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

(herein referred to as ML–DSF) while continuing to ensure device safety and effectiveness. This draft guidance provides recommendations on the information to be included in a Predetermined Change Control Plan (PCCP) in a marketing submission for an ML–DSF. Such a plan describes the anticipated ML–DSF modifications and the associated methodology to implement those modifications, which would be reviewed in the marketing submission to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for each modification described in the PCCP. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 3, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 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 Docket No. FDA–2022–D–2628 for "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions." Received comments will be placed in the docket 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.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https:// www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Brendan O'Leary, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5530, Silver Spring, MD 20993–0002, 301–796–6898; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–8113; Tala Fakhouri, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6330, Silver Spring, MD 20993–0002, 301–837–7407; or John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130, HFG–3, Silver Spring, MD 20993–0002, 301–796–8941.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has a longstanding commitment to developing and applying innovative approaches to the regulation of medical device software and other digital health technologies to ensure their safety and effectiveness. As technology continues to advance all facets of healthcare, software incorporating AI, and specifically the subset of AI known as ML, has become an important part of many medical devices. In April 2019, FDA published the "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)—Discussion Paper and Request for Feedback." [1]

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[1] Available at *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-*

The discussion paper received a generous amount of stakeholder feedback that assisted in development of a tailored regulatory framework for AI/ML-enabled medical devices. This draft guidance, which was developed in response to stakeholder feedback, represents the Agency's next step in working to develop a tailored regulatory framework for ML–DSF. The discussion paper focused on a framework for SaMD only and introduced the term ''SaMD Pre-Specifications.'' In this draft guidance, the Agency is broadening the scope of the framework to include Software in a Medical Device (SiMD).

Additionally, section 3308 of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022, added section 515C ''Predetermined Change Control Plans for Devices'' to the FD&C Act. Section 515C provides FDA with express authority to approve or clear PCCPs for devices requiring premarket approval or premarket notification. For example, section 515C provides that supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP previously approved or cleared by FDA. Section 515C also provides that FDA may require that a PCCP include labeling for safe and effective use of a device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan. In this draft guidance, we provide recommendations on the

marketing submission content for PCCPs, which are based on the statute and feedback obtained through our various interactions with stakeholders.

The purpose of this draft guidance is to promote the development of safe and effective medical devices that use ML models trained by ML algorithms. This draft guidance provides recommendations on the information to be included in a PCCP in a marketing submission for an ML–DSF. The PCCP describes the anticipated ML–DSF modifications and the associated methodology to implement those modifications, which would be reviewed in the marketing submission to assure the continued safety and effectiveness of the device without necessitating additional marketing submissions for each modification described in the PCCP.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available

at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.* Persons unable to download an electronic copy of ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00020049 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
860, subpart D	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: March 28, 2023.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2023–06786 Filed 3–30–23; 8:45 am]

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