Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule,'' published on November 22, 2023 (88 FR 81540, 82076 through 82079). This final rule revised the following conditions of participation: *Personnel qualifications* (§ 485.904), *Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client* (§ 485.914); *Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services* (§ 485.916); and *Organization, Governance, Administration of Services, Partial Hospitalization Services* (§ 485.918).

Medicare Part B covers partial hospitalization (PHP) services and intensive outpatient (IOP) services furnished by or under arrangements made by the CMHC if they are provided by a CMHC as defined in 42 CFR 410.110. Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) amended sections 1832(a)(2) and 1861(ff)(3) of the Act to allow CMHCs to provide PHP services. Furthermore, the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238) established in section 4124 coverage of IOP services in CMHCs. The legislation extended Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, adding to the existing coverage and payment for PHP services in CMHCs. Section 4121 of the CAA, 2023 also established a new Medicare benefit category for services furnished and directly billed by Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs).

The services provided by CMHCs must be furnished by, or under arrangement with a CMHC participating in the Medicare program. They must include the following:

- Prescribed by a physician and furnished under the general supervision of a physician.
- Subject to certification by a physician in accordance with 42 CFR 424.24(e)(1).
- Furnished under a treatment plan that meets the requirements of 42 CFR 424.24(e)(2).
- Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from inpatient mental health facilities.
- Provides 24-hour-a-day emergency care services.
- Provides day treatment, partial hospitalization services (PHP) or intensive outpatient services (IOP) other than an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.
- Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such services unless otherwise directed by State law.
- Meets applicable licensing or certification requirements for CMHCs in the state in which it is located.
- Provides at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Act.

We collect information on several health and safety aspects, such as *Client rights* (§ 485.910) *active treatment plans* (§ 485.916), *Quality assessment and performance improvement* (§ 485.917), and *governance* (§ 485.918).

The primary users of this information will be Federal and State agency surveyors for determining through the survey process, whether a CMHC qualifies for approval or re-approval under Medicare. CMS and its contractors will use this information to review claims to determine whether the patient is eligible for the PHP or IOP benefit and whether the claim meets the criteria for coverage and Medicare payment. Lastly, the information will be used by CMHCs to ensure their own compliance with all requirements to assist in guiding their patient care and quality programs. *Form Number:* CMS–10506 (OMB control number: 0938–1245); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit organizations; *Number of Respondents:* 1,475; *Total Annual Responses:* 7,420; *Total Annual Hours:* 1,434. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

William N. Parham, III,

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

[FR Doc. 2025–12149 Filed 6–27–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10849]

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 August 29, 2025.

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**).

CMS–10849 Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request

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:* Drug Price Negotiation for Initial Price Applicability Year 2028 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 third cycle of the Negotiation Program, the Secretary of Health and Human Services (the ''Secretary'') will select up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D for negotiation. In accordance with section 1194(f)(4) of the Act, CMS will also renegotiate MFPs for drugs selected for renegotiation, if any, for initial price applicability year 2028.

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 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, 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; *Number of Responses:* 405; *Total Annual Hours:* 51,940. (For 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. 2025–11979 Filed 6–27–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant