visible sign in plain view posting their normal hours of operation; if the provider's or supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building (or the hours can be posted at the entrance of the supplier). *Form Number:* CMS-10995; OMB control number: 0938-New); *Frequency:* Annually; *Affected Public:* Business and not-for profit institutions; *Number of Respondents:* 66,667; *Total Annual Responses:* 66,667; *Total Annual Hours:* 333,333. (For policy questions regarding this collection contact Alisha Sanders at (443) 827–6187.)

William N. Parham, III,

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

[FR Doc. 2026–24026 Filed 11–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–235, CMS–10137, and CMS–10971]

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 December 28, 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 Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Use Agreement (DUA) Limited Data Set (LDS) Forms Research Identifiable Files (RIF) Forms; *Use:* The Privacy Act of 1974, § 552a requires the Centers for Medicare & Medicaid Services (CMS) to track all disclosures of the agency's Personally Identifiable Information (PII). CMS is also required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Federal Information Security Management Act (FISMA) of 2002 to properly protect all Protected Health Information (PHI) data maintained by the agency and account for the disclosure of PHI. When entities, such as academic, federal or state agency researchers request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA. The DUA form enables the data recipient and CMS to document the request and approval for release of CMS data. *Form Number:* CMS–R–235 (OMB control number: 0938–0734); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local or Tribal Government, Not-for-profit institutions and Business or other for-profits; *Number of Respondents:* 5,250; *Total Annual Responses:* 5,250; *Total Annual Hours:* 3,668. (For policy questions regarding this collection contact James Krometis at (410) 786–0340.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2028 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All-Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected

information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private Sector—Not-for-profit institutions and Business or other for-profits; *Number of Respondents:* 750; *Total Annual Responses:* 380; *Total Annual Hours:* 1,643.47. (For policy questions regarding this collection contact April Forsythe at 410–786–8493 or *April.Forsythe@cms.hhs.gov.*)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Acute Hospital Care at Home (AHCAH) Quantity, Intensity, and Mix of Services (QIMS) Data Collection Tool; *Use:* This is a new information collection request. The Consolidated Appropriations Act (CAA) of 2026 Section 6210(c) requires CMS to evaluate care provided to patients served through the Acute Hospital Care at Home (AHCAH) initiative, including the quantity, intensity, and mix of services (QIMS) furnished. This includes, but not limited to, the number of clinician visits, food services, and pharmacy services provided to patients while on the hospital-at-home service.

To participate in the AHCAH initiative hospitals are granted individual waivers at the CMS Certification Number (CCN) level. The AHCAH initiative waives specific Hospital Conditions of Participation (CoPs), 42 CFR 483, which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient.

In-patient healthcare services are provided to patients served under the AHCAH initiative. CMS has developed a tool to quantify the mix and intensity of the services for the purposes of analysis as required by CAA 2026. CMS is seeking OMB approval for information collection via this tool.

CMS will use this information to describe the quantity, mix, and intensity of services (QIMS) provided to patients in the AHCAH initiative. This includes patients admitted from an emergency department (ED) and patients transferred from an inpatient hospital unit. CMS will use this data to report to Congress. *Form Number:* CMS–10971 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private Sector—Not-for-profit institutions and Business or other for-profits; Federal Government and State, Local or Tribal Governments; *Number of Respondents:* 365; *Total Annual Responses:* 13,000; *Total Annual Hours:* 13,000. (For policy questions regarding this collection contact Cheryl Lehane at (617) 461–4888.)

William N. Parham, III,

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

[FR Doc. 2026–24024 Filed 11–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8482]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

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 December 28, 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 0910–0769. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control Number 0910–0769—Extension

This information collection supports the voluntary submission of allegations of regulatory misconduct to FDA's Center for Devices and Radiological Health (CDRH). An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices or electronic products regulated by CDRH may be doing so in a manner that violates the law. Reporting these allegations can help make FDA aware of regulatory concerns it may not learn of otherwise. This information can help FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion.

You can submit an allegation through the Allegations of Regulatory Misconduct Form (*https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form*), by email, or by regular mail.

In the **Federal Register** of August 26, 2026 (91 FR 55101), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that was PRA related.

The commenter questioned the usefulness of the form, citing submission concerns and recommended publishing submissions with identifying information removed. The comment did not address the proposed changes to the