

Resource Centers) in their efforts to help low income beneficiaries.

The NCBOE works to utilize cost-effective strategies to find older individuals and people with disabilities with greatest economic need and facilitate their enrollment in the individuals in the programs for which they are qualified. As part of this effort, the NCBOE should support state and federal efforts to streamline benefits eligibility systems. This should include conducting a feasibility assessment to determine best ways to streamline the application process and centralize the eligibility guidelines for key benefits, including the automation of enrollment through a rules engine. The study should explore the governance structure and technical expertise necessary to create and maintain such a process. Additionally, it should explore what a realistic scope is for the project how the current benefits screening tools could evolve to benefit from further automation of eligibility. NCBOE should collaborate with ACL and the administration in conducting the feasibility assessment to coordinate with planned and emerging efforts to streamline eligibility benefits for low income individuals.

Program Name: The National Center for Benefits Outreach and Enrollment (NCBOE).

Recipient: National Council on Aging (NCOA).

Period of Performance: The award will be issued for the current project period of September 1, 2021 through August 31, 2022.

Total Award Amount: \$14,509,007 in FY 2021.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The statutory authority is contained in the 2006 Reauthorization of the Older Americans Act and the Medicare Improvements for Patients and Providers Act of 2008, as amended by the Patient Protection and Affordable Care Act of 2010, and reauthorized by the American Taxpayer Relief Act of 2012, Protecting Access to Medicare Act of 2014, Bipartisan Budget Act of 2018, and Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, and Consolidated Appropriations Act of 2021.

Basis for Award: The National Council on Aging (NCOA) is currently funded to carry out the NCBOE Project for the period of September 1, 2020 through August 31, 2025. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the NCBOE project and the beneficiaries

being served for the ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

NCOA is uniquely placed to complete the work under the NCBOE grant. Since 2001, NCOA has been the national leader in improving benefits access to vulnerable older adults. They have an unparalleled history of working with community-based organizations to develop and replicate outreach and enrollment solutions, while maintaining and enhancing technology to make it easier and more efficient to find benefits. NCOA through NCBOE accomplishes its mission by developing and sharing tools, resources, best practices, and strategies for benefits outreach and enrollment via its online clearinghouse, electronic and print publications, webinars, and training and technical assistance.

In addition, NCOA has BenefitsCheckUp which is, by far, the nation's most comprehensive and widely-used web-based service that screens older and disabled adults with limited incomes and resources and informs them about public and private benefits for which they are very likely to be eligible. Since the BenefitsCheckUp was launched in 2001, nearly 9.5 million people have discovered \$39.5 billion in benefits. In addition to the focus on Low-Income Subsidy and Medicare Savings Programs, BenefitsCheckUp also includes more than 2,500 benefits programs from all 50 states and DC, including over 50,000 local offices for people to apply for benefits; and more than 1,500 application forms in every language in which they are available. NCOA is successfully meeting all programmatic goals under the current NCBOE grant.

Dated: April 19, 2021.

Alison Barkoff,

Acting Assistant Secretary for Aging and Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Single-Source Supplement for the Amputee Coalition of America, Inc. for the National Limb Loss Resource Center Cooperative Agreement

ACTION: Announcing the Intent to Award a Single-Source Supplement for the Amputee Coalition of America, Inc. for

the National Limb Loss Resource Center cooperative agreement.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the Amputee Coalition of America, Inc. for the National Limb Loss Resource Center (NLLRC). The purpose of this project is to expand on current grant activities occurring across communities. These activities include programs that promote independence, community living, and the adoption of healthy behaviors that promote wellness and prevent and/or reduce chronic conditions associated with limb loss and increase partnerships and collaborations with ACL programs that will benefit all people living with limb loss or limb differences. The administrative supplement for FY 2021 will be for \$487,857 bringing the total award for FY 2021 to \$3,883,387.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Elizabeth Leef, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, Office of Disability Services Innovation; telephone (202)-475-2486 email: Elizabeth.leef@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: The additional funding will not be used to begin new projects. The funding will be used to enhance and expand existing programs that can serve an increased number of veterans and people living with limb loss and limb differences by providing increased technical assistance activities; promoting health and wellness programs; addressing healthcare access issues, including maternity care; promoting the adoption of healthy behaviors with the objective of preventing and/or reducing chronic conditions associated with limb loss; increasing partnerships and collaborations with ACL programs that will benefit all people living with limb loss or limb differences; enhancing and expanding the evaluation activities currently under way; and enhancing website capacities for improved information dissemination.

Program Name: National Limb Loss Resource Center.

Recipient: The Amputee Coalition of America, Inc.

Period of Performance: The supplement award will be issued for the third year of the five-year project period of April 1, 2019, through March 29, 2024.

Total Supplement Award Amount: \$487,857 in FY 2021.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: This program is authorized under Section 317 of the Public Health Service Act (42 U.S.C. 247(b-4)); Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235 (Dec. 16, 2014).

Basis for Award: The Amputee Coalition of America, Inc. is currently funded to carry out the objectives of this program, entitled *The National Limb Loss Resource Center* for the period of April 1, 2019, through March 29, 2024. Almost 2 million Americans have experienced amputations or were born with limb difference and another 28 million people in our country are at risk for amputation. The supplement will enable the grantee to carry their work even further, serving more people living with limb loss and/or limb differences and providing even more comprehensive training and technical assistance in the development of long-term supportive services. The additional funding will not be used to begin new projects or activities. The NLLRC will enhance and expand currently funded activities such as conducting national outreach for the development and dissemination of patient education materials, programs, and services; providing technical support and assistance to community based limb loss support groups; and raising awareness about the limb loss and limb differences communities.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the people living with limb loss and limb differences currently being served by this program could be negatively impacted by a service disruption, thus posing the risk of not being able to find the right resources that could negatively impact on health and wellbeing. If this supplement were not provided, the project would be less able to address the significant unmet needs of additional limb loss survivors. Similarly, the project would be unable to expand its current technical assistance and training efforts in NLLRC concepts and approaches, let alone reach beyond traditional providers of services to this population to train more “mainstream” providers of disability services.

Dated: April 19, 2021.

Alison Barkoff,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-D-0987, FDA-2020-D-1106, FDA-2020-D-1136, FDA-2020-D-1137, FDA-2020-D-1825]

Guidance Documents Related to Coronavirus Disease 2019; 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 FDA guidance documents related to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID-19-related guidances. The guidances identified in this notice address issues related to the COVID-19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency’s good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on April 23, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) 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>.