

Telephone: (513) 841-4515 (this is not a toll-free number); Email: TCarreonValencia@cdc.gov.

SUPPLEMENTARY INFORMATION:

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to accomplishing the committee's objectives. The Administrator of the WTC Health Program is seeking nominations for members fulfilling the following categories:

- Occupational physician who has experience treating WTC rescue and recovery workers;
- Environmental medicine/environmental health professional;
- Toxicologist;
- Epidemiologist;
- Occupational physician;
- Representative of WTC responders; and
- Representative of certified-eligible WTC survivors.

Members may be invited to serve for four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of STAC objectives. More information on the committee is available at <https://www.cdc.gov/wtc/stac.html>. The U.S. Department of Health and Human Services (HHS) policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. NIOSH identifies potential candidates and provides a slate of nominees for consideration to the Director of CDC for STAC membership each year, CDC reviews the proposed slate of candidates, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in October, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate

who is not selected in one year may be reconsidered in a subsequent year.

Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address);
- The category of membership (environmental medicine or environmental health specialist, occupational physician, pulmonary physician, representative of WTC responders, certified-eligible WTC survivor representative, industrial hygienist, toxicologist, epidemiologist, or mental health professional) that the candidate is qualified to represent;
- A summary of the background, experience, and qualifications that demonstrates the candidate's suitability for the nominated membership category; and
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate. The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10307 and CMS-10495]

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 December 28, 2020.

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, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Call the Reports Clearance Office at (410) 786-1326.

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-10307 Medical Necessity and Claims Denial Disclosures under MHPAEA

CMS-10495 Data Collection and Submission, Registration, Attestation, Dispute and Resolution, Record Retention, and Assumptions Document Submission, for Open Payments

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:* 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, 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, 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.)

2. Type of Information Collection

Request: Extension of a currently approved collection; *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 CFR 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.)

Dated: October 23, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10570 and CMS-10437]

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 November 27, 2020.

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' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. 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:* Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services; *Use:* Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, "Recognizing Appropriate Use Criteria

for Certain Imaging Services," which directs the Secretary to establish a program to promote the use of AUC. This program is codified at 42 CFR 414.94. Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. A provider-led entity (PLE) as defined in 42 CFR 414.94(b) is a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside the organization, predominantly provide direct patient care. This program requires professionals ordering applicable imaging services as defined in § 414.94(b) to consult with specified applicable AUC, which are criteria developed, endorsed or modified by a qualified PLE.

The cornerstone of the PLE qualification process is for PLEs to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. In the 2016 Physician Fee Schedule Final Rule with comment period (80 FR 70886, November 16, 2015; see pages 71102-71116 and pages 71380-71382) we established a qualification process and requirements for qualified PLEs in order to ensure that the AUC development or endorsement processes used by a PLE result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B).

In order to become and remain a qualified PLE, we require PLEs to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. To ensure that these requirements are met, we require PLEs to submit information demonstrating their adherence to these requirements. CMS qualifies those PLEs that demonstrate adherence to the requirements for a period of five years. Qualified PLEs are also required, during the 5th year after their most recent approval date, to ensure adherence has been maintained and to account for any changes in the entities' processes. Qualified PLEs must reapply every five years and must submit the applications by January 1 of the 5th year after the PLE's most recent approval date. *Form Number:* CMS-10570 (OMB control number: 0938-1288); *Frequency:* Occasionally; *Affected Public:* Private: