

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: Alison Barkoff, Acting Administrator and Assistant Secretary

for Aging, Administration for Community Living, 330 C Street SW, Washington, DC 20201.

Letters of Assurance should be submitted electronically via email to your ACL program officer. The following table identifies the designated program officer against each of the 10 ACL regions:

| | ACL regions | Email/phone |
|---------------------------------|--|--|
| Peter Nye—Program Officer | Region II • NY, NJ, PR, VI Region V • IL, IN, MI, MN, OH, WI Region X • AK, ID, OR, WA | peter.nye@acl.hhs.gov ; 202–795–7606. |
| Veronica Hogan | Region I • CT, MA, ME, NH, RI, VT Region III • DC, DE, MD, PA, VA, WV Region VII • IA, KS, MO, NE | veronica.hogan@acl.hhs.gov ; 202–795–7365. |
| Jennifer Martin | Region IV • AL, FL, GA, KY, MS, NC, SC, TN Region VI • AR, LA, OK, NM, TX | jennifer.martin@acl.hhs.gov ; 202–795–7399. |
| Kimball Gray | Region VIII • CO, MT, UT, WY, ND, SD Region IX • CA, NV, AZ, HI, GU, CNMI, AS | kimball.gray@acl.hhs.gov ; 202–795–7353. |

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on April 23, 2021. 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 inquiries to Program Officer found in the table in “Section IV. Submission Information.”

2. Submission Issues

Direct inquiries regarding submission of the Letters of Assurance to Program Officer found in the table in “Section IV. Submission Information.”

Dated: April 5, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–07290 Filed 4–8–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Availability of Program Application Instructions for the Protection and Advocacy Systems Network To Expand COVID–19 Vaccine Access for People With Disabilities

Title: Expanding Disabilities Network’s (Protection and Advocacy Systems) Access to COVID–19 Vaccines.

Announcement Type: Initial.

Statutory Authority: Subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act).

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

DATES: The deadline date for the submission of the Expanding Disabilities Network’s (Protection and Advocacy Systems) Access to COVID–19 Vaccines is 11:59 p.m. Eastern Time April 23, 2021.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

The Administration for Community Living (ACL) announced a new funding opportunity to increase vaccine access for people with disabilities. With funding and partnership support from the Centers for Disease Control and Prevention (CDC), ACL is providing

grants to disability networks to provide critical services to help communities combat COVID–19. A leading priority of this joint effort is to ensure vaccines are equally accessible to the disability population. Approximately 61 million adults living with in the US have a disability, representing approximately 26 percent of the adult population. People with disabilities may have an increased risk for contracting COVID–19 based on where they live or the services they receive. Some people with disabilities live in group settings, which places them at higher risk for acquiring COVID–19 in comparison to people without disabilities. People with disabilities may also require close contact with direct service providers, including personal care attendants or other care providers, who help with activities of daily living. Moreover, many people with disabilities have underlying health conditions (e.g., diabetes, heart disease, and obesity) that increases the risk of severe illness due to COVID–19. In addition, research also found that people with Down Syndrome are significantly more likely to be hospitalized from COVID–19 than the general population.

There are increasing reports of barriers of unequal access in communities to vaccinate people with disabilities. For example, some people with disabilities may experience difficulties scheduling appointments, communicating, obtaining accessible transportation or require direct support services to attend vaccination appointments. Others living in the community may be isolated or unable to leave their home and may require in-home vaccination.

This funding opportunity is designed to breakdown those barriers to expand vaccine access in communities. Examples of activities consistent with the purpose of this funding are the following:

- Education about the importance of receiving a vaccine;
- Identifying people unable to independently travel to a vaccination site;
- Helping with scheduling a vaccine appointment;
- Arranging or providing accessible transportation;
- Providing companion/personal support;
- Reminding people of the second vaccination appointment if needed; and/or
- Providing technical assistance to local health departments or other entities on vaccine accessibility.

Awards authorized under Subtitle C of the DD Act to the Protection and Advocacy Systems (P&As) shall be provided funding under this opportunity. Award recipients will be required to submit annual progress reports in the form of a written summary on the activities conducted, challenges, successes, and lessons learned. In addition, to show impact of the grant awards, the grantee will include the number of people served or impacted by the services provided, against each of the activities chosen to be implemented. To be eligible to receive this grant, the grantee 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 complete assurance requirements below, or otherwise indicate no desire to receive funds will be excluded from receiving funds.

ACL may establish ad hoc dates based on the need of the COVID–19 response, e.g., to meet unanticipated issues related to COVID–19 and/or to allow impacted eligible applicants that missed the cut-off date to submit an application for consideration. ACL intends to issue initial notices of award as applications

are received prior to the application due date to address urgent COVID–19 response needs. Second notices of award are planned after the actual number of applicants is finalized.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of formula grants to P&As.

2. Anticipated Total Funding per Budget Period

Under this program announcement, ACL intends to make grant awards to each State, Territory, the District of Columbia, and the Native American Consortium. Awards made under this announcement have an estimated start date of April 1, 2021 and an estimated end date of December 31, 2022, for a 20-month budget and performance period.

The total available funding for this opportunity is \$4,000,000. Funding will be distributed based on the state/territory population. There are no cost-sharing nor match requirements.

Below are the projected award amounts:

| Jurisdiction | Projected amount |
|----------------------------|------------------|
| Alabama | \$50,203 |
| Alaska | 39,713 |
| Arizona | 74,525 |
| Arkansas | 39,713 |
| California | 404,556 |
| Colorado | 58,963 |
| Connecticut | 39,713 |
| Delaware | 39,713 |
| District of Columbia | 39,713 |
| Florida | 219,907 |
| Georgia | 108,710 |
| Hawaii | 39,713 |
| Idaho | 39,713 |
| Illinois | 129,744 |
| Indiana | 68,930 |
| Iowa | 39,713 |
| Kansas | 39,713 |
| Kentucky | 45,744 |
| Louisiana | 47,598 |
| Maine | 39,713 |
| Maryland | 61,901 |
| Massachusetts | 70,571 |
| Michigan | 102,254 |
| Minnesota | 57,743 |
| Mississippi | 39,713 |
| Missouri | 62,840 |
| Montana | 39,713 |
| Nebraska | 39,713 |
| Nevada | 39,713 |
| New Hampshire | 39,713 |
| New Jersey | 90,943 |
| New Mexico | 39,713 |
| New York | 199,181 |
| North Carolina | 107,386 |
| North Dakota | 39,713 |
| Ohio | 119,683 |
| Oklahoma | 40,515 |
| Oregon | 43,185 |
| Pennsylvania | 131,077 |
| Rhode Island | 39,713 |

| Jurisdiction | Projected amount |
|-------------------------|------------------|
| South Carolina | 52,717 |
| South Dakota | 39,713 |
| Tennessee | 69,923 |
| Texas | 296,883 |
| Utah | 39,713 |
| Vermont | 39,713 |
| Virginia | 87,394 |
| Washington | 77,967 |
| West Virginia | 39,713 |
| Wisconsin | 59,615 |
| Wyoming | 39,713 |
| American Samoa | 21,246 |
| Guam | 21,246 |
| Northern Marianas | 21,246 |
| Puerto Rico | 39,713 |
| Virgin Islands | 21,246 |
| Native American | 21,246 |
| Total | 4,000,000 |

III. Eligibility Criteria and Other Requirements

1. Eligible Entities

The eligible entity for these awards is the agency designated as a P&A per the DD Act.

2. 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 P&A per the DD Act.

2. Assurance that funds will supplement and not supplant existing P&A funding.

3. Assurance that funds will be spent in ways consistent with the purpose of the funding in carrying out one or more of the following activities:

- Education about the importance of receiving a vaccine;
- Identifying people unable to independently travel to a site;
- Helping with scheduling a vaccine appointment;
- Arranging or providing accessible transportation;
- Providing companion/personal support;
- Reminding people of their second vaccination appointment if needed; and/or,
- Providing technical assistance to local health departments or other entities on vaccine accessibility.

4. Assurance that the award recipient will do outreach to Aging and Disability Resource Centers, Centers for Independent Living, State Councils on Developmental Disabilities, and University Centers for Excellence in Developmental Disabilities Education,

Research, and Service to maximize state coordination wherever possible.

5. Assurance to provide semi-annual federal financial reports annual program reports that describes activities conducted, challenges, successes, and lessons learned. The written summary will also include number of people served or impacted by the services provided.

B. DUNS Number

All grant applicants must obtain and keep current a D–U–N–S number from 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: Alison Barkoff, Acting Administrator and Assistant Secretary for Aging, Administration for Community Living, 330 C Street SW, Washington, DC 20201.

Letters of Assurance should be submitted electronically via email to your ACL program officer. The following table identifies the designated program officer for each P&A:

| P&A | Program officer | Email address |
|----------------------|--------------------------|--|
| Alabama | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Alaska | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| American Samoa | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Arizona | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| Arkansas | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| California | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Colorado | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Connecticut | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| Delaware | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| District of Columbia | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| Florida | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Georgia | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| Guam | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Hawaii | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| Idaho | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| Illinois | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Indiana | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Iowa | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Kansas | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Kentucky | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| Louisiana | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Maine | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Maryland | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Massachusetts | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Michigan | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Minnesota | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Mississippi | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Missouri | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Montana | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| Native American | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Nebraska | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Nevada | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| New Hampshire | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| New Jersey | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| New Mexico | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| New York | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| North Carolina | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| North Dakota | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Northern Marianas | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Ohio | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Oklahoma | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Oregon | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| Pennsylvania | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Puerto Rico | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| Rhode Island | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| South Carolina | Larissa Crossen | <i>Larissa.Crossen@acl.hhs.gov.</i> |
| South Dakota | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Tennessee | Dana Fink | <i>Dana.Fink@acl.hhs.gov.</i> |
| Texas | Elizabeth Leef | <i>Elizabeth.Leef@acl.hhs.gov.</i> |
| Utah | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Vermont | Wilma Roberts | <i>Wilma.Roberts@acl.hhs.gov.</i> |
| Virgin Islands | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| Virginia | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |
| Washington | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |
| West Virginia | Rebecca Ellison | <i>Rebecca.Ellison@acl.hhs.gov.</i> |
| Wisconsin | Melvenia Wright | <i>Melvenia.Wright@acl.hhs.gov.</i> |

| P&A | Program officer | Email address |
|---------------|--------------------------------|--|
| Wyoming | Katherine Cargill-Willis | <i>Katherine.Cargill-Willis@acl.hhs.gov.</i> |

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on April 23, 2021. 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 Issues

Direct programmatic inquiries to your program officer listed above or Ophelia McLain at *Ophelia.mclain@acl.hhs.gov*.

2. Submission Issues

Direct inquiries regarding submission of the Letters of Assurance to the appropriate ACL Program Officer found in the table in “Section IV. Submission Information.”

Dated: April 5, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021-07292 Filed 4-8-21; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0039]

Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing the availability of version 2.2 of the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports (ICSRS) for Vaccines (Specifications). The version update is not applicable to CBER-regulated drug products marketed for human use with approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs); CBER-regulated therapeutic biological products marketed for human use with approved Biologic License Applications (BLAs); Whole Blood or blood components; and human cells, tissues,

and cellular and tissue-based products (HCT/Ps) regulated solely under the Public Health Service Act.

ADDRESSES: You may submit either electronic or written comments 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-2021-N-0039 for “Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification”. 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, 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 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 laws. 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: