for Public Comments'' or by using the search function.

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 Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Patient Access through Application Programming Interfaces (API); *Use:* This final rule is the first phase of policies centrally focused on advancing interoperability and patient access to health information using the authority available to the Centers for Medicare & Medicaid Services (CMS). We believe this is an important step in advancing interoperability, putting patients at the center of their health care, and ensuring they have electronic access to their health information. We are committed to working with stakeholders to solve the issue of interoperability and getting patients access to information about their health care, and we are taking an active approach to move participants in the health care market toward interoperability and the secure and timely exchange of electronic health information by adopting policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and qualified health plan (QHP) issuers on the individual market Federally-facilitated Exchanges (FFEs). For purposes of this rule, references to QHP issuers on the FFEs excludes issuers offering only stand-alone dental plans (SADPs). Likewise, we are also excluding QHP issuers only offering QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF–SHOPs) from the provisions of this rule. This rule requires these impacted payers to maintain and use standards-based APIs to make certain information available to enrollees. CMS regulations at 42 CFR 417.414, 417.416, 422.112(a)(1)(i), and 422.114(a)(3)(ii) require that all Medicare Advantage organizations (MAOs) offering coordinated care plans, network-based private fee-for-service (PFFS) plans, and as well as section 1876 cost organizations, maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To enforce this requirement, CMS regulations at § 422.116 outline network adequacy criteria which set forth the minimum number of providers and maximum travel time and distance from enrollees to providers, for required provider specialty types in each county in the United States and its territories. Organizations must be in compliance with the current CMS network adequacy criteria guidance, which is updated and published annually on CMS's website. This collection of information is essential to appropriate and timely compliance monitoring by CMS, in order to ensure that all active contracts offering network-based plans maintain an adequate network. *Form Number:* CMS–10767 (OMB control number: 0938–1412); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 345; *Number of Responses:* 345; *Total Annual Hours:* 589,950. (For policy questions regarding this collection contact Lorraine Doo at 410–786–6597.)

William N. Parham, III,

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

[FR Doc. 2024–18868 Filed 8–21–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10653]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 21, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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.

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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.