titled the ''Hospice Item Set'' (HIS) V1.00.0. The HIS is used for the collection of quality measure data related to the Hospice Quality Reporting Program (HQRP), and the HIS V1.00.0 specified the collection of data items that supported seven Consensus Based Entity (CBE) endorsed Quality Measures (QMs) for hospice. On April 1, 2017, hospices began using an updated HIS V2.00.0, which includes the same items from the HIS V1.00.0 along with the addition of several new items for use in new measures, measure refinement, patient record matching, and future public reporting. Data collected from the HIS are used to calculate the seven CBE-endorsed QMs and the CBE-endorsed Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission QM.

During the FY 2021 rule, the Hospice Visits when Death is Imminent measure pair was removed and replaced with the claims-based Hospice Visits in Last Days of Life (HVLDL) measure. The reduction in provider burden and costs occurred when CMS replaced the HIS-based HVWDII quality measure via the HIS information collection request that OMB approved on February 16, 2021. CMS is requesting to extend the expiration date. The HIS V3.00.0 consists of data elements that are designed to collect standardized, patient-level data for the following domains of care: pain, respiratory status, medications, patient preferences and beliefs and values. The HIS V3.00.0 was developed specifically for use by hospices and contains data elements that we can use to collect patient-level data to calculate eight CBE endorsed quality measures. *Form Number:* CMS–10390 (OMB control number: 0938–1153); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); individuals or households; *Number of Respondents:* 5,640; *Total Annual Responses:* 2,763,850; *Total Annual Hours:* 1,323,883. (For policy questions regarding this collection contact Jermama Keys at (410) 786–7778.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease; *Use:* On April 7, 2022, CMS finalized the national coverage determination (NCD) to cover FDA approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of Alzheimer's disease (AD) under coverage with evidence development (CED) in patients who have a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD. For anti-amyloid mAbs that have accelerated approval, the mAb may be covered in a randomized controlled trial conducted under an investigational new drug (IND) application or any NIH sponsored trial. For antiamyloid mAbs that have traditional FDA approval (as opposed to accelerated approval), the NCD specifies coverage under CED in CMS approved prospective comparative studies, where data may be collected in a registry. In addition to satisfying the study criteria specified in the NCD, CMS approved studies for anti-amyloid mAbs that have received traditional FDA approval must address all of the questions below:

- Does the antiamyloid mAb meaningfully improve health outcomes (*i.e.,* slow the decline of cognition and function) for patients in broad community practice?
- Do benefits, and harms such as brain hemorrhage and edema, associated with use of the antiamyloid mAb, depend on characteristics of patients, treating clinicians, and settings?
- How do the benefits and harms change over time?

In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we must formally reopen and reconsider the policy. CMS supported development of a registry, the ''Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry'' (mAb Registry), to facilitate coverage under the NCD. Additionally, CMS is working with multiple organizations preparing to open their own registries. Once more registries are available, they will also be listed at *https://www.cms.gov/medicare/coverage-evidence-development/monoclonalantibodies-directed-against-amyloid-treatment-alzheimers-disease-ad,* and clinicians will be able to choose which registry to participate in.

The data collected and analyzed in the CMS-supported mAb Registry and potential CMS-approved registries will be used by to determine if monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD) is reasonable and necessary (*e.g.,* improves health outcomes) for Medicare beneficiaries under section 1862(a)(1)(A) of the Act. CMS is collecting information to learn more about which individuals benefit the most from this drug. CMS refers to this as coverage with evidence development or CED. The information being collected via registry will be analyzed to assist clinicians and patients make informed treatment decisions. Furthermore, data from the mAb Registry will assist the pharmaceutical industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of these types of drugs. *Form Number:* CMS–10865 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 40,000; *Number of Responses:* 40,000; *Total Annual Hours:* 3,320. (For policy questions regarding this collection, contact Lori Ashby at 410–786–6322.)

Dated: November 15, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–25601 Filed 11–17–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #37]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register**

notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit 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 December 4, 2023.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). 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: CMS–10398 (#37)/OMB control number: 0938–1148, 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/PRAListing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* Managed Care Rate Setting Guidance; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* In accordance with 42 CFR 438.7, states must submit to CMS for review and approval all rate certifications for managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs). The rate certification itself is prepared by a state's actuary who certifies the managed care program's capitation rates as actuarially sound for a specific time period, and documents the rate development process and final certified capitation rates.

Our Medicaid Managed Care Rate Development Guide (otherwise referred to as the ''rate guide'') outlines the rate development standards and CMS' expectations for documentation included in rate certifications such as descriptions of base data used, trend factors to base data, projected benefit and non-benefit costs, and any other considerations or adjustments used when setting capitation rates. The information outlined in the rate guide must be included within the rate certification in adequate detail to allow CMS to determine compliance with applicable provisions of 42 CFR part 438, including that the data, assumptions, and methodologies used for rate development are consistent with generally accepted actuarial principles and practices and that the capitation rates are appropriate for the populations and services to be covered. There is no required template that states' actuaries must utilize for the rate certification, but the guidance outlined in the rate guide serves as a resource for states and their actuaries. Adherence by states and their actuaries to the rate development standards and documentation expectations outlined in the rate guide, will aid in ensuring compliance with the regulations and support CMS's review and approval of actuarially sound capitation rates and associated federal financial participation. *Form Number:* CMS–10398 (#37) (OMB control number: 0938–1148); *Frequency:* Annual; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 137; *Total Annual Hours: 753.* For policy questions regarding this collection contact Rebecca Burch-Mack at 303–844–7355.

Dated: November 15, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–25631 Filed 11–17–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Financing for Early Care and Education: Quality and Access for All (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services seeks approval to collect information to explore the role of Head Start in the early care and education (ECE) financing landscape, as well as how the use of multiple funding sources within a single Head Start program may be associated with the provision of Head Start's comprehensive services and with state-level differences in ECE funding. Survey data will be collected from Head Start program directors and state government administrators.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed data collection seeks to better understand