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Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10390 and CMS-10865]

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 (the 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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 web site 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-10390 Hospice Quality Reporting Program

CMS-10865 Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

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 Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Quality Reporting Program; *Use:* On July 1, 2014, hospices began using a newly created data collection instrument, 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: August 31, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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