

consensus recommendations, under the *Better Respiratory Equipment using Advanced Technologies for Healthcare Employees* project (Project BREATHE), to improve respiratory protective equipment used by healthcare workers. These earlier consensus recommendations will be modified as NIOSH develops the consensus recommendations for the project New Generation PAPRs.

This project seeks to improve respirator tolerability, comfort, and other functional characteristics, while maintaining a level of protection equivalent to or greater than current standards. The design changes contemplated in this project could increase compliance with respiratory protection guidelines and standards among healthcare workers.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Intent To Issue One OPDIV-Initiated Supplement to BCFS Health and Human Services Under the Standing Announcement for Residential (Shelter) Services for Unaccompanied Alien Children, HHS-2017-ACF-ORR-ZU-1132

AGENCY: Unaccompanied Alien Children's (UAC) Program, Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of intent to issue one OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, Texas under the UAC Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the intent to issue one OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, Texas in the amount of up to \$300,800,000. ORR announces the issuance of the first installment for 60 days in the amount of up to \$50,000,000.

ORR has been identifying additional capacity to provide shelter for potential increases in apprehensions of Unaccompanied Alien Children at the

U.S. Southern Border. Planning for increased shelter capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter for Unaccompanied Alien Children referred to its care by the Department of Homeland Security (DHS).

To ensure sufficient capacity to provide shelter to unaccompanied alien children referred to HHS, ORR is requesting that BCFS provide up to 1,300 temporary shelter beds at Carrizo Springs, Texas over a graduated timeframe.

DATES: Supplemental award funds will support activities until January 31, 2020. The first installment will support activities for 60 days.

FOR FURTHER INFORMATION CONTACT: Stephen Antkowiak, Office of Refugee Resettlement, Division of Unaccompanied Alien Children Operations, 330 C Street SW, Washington, DC 20201. Phone: 202-260-6165. Email: stephen.antkowiak@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: ORR is continuously monitoring its capacity to shelter the unaccompanied alien children referred to HHS, as well as the information received from interagency partners, to inform any future decisions or actions.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing program and its services through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility to provide shelter for Unaccompanied Alien Children referred to its care by DHS and so that the U.S. Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85-4544RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110-457), which authorizes post release services under certain

conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85-4544-RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Karen Shields,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2019-13992 Filed 6-26-19; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement for the National Center for Benefits Outreach and Enrollment

ACTION: Notice.

The Administration for Community Living (ACL) announces the intent to award a single-source supplemental to the current cooperative agreement held by the National Council on Aging (NCOA) for the National Center for Benefits Outreach and Enrollment (NCBOE). The purpose of the NCBOE is to provide technical assistance to states, area agencies on aging, and service providers to provide outreach and low-income benefits enrollment assistance, particularly to older individuals with greatest economic need for federal and state programs. The administrative supplement for FY 2019 will be for \$390,861, bringing the total award for FY 2019 to \$11,390,861. With this supplemental funding, NCOA will develop specialized training and tools around integrated care models that can be used by SHIPs, MIPPA grantees, and other partners of ACL like Centers for Independent Living (CILs) and the Aging and Disability Resource Centers (ADRCs) to expand the NCBOE's outreach and education efforts targeting older adults with the greatest economic need. This includes reaching out to current MIPPA grantees to evaluate their needs and to determine what the grantees believe would be helpful and conducting other stakeholder group meeting(s) to discuss what should be created around these integrated care models. Stakeholders could include MIPPA and other ACL grantees, health plans, CMS, and other non-federal partners. Additionally, NCOA will continue, expand, and complete the work they are currently undertaking with the NCBOE award without disrupting services.

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 30, 2017 through September 29, 2020.

Total Award Amount: \$11,390,861 in FY 2019.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Medicare Improvements for Patients and Providers Act of 2008—Section 119, Public Law (Pub. L.) 110–275 as amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), reauthorized by the American Taxpayer Relief Act of 2012 (ATRA) and reauthorized by section 110 of the Protecting Access to Medicare Act of 2014.

Basis for Award: The National Council on Aging (NCOA) is currently funded to carry out the NCBOE Project for the period of September 30, 2017 through September 29, 2020. 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.

The NCOA is uniquely placed to complete the work under the NCBOE grant. Since 2001, the 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. The 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, the NCOA has the 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, over 7.6 million individuals have been

assisted to identify over \$29.6 billion in potential annual benefits. In addition to a focus on Low-Income Subsidy and Medicare Savings Programs, the BenefitsCheckUp also includes more than 2,500 benefits programs from all 50 states and DC, including the addition of Medicaid expansion programs as part of Affordable Care Act; over 50,000 local offices for people to apply for benefits; nearly 2,000 application forms in every language in which they are available; and user-friendly mapping tools that allow streamlined access to program fact sheets and application forms based upon a person's locality.

NCOA is successfully meeting all programmatic goals under the current NCBOE grant.

For Further Information Contact: For further information or comments regarding this program supplement, contact Rebecca Kinney, U.S. Department of Health and Human Services, Administration for Community Living, Center for Integrated Programs, Office of Healthcare Information and Counseling; telephone (202) 795–7375; email Rebecca.Kinney@acl.hhs.gov

Dated: June 24, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–13962 Filed 6–28–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–N–0809 and FDA–2018–N–4609]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that KANUMA (sebelipase alfa), manufactured by Alexion Pharmaceuticals Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: althea.cuff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that KANUMA (sebelipase alfa), manufactured by Alexion Pharmaceuticals Inc., meets the criteria for a priority review voucher. KANUMA (sebelipase alfa), is indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase deficiency.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about KANUMA (sebelipase alfa), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: June 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2430]

Request for Nominations on Device Good Manufacturing Practice Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) in the Center for Devices and Radiological Health notify