SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995 SUBMISSIONS

A. Justification

1. *Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.*

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) was enacted on October 3, 2008 as sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Public Law 110-343). MHPAEA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), and the Internal Revenue Code of 1986 (Code). In 1996, Congress enacted the Mental Health Parity Act of 1996, which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical and surgical benefits. Those mental health parity provisions were codified in section 712 of ERISA, section 2705 of the PHS Act, and section 9812 of the Code. The changes made by MHPAEA are codified in these same sections and consist of new requirements as well as amendments to several of the existing mental health parity provisions applicable to group health plans and health insurance coverage offered in connection with a group health plan. MHPAEA and the interim final regulations do not apply to small employers who have between two and 50 employees. The changes made by MHPAEA are generally effective for plan years beginning after October 3, 2009.

On April 28, 2009, the Departments of the Treasury, Labor, and HHS (collectively, the Departments) published in the Federal Register (74 FR 19155) a request for information (RFI) soliciting comments on the requirements of MHPAEA. After consideration of the comments received in response to the RFI, the Departments are publishing these interim final regulations. These regulations generally become applicable to plans and issuers for plan years beginning on or after July 1, 2010.

MHPAEA and the interim final regulations (29 CFR 2590.712(d)) require plan administrators to provide two disclosures regarding MH/SUD benefits--one providing criteria for medical necessity determinations (medical necessity disclosure) and the other providing the reason for denial of claims reimbursement (claims denial disclosure). These disclosures are information collection requests for purposes of the Paperwork Reduction Act and are discussed below.

Medical Necessity Disclosure under MHPAEA

MHPAEA and section 29 CFR 2590.712(d) (1) require plan administrator 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. Accordingly,

any plan that receives a request from a current or potential plan participant, beneficiary, or contracting health care provider must provide that party with a Medical Necessity Disclosure under MHPAEA. The Department of Labor, however, is not proposing that plans or issuers use a specific form.

Claims Denial Disclosure under MHPAEA

MHPAEA and these interim final regulations (29 CFR 2510.712(d)(2) also provide that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary. The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, plans to provide a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Therefore, the interim final regulations provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation.

2. *Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.*

Medical Necessity Disclosure

As discussed above, MHPAEA and these interim final regulations require plans and issuers to provide a Medical Necessity Disclosure. Receiving this information will enable potential and current participants and beneficiaries to make more informed decisions regarding the choices available to them under their plans and hopefully result in better treatment of their MH/SUD conditions. MHPAEA also requires plans administrators to provide the Medical Necessity Disclosure to current and potential contracting health care providers. Because medically necessary criteria generally indicate appropriate treatment for certain illnesses in accordance with standards of good medical practice, this information should enable physicians and institutions to structure available resources to provide the most efficient mental health care for their patients.

Claims Denial Disclosure

Upon request, MHPAEA and the interim final regulations require plans and issuers to explain the reason that a specific claim is denied. Most practically, participants and beneficiaries need this information to determine whether they agree with the decision and, if not, whether to pursue an appeal.

3. *Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.*

The regulation does not restrict plans or issuers from using electronic technology to provide either disclosure. The Department of Labor's regulations under 29 C.F.R. § 2520.104b-1(b) provide that, "where certain material, including reports, statements, and documents, is required under Part I of the Act and this part to be furnished either by direct operation of law or an individual request, the plan administrator shall use measures reasonably calculated to ensure actual receipt of the material by plan participants and beneficiaries." Section 29 CFR 2520.104b-1(c) establishes the manner in which disclosures under Title I of ERISA made through electronic media will be deemed to satisfy the requirement of § 2520.104b-1(b). Section 2520-107-1 establishes standards concerning the use of electronic media for maintenance and retention of records. Under these rules, all pension and welfare plans covered under Title I of ERISA may use electronic media to satisfy disclosure and recordkeeping obligations, subject to specific safeguards.

The Government Paperwork Elimination Act (GPEA) requires agencies to allow customers the option to submit information or transact with the government electronically, when practicable. Where feasible, and subject to resource availability and resolution of legal issues, EBSA has implemented the electronic acceptance of information submitted by customers to the federal government.

4. *Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.*

MHPAEA amended ERISA and the Internal Revenue Code in addition to the PHS Act. Accordingly, both the Department of Health and Human Services (HHS) and the Department of the Treasury (Treasury) will require plans and issuers to provide, upon request, medical necessity and claims denial disclosures as well as the Department of Labor. There will be no duplication of effort with HHS and Treasury, however, because only the Department of Labor oversees ERISA-covered group health plans.

5. *If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.*

The information collection does not impact small businesses or entities.

6. *Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.*

The information collection arises in connection with the occurrence of individual claims for benefits and consists of third-party notices and disclosures. While no information is reported to the Federal government, if the plans and issuers do not provide the two disclosures or provide those disclosures less frequently, the Federal policy goals underlying MHPAEA would be impeded. Access to information about reasons for denials and medical necessity criteria enables participants, beneficiaries, and health care providers to better utilize health care resources which in turn may result in better treatment for mental health/substance use disorder conditions. At the very least, these disclosures make it easier to determine whether plans are making decisions about mental health/substance use disorder conditions in parity to those made regarding med/surg conditions.

7. *Explain any special circumstances that would cause an information collection to be conducted in a manner:*

- *requiring respondents to report information to the agency more often than quarterly;*
- *requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;*
- *requiring respondents to submit more than an original and two copies of any document;*
- *requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;*
- *in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;*
- *requiring the use of a statistical data classification that has not been reviewed and approved by OMB;*
- *that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or*
- *requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.*

None.

8. *If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.*

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

On April 28, 2009, the Departments of the Treasury, Labor, and HHS (collectively, the Departments) published in the Federal Register (74 FR 19155) a request for information (RFI) soliciting comments on the requirements of MHPAEA. After consideration of the comments received in response to the RFI, many of which were received from members of the regulated community that will be required to comply with the information collection, the Departments drafted these interim final regulations.

Also, the interim final rule provide the public with a 90-day period to submit written comments on the rule.

9. *Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.*

None.

10. *Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.*

Not applicable

11. *Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.*

Not applicable.

12. *Provide estimates of the hour burden of the collection of information. The statement should indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.*

- *If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.*

- *Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.*

- *The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.*

As discussed in item 1 above, MHPAEA and these regulations (29 CFR 2590.712(d)(1)) contain two new disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan that are addressed in paragraph (d) of the rules. The Claims Denial Disclosure provides that the reason for any denial under a group health plan (or health insurance coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available upon request or as otherwise required by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary.

The Department of Labor's ERISA claims procedure regulation (29 CFR 2560.503-1) requires, among other things, plans to provide a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. Therefore, the interim final regulations (29 CFR 2590.712(d)(2) provide that ERISA-covered plans (and health insurance coverage offered in connection with such plans) will be deemed to satisfy the MHPAEA claims denial disclosure requirement if they comply with the ERISA claims procedure regulation. The Department is not soliciting comments concerning an ICR pertaining to the claims denial notice, because the costs and burdens associated with complying with the claims denial disclosure requirement already are accounted for under the Department of Labor's Employee Benefit Plan Claims Procedure Under ERISA regulation (OMB Control Number 1210-0053).

MHPAEA and the interim final regulations (29 CFR 2590.712(d)(2)) also require plan administrators to make the plan's medical necessity determination criteria available upon request to potential participants, beneficiaries, or contracting providers. The Department is unable to estimate with certainty the number of requests for medical necessity criteria disclosures that will be received by plan administrators. Based on the best available information, the Department has estimated that there are 111 million participants covered by 446,400 plans that are subject to the

MHPAEA disclosure requirements that apply to employers with more than 50 employees[1]. Estimating that each plan affected by the rule will receive one request means that plans will need to provide 446,400 Medical Necessity Disclosures.

The Department estimates that approximately 93 percent of large plans and all small plans administer claims using service providers; therefore, 5.1 percent of the medical necessity criteria disclosures will be done in-house. For PRA purposes, plans using service providers will report the costs as a cost burden, while plans administering claims in-house will report the burden as an hour burden.

The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each of the 22,800 request for medical necessity disclosures at a labor rate of $26.85 per hour.[2] This results in an annual hour burden of nearly 1,900 hours and an associated equivalent cost of nearly $51,000 for the requests done in-house by plans. Because the Department of Labor and the Department of the Treasury share enforcement jurisdiction against group health plans and employers under the MHPAEA provisions (see section 712 of ERISA and section 9812 of the Internal Revenue Code), the aggregate paperwork burden of this information collection is divided equally between those two Departments. Therefore, the portion of the hour burden allocated to the Department of Labor is 950 hours with an equivalent cost of $25,500.

The Department estimates that the remaining approximately 424,000 medical necessity criteria disclosures will be provided through service providers resulting in a cost burden reported in Item 13, below.

13. *Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)*

As reported above in Item 12, above, plans using service providers will report the costs associated with the medical necessity disclosure as a cost burden. The Department estimates that 94.9 percent of claims are done using a service provider resulting in nearly 423,600 medical necessity criteria disclosures being provided through service providers. The Department assumes that it will take a medically trained clerical staff member five minutes to respond to each of the 423,600 request at a labor rate of $26.85 per hour. This results in a cost burden of approximately $948,000.

The Department also calculated the cost to deliver the requested medical necessity criteria disclosures (regardless of whether the disclosure is prepared in-house or by service

1 EBSA estimates from the 2006 form 5500.
2 EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index (June 2009, Bureau of Labor Statistics).

providers). Many insurers and plans already may have the information prepared in electronic form, and the Departments assume that 38 percent of requests will be delivered electronically resulting in a de minimis cost. The Departments estimate that the cost burden associated with distributing the approximately 277,000 medical necessity criteria disclosures sent by paper will be approximately $177,000. This estimate is based on an average document size of four pages, five cents per page material and printing costs, and 44 cents postage costs.

Based on the foregoing, the preparation and delivery of the medical necessity disclosures is estimated to have a total cost burden of approximately $1,125,000. Because the Department of Labor and the Department of the Treasury share enforcement jurisdiction against group health plans and employers under the MHPAEA provisions (see section 712 of ERISA and section 9812 of the Internal Revenue Code), the aggregate paperwork burden of this information collection is divided equally between those two Departments. Therefore, the portion of the cost burden allocated to the Department of Labor is $562,500.

14. *Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.*

Not applicable.

15. *Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83-I.*

Not Applicable.

16. *For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.*

There are no plans to publish the results of this collection of information.

17. *If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.*

The OMB expiration date will be published in the Federal Register following OMB approval.

18. *Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB 83-I.*

None.

B. Collections of Information Employing Statistical Methods

Not applicable.