the Disability

Networks: Protection and Advocacy Systems.

Announcement Type: Initial.

Statutory Authority: The statutory authority for grants under this program announcement is Section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117-2) and awards authorized under Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C 15041 *et seq.*), Protection and Advocacy Systems, shall be provided funding under this opportunity.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.630.

DATES: The deadline date for the submission of the Expanding the Public Health Workforce within Disability Networks: Protection and Advocacy

Systems is 11:59 p.m. Eastern Time February 11, 2022.

I. Funding Opportunity Description

The Administration for Community Living (ACL) announced a new funding opportunity to expand the public health workforce within the disability networks. Public health promotes and protects the health of people and the communities where they live, learn, work, and play. The disability networks funded by the Administration for Community Living (ACL) play an essential role in that work. The disability networks consist of trusted organizations and programs that reach and provide services and supports to people with disabilities in every community throughout the nation, including those related to public health

such as health and wellness education and information, counseling, case management and guidance related to health and social needs, as well as how to access those supports. These networks have over 50 years of community experience and possess intimate knowledge of the public health and other resources available and the needs of people with disabilities in their direct area.

As part of its ongoing COVID-19 response efforts, the Biden-Harris Administration is investing federal funds through the American Rescue Plan Act of 2021 (ARPA)¹ to recruit, hire, and train public health workers to respond to the pandemic and prepare for future public health challenges. Specifically, the Secretary of the U.S. Department of Health and Human Services (HHS) will “carry out activities related to establishing, expanding, and sustaining a public health workforce . . . ,” ARPA § 2501(a), and funds may be used to support costs, including wages and benefits, of a range of public health professionals including but not limited to social support professionals, community health workers, communication and policy experts and “. . . other positions as may be required to prevent, prepare for, and respond to COVID-19 . . . ,” ARPA § 2501(b)(1).

To help advance these efforts, ACL has created the Expanding the Public Health Workforce within Disability Networks program. This program aims to increase through the support of wages and benefits the number of public health professionals within the disability networks to address the unique needs of individuals with disabilities. Public health professionals supported through this program may provide a wide range of public health services and supports, including provision of culturally affirmative and linguistically accessible information, access assistance for vaccines and boosters, transition and diversion from high-risk congregate settings to community living, provision and connections to health and wellness programs, activities that address social isolation and social determinants of health, and other activities that support the public health and wellbeing of people with disabilities.

Protection and Advocacy Systems (P&As) under the Developmental Disabilities Assistance and Bill of Rights Act (DD Act)—the eligible entities for this opportunity—shall be provided funding to support new staff or increase the full-time equivalent (FTE) of

existing staff under this opportunity to carry out public health services and supports. Although not required for funding, grantees are encouraged to explore options for funding to sustain the new FTE after the end of the grant. There is no cost sharing or matching requirement for this funding.

Award recipients will be required to submit annual progress reports in the form of a written summary on the number of full-time equivalents (FTEs) funded, type of public health professional(s) hired, and the activities they are engaged in to advance public health. To be eligible to receive this grant, the P&As must submit a Letter of Assurance to ACL containing all the assurances required, (see below, “Section III. Eligibility Criteria and Other Requirements” and “Section IV. Submission Information”). P&As that do not submit a Letter of Assurance or otherwise indicate no desire to receive funds, will be excluded from receiving funds.

ACL may extend deadlines based on the need of the COVID-19 response, e.g., to meet unanticipated issues related to COVID-19 and/or to allow impacted P&As that missed the cut-off date to submit a letter of assurance for consideration. ACL intends to issue notices of award as soon as possible with an estimated start date of March 1, 2022. However, the actual award may be released earlier or later than that date. Because the total amount awarded to each grantee is contingent upon the total number of grantees applying for funding, grant awards will be issued after ACL receives responses from all eligible P&As. Regardless of the date of award, the funding will be available until September 30, 2024. Grantees may use the funds over any period of time before this date but are encouraged to use the funding as soon as possible to have the greatest impact.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of new grants, evenly distributed to eligible entities.

2. Anticipated Total Funding per Budget Period

Awards made under this announcement will have an estimated start date of March 1, 2022 and an end date of September 30, 2024.

The total available funding for this opportunity is \$6,384,000.

Eligible entities who do not complete assurance requirements below, or otherwise indicate no desire to receive funds will be excluded from receiving

funds. This will have the effect of increasing the amount of funds available for eventual recipients.

ACL will distribute the \$6,384,000 evenly to all eligible entities to ensure a sufficient level of funding to provide substantive support for the public health workforce, which equates to a minimum award of \$112,000. This figure is based on the current number of eligible entities and would rise if some eligible entities refuse or are deemed ineligible.

III. Eligibility Criteria and Other Requirements

1. Eligible Entities

The eligible entity for these awards is designated by ACL as Protection and Advocacy Systems authorized under Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000.

2. Match

Cost Sharing or Matching is not required.

3. Other Requirements

A. Letter of Assurance

A Letter of Assurance is required to be submitted by the eligible entity in order to receive an award. The Letter of Assurance must include the following:

1. Assurance that the award recipient is the agency or entity designated as the Protection and Advocacy System in the state or territory under section 143 of the DD Act (42 U.S.C. 15042).
2. Assurance that funds will be spent in ways consistent with the purpose of the funding to support the cost of wages and benefits for public health professionals, directly or through contract such as:

- Case investigator,
- Contact tracer,
- Social support specialist,
- Community health worker,
- Public health nurse,
- Disease intervention specialist,
- Epidemiologist,
- Program manager,
- Laboratory personnel,
- Informaticians,
- Communication and policy experts,
- Other positions as may be required

to prevent, prepare for, and respond to COVID-19.

3. Assurance to provide semi-annual federal financial reports and annual program reports that include the number and type of full-time equivalents hired, and activities performed to advance public health.

B. DUNS Number

All grant applicants must obtain and keep current a D-U-N-S number from

¹ American Rescue Plan Act of 2021, Public Law 117-2, 135 Stat 4 (Mar. 11, 2021).

Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number can be obtained from: <https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm>.

C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to PHWF@acl.hhs.gov.

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022. Letters of Assurance should be submitted *electronically via email* and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic and Submission Issues

Direct programmatic and submission inquiries to PHWF@acl.hhs.gov.

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022-00401 Filed 1-11-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-E-1817, FDA-2020-E-1818, and FDA-2020-E-1820]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** of November 1, 2021, for the determination of a regulatory review

period for purposes of patent extension for the human biological product, ENHERTU. This document corrects that notice by adjusting the applicable regulatory review period for the testing phase and approval phase of the product, ENHERTU.

DATES: All due dates for submission of comments, redetermination requests, and submission of petitions for due diligence as well as the dates used to determine the regulatory review periods for the products noted above remain the same as originally published.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION: On November 1, 2021, the Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** determining the regulatory review period for the human biological product ENHERTU. This correction to the notice adjusts the applicable regulatory review period of the product with the number of days occurring during the testing phase and the approval phase of the product ENHERTU.

Correction

In the **Federal Register** of November 1, 2021 (86 FR 60252), in FR Doc. 2021-23725, appearing on page 60253, in the third column, in section II, “Determination of Regulatory Review Period,” in the first two sentences, the following correction is made:

FDA has determined that the applicable regulatory review period for ENHERTU is 1,395 days. Of this time, 114 days occurred during the testing phase of the regulatory review period, while 1,281 days occurred during the approval phase.

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-00404 Filed 1-11-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updates to the Bright Futures Periodicity Schedule

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Effective December 30, 2021, HRSA accepted recommended updates to the Bright Futures Periodicity Schedule, a HRSA-supported guideline for infants, children and adolescents for purposes of ensuring that non-grandfathered group and individual health insurance issuers provide coverage without cost sharing under the Public Health Service Act. The updates to the Bright Futures Periodicity Schedule are: A new category for sudden cardiac arrest and sudden cardiac death risk assessment, a new category for hepatitis B virus infection risk assessment, addition of suicide risk as an element of universal depression screening for children ages 12–21, and updated category title from “Psychosocial/Behavioral Assessment” to “Behavioral/Social/Emotional Screening,” with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added, with no associated recommended changes to clinical practice or health insurance coverage. Please see <https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html> for additional information.

FOR FURTHER INFORMATION CONTACT:

Savannah Kidd, M.S. MFT, HRSA/ Maternal and Child Health Bureau by calling 301-287-2601 or by emailing at SKidd@hrsa.gov.

SUPPLEMENTARY INFORMATION: The Bright Futures program has been funded by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and recommend updates to the *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents*, a set of materials and tools that provide theory-based and evidence-driven guidance for all preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program’s existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child’s development.

Section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13), added by the Patient Protection and Affordable Care Act (Pub. L. 111-148), requires that non-grandfathered group health plans and health insurance issuers offering