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

Products for Treatment or Prevention.'' FDA is also announcing the withdrawal of the guidance entitled ''COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention.''

DATES: Submit either electronic or written comments on the draft guidance by February 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–2023–D–5259 for ''Master Protocols for Drug and Biological Product Development.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott N. Goldie, Center for Drug Evaluation and Research, Office of Biostatistics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 of this guidance is on randomized umbrella and platform trials that are intended to contribute to a demonstration of safety and substantial evidence of effectiveness. The concepts discussed may also be useful to consider for early-phase or exploratory umbrella and platform trials as well as those conducted to satisfy post-marketing commitments or requirements. The considerations in this draft guidance apply to a range of therapeutic areas.

Well-designed and -conducted trials using master protocols can accelerate drug development by maximizing the amount of information obtained from the research effort. Compared with stand-alone trials under separate protocols, a master protocol may offer certain advantages by leveraging a shared control arm and other shared protocol elements (*e.g.,* visit schedule, measurement procedures), shared infrastructure (*e.g.,* network of clinical sites, central facilities, central randomization system, data management systems), and shared oversight (*e.g.,* steering committee, data review committee). At the same time, master protocols add elements of complexity, which can increase startup time and can lead to design challenges such as ensuring adequate blinding to treatment assignment. Additionally, master protocols involving multiple stakeholders will require a high degree of coordination.

FDA provided recommendations on master protocols for COVID–19 drug and biological products in the guidance entitled ''COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention,'' which posted May 2021 and was announced in the **Federal Register** on June 24, 2021 (86 FR 33309) (hereafter ''2021 COVID–19 Master Protocols Guidance''). FDA issued the guidance to communicate its policy for the duration of the COVID–19 public health emergency (PHE) declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the guidance documents that will no longer be effective with the expiration of the PHE declaration, guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The 2021 COVID–19 Master Protocols Guidance is included in the latter category. The 2021 COVID–19 Master Protocols Guidance was revised to remain in effect for 180 days post expiration of the PHE declaration, and then revised again to remain in effect until March 7, 2024, so that FDA could further revise the 2021 guidance.

FDA is issuing this draft guidance because many of the issues addressed in the 2021 guidance arise outside the context of the COVID–19 PHE. The recommendations in this draft guidance apply to a range of therapeutic areas, not just COVID–19. The draft guidance also provides a more comprehensive discussion of many of the design and analysis topics covered in the 2021 COVID–19 Master Protocols Guidance. For example, the draft guidance provides more detailed considerations related to randomization, the choice of control group, informed consent, blinding to treatment assignment, adaptive design, multiplicity, comparisons between drugs, and the evaluation of drug safety. The draft guidance also expands on considerations for trial oversight, data sharing, dissemination of information, and submissions to support regulatory review. The draft guidance, when finalized, will represent the Agency's current thinking on the use of master protocols in drug and biological product development.

FDA is issuing this guidance to satisfy, in part, a mandate under section 3607(b)(2)(C–F) of the Food and Drug Omnibus Reform Act of 2022 (FDORA). Consistent with the FDORA mandate, this guidance discusses recommendations for clinical trials to streamline logistics and facilitate the efficient collection and analysis of data, as well as important principles for the evaluation of effectiveness, recommendations for communication between sponsors and FDA, and considerations related to ensuring participant safety and data integrity in such trials.

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 ''Master Protocols for Drug and Biological Product Development.'' 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.

FDA is also announcing that the 2021 COVID–19 Master Protocols Guidance will be withdrawn upon publication of this draft guidance. FDA has determined that the 2021 COVID–19 Master Protocols Guidance is no longer needed because this new draft is available and its recommendations, when finalized, will be applicable outside the context of the COVID–19 PHE.

II. Paperwork Reduction Act of 1995

While this guidance contains no 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 21 CFR part 312 for the submission of investigational new drug applications (INDs), including protocols, protocol amendments, and information amendments, have been approved under OMB control number 0910–0014. The information collections for new drug application (NDA) regulations (including abbreviated new drug applications (ANDAs)) (21 CFR part 314) and related guidances are approved under OMB control number 0910–0001, and our biological licensing applications (BLA) regulations (21 CFR part 601) are approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 50 and 56 for the protection of human subjects and institutional review boards have been approved under OMB control number 0910–0130. The collections of information related to the protection of human subjects under 45 CFR part 46 and to IRB recordkeeping under 45 CFR 46.115 have been approved under OMB control number 0990–0260. The collections of information in 21 CFR part 11, Electronic Records; Electronic Signatures, have been approved under OMB control number 0910–0303. The information collection requirements in FDA's guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581. The information collection requirements in FDA's guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' and FDA's final guidance for industry entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations'' have been approved under OMB control number 0910–0733. The information collections in FDA's guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28210 Filed 12–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–3017]

Determination of Regulatory Review Period for Purposes of Patent Extension; Emgality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.