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 on the collection(s) of information must be received by the OMB desk officer by January 22, 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 30-day Review—Open 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:* Extension of a currently approved collection; *Title of Information Collection:* 1915(c) Home and Community-Based Services (HCBS) Waiver Application; *Use:* Although we published a **Federal Register** notice on September 11, 2023 (88 FR 62377) that set out revisions to what is active and currently approved by OMB, this December 2023 iteration is an extension that does not propose any change. The subsequent 30-day notice for the September 11, 2023, revisions is expected to publish in the **Federal Register** in January/February 2024. We use the application to review and adjudicate individual waiver actions. The application is also used by states to submit and revise their waiver requests. *Form Number:* CMS–8003 (OMB control number 0938–0449); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 71; *Total Annual Hours:* 6,005. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

Dated: December 19, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–28288 Filed 12–21–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10883, CMS–R–64 and CMS–10396]

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 February 20, 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–10883 American Dental Association (ADA) Dental Claim Form
CMS–R–64 Indirect Medical Education and Direct Graduate Medical Education
CMS–10396 Medication Therapy Management Program Improvements—Standardized Format

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 Collection

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* American Dental Association (ADA) Dental Claim Form; *Use:* Medicare has traditionally accepted the Professional (CMS–1500/837P transaction) and Institutional (UB04/837I transaction) claims forms to provide payment for Medicare-covered services. The Centers for Medicare & Medicaid Services (CMS) now plans to allow providers to submit Medicare-covered dental services on the dental claim form, a similar information collection as the already-approved professional and institutional claim forms. The ADA Dental Claim Form will be used to deliver information from dental providers to CMS for CMS to reimburse for provided dental services. Medicare Part B MACs will use the data collected on the ADA dental form to determine the proper amount of reimbursement for Part B dental services provided to Medicare beneficiaries. Submission of information on the ADA Dental Claim Form and associated HIPAA-standard 837D transaction format permits Medicare Part B MACs to receive consistent data for proper benefit payment. *Form Number:* CMS–10883 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector, Businesses and other for-profits; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 12,500. (For policy questions regarding this collection contact Charlene Parks at 410–786–8684.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Indirect Medical Education and Direct Graduate Medical Education; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, title 42, part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities.

The information collected on IRs is used by Part-A Medicare Administrative Contractors (MAC) to verify the number of IRs FTE used in the calculation of Medicare payments for IME and GME. The IR data submitted by the hospitals to the MACs is uploaded into CMS' Intern and Resident Information System (IRIS) database to identify duplicate FTEs reported for any IR.

The MACs use the information collected on IRs to ensure that all program payments for IME and GME are accurate and are in accordance with Medicare regulations. The IR data submitted by the hospitals to the MACs are used to audit the Medicare cost reports filed by the hospitals. *Form Number:* CMS–R–64 (OMB control number: 0938–0456); *Frequency:* Monthly; *Affected Public:* Private sector and Federal Government; *Number of Respondents:* 1,245; *Total Annual Responses:* 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Owen Osaghae at 410–786–7550.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medication Therapy Management Program Improvements—Standardized Format; *Use:* Section 1860D–4(c)(2)(C)(i) of the Act requires plan sponsors to offer MTM services that include an annual CMR with a written summary and action plan provided in a standardized format developed in consultation with stakeholders. This requirement is codified at § 423.153(d)(1)(vii)(D), which requires that the standardized action plan and summary comply with requirements specified by CMS for the standardized format. Components of the CMR summary in Standardized Format should include a cover letter, personalized medication list, and action plan if applicable.

Users include members in a Part D sponsors' plan who are eligible are enrolled in the sponsors' MTM program and offered a CMR. The CMR is a consultation between the MTM provider (such as a pharmacist) with the beneficiary to review their medications. The MTM provider is either an employee/contractor of the plan itself or of a downstream entity contracted by the plan to provide MTM services. After a CMR is performed, the sponsor creates and sends a summary of the CMR to the beneficiary that includes a medication action plan and personal medication list using the Standardized Format.

Information collected by Part D MTM programs as required by the Standardized Format for the CMR summary is used by beneficiaries or their authorized representatives, caregivers, and their healthcare providers to improve medication use and achieve better healthcare outcomes. *Form Number:* CMS–10396 (OMB control number: 0938–1154); *Frequency:* Yearly; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 842; *Total Annual Responses:* 2,382,774; *Total Annual Hours:* 1,588,595. (For policy questions regarding this collection contact Victoria Dang at 410–786–3991 or *Victoria.dang@cms.hhs.gov.*)

Dated: December 19, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–28292 Filed 12–21–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5259]

Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; 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 draft guidance for industry entitled ''Master Protocols for Drug and Biological Product Development.'' The draft guidance addresses the design and analysis of trials conducted under a master protocol as well as the submission of documentation to support regulatory review. The primary focus is on randomized umbrella and platform trials that are intended to contribute to a demonstration of safety and substantial evidence of effectiveness. The considerations in this guidance apply to a range of therapeutic areas. The draft guidance is intended to clarify the Agency's thinking on the use of master protocols in drug and biological product development, which was previously addressed in FDA's guidance entitled ''COVID–19: Master Protocols Evaluating Drugs and Biological