

eligibility and available services; and (13) works with vendors, primarily the Health Program Support/Third Party Administrator vendor and the Centers for Medicare & Medicaid Services (CMS), to ensure providers receive appropriate reimbursement for initial health evaluations, annual medical monitoring, cancer screening, diagnostic services, and treatment of covered health conditions.

Research and Evaluation Branch (CCPC). The Research and Evaluation Branch establishes and manages a research agenda and research translation program to increase understanding of 9/11 health effects as well as to improve WTC Health Program member health and well-being. Specifically, the branch: (1) establishes an evaluation program for quality management and program integrity and improvement; (2) establishes a research agenda to address existing knowledge gaps, investigate the emergence of health conditions linked to 9/11 exposures, and build upon current knowledge for research translation; (3) designs the competitive funding opportunity announcements in coordination with the NIOSH Office of Extramural Programs; (4) establishes a process to obtain insight from community members, patients, and other stakeholders that helps shape the evolving research agenda over time; (5) conducts reviews—through assessing and integrating data sources—to identify research gaps, using the Program's logic model on research translation; (6) reviews and assesses information on potential emerging conditions that should be further evaluated and utilizes research solicitations in doing so; (7) conducts scientific reviews of the literature to determine if new health conditions, including those petitioned by interested parties, should be recommended to the Administrator of the WTC Health Program for addition to the List of WTC-Related Health Conditions; (8) ensures that the WTC database of research publications is maintained and current; (9) aids in administering the statutorily-established WTC Health Program Scientific/Technical Advisory Committee; (10) supports, develops, and implements research products, such as research seminars, science blogs, and a research summary database, to disseminate information about research findings and assist in the translation of those findings to the member healthcare component of the Program; (11) ensures uniform data collection and scientific data integration; supports collaboration between the Data Centers and the WTC Health Registry; and oversees the

transfer of member data from the Nationwide Provider Network to the cohort-specific Data Center(s) for inclusion in health surveillance analyses and program-funded research; (12) coordinates and evaluates administrative quality control and enterprise risk management for the WTC Health Program; (13) implements the WTC Health Program's approved processes and procedures to identify and address fraud, waste, and abuse; (14) provides subject matter expertise for administrative and clinical quality metrics for the Clinical Centers of Excellence, the Nationwide Provider Network, and the Pharmacy Benefit Manager contract statements of work; (15) ensures the 9/11 exposure-based WTC Health Registry is maintained in accordance with statutory requirements and that appropriate analysis plans are implemented; and (16) provides subject matter expertise for the WTC Health Program annual report to Congress and government audits of the WTC Health Program.

Business Operations Branch (CCPD). The Business Operations Branch leads strategic acquisition planning as well as the development and dissemination of technical documentation to support the division. Specifically, the branch: (1) improves the WTC Health Program's efficiency through process improvement and solution development and workforce management and development; (2) oversees training, project management, and travel; (3) develops and oversees acquisition and procurement strategy, the acquisition plan and performance work statements for contract awards—for the Clinical Centers of Excellence, Data Centers, Nationwide Provider Network, Pharmacy Benefit Manager, Health Program Support/Third Party Administrator, and for other support contracts—to carry out the mission of the WTC Health Program in coordination with the CDC Office of Acquisitions; (4) manages the reimbursement of the Clinical Centers of Excellence and the Nationwide Provider Network for infrastructure costs, the Data Centers, Pharmacy Benefit Manager, Health Program Support/Third Party Administrator, and other support contracts; (5) implements agreement with New York City for purposes of collecting 10% of specified Program expenses, in accordance with the authorizing legislation; (6) administers and/or collects recoupments from private insurance and workers compensation; (7) enters into agreement(s) with CMS for provider reimbursements; (8) ensures all

requirements pursuant to the Health Information Portability and Accountability Act (HIPAA) and implementing regulations are followed and coordinates implementation of approved processes and procedures to ensure member information is securely transmitted and used in alignment with both HIPAA and the Privacy Act; (9) ensures compliance with all records management requirements and that WTC Health Program data and records are maintained in alignment with agency and National Archives and Records Administration requirements; and (10) provides expertise to the division on process improvement and use of technology and business solutions to meet the division's missions.

Delegations of Authority

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Xavier Becerra,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10440]

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 May 6, 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-10440 Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies

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:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each state a single, streamlined application form that may be used to apply for coverage through a Marketplace and for APTC/CSR, Medicaid, and CHIP (which we refer to collectively as insurance affordability programs). The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who may qualify for the programs by developing materials at appropriate literacy levels and ensuring accessibility.

45 CFR 155.405(a) provides more detail about the application that must be used by Marketplaces to determine eligibility and to collect information necessary for enrollment. Eligibility standards for the Marketplace are set forth in 45 CFR 155.305. The information will be required of each applicant upon initial application, with some subsequent information collections for the purposes of confirming accuracy of previous submissions and for changes in an applicant's circumstances. 42 CFR 435.907 and 457.330 establish the standards for state Medicaid and CHIP agencies related to the use of the application. CMS has designed a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to

particular questions in the FFM (please note SBM implementations may vary but the essence of the data collection must adhere to the same parameters). The paper version of the application will not be tailored in the same way but will require only the data necessary to determine eligibility.

Information collected by the Marketplace, Medicaid or CHIP agency will be used to determine eligibility for coverage through the Marketplace and insurance affordability programs (*i.e.*, Medicaid, CHIP, and APTC), and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs. Additionally, this application provides consumers interested in voting resources. *Form Number:* CMS-10440 (OMB control number: 0938-1191); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 5,550,000; *Total Annual Responses:* 5,550,000; *Total Annual Hours:* 2,446,440. (For policy questions regarding this collection contact Erin Richardson at 202-619-0630.)

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-N-0008]

Advisory Committee; Gastrointestinal Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Gastrointestinal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 3, 2026, expiration date.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2026, unless the