



Centers for Medicare & Medicaid Services

[Document Identifier CMS-18F5, CMS-10307, CMS-10495 and CMS-10454]

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at:

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

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:* Revision of a currently approved collection; *Title of Information Collection:* Application for Enrollment in Medicare Part A Internet Claim (iClaim) Application Screen Modernized Claims System and Consolidated Claim Experience Screens; *Use:* Individuals who are already entitled to retirement or disability benefits under Social Security or Railroad Retirement Board (RRB) benefits are automatically entitled to premium-free Medicare Hospital Insurance (Part A) when they attain age 65 or reach the 25th month of disability benefit entitlement. These individuals do not file a separate application for Medicare Part A because their application for Social Security or RRB benefits is also an application for Part A. The form is for individuals who are not eligible for Social Security for RRB benefits, but may qualify for premium-free Medicare Part A based on certain requirements

outlined in § 406.11 and 406.15 or for certain disabled individuals who may enroll in premium Medicare Part A based on certain requirements outlined in § 406.20. Individuals may also choose to enroll in Medicare Part B at the same time they apply for Medicare Part A.

The Application for Enrollment in Medicare Part A (CMS-18F5 and CMS-18F5-SP) was designed to capture all the information needed to make a determination of an individual's entitlement to Part A. This Information Collection Request (ICR) adds the collection instruments SSA uses to collect information from individuals who are filing an Application for Hospital Insurance, updates the burden information. CMS will begin reporting for additional collection instruments, including the Internet Claim System (iClaim), Modernized Claims System (MCS), and the Consolidated Claims Experience (CCE). *Form Number:* CMS-18F5 (OMB control number: 0938-0251); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,394,264; *Total Annual Responses:* 1,394,264; *Total Annual Hours:* 348,566. (For policy questions regarding this collection contact Carla Patterson at 410-786-1000.)

2. *Type of Information Collection Request:* Extension; *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) (P.L.110-343) generally requires that group health plans and group health insurance issuers offering mental health or substance use disorder (MH/SUD) benefits in addition to medical and surgical (med/surg) benefits ensure that they 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 applied to substantially all med/surg benefits.

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, was enacted on March 30, 2010, collectively known as the "Affordable Care Act." The Affordable

Care Act 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).

MHPAEA section 512(b) 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 Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (75 FR 5410, February 2, 2010) and the Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 set forth rules for providing criteria for medical necessity determinations. CMS oversees non-Federal governmental plans and health insurance issuers.

MHPAEA section 512(b) specifically amends the PHS Act to require plan administrators or health insurance issuers to supply, 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 Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (75 FR 5410, February 2, 2010) and the Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 implement 45 CFR 146.136(d)(2), which sets forth rules for providing reasons for claims denial. CMS oversees non-Federal governmental plans and health insurance issuers, 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) of the final rule 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.

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 NQTLs that may affect patients' MH/SUD benefits or that may have resulted in their coverage being denied. *Form Number:* CMS-10307 (OMB control number: 0938-1080); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector, Individuals; *Number of Respondents:* 250,137; *Total Annual Responses:* 987,714; *Total Annual Hours:* 35,475. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650.)

3. *Type of Information Collection Request:* Extension; *Title of Information Collection:* Data Collection and Submission, Registration, Attestation, Dispute and Resolution, Record Retention, and Assumptions Document Submission, for Open Payments; *Use:* Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (the Act), which requires applicable manufacturers of covered drugs, devices, biologicals, or medical supplies (as defined at 42 C.F.R § 403.902) to report annually to the Secretary certain payments or other transfers of value to covered recipients. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Specifically, manufacturers of covered drugs, devices, biologicals, and medical supplies

(applicable manufacturers) are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to covered recipients during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. *Form Number:* CMS-10495 (OMB control number: 0938-1237); *Frequency:* Once; *Affected Public:* Private sector; Business or other for-profits; *Number of Respondents:* 34,616; *Total Annual Responses:* 78,812; *Total Annual Hours:* 1,897,790. (For policy questions regarding this collection contact Kathleen Ott 410-786-4246.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosure of State Rating Requirements; *Use:* The final rule “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” implements sections 2701, 2702, and 2703 of the Public Health Service Act (PHS Act), as added and amended by the Affordable Care Act, and sections 1302(e) and 1312(c) of the Affordable Care Act. The rule directs that states submit to CMS certain information about state rating and risk pooling requirements for their individual, small group, and large group markets, as applicable. Specifically, states will inform CMS of age rating ratios that are narrower than 3:1 for adults; tobacco use rating ratios that are narrower than 1.5:1; a state-established uniform age curve; geographic rating areas; whether premiums in the small and large group market are required to be based on average enrollee amounts (also known as composite premiums); and, in states that do not permit any rating variation based on age or tobacco use, uniform family tier structures and corresponding multipliers. In addition, states that elect to merge their individual and small group market risk pools into a combined pool will notify CMS of such election. This information will allow CMS to determine whether state-specific rules apply or Federal default rules apply. It will also support the accuracy of the federal risk adjustment methodology. *Form*

Number: CMS-10454 (OMB control number: 0938-1258); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 3; *Total Annual Responses:* 3; *Total Annual Hours:* 17. (For policy questions regarding this collection contact Russell Tipps at 301-869-3502.)

Dated: February 9, 2021.

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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