variety of subjects related to consumer, patient, or healthcare professional perceptions and about use of drug products and related materials, including but not limited to: (1) direct-to-consumer prescription drug promotion; (2) labeling and information about prescription and over-the-counter drugs; (3) patient medication guides; (4) safety and risk communications; (5) online sale of medical products; and (6) consumer and professional education. Annually, we project about 75 communication studies using the variety of research methods listed in this document. FDA is requesting an extension of these burden hours so as not to restrict its ability to gather information on public opinion for its regulatory and communications programs.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys	45,000	1	45,000	0.75 (45 minutes)	33,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection has changed since the last OMB approval. We attribute this change to screening more potential participants to obtain the very specialized and hard-to-recruit populations often needed for these studies, *e.g.,* vulnerable populations, and patients taking or users of a specific drug or type of drug, such as opioids and other controlled substances, biosimilars, etc.

Dated: September 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21419 Filed 9–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0996]

Technical Considerations for Medical Devices With Physiologic Closed-Loop Control Technology; 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 a final guidance entitled ''Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology.'' Physiologic closed-loop control (PCLC) devices are intended for automatic control of a physiologic variable(s) through delivery of energy or substance using feedback from physiologic sensors. PCLC devices may play an important role in reducing cognitive overload, minimizing human error, and enhancing medical care during emergency response and medical surge situations. This guidance provides technical considerations for PCLC technology in order to promote development and availability of safe and effective PCLC medical devices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 2023.

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 Docket No. FDA–2021–D–0996 for ''Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology.'' 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 guidance document entitled ''Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology'' to the Office of Policy, Center for Devices and Radiological Health (CDRH), 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: Christopher Scully, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1130, Silver Spring, MD 20993–0002, 301–796–2928.

SUPPLEMENTARY INFORMATION:

I. Background

PCLC technology can enable automation in a variety of medical device types including infusion systems, ventilators, extracorporeal systems, and stimulation systems. Automated adjustments of a physiologic variable(s) through the delivery or removal of energy or article (*e.g.,* drugs,[1] or liquid or gas regulated as a medical device), such as automated fluid resuscitation, ventilation/oxygenation and anesthesia delivery, are emerging applications for the critical and emergency care environments. PCLC devices may benefit the patient by facilitating safe and effective, consistent, and timely delivery or removal of energy or article. However, introducing automation and reducing clinician involvement can incur new types of hazards which may render the medical device unsafe if not properly designed or evaluated. This guidance provides technical considerations for PCLC technology during device development to support the safe and effective design and evaluation of PCLC medical devices.

CDRH held a public workshop entitled ''Physiological Closed-Loop Controlled Devices'' on October 13 and 14, 2015 [2] with the aim of fostering an open discussion on design and evaluation considerations associated with PCLC devices used in critical care environments. This workshop provided a forum for medical device manufacturers, clinical users and academia to discuss technical considerations for automated medical devices with PCLC technology. The feedback and recommendations provided at the meeting were incorporated in this guidance.

A notice of availability of the draft guidance appeared in the **Federal Register** of December 23, 2021 (86 FR 72971). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification that the scope of the guidance is limited to recommendations regarding PCLC aspects of a device, adding potential benefits of PCLC devices, adding references to applicable guidance documents and standards, adding more examples of PCLC device functions, revising technical considerations in PCLC device design, and addressing device interoperability.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology. 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 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 or https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01500085 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844

[1] The term drug as used in this guidance refers to both human drugs and biological products unless otherwise specified.

[2] See *http://wayback.archive-it.org/7993/20170112084803/http:/www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm457581.htm.*

21 CFR part or guidance	Topic	OMB control No.
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
803	Medical Device Reporting	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: September 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21412 Filed 9–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Infant, Child, and Adolescent Preventive Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: In fiscal year (FY) 2023, HRSA will provide supplemental funds to continue to provide technical assistance to pediatric primary care providers nationwide to connect them with Pediatric Mental Health Care Access (PMHCA) programs in their areas and to increase their capacity to provide pediatric mental and behavioral health care services.

FOR FURTHER INFORMATION CONTACT: Lauren Ramos, Director, Division of Maternal and Child Health Workforce Development, Maternal and Child Health Bureau, Health Resources and Services Administration, at *LRamos@hrsa.gov* and 301–443–6091.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The American Academy of Pediatrics (AAP), as the sole recipient under HRSA–23–074.

Amount of Non-Competitive Award: One award for $2,000,000. Supplemental funding for similar activities may be considered in FYs 2024 and 2025, subject to availability of funding for the activity and satisfactory performance of the recipient.

Project Period: September 30, 2023, to September 29, 2024.

CFDA Number: 93.110.

Award Instrument: Supplement for Services.

Authority: 42 U.S.C. 254c-19 (§ 330M of the Public Health Service Act), as amended by Section 11005 of the Bipartisan Safer Communities Act (Pub. L. 117–159)).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Award amount
U04MC31627	American Academy of Pediatrics	Itasca, IL ..	$2,000,000

Justification: Congress provided additional appropriations for the PMHCA program in FY 2022 that have allowed existing PMHCA projects to enhance workforce capacity to address the growing behavioral health needs among children and adolescents. This supplemental funding will support continued expansion of the reach and capacity of PMHCA programs in providing training and tele-consult support to pediatric primary care providers.

Carole Johnson,

Administrator.

[FR Doc. 2023–21485 Filed 9–28–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Emergency Medical Services for Children Innovation and Improvement Center

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: For fiscal year 2023, HRSA will provide additional supplemental funds for the Emergency Medical Services for Children Innovation and Improvement Center to continue to provide assistance to a Pediatric Mental Health Care Access (PMHCA) award recipient so that they can improve access to PMHCA program activities in emergency departments.

FOR FURTHER INFORMATION CONTACT: Lauren Ramos, Director, Division of Maternal and Child Health Workforce Development, Maternal and Child Health Bureau, Health Resources and Services Administration, at *LRamos@hrsa.gov* and (301)443–6091.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The University of Texas at Austin, the sole recipient of HRSA–20–037

Amount of Non-Competitive Award: One award for $1,000,000.

Project Period: September 30, 2023, to September 29, 2024.

CFDA Number: 93.110.

Award Instrument: Supplement.

Authority: 42 U.S.C. 254c–19 section 330M of the Public Health Service Act as amended by section 11005 of the Bipartisan Safer Communities Act (Pub. L. 117–159))