

The two laws implement various health insurance policies, including the essential health benefits (EHB). Beginning in 2014, all non-grandfathered health plans in the individual and small group market must cover EHB, as defined by the Secretary of Health and Human Services.

In the final rule entitled *HHS Notice of Benefit and Payment Parameters for 2023* (2023 Payment Notice; CMS–9911–F),² we repealed the ability for States to permit between category substitution of the EHBs at 45 CFR 156.115. Thus, we revise this Supporting Statement to remove any burden associated with States opting to permit between category substitution of the EHBs and remove the form Essential Health Benefits (EHB) State Substitution Notification (Appendix F) from this collection.

For annual reporting of state mandates, in the final rule entitled *HHS Notice of Benefit and Payment Parameters for 2021* (2021 Payment Notice; CMS–9916–F),³ we finalized amendments to § 156.111(d) and adding new § 156.111(f) to require states to annually notify HHS in a format and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual and/or small group market that are considered to be “in addition to EHB” in accordance with § 155.170(a)(3).

In the final rule entitled *HHS Notice of Benefit and Payment Parameters for 2023* (2023 Payment Notice; CMS–9911–F), we repealed the annual reporting requirement at § 156.111(d) and (f), including revising the section heading to § 156.111 to instead read, “State selection of EHB benchmark plan for PYs beginning on or after January 1, 2020.” Thus, we have revised this Supporting Statement to reflect that States are no longer required to annually notify HHS of any State-required benefits applicable to QHPs in the individual or small group market that are considered to be “in addition to EHB” or any benefits the State has identified as not in addition to EHB and not subject to deferral. We also remove the forms State Annual Report on State-Required Benefits (Appendix G) and State Certification of Annual Report on State-Required Benefits (Appendix H) from this collection.

This information collection also previously included estimates for the burden on issuers to report their intent to offer SADPs. We no longer collect this information from issuers; we revise this Supporting Statement to remove the burden associated with this report. In this package, we make minimum

required revisions to reflect only the regulatory changes that have occurred since it was last authorized in 2021. No comments were received in response to the 60-day FR Notice (September 27, 2023 (88 FR 66452). *Form Number*: CMS–10448 (OMB control number: 0938–1174); *Frequency*: Annually; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 10; *Number of Responses*: 10; *Total Annual Hours*: 470. (For questions regarding this collection, contact Ken Buerger at 410–786–1190).

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 Identifiers: CMS–10711 and CMS–10725]

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 (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 April 8, 2024.

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 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 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–10711 Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services
CMS–10725 Pharmacy Benefit Manager Transparency for Qualified Health Plans

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:* New collection of information; *Title of Information Collection:* Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services; *Use:* Section 1833(t)(2)(F) of the Act authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services. CMS believes the increases in volume associated with certain covered OPD services are unnecessary because the data show that the volume of utilization of these OPD service categories far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries. Therefore, CMS is using the authority under section 1833(t)(2)(F) of the Act to require prior authorization for certain covered OPD services as a condition of Medicare payment. The reviews conducted under the program help to reduce unnecessary utilization and payments for these services.

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. Trained clinical reviewers at the Medicare Administrative Contractors (MACs) receive and review the information required for this collection. Review of that documentation is used to determine if the requested services are medically necessary and meet Medicare requirements to help reduce unnecessary increases for these services. *Form Number:* CMS-10711 (OMB Control Number: 0938-1368); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits; *Number of Respondents:* 11,469; *Number of Responses:* 564,010; *Annual Hours:* 316,412. (For policy questions regarding this collection contact Yuliya Cook at Yuliya.Cook@cms.hhs.gov)

2. *Title of Information Collection:* Pharmacy Benefit Manager Transparency for Qualified Health Plans; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* Implementation of section 1150A of the Social Security Act, as added by section 6005 of the Patient Protection and Affordable Care Act (ACA), requires, among other entities, Qualified Health Plans (QHPs) and pharmacy benefit

managers (PBMs) that serve QHP issuers to report information on prescription drug benefits to the U.S. Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. CMS finalized regulations for this reporting at 45 CFR 156.295 and 184.50.

Under these requirements a QHP issuer is required to report issuer and plan level prescription drug data to CMS only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Section 1150A(a)(1) of the Social Security Act authorizes CMS to collect the same prescription drug and rebate information from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVIII. Since 2012, CMS has collected these data from Part D sponsors as part of the Medicare Part D Direct and Indirect Remuneration (DIR) reporting requirement, and detailed drug information for each National Drug Code (NDC) from the Prescription Drug Event (PDE) data that plans are required to submit.

CMS is requesting to renew this collection of information in connection with submission from QHP issuers that do not contract with a PBM and PBMs (hereinafter referred to as "submitters"). The information required from submitters and the process of submission has changed since the previous collection was approved in 2021. The submitters are now required to complete a web form that reports the allocation methodology that is selected by the submitters to allocate data, where necessary. Submitters are required to maintain internal documentation of the allocation methodologies chosen, as CMS may need to follow up with the submitters to better understand the methodology. The burden estimates for the collection of information included in this package reflect the time and effort for submitters to provide prescription drug benefit information to CMS using the Health Information Oversight System (HIOS) module. *Form Number:* CMS-10725 (OMB control number: 0938-1394); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other For-Profits; *Number of Respondents:* 278; *Number of Responses:* 278; *Total Annual Hours:* 1,285. (For questions regarding this

collection, contact LeAnn Brodhead at (301) 492-4493.)

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

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required); NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44 Clinical Trial Required); Clinical Trial Planning Grants (R34 Clinical Trials)

Date: February 29, 2024.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852, 240-627-3390, aabbey@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)