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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Single-Source Supplement the Link Center: Bridging Intellectual and/or Developmental Disabilities (I/DD) and Mental Health Systems Cooperative Agreement

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the National Association for State Directors of Developmental Disabilities Services (NASDDDS) for the Link Center: Bridging I/DD and Mental Health Systems cooperative agreement. The purpose of this project is to improve the quality of life for people with intellectual and/or developmental disabilities (I/DD) and mental health conditions by supporting state agencies with policy development, service design, and service coordination resources, and sharing resources to individuals, families, direct support professionals, clinicians, and other policymakers. The administrative supplement for FY 2023 will amount to $540,000, bringing the total award for FY 2023 to $1,214,978.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Allison Cruz, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, (202) 795–7334 or via email *allison.cruz@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: This supplementary funding from the Substance Abuse and Mental Health Services Administration (SAMHSA) will expand The Link Center: Bridging I/DD and Mental Health Systems by coordinating, planning, and implementing activities to support 988 call centers to support people with I/DD and mental health conditions. A key activity will be the 988 Policy Academy. As a result of this funding, ACL and SAMHSA expect that:

- Up to 6 States will improve their systems to more effectively address the needs of individuals with I/DD and mental health conditions.
- Targeted State teams will have engaged in six (6) virtual learning engagements and participated in a two-day session to finalize actions steps. These States will receive follow-along supports towards implementations and sustainability activities to more effectively address the needs of individuals with I/DD and mental health conditions.

This supplement will fund the following.

Academy Structure

Membership

The policy academy will be open to 5–6 states. Each state will bring a team of partners, including:

- SAMHSA 988 Office and CMHS leadership and/or key staff, including the representatives from the Lifeline network administrator
- State mental health authority leadership and core staff involved in 988 and Crisis Response
- State I/DD authority leadership and core staff involved in supporting individuals with complex support needs
- State Medicaid leader(s) with knowledge and oversight of MH and/or LTSS
- State Head Injury Administrators/core staff or partner organizations
- People with lived experience
- One or more State DD Act Partner organizations (DD Councils, UCEDDs, Protection and Advocacy Organizations)
- Leadership from the National Association of County Behavioral Health & Developmental Disability Directors

Optional:

- Child welfare officials, especially those supporting children with complex support needs
- Law enforcement
- Other partners as determined by the state

Each team should be led by 2–3 individuals from State Mental Health, 988/Lifeline and I/DD Agencies. Each state team may consist of 8–10 individuals. Team composition should reflect a lens toward ensuring that the state-level solutions will be informed by diversity, equity, and inclusion. States may include team members that are key to building a responsive network of information sharing, potential warm hand-offs, and available supports.

Approach

Exploratory survey/Environmental scan:

- Prior to selection of state participants, collect information related to general areas of need that will inform and give an aggregate scope of focus for succeeding academy activities

State Tailored Interventions:

- State specific planning meetings with state leads
- Convene state-level (virtual) town hall discussions to provide landscape information on areas of need
- Develop target areas for state team

Virtual Learning Opportunities:

- Based on state target areas, develop series of six (6) virtual learning engagements for cross-state participation (identifying peers for both elevation of good practice and group solution identification)

In Person Academy:

- Convene a two-day symposium in the Washington DC area focused on cultivating sustainable networks and ongoing information sharing (Strongly encourage in-person participation, accommodate virtual if needed). Will include group learning and state-specific breakout sessions to optimize learning, sharing and action plan development.
  - Will include pre-planning with each state (two meetings)
  - Will include post-meeting follow up activities, including plan for implementation and sustainability

Post Meeting Activities and Follow-Along Technical Assistance:

- TA Collaborative will meet with state teams to finalize action steps developed from in person meeting;
- TA Collaborative will meet monthly with state teams to provide follow-along support toward implementation and sustainability activities.
- A post convening synthesis will be developed as a resource for partners engaged in this work.

Program Name: The Link Center: Bridging I/DD and Mental Health Systems.

Recipient: The National Association of State Directors of Developmental Disabilities Services.

Period of Performance: The supplement award will be issued for the second year of the five-year project period of September 30, 2023, through August 31, 2024.

Total Supplement Award Amount: $540,000.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 Public Law 106–402, section 161(2)(B), (C), and (D).

Basis for Award: The National Association of State Directors of Developmental Disabilities Services is

currently funded to carry out The Link Center Project for the period of September 1, 2022, through August 31, 2027. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the Link Center project and the beneficiaries being served for ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner. SAMHSA also has determined that the award of another contract or grant to provide these services would duplicate the activities carried out under this cooperative agreement. SAMHSA has further determined that a grant supplement to support the 988 State Policy Academy through this cooperative agreement is likely to be less expensive than a separate arrangement. This agreement promotes government efficiency and reduces the possibility of costly duplication of effort.

Dated: September 21, 2023.

Alison Barkoff,

Senior Official Performing the Duties of the Administrator and the Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of two additional draft chapters of a multichapter draft guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' This multichapter draft guidance, when finalized, will explain FDA's current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under FDA's regulation entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' The newly available draft chapters are entitled ''Chapter 11—Food Allergen Program'' and ''Chapter 16—Acidified Foods.'' This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 25, 2024 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–2016–D–2343 for ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' 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, 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 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.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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Linda Kahl, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2784.