

and associated materials (see **ADDRESSES**).

CMS-10239 Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations; *Use:* The purpose of this package is to request from the Office of Management and Budget (OMB) the approval to reinstate, with changes, the information collection request, associated with OMB Control Number 0938–1043, titled “Critical Access Hospital (CAH) Conditions of Participation (CoPs) and Supporting Regulations.”

Sections 1820 and 1861(mm) of the Social Security Act provide that CAHs participating Medicare meet certain specified requirements. The regulations containing the information collection requirements are located at 42 CFR part 485, subpart F. These regulations implement sections 1102, 1138, 1814(a)(8), 1820(a–f), 1861(mm), 1864, and 1871 of the Act.

This is a reinstatement of the information collection request that expired on March 31, 2024. The previous iteration of this OMB No. 0938–1043 (approved March 25, 2021) had a burden of 33,905 annual hours. For this requested reinstatement, with changes, the estimated total annual burden hours for the industry is 898,332 hours and the estimated annual burden costs are \$74,020,673.

The increase in burden hours from the prior package is primarily due to new

information collections associated with new CoPs for CAHs outlined in the two CMS rules referenced below. The new CoPs include multiple information collection requirements that are one-time burdens for developing new policies and protocols and ongoing reporting requirements, such as daily or biweekly reporting of respiratory illnesses as well as maternal deaths. The reasons for the increased information collections are discussed in more detail in the rules and are summarized in the information collection request.

(1) Obstetrical services included in the proposed rule, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities, 89 FR 59186 (July 22, 2024) (hereinafter referred to as the “July 2024 Proposed Rule”).

(2) Reporting of acute respiratory illnesses in the interest of public health and ensuring resiliency in the U.S. health care system included in the Final rule: Medicare and Medicaid Programs and the Children’s Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes. The aforementioned final rule, CMS–1808–F (RIN 0938–AV34), is currently on display at the Office of the Federal Register and scheduled for publication on August 28, 2024 (hereinafter referred to as the “August 2024 Final Rule”).

The change in total burden hours is also due to prior information collection requests are exempt from the PRA because the requirements are customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs. *Form Number:* CMS–10239 (OMB control number: 0938–1043); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit); *Number of*

Respondents: 1,245; *Total Annual Responses:* 9,145; *Total Annual Hours:* 898,332 (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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10884]

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 September 12, 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Prior Authorization Demonstration for Certain Ambulatory Surgical Center (ASC) Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to “develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act).” Pursuant to this authority, CMS seeks to develop and implement a Medicare demonstration project, which CMS believes will assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring in ambulatory surgical centers providing services to Medicare beneficiaries. The information required for the prior authorization request includes all documentation necessary to show that

the service meets applicable Medicare coverage, coding, and payment rules. Prior to rendering the services, ASC providers should submit this information to the Medicare Administrative Contractors (MACs). Trained clinical reviewers at the MACs will review the information required for this collection to determine if the requested services are medically necessary and meet Medicare requirements. If an ASC provider does not submit a prior authorization request before rendering the service and submitting a claim to Medicare for payment, the MAC will request the required information from the ASC provider to determine if the service meets applicable Medicare coverage, coding, and payment rules before the claim is paid. *Form Number:* CMS-10884 (OMB Control Number: 0938-NEW); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits; *Number of Respondents:* 4,038; *Number of Responses:* 95,579; *Total Annual Hours:* 59,904. (For policy questions regarding this collection contact Kelly Wojciechowski at kelly.wojciechowski@cms.hhs.gov or Justin Carlisle at Justin.Carlisle@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-2022-N-0691]

Advisory Committee; Peripheral and Central Nervous System Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Peripheral and Central Nervous System Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Peripheral and Central Nervous System Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 4, 2026, expiration date.

DATES: Authority for the Peripheral and Central Nervous System Drugs Advisory Committee will expire on June 4, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Jessica Seo, Center for Drug Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, PCNS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Peripheral and Central Nervous System Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs.

Pursuant to its Charter, the Committee shall consist of a core of 12 voting members including two Chairpersons. Members and the Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of neurology, pediatric neurology, epidemiology, statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.