DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10307 and CMS–R–263]

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 20, 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: Extension of a currently approved collection; *Title of Information Collection:* Medical Necessity and Claims Denial Disclosures under MHPAEA; *Use:* The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343) generally requires that group health plans and group health insurance issuers offering both medical and surgical (med/surg) and mental health or substance use disorder (MH/SUD) benefits do not apply any more restrictive financial requirements (*e.g.,* co-pays, deductibles) and/or treatment limitations (*e.g.,* visit limits) to MH/SUD benefits than those requirements and/or limitations as applied to med/surg benefits. The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010. These statutes are collectively known as the ''Affordable Care Act'' (ACA). The ACA extended MHPAEA to apply to the individual health insurance market. Additionally, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) requires health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets, through an Exchange or outside of an Exchange, to comply with the requirements of the MHPAEA regulations in order to satisfy the requirement to cover EHB (45 CFR 147.150 and 156.115).

Medical Necessity Disclosure Under MHPAEA

MHPAEA specifically amends the Public Health Service (PHS) Act to require plan administrators or health insurance issuers to provide, upon request, the criteria for medical necessity determinations made with respect to MH/SUD benefits to current or potential participants, beneficiaries, or contracting providers. The Final Rules under MHPAEA set forth rules for providing criteria for medical necessity determinations. CMS administers MHPAEA with respect to self-insured non-Federal governmental plans in all States, and health insurance issuers in two States.

Claims Denial Disclosure Under MHPAEA

MHPAEA specifically amends the PHS Act to require plan administrators or health insurance issuers to provide, upon request, the reason for any denial or reimbursement of payment for MH/SUD services to the participant or beneficiary involved in the case. The Final Rules under MHPAEA at 45 CFR 146.136(d)(2) implement MHPAEA. CMS administers MHPAEA with respect to self-insured non-Federal governmental plans in all States and health insurance issuers in two States, and the regulation provides a safe harbor such that non-Federal governmental plans (and issuers offering coverage in connection with such plans) are deemed to comply with requirements of paragraph (d)(2) of 45 CFR 146.136 if they provide the reason for claims denial in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503–1. Section 146.136(d)(3) clarifies that PHS Act section 2719 governing internal claims and appeals and external review as implemented by 45 CFR 147.136, covers MHPAEA claims denials and requires that, when a non-quantitative treatment limitation (NQTL) is the basis for a claims denial, that a non-grandfathered plan or issuer must provide the processes, strategies, evidentiary standard, and other factors used in developing and applying the NQTL with respect to med/surg benefits and MH/SUD benefits.

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on

their behalf, may use this optional model form to request information from plans regarding the medical necessity and claims denials disclosures referenced above. *Form Number:* CMS–10307 (OMB control number: 0938–1080); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments, Private Sector, Individuals; *Number of Respondents:* 282,657; *Total Annual Responses:* 1,125,558; *Total Annual Hours:* 93,797. (For policy questions regarding this collection contact Erik Gomez at 667–414–0682.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* On-Site Inspection for Durable Medical Equipment (DME) Supplier Location and Supporting Regulations in 42 CFR, Section 424.57; *Use:* CMS is mandated to identify and implement measures to prevent fraud and abuse in the Medicare program. To meet this challenge, CMS has moved forward to improve the quality of the process for enrolling suppliers into the Medicare program by establishing a uniform application for enumerating suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Implementation of enhanced procedures for verifying the enrollment information has also improved the enrollment process. As part of this process, verification of compliance with supplier standards is necessary. The site investigation form has been used in the past to aid the Medicare contractor (the National Supplier Clearinghouse and/or its subcontractors) in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services. *Form Number:* CMS–R–263 (OMB control number: 0938–0749); *Frequency:* Yearly; *Affected Public:* Private sector, Business or other for-profits; *Number of Respondents:* 48,087; *Number of Responses:* 48,087; *Total Annual Hours:* 48,087. (For policy questions regarding this collection contact Alisha Sanders at 410–786–0671.)

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

[CMS–7076–N]

Announcement of the Advisory Panel on Outreach and Education (APOE) In-Person Meeting

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the APOE (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Health Insurance Marketplace®,[1] Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

DATES:

Meeting Date: Thursday, September 19, 2024, from 8:30 a.m. to 4 p.m. eastern daylight time (e.d.t).

Deadline for Meeting Registration, Presentations, Special Accommodations, and Comments: Thursday, September 5, 2024, 5 p.m. (e.d.t).

ADDRESSES:

Meeting Location: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Presentations and Written Comments: Presentations and written comments should be submitted to: Walt Gutowski, Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–04–08, Baltimore, MD 21244–1850, 410–786–6818, or via email at *APOE@cms.hhs.gov*.

Registration: Persons wishing to attend this meeting must register at the website *https://CMS-APOE-September2024.rsvpify.com* or by contacting the DFO listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Walt Gutowski, Designated Federal Official, Office of Communications, 7500 Security Boulevard, Mailstop S1–04–08, Baltimore, MD 21244–1850, 410–786–6818, or via email at *APOE@cms.hhs.gov*.

Additional information about the APOE is available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background and Charter Renewal Information

A. Background

The Advisory Panel for Outreach and Education (APOE) (the Panel) is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of federal advisory committees. The Panel is authorized by section 1114(f) of the Social Security Act (the Act) (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a).

The Panel, which was first chartered in 1999, advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (the Department) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the effective implementation of national Medicare, Medicaid, Children's Health Insurance Program (CHIP) and Health Insurance Marketplace® outreach and education programs.

The APOE has focused on a variety of laws, including the Medicare Modernization Act of 2003 (Pub. L. 108–173), and the Affordable Care Act (Patient Protection and Affordable Care Act, (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)).

The APOE helps the Department determine the best communication

[1] Health Insurance Marketplace® is a registered service mark of the U.S. Department of Health & Human Services.