Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10680, CMS–10844 and CMS–10506]

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 October 30, 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. *Title of Information Collection:* Electronic Visit Verification Compliance Survey; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* The web-based survey will allow states to self-report their progress in implementing electronic visit verification (EVV) for personal care services (PCS) and home health care services (HHCS), as required by section 1903(l) of the Social Security Act. CMS will use the survey data to assess states' compliance with section 1903(l) of the Act and levy Federal Medical Assistance Percentage (FMAP) reductions where necessary as required by section 1903(l) of the Act.

The survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) and the Medicaid agencies of five US territories. States will be required to complete the survey in order to demonstrate that they are complaint with section 1903(l) of the Act by reporting on their EVV implementation status for PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115 of the Act; and HHCS provided under section 1905(a)(7) of the Act or under a demonstration project or waiver (*e.g.,* section 1915(c) or 1115 of the Act).

The survey will be a live form, meaning states will have the ability to update their section 1903(l) compliance status on a continuous basis. As FMAP reductions are assigned quarterly per section 1903(l) of the Act, states who are not in compliance will be asked to review their survey information on a quarterly basis to ensure it is up-to-date and to update their survey responses as needed until they come into compliance. *Form Number:* CMS–10680 (OMB control number: 0938–1360); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Number of Responses:* 336; *Total Annual Hours:* 504. (For questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

2. *Type of Information Collection Request:* Revision with of a currently approved collection; *Title of Information Collection:* Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request; *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 information collection request forms for the Small Biotech Exception, the Biosimilar Delay, and the Selection of Renegotiation-Eligible Drugs for initial price applicability year 2028 must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2028.

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the term ''negotiation-eligible drug'' excludes, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the ''Small Biotech Exception,'' or ''SBE''). This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in

accordance with section 1192(d)(2) of the Act. To ensure that drugs payable under Part B and/or drugs covered under Part D that meet the requirements for the SBE are excluded from the term ''negotiation-eligible drug,'' a manufacturer that seeks the SBE for its drug payable under Part B and/or covered under Part D (''Submitting Manufacturer'') must submit information to CMS about the company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the SBE for a drug payable under Part B and/or covered under Part D it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021 for drugs covered under Part D and information related to the holder of the New Drug Application(s) (NDA)(s) or Biologics License Applications(s) (BLA)(s) as of December 31, 2021 for drugs payable under Part B. If the Submitting Manufacturer was acquired by another entity after December 31, 2021, the Submitting Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii) of the Act.

Biosimilar Delay: In accordance with section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product (''Biosimilar Manufacturer'' of a ''Biosimilar'') may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a ''Reference Drug'') on the selected drug list for a given initial price applicability year (the ''Biosimilar Delay''). This information is required in order for CMS to accurately determine if a drug meets the criteria for the Biosimilar Delay for initial price applicability year 2028 in accordance with section 1192(f) of the Act. To ensure that the delay of selection and negotiation of biologics is only applied if there is a high likelihood that the Biosimilar will be licensed and marketed, a Biosimilar Manufacturer that seeks the Biosimilar Delay must submit information to CMS related to the Biosimilar. This information includes identifying information for the Biosimilar and the Reference Drug; the licensure status of the Biosimilar; attestations that the Biosimilar Manufacturer is not the same or treated as the same entity as the Reference Manufacturer, that the Biosimilar Manufacturer and the Reference Manufacturer (who is the manufacturer of the Reference Drug) have not entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit the Biosimilar Delay, or directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and documentation specified under section 1192(f)(3) of the Act to demonstrate there is a high likelihood that the Biosimilar will be licensed and marketed within two years of the statutorily-defined selected drug publication date for initial price applicability year 2028.

Selection of Renegotiation-Eligible Drugs: Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs and selection of drugs for renegotiation. CMS will offer Primary Manufacturers [1] the voluntary option to submit information to CMS to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug and may be selected for renegotiation in accordance with section 1194(f)(3) of the Act. Specifically, section 1194(f)(2)(D) of the Act instructs CMS to identify whether a selected drug is eligible for renegotiation because a new indication has been added to the selected drug and based on a material change to any of the factors listed in section 1194(e) of the Act. *Form Number:* CMS–10844 (OMB control number 0938–1443); *Frequency:* Once; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 65; *Number of Responses:* 65; *Total Annual Hours:* 3,677.50. (For questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

3. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Community Mental Health Centers and Supporting Regulations; *Use:* The purpose of this package is to request a re-instatement with change to the Office of Management and Budget (OMB) of the collection of information requirements associated with the conditions of participation (CoPs) that Community Mental Health Centers (CMHCs) must meet to participate in the Medicare program.

On October 29, 2013, we published CoPs, for CMHCs (78 FR 64630). The CoPs included the following: *Personnel qualifications* (§ 485.904); *Client Rights* (§ 485.910); *Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client* (§ 485.914*); Treatment Team, Active Treatment Plan, and Coordination of Services* (§ 485.916); *Quality Assessment and Performance Improvement* (§ 485.917); and *Organization, Governance, Administration of Services, and Partial Hospitalization Services* (§ 485.918). We finalized emergency preparedness requirements for CMHCs (§ 485.920) in the ''2016 Emergency Preparedness (EP) Final Rule'' published on September 16, 2016 (81 FR 63921). The information collections associated with the EP CoPs requirements can be found under OMB Control Number 0938–1325.

On September 30, 2019, we published final rule, ''*Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care,*'' which revised the CMHC CoPs at § 485.914 (84 FR 51829, 51752 through 51754).

We finalized revisions to the CMHC CoPs in the ''CY 2024 Hospital 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

[1] 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'').

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. 2025–18979 Filed 9–29–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0488]

Proposed Information Collection Activity; Provision of Child Support Services in IV–D Cases Under the Hague Child Support Convention; Federally Approved Forms

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

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services is requesting a 3-year extension of the Provision of Child Support Services in IV–D Cases under the Hague Child Support Convention; Federally Approved Forms (Office of Management and Budget (OMB) #: 0970–0488, expiration March 31, 2026). There are no changes requested to these forms.

DATES: *Comments due* December 1, 2025.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Administration for Children and Families (ACF) is soliciting public comment on the specific aspects of the information collection described above. 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: On January 1, 2017, the 2007 Hague Convention on the International Recovery of Child Support and Other Forms of Family Maintenance (the Convention) entered into force for the United States. This multilateral Convention contains provisions that, on a worldwide scale, establish uniform, simple, fast, and inexpensive procedures for processing international child support cases. Under the Convention, U.S. states process child support cases with other countries that have ratified the Convention under the requirements of the Convention and Article 7 of the Uniform Interstate Family Support Act (UIFSA 2008). To comply with the Convention, the United States implements the Convention's case processing forms.

State and federal law require states to use federally approved case processing forms. Section 311(b) of UIFSA 2008, which has been enacted by all 50 states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands, requires states to use forms mandated by federal law. 45 CFR 303.7 also requires child support programs to use federally approved forms in intergovernmental IV–D cases unless a country has provided alternative forms as a part of its chapter in a Caseworker's Guide to Processing Cases with Foreign Reciprocating Countries.

Respondents: State agencies administering a child support program under title IV–D of the Social Security Act.

Annual Burden Estimates

Annual burden estimates have been updated to reflect a decrease in the nationwide child support case load since the most recent full OMB review and approval process in 2023. Therefore, the annual number of responses per respondent has decreased, resulting in an overall decrease in estimated annual burden. The number of respondents and estimated time per response has not changed.