

*Program Name:* Institute of Community Inclusion.

*Award Amount:* \$350,000.00.

*Statutory Authority:* The Developmental Disabilities and Bill of Rights Act of 2000.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.631.

*Program Description:* The Administration on Developmental and Intellectual Disabilities, an agency of the U.S. Administration for Community Living, has been funding the ICI for thirty-five years. The project's activities include: Studying the effectiveness of state developmental disabilities agencies and vocational rehabilitation agencies in promoting full inclusion of individuals with intellectual and developmental disabilities through employment and other community activities; describing national trends in the employment and economic status of youth and adults with intellectual and developmental disabilities on a state and national basis; highlighting practices and outcomes in the transition from school to employment and promote policy enhancing integrated employment at both the systems and customer levels; developing guidelines for community-based non-work activities; implementing [www.statedata.info](http://www.statedata.info), a Web site illustrating service system investment in day and employment services, and [www.realworkstories.org](http://www.realworkstories.org), a Web site featuring successes of youth with intellectual and developmental disabilities in paid jobs in their communities; provide an online catalog of innovative state-level strategies that influence policy and facilitate access to integrated employment; collaborate with the University of Minnesota and the University of Colorado to show targeted current year and longitudinal data on the project Web site and providing a create-a-chart option allowing reports to be customized. The project provides comparative nationwide longitudinal study of the employment trends of people with Intellectual/Developmental Disabilities and is a thirty-five year body of work.

*Agency Contact:* For further information or comments regarding this supplemental action, contact Katherine-Cargill-Willis, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, 330 C Street SW., Washington, DC 20201; telephone 202-795-7322; email [katherine.cargill-willis@acl.hhs.gov](mailto:katherine.cargill-willis@acl.hhs.gov).

Dated: July 17, 2017.

**Mary Lazare,**

*Acting Administrator and Assistant Secretary for Aging.*

[FR Doc. 2017-15663 Filed 7-25-17; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Notice of Intent To Award a Single-Source Non-Competing Continuation Application to the University of Minnesota for an Additional 12 Months

**SUMMARY:** The Administration for Community Living (ACL) recently announced the awarding of the University of Minnesota to the Residential Information System Project (RISP). The University of Minnesota will maintain and continue the longitudinal study of annual state-by-state and national statistics on residential services and supports for people with intellectual and developmental disabilities.

#### SUPPLEMENTARY INFORMATION:

*Program Name:* Residential Information Systems Project.

*Award Amount:* \$350,000.00.

*Statutory Authority:* The Developmental Disabilities and Bill of Rights Act of 2000.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.631.

*Program Description:* The Administration on Developmental and Intellectual Disabilities, an agency of the U.S. Administration for Community Living, has been funding the RISP for thirty-five years. The project's activities include: Utilizing a large multistate database on individuals with developmental disabilities to examine the associations between personal characteristics, housing, financing and support models, state systems on inclusion, self-determination, satisfaction, and outcomes; conducting state policy and program surveys on key topics in residential and other community services; maintaining a clearinghouse of information and resources on consumer-controlled housing, the direct support workforce, and community living outcomes; collaborating with the University of Massachusetts and the University of Colorado to show targeted current year and longitudinal data on the project Web site and providing a create-a-chart option allowing reports to be customized. The comparative nationwide longitudinal study of the residential settings where people with

Intellectual and Developmental Disabilities and supports is a forty year body of work.

*Agency Contact:* For further information or comments regarding this supplemental action, contact Katherine Cargill-Willis, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, 330 C Street SW., Washington, DC 20201; telephone 202-795-7322; email [katherine.cargill-willis@acl.hhs.gov](mailto:katherine.cargill-willis@acl.hhs.gov).

Dated: July 17, 2017.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Notice of Intent To Award a Single-Source Non-Competing Continuation Application To Fund Grant Number 90DN0296 the University of Colorado for an Additional 12 Months

**SUMMARY:** The Administration for Community Living (ACL) recently announced the awarding of the University of Colorado for the State of the States in Intellectual and Developmental Disabilities (State of the States) project. The University of Colorado will maintain and advance a comparative nationwide longitudinal study of public financial commitments and programmatic trends in developmental disabilities services and supports.

#### SUPPLEMENTARY INFORMATION:

*Program Name:* State of the States on Intellectual and Developmental Disabilities.

*Award Amount:* \$350,000.00.

*Statutory Authority:* The Developmental Disabilities and Bill of Rights Act of 2000.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.631.

*Program Description:* The Administration on Developmental and Intellectual Disabilities, an agency of the U.S. Administration for Community Living, has been funding the State of the States project for thirty-five years. The project's activities include: A analyzing developmental disabilities financial and programmatic trends in each state and the District of Columbia; identifying trends and innovations in the financing of family support supported living, and supported employment in the states;

completing special studies, such as Medicaid spending for special education; collaborating with the University of Massachusetts and the University of Minnesota to show targeted current year and longitudinal data on the project Web site and providing a create-a-chart option allowing reports to be customized. The comparative nationwide longitudinal study of public financial commitments and programmatic trends in developmental disabilities services and supports is a thirty-year body of work.

**Agency Contact:** For further information or comments regarding this supplemental action, contact Katherine-Cargill-Willis, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, 330 C Street SW., Washington, DC 20201; telephone 202-795-7322; email [katherine.cargill-willis@acl.hhs.gov](mailto:katherine.cargill-willis@acl.hhs.gov).

Dated: July 17, 2017.

**Mary Lazare,**

*Acting Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0880]

#### Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance; 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 the guidance entitled “Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance.” The Generic Drug User Fee Amendments of 2012 (GDUFA) are designed to speed the delivery of safe and effective generic drugs to the public and to improve the review process for abbreviated new drug applications (ANDAs). This guidance is intended to provide answers to common questions from the generic drug industry and other interested parties involved in the development and/or

testing of generic drug products regarding the requirements and commitments of GDUFA. This guidance finalizes the draft guidance originally issued in August 2012 and issued in revised draft form in September 2013.

**DATES:** Submit either electronic or written comments on this guidance at any time.

**ADDRESSES:** You may submit comments 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-2012-D-0880 for “Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance.” 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 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.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Sonia Kim, Center for Drug Evaluation and Research, Food and Drug