DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10110]

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 also required to publish notice in the **Federal Register** concerning each proposed collection of information before the agency's request is submitted to OMB for approval.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 2, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-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.

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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–806; *Use:* The revisions in this iteration are associated with our November 5, 2025 (90 FR 49266) CY 2026 Physician Fee Schedule (PFS) final rule (CMS–1832–F, OMB 0938–AV50). In this **Federal Register** notice we are soliciting public comment on the subject ASP collection of information request that is set out in the aforementioned supporting statement and associated attachments (see **DATES** and **ADDRESSES** for details).

This solicitation for public review and comment is an additional comment period that is specific to the aforementioned supporting statement and attachments. This notice provides an additional 60-day comment period that will not be supplemented with a subsequent 30-day notice or comment period.

The CY 2026 PFS final rule revised § 414.804(a)(5) adding submission requirements for ASP data reporting to include: (1) reasonable assumptions for calculating the manufacturer's ASP, including a summary of the methodology used to determine fair market value for fee arrangements as described at § 414.804 and (2) warranty or certification letter from the recipient of a fee from a manufacturer as evidence that a fee was not passed on in accordance with submission requirements at § 414.804.

Currently, in the absence of specific guidance in statute or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the law, Federal regulations, and the manufacturer's customary business practices. The reasonable assumptions explain the methodology used by the manufacturer to calculate ASP.

The rule specifies that for sales beginning January 1, 2026, the reasonable assumptions document, which is currently submitted voluntarily by some manufacturers along with ASP data, is a required component of the quarterly ASP data submission. The warranty or certification from the recipient of a bona fide service fee is a new document that we finalized to be required as evidence of whether or not a fee was passed on. As discussed in the final rule, the new requirements are effective for sales occurring on or after January 1, 2026; that data would be due to CMS by April 30, 2026, and used in the July 2026 Medicare Part B Drug Payment Limit File.

Form Number: CMS–10110 (OMB control number: 0938–0921); *Frequency:* Quarterly; *Affected Public:* Private Sector; *Number of Respondents:* 500; *Total Annual Responses:* 2,000; *Total Annual Hours:* 33,495. (For policy questions regarding this collection contact: Rebecca Ray at 667–414–0879 or Laura Kennedy at 410–786–3377.)

William N. Parham, III,

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

[FR Doc. 2025–23924 Filed 12–29–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10511]

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 January 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.

1. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies; *Use:* Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201–405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. *Form Number:* CMS–10511 (OMB control number: 0938–1250); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 118 *Total Annual Responses:* 118; *Total Annual Hours:* 236. (For policy questions regarding this collection contact Xiufen Sui at 410–786–3136.)

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

Administration for Children and Families

[Assistance Listing Number: 93.576]

Announcement of the Intent To Award a Sole-Source Cooperative Agreement to the Welcoming Initiative for Newcomers in San Diego, CA

AGENCY: Refugee Program Bureau, Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of Issuance of a Single-Source Cooperative Agreement.

SUMMARY: ACF, Office of Refugee Resettlement (ORR) announces the intent to award a single-source cooperative agreement in the amount of up to $1,000,000 to the Welcoming Initiative for Newcomers (WIN) in San Diego, CA to conduct a baseline assessment of state readiness and capacity to implement a state-centered refugee resettlement framework under the Program of Initial Resettlement. The purpose is to empower states with the tools and insights needed to take control of their refugee resettlement recommendations. This nationwide baseline assessment will strengthen each state's capacity to implement a state-centered refugee resettlement framework and will include a nationwide baseline assessment of state readiness and capacity, including a nationwide readiness map, state capacity catalog, and implementation roadmap. The baseline will also include state-specific labor force shortages and corresponding industries.

DATES: The proposed period of performance is January 5, 2026 to September 29, 2026.

FOR FURTHER INFORMATION CONTACT: Miro Marinovich, Office of Refugee Resettlement, Administration for Children and Families, 330 C Street SW, Washington, DC 20201. Telephone: (202) 729–3638; Email: *miro.marinovich@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Office of Refugee Resettlement (ORR) intends to conduct a nationwide State Capacity and Readiness Assessment to support implementation of the Program of Initial Resettlement (PIR). The purpose of this assessment is to develop the analytical tools, data structures, and partnerships necessary for states to assess and communicate their capacity and infrastructure related to refugee placement. The assessment will include