

and service delivery models to reduce program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to individuals under such programs. In October 2012, CMS launched the Comprehensive Primary Care (CPC) initiative as a multi-payer demonstration to test a model that fosters collaboration between public and private health insurance companies ("payers") to strengthen primary care. The program includes 479 participating primary care practices and 38 participating payers across 7 regional areas within the United States. The CMS Innovation Center executed a Memorandum of Understanding (MOU) with each participating payer within the 7 regional areas covered by the program. One of the stated goals in the MOU is improving the flow of cost and utilization data to CPC primary care practices. The test model will aggregate multi-payer data for each primary care practice rather than practices receiving the data individually from each payer.

This single-source cooperative agreement award will allow the inclusion of Medicare data into the CPC multi-payer data model. The awardees will combine Medicare Fee-for-Service (FFS) data with utilization data from participating payers resulting in the creation of uniform and actionable reports to support physicians care coordination and quality improvement efforts.

*Amount of the Award:* There will be three (3) single-source, cooperative agreements awarded in the initial amount of \$200,000–\$450,000 per award for the first budget period. An award for a non-competing continuation at \$200,000–\$450,000 may be awarded for a period of 12 months.

*Justification for Single Source Award:* Commercial payers within the 7 regions have agreed to work together to improve data-sharing to the CPC practices. Each of the awardees currently maintain contracts with all of the CPC payers for data-sharing and have worked with the payers and practices to develop business requirements for the CPC multi-payer claims database system. If CMS were to award another source, the vendor would not be aggregating Medicare claims data with claims data from the regional payers, as each of the payers have selected the three entities of this award to perform this function. Doing so would undermine the CPC practices' ability to improve care and lower costs through care coordination and quality improvement and is counter to CMS's MOU with the payers. In conclusion, the only entities capable of

providing the data aggregation services described are the three entities identified for the single-source awards.

*Project Period:* The anticipated period of performance for each cooperative agreement is 12 months from date of award with one continuation period of up to 12 months.

*Provisions of the Notice:* Title: Testing a Model of Data Aggregation under the Comprehensive Primary Care (CPC) Initiative.

*CFDA Number:* 93.646.

*Estimated Award Date:* September 12, 2015.

CMS has solicited proposal from Rise Health, The Health Collaborative, and My Health to include Medicare data into the multi-payer data model of the CPC initiative.

CMS requested the following to be submitted with each application:

1. Cover Letter
2. Project Abstract Summary
3. Project Narrative to address how the applicant will implement the cooperative agreement program in support of the goals of the Comprehensive Primary Care Initiative.
4. Budget Narrative
5. SF-424: Official Application for Federal Assistance
6. SF-424A: Budget Information Non-Construction
7. SF-424B: Assurances-Non-Construction Programs
8. SF-LLL: Disclosure of Lobbying Activities
9. Project Site Location Form(s) [as applicable]

Applications will be reviewed using the following evaluation criteria:

1. Proposed Approach—describe the development and implementation strategy for collecting and aggregating Medicare data with payer data from across the specified regions, including an anticipated timeline and activities associated with building the infrastructure needed to implement the project.
2. Organizational Capacity and Management Plan—demonstrates sufficient infrastructure and capacity to plan and implement the cooperative agreement activities and associated funding.
3. Evaluation and Reporting—overview of plans for quarterly reporting to CMS on the progress of the data aggregation activities funded under this cooperative agreement.
4. Budget and Budget Narrative—provide a detailed cost breakdown with explanations and justifications for the proposed cooperative agreement activities.

**Authority:** The CMS award is authorized under section 1115A of the Social Security Act, as added by Section 3021 of the Patient Protection and Affordable Care Act (P.L. 111-148) which permits the obligation of funding for CMS to design, implement, and evaluate innovative payment and service delivery models.

Dated: September 1, 2015.

**Daniel F. Kane,**

*Director, Office of Acquisition and Grants Management, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Announcement of the Intent To Award a Single-Source Cooperative Agreement to the Gerontology Institute, University of Massachusetts Boston

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) announces the intent to award a single-source cooperative agreement in the amount of \$75,000 to the Gerontology Institute, University of Massachusetts Boston (UMass Boston) to support and stimulate the expansion of work already underway by UMass Boston in providing pension counseling services to residents of the State of Illinois.

**DATES:** The award will be issued for a project period to run concurrently with the existing grantee's budget period of July 1, 2015 through June 30, 2016.

**FOR FURTHER INFORMATION CONTACT:** Valerie Soroka, Office of Elder Justice and Adult Protective Services, Administration on Aging, Administration for Community Living, 1 Massachusetts Avenue NW., Washington, DC 20001. Telephone: 202-357-3531; Email: [valerie.soroka@acl.hhs.gov](mailto:valerie.soroka@acl.hhs.gov)

**SUPPLEMENTARY INFORMATION:** The ACL's Pension Counseling & Information Program consists of six regional pension counseling projects, covering 29 states. The state of Illinois, with 6.4 million workers and a pension participation rate of 42%, is one of the largest states without an ACL-funded pension counseling project. The Pension Action Center at UMass Boston, which conducts ACL's New England Pension Assistance Project, is currently providing pension counseling services

to residents of Illinois with funding from the Retirement Research Foundation. Additional funds are needed to leverage the foundation's funding, in order to ensure that the current provision of services to Illinois residents will be continued. This supplementary funding would be provided for the approved period.

**Authority:** This program is authorized under Title II of the Older Americans Act (OAA) (42 U.S.C. 3032), as amended by the Older Americans Act Amendments of 2006, Public Law 109-365.

(Catalog of Federal Domestic Assistance 93.048).

Dated: August 14, 2015.

**Kathy Greenlee,**

*Assistant Secretary for Aging and Administrator, Administration for Community Living.*

[FR Doc. 2015-22630 Filed 9-8-15; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Announcement of the Intent To Award Single-Source Grants to the National Association of Area Agencies on Aging and the National Association of States United for Aging and Disabilities

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) announces the intent to award, subject to the availability of funds, single-source grant awards in the amount of \$335,000 to the National Association of Area Agencies on Aging (n4a) and \$153,500 to the National Association of State United for Aging and Disabilities (NASUAD). The awards will continue supporting and stimulating the ongoing work by these organizations to further develop and assist states and community-based organizations with building their business capacity for managed long-term services and supports and delivery system reform. CFDA Numbers: 93.048

**DATES:** The awards will be issued for a project period of September 30, 2015 through September 29, 2016.

**FOR FURTHER INFORMATION CONTACT:** Marisa Scala-Foley, Office of Integrated Care Innovations, Administration for Community Living, 1 Massachusetts Avenue NW., Washington, DC 20001. Telephone: 202-357-3516; Email: [Marisa.Scala-Foley@acl.hhs.gov](mailto:Marisa.Scala-Foley@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 2012, n4a and NASUAD were awarded grants from ACL to build the business capacity of state and community-based aging and disability organizations for managed long-term services and supports (MLTSS). This one-year of grant funding, through continuation grant, will continue to support n4a and NASUAD in their efforts to:

- Identify and track emerging trends, best practices, barriers, lessons learned and progress in the aging and disability networks' integration into MLTSS and delivery system reform;
- increase state and community-based aging and disability organizations' capacity, readiness and involvement in the provision of MLTSS through the provision of broad-based and targeted technical assistance, education and training; and
- develop products that complement and enhance the first two areas of focus.

This program is authorized under the Older Americans Act of 1965, as amended in 2006, Public Law 109-365.

Dated: August 28, 2015.

**Sharon Lewis,**

*Principal Deputy Administrator, Administration for Community Living.*

[FR Doc. 2015-22631 Filed 9-8-15; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-1213]

#### Use of Donor Screening Tests To Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products for Infection With *Treponema pallidum* (Syphilis); Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with *Treponema pallidum* (Syphilis); Guidance for Industry." The guidance document provides establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/P Establishments) with updated recommendations concerning donor testing for evidence of *Treponema pallidum* (*T. pallidum*) infection, the

etiologic agent of syphilis. HCT/P Establishments must, as required under Federal regulations, test a donor specimen for evidence of *T. pallidum* infection using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exception to this requirement applies. The guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor testing for *T. pallidum* infection under the criteria specified in Federal regulations. The guidance announced in this notice finalizes the draft guidance of the same title, dated October 2013. The recommendations in the guidance announced in this notice supersedes those recommendations for testing HCT/P donors for evidence of *T. pallidum* infection contained in the document entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated August 2007.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a document entitled "Use of Donor Screening Tests to Test Donors of