update data more frequently on LTC providers and service users for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC sectors and timely monitoring of supply and use of these sectors over time.

Data will be collected from national samples of two types of LTC providers in the 50 states and the District of Columbia: 2,090 RCCs and 1,750 ADSCs. The RCC sampling frame will contain all of the state-licensed RCCs that are licensed for four or more beds. Participants in the ADSC component will be sampled from a comprehensive listing of ADSCs maintained by the National Adult Day Services Association (NADSA).

Data were collected in 2012, 2014, 2016, 2018, and 2020. The data to be collected in 2022 include the basic characteristics, services, staffing, and practices of RCCs and ADSCs, and the demographics, selected health conditions and health care utilization, physical functioning, and cognitive functioning of RCC residents and ADSC participants. The 2022 NPALS also includes interviews with subject matter experts about electronic health records (EHRs) use among ADSCs and RCCs and available EHRs data for them.

Expected users of data from this collection effort include, but are not limited to, CDC; other DHHS agencies, such as the Office of the Assistant Secretary for Planning and Evaluation, The Administration for Community Living, and the Agency for Healthcare Research and Quality; associations, such as LeadingAge, National Center for Assisted Living, American Seniors Housing Association, Argentum, Advancing States, and National Adult Day Services Association; universities; foundations; and other private sector organizations such as the Alzheimer's Association, the AARP Public Policy Institute, and the National Academies of Sciences, Engineering, and Medicine.

Expected average burden for data collection is 60 minutes per respondent: 30 minutes for a provider questionnaire and 30 minutes for a services user questionnaire. In addition, 20 individuals with subject matter expertise in the use of electronic health records (HER) will be recruited to participate in a one-hour interview.

Changes to be implemented in 2022 include; reducing the number of sampled RCCs and ADCSs; use of a provider questionnaire and a services user questionnaire (instead of a multi-purpose form); and minor changes to questions and response options to improve usability and data quality.

OMB approval is requested for two years. The annualized estimates for number of respondents and burden hours are summarized below, assuming a 100% response rate. The total estimated annualized burden hours are 1,932. Participation is voluntary and there is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
RCC Director/Designated Staff Member	RCC Provider Questionnaire	1,045	1	30/60
ADSC Director/Designated Staff Member	ADSC Provider Questionnaire	875	1	30/60
RCC Director/Designated Staff Member	RCC Services User Questionnaire	1,045	1	30/60
ADSC Director/Designated Staff Member	ADSC Services User Questionnaire	875	1	30/60
RCC/ADSC Subject Matter Experts	EHRs Subject Matter Expert Interview	10	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–12146 Filed 6–6–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

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

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 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 2022 will be for $490,698 bringing the total award for FY 2022 to $3,883,259.

FOR MORE 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 fourth year of the five-year project period of April 1, 2019, through March 29, 2024.

Total Supplement Award Amount: $490,698 in FY 2022.

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.

Date: May 27, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–12205 Filed 6–6–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1138]

Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised); Withdrawal of Guidance

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance document entitled ''Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised),'' which was issued in June 2020 (and updated December 2020). FDA is withdrawing this guidance document in recognition that the conditions that created the need for these policies have evolved, such that these policies are no longer needed.

DATES: The withdrawal date is July 7, 2022.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–5640, *Joshua.Nipper@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, in June 2020, the Agency published this guidance document (June 23, 2020 at 85 FR 34638) and updated it in December 2020, to recognize that the COVID–19 public health emergency was affecting the public health in numerous direct and indirect ways, including device development programs.[2] This guidance document answered frequently asked questions and implemented temporary policies to reduce industry burden.

FDA has continually assessed the needs and circumstances related to these temporary policies, and as relevant needs and circumstances evolved, the Agency made updates and modifications to these temporary policies. FDA has determined that the needs and circumstances related to the temporary policies described in the guidance document have evolved, such that they are no longer needed, and the guidance document should be withdrawn. In weighing the current burden to industry and the Agency relating to the COVID–19 response efforts with the need to ensure patients have timely access to new devices, FDA is withdrawing this guidance document. Below is a brief description of the guidance document and temporary policies that will be withdrawn:

The guidance articulated FDA's policy that for marketing submissions and applications on hold, FDA did not intend to consider a submission or application to be withdrawn for an additional 180 days beyond the relevant response date. Returning to pre-pandemic policies for marketing submissions and applications placed on hold after the withdrawal of this guidance means FDA will generally consider the submission or application to be withdrawn if the submitter or applicant does not provide a complete response to major deficiency letters for Premarket Approval Applications (PMAs) (original and supplements) [3] and Humanitarian Device Exemption (HDE) applications (original and supplements) [4] within 360 days or to additional information letters for 510(k) [5] and De Novo requests [6] within

[1] The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19).

[2] The term ''device(s)'' in this document refers to devices regulated by the Center for Devices and Radiological Health (CDRH) as well as devices regulated by the Center for Biologics Evaluation and Research (CBER), including devices regulated as biological products under section 351 of the Public Health Service (PHS) Act.

[3] For more information, please see the FDA guidance document entitled ''FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals*).

[4] For more information, please see the FDA guidance document entitled ''Humanitarian Device Exemption (HDE) Program'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program*).

[5] For more information, please see the FDA guidance document entitled ''FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals*).

[6] For more information, please see the FDA guidance document entitled ''FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals'' (*https://www.fda.gov/regulatory-information/search-fda-*

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