comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every hospital must have an agreement only with its designated OPO to identify potential donors.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary of the Department of Health and Human Services (the Secretary) under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to submit comments during the 60-day comment period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under section 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Atrium Medical Center, Middletown, Ohio, is requesting a waiver to work with: Life Connection of Ohio, 3661 Briarfield Boulevard, Suite 105, Maumee, OH 43537.

The Hospital's Designated OPO is: LifeCenter Organ Donor Network, 615 Elsinore Place, Suite 400, Cincinnati, OH 45202.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

We will consider all comments we receive by the date specified in the **DATES** section of this document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 27, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–06764 Filed 3–31–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Administration on Disabilities Evaluation of Technical Assistance for Independent Living Grantees OMB Control Number 0985—New

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that

the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the Administration on Disabilities Evaluation of Technical Assistance for Independent Living Grantees.

DATES: Submit written comments on the collection of information by May 3, 2023.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC, 20201, (202) 795–7606, or *OILPPRAComments@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

The Administration for Community Living (ACL) is requesting approval to collect data for the Administration on Disabilities Evaluation of Technical Assistance for Independent Living Grantees.

ACL is currently engaged in an effort to better understand the implementation and effectiveness of the technical assistance (TA) provided to Independent Living (IL) grantees (Centers for Independent Living (CILs), statewide independent living councils (SILCs), and designated state entities (DSEs)).

The Rehabilitation Act of 1973, as amended authorizes the IL grantees to provide, expand, and improve independent living services for people with disabilities. Title VII, Part C authorizes funding to CILs.

Section 711A(a) requires ACL to reserve funds for training and TA to SILCs, and section 721(b)(1) requires ACL to reserve funds for training and TA to CILs.

TA efforts can support IL grantees in creating and maintaining effective organizations and services. TA, such as one-on-one TA, peer-to-peer mentoring, and webinars, is made available by the Independent Living Research Utilization (ILRU) program, the Association of Programs for Rural Independent Living (APRIL), the National Association of Statewide Independent Living Councils (NASILC), the National Council on IL (NCIL), and the TA centers that ACL funds, including the Disability Employment TA Center (DETAC) and the Federal Housing and Services Resource Center (HSRC) (referred to as AoD TA providers).

Although ACL monitors these AoD TA providers activities, the effectiveness of the TA approach has yet to be assessed. The goal of this data-collection effort is to provide ACL with IL-grantee feedback on the TA approach, including what elements are effective, that can be incorporated into a future TA strategy that is most beneficial to IL grantees. In this IC, ACL will be surveying a total of approximately 464 Part C CILs, DSEs, and SILCs. The web-based survey will be sent electronically to representatives from all Part C CILs, SILCs, and DSEs. ACL will provide the survey in alternative modes, such as by mail or telephone, on grantee request an alternative mode can be provided. Results from this survey will provide ACL with a better understanding of the implementation and effectiveness of the current TA approach from the perspective of IL grantees.

Comments in Response to the 60-Day Federal Register Notice

There were no public comments received during the 60-day FRN.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: The survey will be sent to approximately 464 representatives of CILs, SILCs, and DSEs. The approximate burden for web-based survey completion will be 25 minutes per respondent, which includes time to review the instructions, read the questions, and complete responses. This results in a total survey burden estimate of 11,600 minutes, which is 193.333 hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours *
Survey	464	1	0.41667	193.333
Total:	464	1	0.41667	193.333

Dated: March 28, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–06789 Filed 3–31–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2628]

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning-Enabled Device Software Functions; Draft Guidance for Industry and Food and Drug Administration Staff; 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 draft guidance entitled ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions.'' This draft guidance demonstrates FDA's commitment to developing innovative approaches to the regulation of machine learning-enabled medical devices and describes an approach that would often be the least burdensome and would support iterative improvement through modifications to machine learning-enabled device software functions