DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-718–721 and CMS-10307]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 the date of publication in the Federal Register]**.

ADDRESSES: When commenting on the proposed information collections, please reference the

document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: *OIRA_submission@omb.eop.gov*

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-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

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: Reinstatement of a previously approved collection; Title of Information Collection: Business Proposal Forms for Quality Improvement Organizations (QIOs); Use: The submission of proposal information by current quality improvement associations (QIOs) and other bidders, on the appropriate forms, will satisfy our need for meaningful, consistent, and verifiable data with which to evaluate contract proposals. We use the data collected on the forms associated with this information collection request to negotiate QIO contracts. We will be able to compare the costs reported by the QIOs on the cost reports to the proposed costs noted on the business proposal forms. Subsequent contract and modification negotiations will be based on historic cost data. The business proposal forms will be one element of the historical cost data from which we can analyze future proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness. Form Number: CMS–718-721 (OMB control number: 0938–0579); Frequency: Annually; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 20; Total Annual Responses: 20;

Total Annual Hours: 1,000. (For policy questions regarding this collection contact Benjamin Bernstein at 410-786-6570.)

2. Type of Information Collection Request: Reinstatement with change of a previous approved information 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) (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. These statutes are 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).

Medical Necessity Disclosure under MHPAEA

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.

Claims Denial Disclosure under MHPAEA

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.

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 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: 267,538; Number of Responses: 1,081,929; Total Annual Hours: 43,327. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650.)

Dated: December 5, 2017 _____

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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