

- **Consultation Policy:** Provide research support on the use and effectiveness of the CMS Tribal Consultation Policy, national consultations and listening sessions with Tribes on CMS program issues, and annual HHS National and Regional Consultation Sessions with Tribes. Track issues raised at Tribal consultation/listening sessions and develop an executive summary on key issues and recommended actions for resolution and/or further analysis.

- **Enrollment and Outreach:** Evaluate the effectiveness of CMS outreach and enrollment efforts to AI/ANs enrolled in CMS-regulated programs by conducting quarterly trainings on these programs for Tribal enrollment assisters, ITU providers, ITU third-party resource staff, and AI/ANs. NIHB will complete an assessment and compile best practices to increase AI/AN enrollment in Medicare, Medicaid, CHIP, and Health Insurance Marketplace® coverage. In addition, NIHB, in collaboration with CMS, will develop culturally appropriate Tribal outreach materials. The information NIHB uses to evaluate CMS outreach and enrollment efforts will be collected based on feedback from CMS annual ITU trainings, AI/AN outreach events, and other data sources. NIHB, in collaboration with Tribal leadership and CMS, will summarize lessons learned and make recommendations on how CMS could improve AI/AN outreach efforts in Indian Country.

Amount of the Award

The total amount of funding available over a 5-year period will be up to \$4,000,000 pending availability of funds and satisfactory performance by the recipient. The cooperative agreement will be awarded consistent with the overall quality of the proposal and the applicant's ability to meet project goals. The amount of funding awarded will be no more than \$800,000 per 12-month budget period, subject to availability of funds, and there will be five 12-month budget periods under this award. Funding for budget periods 2–5 is non-competitive and is subject to the availability of funds as well as satisfactory performance of the recipient. The total award will not exceed \$4,000,000.

Justification for Single Source Award

In 2012, CMS awarded a five-year single-source cooperative agreement to NIHB under Section 1110 of the Social Security Act and in 2017, CMS awarded a second five-year single source cooperative agreement to NIHB under the same authority. With this NOFO,

CMS has sought an application from NIHB for a third five-year single source award, under the same authority.

Through its two previous cooperative agreements, since 2012, NIHB has provided analysis and research on the potential and actual impact of CMS policies and guidance on AI/ANs and the Indian Health Care System. The work has included analysis and research on Medicare and Medicaid enrollment of AI/ANs in order to gain a better understanding of AI/AN utilization of CMS programs.

In addition, NIHB has been instrumental in tracking CMS regulation and policy changes, and has provided a better understanding of the implications that CMS regulations and guidance have had for Indian Health Care System providers and AI/AN individuals. This includes evaluating the impact of effective and meaningful Tribal consultation. NIHB has a long history of providing unique forums for showcasing how CMS works within Indian Country to promote enrollment of AI/ANs and Indian Health Care System providers in CMS programs.

Based on this past experience, NIHB is the only entity capable of carrying out the scope of activities in Fiscal Years (FY) 2022–2027 because the scope of the work that would be performed under this award builds on past experience and knowledge. Any other source would not have all of the knowledge and experience NIHB has gained in the last ten years.

Project Period

The anticipated period of performance for this cooperative agreement is September 29, 2022 through September 28, 2027 with funding awarded in 12-month budget increments subject to the availability of funds and satisfactory performance.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Authority: Social Security Act section 1110.

Dated: August 30, 2022.

Evell Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–19085 Filed 9–1–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10465]

Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by October 3, 2022.

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, you may make your request using one of following:

1. Access CMS' website address at website address at: <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:* Minimum Essential Coverage; *Use:* The final rule titled "Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions," published July 1, 2013 (78 FR 39494) designates certain types of health coverage as minimum essential coverage. Other types of coverage, not statutorily designated and not designated as minimum essential coverage in regulation, may be recognized by the Secretary of Health and Human Services (HHS) as minimum essential coverage if certain substantive and procedural requirements are met. To be recognized as minimum essential coverage, the coverage must offer substantially the same consumer protections as those enumerated in the title I of the Affordable Care Act relating to non-grandfathered, individual health insurance coverage to ensure consumers are receiving adequate coverage. The final rule requires sponsors of other coverage that seek to have such coverage

recognized as minimum essential coverage to adhere to certain procedures. Sponsoring organizations must submit to HHS certain information about their coverage and an attestation that the plan substantially complies with the provisions of title I of the Affordable Care Act applicable to non-grandfathered individual health insurance coverage. Sponsors must also provide notice to enrollees informing them that the plan has been recognized as minimum essential coverage. *Form Number:* CMS-10465 (OMB Control Number 0938-1189); *Frequency:* Occasionally; *Affected Public:* Public and Private sectors; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 53. (For policy questions regarding this collection contact Russell Tipps at 301-492-4371.)

Dated: August 25, 2022.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022-19005 Filed 9-1-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1914]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on October 20, 2022, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an

online teleconferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2022-N-1914. The docket will close on November 18, 2022. Either electronic or written comments on this public meeting must be submitted by November 18, 2022. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before October 4, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate. You may submit comments 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").