DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10506 and CMS–10846]

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 November 3, 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. *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 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.)

2. *Type of Information Collection Request:* Revision with of the currently approved collection; *Title:* Medicare Part D Manufacturer Discount Program; *Use:* Congress enacted the Inflation Reduction Act of 2022, Public Law 117–169 (IRA). Section 11201 of the IRA eliminates the coverage gap phase of the Part D benefit. It also sunsets the coverage gap discount program (CGDP) after December 31, 2024, and amends the Social Security Act (the Act) to add section 1860D–14C, requiring the Secretary to establish a new Medicare Part D manufacturer discount program (MDP) beginning January 1, 2025. Under the MDP, participating manufacturers are required to provide discounts on their ''applicable drugs'' (brand drugs, biologics, and biosimilars) both in the initial coverage phase and in the catastrophic coverage phase of the Part D benefit.

Information in this collection is needed to set up agreements between manufacturers and CMS. Under section 1860D–14C(a) of the Act, such agreements are required for manufacturers in order to participate in the MDP and, under section 1860D43(a) of the Act, for their applicable drugs to be covered under Part D beginning in 2025. The information collected from manufacturers in the Health Plan Management System (HPMS) (Appendix A) is needed to create and execute MDP agreements and to determine which manufacturers qualify as a specified manufacturer or specified small manufacturer for phased-in discounts under section 1860D–14C(g)(4) of the Act. Banking information collected by the TPA from manufacturers and plan sponsors (Appendix B) is needed to prepare invoices and process financial transactions (deposits and payments) through the ACH. *Form Number:* CMS–10846 (OMB control number: 0938–1451); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profits and not for profits institutions; *Number of Respondents:* 40; *Number of Responses:* 40; *Total Annual Hours:* 320. (For questions regarding this collection, contact Beckie Peyton at (410) 786–1572 or *beckie.peyton@cms.hhs.gov*).

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

Food and Drug Administration

[Docket No. FDA–2025–N–3792]

Revocation of Emergency Use of Three Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUA) (the Authorizations) issued to Pfizer, Inc. for Pfizer-BioNTech COVID–19 Vaccine; to ModernaTX, Inc. for Moderna COVID–19 Vaccine; and to Novavax, Inc. for Novavax COVID–19 Vaccine, Adjuvanted. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorizations for Pfizer-BioNTech COVID–19 Vaccine, Moderna COVID–19 Vaccine, and Novavax COVID–19 Vaccine, Adjuvanted are revoked as of August 27, 2025.

ADDRESSES: Submit written requests for single copies of the revocations to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The revocations may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010 or emailing *industry.biologics@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.