• Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records—VA (58VA21/22/28), last published at 88 FR 61858.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10949 and CMS–10717]

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 August 5, 2026.

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.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Rural Health Transformation Program Reporting; *Use:* On July 4, 2025, President Trump signed Public Law 119–21 which the Centers for Medicare & Medicaid Services (CMS) refers to as the ''Working Families Tax Cut'' (WFTC) legislation, into law. The legislation authorized the Rural Health Transformation (RHT) Program, marking a significant federal investment of up to $50 billion over five years and is designed to empower as many as 50 State awardees to catalyze transformative improvements within their rural healthcare ecosystems. The principal objective is to enhance healthcare access, quality, and outcomes through innovative, system-wide change, thereby investing in the health of rural communities for future generations.

Funding for approved State awardees is determined through a formal scoring and allocation process. The financial architecture of the program is composed of two primary streams: baseline funding, distributed equally among all awardees, and performance-based workload funding, which is allocated based on the scoring of specific rural and technical score factors within each State's application and their subsequent annual performance.

To ensure continued eligibility and funding, State awardees must adhere to key program requirements, including the submission of annual and quarterly reports. CMS will re-calculate each approved State's technical score and corresponding Workload funding amount for each subsequent budget period based on the information and data the approved State provides in the required annual reporting each year. In these reports, States will provide updates on programmatic milestones, report on performance and evaluation metrics, and detail the expenditure of funds. *Form Number:* CMS–10949 (OMB control number: 0938–TBD); *Frequency:* Quarterly and yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 200; *Total Annual Hours:* 20,000. (For policy questions regarding this collection contact Anthony (Tony) DiFondi at 215–861–4318.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols; *Use:* CMS is responsible for overseeing the Medicare Advantage (MA) and Part D programs to ensure that beneficiaries receive appropriate and timely benefits, services, and drugs. Under Sections 1857(d) and 1860D–12 of the Social Security Act, and related regulations at 42 CFR 422.503, 422.504, 422.516, 423.504, and 423.505, CMS has the authority to inspect, evaluate, and monitor the benefits provided by Sponsoring organizations. To carry out this oversight, Sponsoring organizations must provide CMS with access to relevant records, documentation, and systems. They are also required to report information on service utilization and other data as requested by CMS to confirm ongoing compliance with program requirements. CMS uses the data collected by way of these audit protocols to thoroughly assess whether Sponsoring organizations are meeting specific federal requirements.

The information gathered during this program audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) to assess Sponsoring organizations' compliance

with Medicare program requirements. MOEG reviews submitted data and selected samples from that data to ensure appropriate enrollee access to benefits, services and drugs. Specifically, CMS reviews data to ensure Part D organizations are administering their formulary and transition benefit in accordance with their CMS-approved formulary; CMS reviews coverage requests and appeals to ensure regulatory requirements are followed when enrollees request services; and, if the audited MA organization offers a SNP, MOEG's review evaluates whether the SNP is coordinating care in accordance with CMS requirements. *Form Number:* CMS–10717 (OMB control number: 0938–1395); *Frequency:* Annually; *Affected Public:* Private sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 12,795. (For policy questions regarding this collection contact Caroline Zeman at 410–786–0116 or *caroline.zeman@cms.hhs.gov.*)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–13603 Filed 7–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2431]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Practices and Procedures; Formal Hearings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 5, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0191. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Practices and Procedures; Formal Hearings—21 CFR Parts 10, 12–16, and 19

OMB Control Number 0910–0191—Extension

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations found in 21 CFR part 10, 21 CFR parts 12 through 16, and 21 CFR part 19 (21 CFR 10, 12–16, and 19), which implement general provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The regulations were promulgated in accordance with the Administrative Procedures Act and establish administrative practice and procedures to give instructions to those conducting business with FDA. Regulations in part 10 (21 CFR part 10) describe general administrative practices and include content and format instructions on submitting information to the agency, petitions for agency action, and other topics such as the public calendar. Regulations in 21 CFR parts 12 through 16 cover formal evidentiary, public, and regulatory hearings. We also account for burden associated with waiver requests under 21 CFR part 10.19. Unless a waiver, suspension, or modification submitted under § 10.19 (21 CFR 10.19) is granted by the Commissioner of Food and Drugs (the Commissioner), the regulations in 21 CFR part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Although we have not received requests under § 10.19, to reflect the attendant burden resulting from submitting such a request, we provide an estimate of 1 response and 1 burden hour annually, as reflected in Question-12 of this supporting statement. Also, because most information associated with regulations in parts 12–16 is obtained during the conduct of an official administrative action as described under 5 CFR 1320.4, we only include burden associated with initiating hearings pursuant to the applicable regulations.

The information collection also includes activities and burden associated with general meeting requests and correspondence submitted under section 10.65 (21 CFR 10.65), as well and general submissions associated with section 10.115—which provides for public participation in the development of agency guidance documents through requests to our Dockets Management Staff. Although most submissions and attendant burden associated with recommendations found in FDA guidance documents is accounted for in topic-specific and approved ICRs, here we account for burden associated with general public submissions as described in § 10.115(f)(3).

The information collection also includes burden associated with recommendations discussed in the guidance document entitled, ''*Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.*'' The guidance document communicates FDA's interpretation of section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(q)): *Petitions and Civil Actions Regarding Approval of Certain Applications.* The guidance identifies and discusses submission elements including certification, as well as verification of supplemental information. It also addresses the relationship between the review of petitions and pending ANDAs, 505(b)(2) applications, and 351(k) applications for which a decision on approvability has not yet been made.

The information collection also includes burden associated with requests for FDA speakers. FDA receives thousands of requests each year from trade associations and industry-based groups for speakers to participate in external meetings, conferences, and workshops. To facilitate the processing of these requests and determine participation, we have designated contacts throughout the agency and have developed web-based request templates which can be found on our website at *https://www.fda.gov/training-and-continuing-education/contacts-requesting-fda-speaker.*