

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 Collections

1. Type of Information Collection Request: Revision with change of a currently approved collection; **Title of Information Collection:** National Implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS); **Use:** The Agency for Healthcare Research and Quality (AHRQ) and its Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Consortium, in conjunction with the Centers for Medicare & Medicaid Services (CMS), have developed standardized CAHPS Surveys and tools for a variety of patient populations, including commercially insured ambulatory patients, patients whose care is covered by Medicare and Medicaid, dialysis patients, home health patients, hospital inpatients, dental patients, and patients who receive behavioral health care and services. The purpose of the CAHPS family of surveys is to collect data about patients’ assessment and rating of the care they receive from their health care provider or health care system.

The national implementation of OAS CAHPS is designed to allow third-party, CMS-approved survey vendors to administer OAS CAHPS using mail-only, telephone-only, mixed mode (mail with telephone follow-up), mixed-mode (web with mail follow-up), or mixed-mode (web with telephone follow-up). The CMS-approved survey vendors who administer the survey use an electronic data collection system if they administer a telephone-only or mixed-mode survey using web. **Form Number:** CMS–10500 (OMB control number: 0938–1240); **Frequency:** Once; **Affected Public:** Business or other for-profits and Not-for-profits institutions; **Number of Respondents:** 2,045,727; **Total Annual Responses:** 2,045,727; **Total Annual Hours:** 500,805. (For policy questions

regarding this collection contact Memuna Ifedirah 410–786–6849.)

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services; **Use:** Section 1860 D–14 of the Social Security Act (the Act) sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771(b) establishes requirements for determining a beneficiary’s eligibility for full subsidy under the Part D program. Regulations set forth in §§ 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program.

Each month CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the State Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to benchmark Part D plans. Part D plans to receive premium amounts based on the monthly assessments. **Form Number:** CMS–10344 (OMB control number: 0938–1127); **Frequency:** Monthly; **Affected Public:** State, Local, or Tribal Governments and Not-for-profits institutions; **Number of Respondents:** 51; **Total Annual Responses:** 51; **Total Annual Hours:** 612. (For policy questions regarding this collection contact Roland Herrera 410–786–0668.)

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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10410 and CMS–10137]

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 29, 2025.

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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010; *Use:* The State Medicaid and CHIP agencies will collect all information needed to determine and redetermine eligibility for Medicaid and will transmit information, as appropriate, to other insurance affordability programs. The information collection requirements will assist the public to understand information about health insurance affordability programs and will assist CMS in ensuring the seamless, coordinated, and simplified system of Medicaid and CHIP application, eligibility determination, verification, enrollment, and renewal. *Form Number:* CMS-10410 (OMB control number: 0938-1147); *Frequency:* Occasionally; *Affected Public:* Individuals or households, and State, Local, and Tribal Governments; *Number of Respondents:* 25,500,096; *Total Annual Responses:* 76,500,218; *Total Annual Hours:* 21,266,302. (For policy questions regarding this collection contact: Abby Kahn at 410-786-4321.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2027 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:* Yearly; *Affected Public:* Private Sector, Business or other for profits, Not for profits institutions; *Number of Respondents:* 785; *Total Annual Responses:* 402; *Total Annual Hours:* 1,723. (For policy questions regarding this collection contact April Forsythe at 410-786-8493 or April.Forsythe@cms.hhs.gov.)

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-2025-N-0348]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Devices and Radiological Health Appeals Processes

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 29, 2025.

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 0910-0738. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, 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.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910-0738—Revision

This information collection supports implementation of recommendations found in FDA guidance. As discussed in the document entitled “Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes” (March 2022), there