1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2028, 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 the non-Federal average manufacturer price 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 information that the Secretary requires for negotiation and renegotiation, pertaining to the negotiation factors outlined in section 1194(e)(1) of the Act, for the purpose of formulating offers and counteroffers 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 for drugs selected for negotiation or renegotiation. 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. 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 and Renegotiation Process: Any MFPs that are negotiated or renegotiated for these selected drugs will apply beginning in initial price applicability year 2028. For initial price applicability year 2028, the negotiation and renegotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2026.

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 or renegotiation process for initial price applicability year 2028, the Primary Manufacturer must submit the 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:* 405; *Total Annual Responses:* 405; *Total Annual Hours:* 47,620. (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. 2025–20748 Filed 11–21–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10934, CMS–10906 and CMS–10164]

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. 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.

DATES: Comments must be received by January 23, 2026.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. By *regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, 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**).

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* 13th SOW Quality Innovation Network—Quality Improvement Organization (QIN–QIO) and American Indian Alaskan Native (AIAN) Measure Data Collection; *Use:* The Quality Innovation Network—Quality Improvement Organization (QIN–QIO) program and American Indian Alaskan Native (AIAN) program assists providers/practices with high-quality, hands-on quality improvement assistance toward meeting their needs, and the healthcare quality and safety goals for beneficiaries. The purpose of this new information collection within these programs is to quantify performance and improvement in a broad set of quality measures that are not currently available from other sources. Selected measures are derived from the Merit Based Incentive Payment System (MIPS), the Hospital Inpatient Quality Reporting Program (HIQR), the Hospital Outpatient Quality Reporting Program (HOQR), and the CDC National Healthcare Safety Network (NHSN).

Measure data collection is an integral part of the quality improvement process. It is the primary source of knowledge about quality of care, allowing Quality Improvement (QI) practitioners to understand current state and quantitatively measure progress and effectiveness. There are three primary user categories for this data collection:

- Participants in the QIO program will use measure data from their facilities/practices to implement their own quality improvement efforts, and benefit from the collection and analysis of data from other facilities and practices to contextualize progress towards QI goals.
- QI contractors (both QIOs and the AIAN contractor) will use measure data to direct their efforts and understand the effectiveness of interventions, to measure progress towards their contractual objectives, and to report on progress to CMS.
- CMS will use the collected measure data along with derived analytic products to track the success of the program, to inform strategic decisions and priorities, and to calculate return on investment.

Form Number: CMS–10934 (OMB control number: 0938–NEW); *Frequency:* Quarterly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 16,735; *Total Annual Responses:* 66,940; *Total Annual Hours:* 1,471,284. (For policy questions regarding this collection contact Geoffrey Berryman at (410) 786–8766.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Provider Directory Data for Medicare Plan Finder; *Use:* Medicare Plan Finder (MPF) is an online tool where current and prospective beneficiaries can explore their Medicare coverage options. On MPF, individuals can shop for Medicare coverage options and make choices based on a variety of search criteria, such as plan benefits, premiums, deductibles, and star ratings. Previously, MPF had not included search capability or information on MA organizations' contracted provider networks.

To simplify and streamline the Medicare beneficiary shopping experience, CMS is expanding the existing requirements applicable to MA organizations regarding their provider directories that requires MA organizations to: (1) make the information described in 42 CFR 422.111(b)(3)(i) available to CMS/HHS for publication online in accordance with guidance from CMS/HHS; (2) submit or otherwise make available their plan provider directory data, that is the requirements found under § 422.111(b)(3)(i), available to CMS/HHS in a format, manner, and timeframe determined by CMS/HHS; (3) update the information subject to § 422.111(m) within 30 days of the date an MA organization becomes aware of a change; and (4) attest, in a format and manner and at times determined by CMS/HHS, that all information submitted or otherwise made available to CMS/HHS under paragraph (m) is accurate. *Form Number:* CMS–10906 (OMB 0938–TBD); *Frequency:* Once and yearly; *Affected Public:* Private sector; *Number of Respondents:* 700; *Total Annual Responses:* 1,400; *Total Annual Hours:* 6,300. (For questions regarding this collection contact Jim Canavan at 410–786–5223.)

3. *Type of Information Collection Request:* Revision; *Title of Information Collection:* CMS Electronic Data Interchange (EDI) Enrollment Registration, CMS EDI Enrollment Form, and CMS EDI Enrollment Attestation Form; *Use:* The collection consists of three forms used by Medicare providers and suppliers to register for EDI services with Medicare contractors. The updated collection includes the revised CMS EDI Registration Form (10164A) and CMS EDI Enrollment Agreement Form (10164B), both serving as model forms. The collection also introduces the CMS EDI Enrollment Attestation Form (10164C), a new mandatory attestation form requiring formal compliance verification from all participating entities.

The forms collect essential information necessary to identify Medicare providers and suppliers during electronic transactions, authorize requested EDI functions, and establish appropriate access privileges for healthcare entities. These forms ensure compliance with HIPAA transaction standards while implementing strengthened security requirements for billing vendors and clearing houses that handle Medicare data. The information collected by the forms will be uploaded into Medicare contractor computer systems. Medicare contractors will store this information in a database accessed at the time of provider connection to the Medicare Data Contractor Network (MDCN). When authentication is successful and connectivity is established, transactions may be exchanged. *Form Number:* CMS–10164 (OMB 0938–0983); *Frequency:* Yearly; *Affected Public:* Business or other-for-profits and not-for-profits; *Number of Respondents:* 229,767; *Total Annual Responses:* 229,767; *Total Annual Hours:* 153,178. (For questions regarding this collection contact Charlene Parks at 410–786–8684.)

William N. Parham, III

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

[FR Doc. 2025–20787 Filed 11–21–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0467]

Submission for Office of Management and Budget Review; Trafficking Victim Assistance Program Data

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting an extension of approval with revisions of an Office of Management and Budget (OMB) approved information collection: Trafficking Victim Assistance Program