

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-10387 Minimum Data Set 3.0 Nursing Home and Swing Bed Prospective Payment System (PPS) For the collection of data related to the Patient Driven Payment Model and the Skilled Nursing Facility Quality Reporting Program (QRP)

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 Collections

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Minimum Data Set 3.0 Nursing Home and Swing Bed Prospective Payment System (PPS) For the collection of data related to the Patient Driven Payment Model and the Skilled Nursing Facility Quality Reporting Program (QRP); *Use:* We are requesting to implement the MDS 3.0

v1.20.1 beginning October 1, 2025 in order to meet the requirements of policies finalized in the Federal Fiscal Year (FY) 2025 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) final rule (CMS-1802-F, RIN 0938-AV30). Specifically, we finalized the collection of four new items as standardized patient assessment data elements, modified one item collected as a standardized patient assessment data element, and removed twenty-two items that are not needed for case-mix adjusting the SNF per diem payment for PDPM. As a result of these changes, the total annual hour burden across facilities has decreased, and the annual cost burden across facilities has decreased. *Form Number:* CMS-10387 (OMB control number: 0938-1140); *Frequency:* Yearly; *Affected Public:* Private Sector: Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 15,477; *Total Annual Responses:* 1,766,806; *Total Annual Hours:* 2,675,583. (For policy questions regarding this collection contact Heidi Magladry at 410-786-6034).

William N. Parham, III,

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

[FR Doc. 2024-27522 Filed 11-22-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10849]

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 26, 2024.

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:* Revision of a currently approved collection; *Title of Information Collection:* Negotiation Data

Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10849, OMB 0938–1452); *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (“the Act”). The Act establishes the Negotiation Program to negotiate maximum fair prices (“MFPs”), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the second year of the Negotiation Program, the Secretary of Health and Human Services (the “Secretary”) will select up to 15 high expenditure, single source drugs covered under Part D for negotiation.

Negotiation Data Elements: The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be “the manufacturer” of the selected drug (hereinafter the “Primary Manufacturer”). The Primary Manufacturer’s data submissions include non-FAMP and related data for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and the negotiation factors outlined in section 1194(e)(1) of the Act for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer.

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in

section 1194(e)(2) of the Act. Primary Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may also optionally submit evidence about the selected drugs and their alternative treatments.

Drug Price Negotiation Process: Any MFPs that are negotiated for the drugs selected for the second year of the Negotiation Program will apply beginning in initial price applicability year 2027. For initial price applicability year 2027, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2025.

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS’ written initial offer, the Primary Manufacturer may submit an optional written counteroffer no later than 30 days after the date of receipt of CMS’ written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS’ written initial offer during the drug price negotiation process for initial price applicability year 2027 in accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer must submit the Statutory Written Counteroffer Form. *Form Number:* CMS–10849 (OMB control number: 0938–1452); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 340; *Total Annual Responses:* 340; *Total Annual Hours:* 23,764 (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III,

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

[FR Doc. 2024–27490 Filed 11–22–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Services Provided to Unaccompanied Children (Office of Management and Budget #: 0970–0553)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is inviting public comments on the proposed information collection, including proposed changes. The request consists of several forms that will allow the Unaccompanied Children (UC) Bureau to continue providing statutorily mandated services to unaccompanied children in ORR care.

DATES: *Comments due* January 24, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR has undertaken a reorganization of its information collections to promote operational efficiency. The reorganization will result in more collections that contain fewer forms under a single Office of Management and Budget number. This information collection currently contains 22 unique forms (33 including alternative versions). Under the reorganization, ORR proposes to discontinue the use of six forms; transfer 10 forms to new information collections associated with Assessments and Home Studies/Post-Release Services; and revise five existing forms.

The UC Bureau is requesting to discontinue the use of six forms created for the UC Path case management system, which was never implemented. Except where indicated below, the UC Path versions of these forms contain features and/or logic not replicated in the UC Portal, and have never been used, thus maintaining these forms is unnecessary. These forms include:

- Long Term Foster Care Travel Request (Form S–14)—UC Path version only. UC Bureau plans to revise and continue using the UC Portal version.
- Home Study/Post-Release Service (HS/PRS) Provider Entity (Form S–21A).
- Home Study/Post-Release Service (HS/PRS) Subcontractor Entity (Form S–21B).
- Home Study/Post-Release Service (HS/PRS) Primary Provider Profile (Form S–21C).
- Home Study/Post-Release Service (HS/PRS) Subcontractor Profile (Form S–21D).