Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360e–4). Section 515C of the FD&C Act has provisions regarding PCCPs for devices requiring premarket approval or premarket notification. After the enactment of FDORA, FDA issued a draft guidance titled ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions,'' [4] which incorporated stakeholder feedback on the discussion paper and reflected our initial thinking on the statutory change and the types of information we recommend be submitted in a PCCP in a marketing submission for AI/ML-enabled software functions.

This draft guidance provides FDA's current thinking on a policy for PCCPs and recommendations on the information to include in a PCCP in a marketing submission for a device. This draft guidance recommends that a PCCP for a device describe the planned device modifications, the associated methodology to develop, validate, and implement those modifications, and an assessment of the impact of those modifications. FDA reviews the PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing 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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Predetermined Change Control Plans for Devices.'' 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Predetermined Change Control Plans for Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007026 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
860, subpart D	De Novo classification process	0910–0844
''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
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
822	Postmarket Surveillance of Medical Devices	0910–0449
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: August 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18828 Filed 8–21–24; 8:45 am]

BILLING CODE 4164–01–P

[4] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces a change to the 2-day Council on Graduate Medical Education (COGME or Council) public meeting scheduled for September 12, 2024, and September 13, 2024. The meeting will now be a 1-day meeting held on September 12, 2024. Information about COGME, agendas, and materials for this meeting can be found on the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings.* This notice supersedes information about COGME's 2024 meetings found in the **Federal Register** notice dated December 15, 2023, Meeting of the Council on Graduate Medical Education.

DATES: The COGME meeting will be held on:

- September 12, 2024, 10:00 a.m.–5:30 p.m. Eastern Time

ADDRESSES: The meeting will be held by teleconference and/or a video conference platform. For updates on how the meeting will be held, visit the COGME website 20 calendar days before the date of the meeting, where instructions for joining meetings will be posted. For meeting information updates, go to the COGME website meeting page at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Officer, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME provides advice and recommendations to the Secretary of Health and Human Services and Congress on policy, program development, and other matters of significance regarding the issues listed in section 762(a)(1) of the Public Health Service Act. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; foreign medical school graduates; the nature and financing of undergraduate and graduate medical education (GME); appropriation levels for certain programs under Title VII of the Public Health Service Act; and deficiencies in databases concerning the supply and distribution of the physician workforce and postgraduate programs for training physicians. COGME submits reports to the Secretary of Health and Human Services; the Senate Committee on Health, Education, Labor and Pensions; and the House of Representatives Committee on Energy and Commerce. COGME encourages entities providing GME to conduct activities to voluntarily achieve the recommendations of the Council related to appropriate efforts to be carried out by hospitals, schools of medicine, schools of osteopathic medicine, and accrediting bodies with respect to the supply and distribution of physicians in the United States; current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties; and issues relating to foreign medical school graduates, including efforts for changes in undergraduate and GME programs.

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For the September 12, 2024, meeting, agenda items may include, but are not limited to, discussions on team-based care, the Senate Finance Committee's Medicare GME draft policy document, and the 2018 Government Accountability Office's Report on Physician Workforce. Refer to the COGME website listed above for all current and updated information concerning the September meeting, including agendas and meeting materials that will be posted 20 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to COGME should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–18791 Filed 8–21–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 23, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report, OMB No. 0906–0016, Revision.

Abstract: This request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Quarterly Performance Report. The MIECHV Program is administered by the Maternal and Child Health Bureau within HRSA in partnership with the Administration for Children and Families, and provides support to all 56 states and jurisdictions, as well as tribes and tribal organizations. Through a needs assessment, states, jurisdictions, tribes, and tribal organizations identify target populations and select the home visiting service delivery model(s) that best meet their needs. In response to awardee feedback, HRSA is proposing the following revisions to the data collection forms to reduce administrative burden related to this performance report:

- Form 4, Table A.2: Remove Column D: ZIP Codes
- Form 4, Definition of Key Terms: Update definitions for Table A.2
- Form 4: Remove Section B

A 60-day notice published in the **Federal Register** on May 2, 2024, vol. 89, No. 86; pp. 35841–42. HRSA received one comment from an awardee. The commentor discussed the usefulness of collecting ZIP codes of families served by MIECHV-funded sites, suggested considering collection of data on Tables A.2, A.3, and A.4 on an annual basis, and supported the burden estimate. While HRSA recognizes the value of collecting participant ZIP code data, after weighing the significant burden awardees have reported on collecting and reporting this data, and considering that its continued collection of participant county data supports its data needs, HRSA has decided to make no changes to the proposed information