To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10653 Coverage of Certain Preventive Services Under the Affordable Care Act

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collections**

1. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Coverage of Certain Preventive Services Under the Affordable Care Act; *Use:* Section 2713 of the PHS Act requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide benefits for certain preventive services without cost sharing, including benefits for certain women's preventive health services as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). The 2018 final regulations titled ''Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (83 FR 57536) and ''Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (83 FR 57592) finalized interim final rules that expanded exemptions for religious beliefs and established an exemption for moral convictions for certain entities or individuals whose health plans may otherwise be subject to the mandate of contraceptive coverage. The final regulations extended the exemption to health insurance issuers that hold religious or moral objections in certain circumstances, as well as to additional categories of group health plan sponsors.

The 2018 final regulations also left in place, from previous rulemaking, an accommodation process for objecting entities who wish to use it to avoid contracting, arranging, paying, or referring for contraceptive coverage, but made use of the accommodation optional for such entities. An organization seeking to be treated as an eligible organization may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. The eligible organization must provide a copy of its self-certification to each health insurance issuer that would otherwise provide such coverage in connection with the health plan (for insured group health plans or student health insurance coverage). The issuer that receives the self-certification must provide separate payments for contraceptive services for plan participants and beneficiaries (or students and dependents). For a self-insured group health plan, the self-certification must be provided to its third party administrator, which must provide or arrange separate payments for contraceptive services. An eligible organization may submit a notification to the Department of Health and Human Services (HHS) as an alternative to submitting EBSA Form 700 to the eligible organization's health insurance issuer or third party administrator. A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations must provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

Under the 2018 final regulations, eligible organizations can revoke the accommodation process if participants and beneficiaries (or student enrollees and covered dependents) receive written notice of such revocation from the issuer or third party administrator, and such revocation will be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation. The Centers for Medicare & Medicaid Services is requesting an extension of OMB approval for the data collections included in this information collection request. HHS will only implement the information collections to the extent they are consistent with regulations that are in effect. *Form Number:* CMS–10653 (OMB control number: 0938–1344); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 60; *Total Annual Responses:* 595,312; *Total Annual Hours:* 72. (For policy questions regarding this collection contact Russell Tipps at 301–869–3502).

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2024–18866 Filed 8–21–24; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–D–2338]**

### Predetermined Change Control Plans for Medical Devices; 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 ''Predetermined Change Control Plans for Medical Devices.'' A predetermined change control plan (PCCP) is the documentation describing what modifications will be made to a device and how the modifications will be assessed. 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 is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by November 20, 2024 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 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–2024–D–2338 for ''Predetermined Change Control Plans for Medical Devices.'' 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 ''Predetermined Change Control Plans for Medical Devices'' 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:** Jessica Paulsen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1652, Silver Spring, MD 20993–0002, 301–796–6883, or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

While this draft guidance proposes recommendations for PCCPs, the concept of a PCCP is not entirely new to FDA. FDA has previously issued guidance related to this concept, including, for example, how changes in the expiration date for use of a device generally do not require submission of a new premarket notification (510(k)) when the same methods or protocols that are described in the previously cleared 510(k) are used to support the change; [1] and how manufacturers may add certain additional instruments for use with an in vitro diagnostic (IVD) assay that was previously cleared for use with a specific instrument without submission of a new 510(k), in part, by conducting a risk-based assessment and design verification and/or validation activities to assess the use of the IVD assay with the new instrument(s).[2]

FDA initially introduced the term and description of a PCCP in 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,'' [3] which described a potential approach to premarket review of PCCPs for AI/ML-based software modifications. On December 29, 2022, section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Public Law 117–328 added section 515C ''Predetermined Change Control Plans for Devices'' to the

[1] *See* FDA's guidance ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.*

[2] *See* FDA's guidance ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/replacement-reagent-and-instrument-family-policy-in-vitro-diagnostic-devices.*

[3] Available at *https://www.fda.gov/media/122535/download?attachment* and *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.*

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: