year period, to Public Health Accreditation Board (PHAB).

DATES: The period for this award will be July 1, 2023 through June 30, 2028.

FOR FURTHER INFORMATION CONTACT: Liza Corso, Center for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30329–4027 USA, Telephone: 1–800–CDC–INFO (1–800–232–4636), Email: *CSTLTSfeedback@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source award will support the operations and continuous improvement of a national accreditation program for state, tribal, local, and territorial public health departments. Through this project, CDC will support the awardee to (1) provide education regarding accreditation; (2) improve and/or develop new products to ensure a relevant, current, and smoothly functioning program; (3) monitor emerging issues, foster innovation, and strengthen strategic partnerships to support and advance accreditation; (4) strengthen the evidence base for the use of accreditation to advance public health practice; and (5) develop and/or continuously improve accreditation standards, programs, and/or products for programmatic or focused areas of public health services.

PHAB is in a unique position to conduct this work, as it is widely recognized by health departments, national organizations, and federal agencies as the only national accrediting body for state, tribal, local, and territorial health departments. PHAB is a non-profit organization that has the infrastructure necessary to support the accreditation program, including staff, a heavily engaged Board of Directors, national consensus standards and measures developed with extensive input from the field, documentation guidance, and an assessment process. PHAB has continuously improved their standards and tools, including using a robust public vetting process to develop and release updated versions of the standards in 2014 and 2022; and launching the Pathways Recognition Program in 2022 for local, tribal, and territorial health departments who seek recognition for their performance improvement efforts and to facilitate accreditation readiness.

Summary of the Award

Recipient: Public Health Accreditation Board (PHAB).

Purpose of the Award: The purpose of this award is to support the operations and continuous improvement of a national accreditation program for state, tribal, local, and territorial public health departments. As of March 2022, 91% of the U.S. population is served by a PHAB-accredited health department; an increase from 58% of the U.S. population in April 2017. Continued support for the national accreditation program is critical.

Amount of Award: $935,000 in Federal Fiscal Year (FFY) 2023 funds, with a total estimated $4,675,000 for the five-year period of performance, subject to availability of funds.

Authority: This program is authorized under Section 317(k)(2) of the Public Health Service Act, [42 U.S.C. 241(a) and 247 b(k)(2), as amended].

Period of Performance: July 1, 2023 through June 30, 2028.

Dated: November 2, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–24199 Filed 11–4–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1572]

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 (the 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 January 6, 2023.

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–1572 Home Health Agency Survey and Deficiencies Report

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:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Survey and Deficiencies Report; *Use:* This is a request to revise form CMS–1572 by adding fillable text or check blocks to each data field, thus converting it to a fillable .pdf format. A previous version of the CMS–1572 form had been in a fillable format. However, when it was revised in the past, it was placed into a non-fillable format. We also added a new selection to item #7. The CMS–1572 form is used by State Survey Agencies (SAs) when surveying Home Health Agencies (HHAs) and to collect information about an HHA. These regulations were created by CMS under the authority of sections 1861(o) and 1891 of the Social Security Act (''the Act'').

In the Medicare and Medicaid programs, CMS is responsible for developing Conditions of Participation (CoPs) that facilities must meet to become eligible to receive Medicare payments. State survey agencies (SAs) conduct on-site surveys of Home Health Agencies (HHAs) to ensure that HHA facilities are in compliance with these requirements.

Surveys of HHA providers are intended to ensure and strengthen patient health and safety, to enhance quality of care by emphasizing outcomes rather than process, to implement the Omnibus Reconciliation Act of 1987 (OBRA 87), and to achieve more effective compliance with Federal requirements. The CMS–1572 HHA survey form reflects this fundamental change and directs surveyors to observe and monitor the provision of care in the home setting. HHA surveyors use the CMS–1572 form to assist and direct them in evaluating important information relating to the quality of services provided HHAs in the home setting. Moreover, the CMS–1572 form represents a deficiency-based approach to evaluating and reporting compliance. *Form Number:* CMS–1572 (OMB control number: 0938–0355); *Frequency:* Yearly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 3,833; *Total Annual Responses:* 3,833; *Total Annual Hours:* 1,917. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

Dated: November 2, 2022.

William N. Parham, III

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

[FR Doc. 2022–24230 Filed 11–4–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1469]

M10 Bioanalytical Method Validation and Study Sample Analysis; International Council for Harmonisation; 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 final guidance for industry entitled ''M10 Bioanalytical Method Validation and Study Sample Analysis.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The guidance describes recommendations for method validation for bioanalytical assays for nonclinical and clinical studies that generate data to support regulatory submissions, including the procedures and processes that should be characterized for chromatographic and ligand-binding assays that are used to measure the parent and active metabolites of drugs administered in nonclinical and clinical subjects. The guidance is intended to provide industry with harmonized regulatory expectations for bioanalytical method validation of assays used to support regulatory submissions. The guidance replaces the draft guidance ''M10 Bioanalytical Method Validation'' issued on June 27, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–1469 for ''M10 Bioanalytical Method Validation and Study Sample Analysis.'' 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