May 3, 2010

Department of the Treasury
Internal Revenue Services

Department of Labor
Employee Benefits Security Administration

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Dear Sirs,

We greatly appreciate the work that your agencies have done in developing regulations to implement the Wellstone-Domenici Mental Health Parity and Addiction Equity Act, and are pleased with the interim final rules that were put forward. We particularly applaud and welcome the decision to define non-quantitative treatment limitations broadly, including utilization review as we requested in our pre-rule comment. Considering the additional administrative obstacles that have historically increased the difficulty of both accessing and providing mental healthcare, the broad definition of non-quantitative treatment limitations in the proposed regulations does much to further the spirit of the legislation.

At this time, we would like to offer further opinions on topics we would like to see addressed, particularly regarding scope of service and step therapies as per your most recent solicitation for public comments.

With regard to utilization review and medical necessity, we request a further clarification. Specifically, we would like to see regulations protecting coverage of appropriate preventive mental healthcare, and believe this can be addressed within the scope of the legislation. In many health insurance plans in the status quo, coverage of mental healthcare is dependent upon diagnosis. However, substantial evidence suggests that the absence of a 12-month *DSM* diagnosis should not necessarily preclude coverage of mental health services. Although approximately half of all persons currently treated for mental illness do not meet the criteria for a 12-month *DSM* diagnosis, it appears that most such patients have some indicators of need for mental health services[1]. According to the 2001-2003 National Comorbidity Survey Replication (NCS-R), the most comprehensive survey ever conducted of prevalence of mental disorders in the United States, more than 75 percent of patients treated without meeting the criteria for a 12-month *DSM* diagnosis had a subthreshold condition, reported a serious long-term stressor, or had a history of hospitalization; 92 percent of all patients treated had at least one of a list of indicators of need. Based on these numbers, it is evident that treatment of patients without a *DSM* diagnosis is medically justified in the vast majority of cases; and furthermore, that evaluation of need for mental health services should not be based exclusively on *DSM* diagnoses. Understanding that need for mental healthcare can be difficult to evaluate from an administrative standpoint, and also recognizing the risk of progression from mild

[1] Druss, Benjamin, et al. (2007) Understanding Mental Health Treatment in Persons Without Mental Diagnosis. *Archives of General Psychiatry*, 64(10), 1196-1203.

American Medical Student Association/Foundation
1902 Association Drive
Reston, VA 20191-1502
703-620-6600 Ext 201 Phone
703-620-6531 Fax
www.amsa.org

mental illness to more severe symptoms if left untreated[2], we suggest that it would be most appropriate to consider such treatment to be preventive care. As such, treatment limitations (as already defined in the proposed regulations) should be no more restrictive than those applied to physician office visits in general. Regulations should prevent the fairly common practice of placing arbitrary numerical limits on mental health office visits where such limits do not exist for medical/surgical office visits. It should be noted that many existing health insurance plans would already comply with such regulations. This "preventive care" clarification may be necessary in order to close the potential loophole whereby it might be argued that preventive mental health services do not constitute parity mental health benefits.

We would like to reiterate our support for guaranteeing coverage of as broad a range of evidence-based therapies as possible, in accordance with our goal of ensuring access to affordable, patient-centered health services. Therefore, we are of the opinion that plans should be required to cover the full scope of medically appropriate services for mental health conditions if they cover the full scope of medically appropriate services for medical/surgical conditions. Because mental health services include a number of settings that have no direct medical/surgical analogues, it is inappropriate, both by any clinical standard and by the intent of the legislation, to interpret the MHPAEA as not requiring coverage on the basis that the same setting is not covered for medical/surgical conditions. Such an interpretation would leave significant holes in the continuum of care available to patients. The interpretation more consistent with legislative intent would allow exclusions of treatment modalities only where roughly equivalent exclusions apply predominantly to all medical/surgical conditions, where "predominantly" is defined by existing regulations. In cases where no direct analogues exist, agency judgment should be able to adequately define rough equivalents, with reference to professional expertise as necessary on this very specific subject.

Finally, we wish to address coverage of step therapy, a topic mentioned in your request for comments. Step therapy requirements are best applied to conditions for which well-established guidelines exist, and for which drugs are largely interchangeable with minimal consequences[3]. While many of the most common medical conditions have these characteristics, the majority of psychiatric conditions do not, making them ill-suited to step therapy. As efficacy and safety of psychiatric medications can vary greatly from patient to patient and from drug to drug, even within a single category of drugs with similar mechanisms, it is highly unlikely that a group of patients with the same condition will respond best to the same medications. Therefore, it is not equitable or appropriate to allow a plan to restrict mental health coverage by step therapy purely on the basis of two-thirds of medical conditions also being subject to the same. A more appropriate standard must consider whether protocols or guidelines have been issued by a professional organization or independent agency for the treatment of a condition. In order to determine whether a step therapy requirement is permissible, the specific psychiatric diagnosis in question should be compared only to medical conditions for which treatment protocols are at a similar level of development.

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[2] Kessler, Ronald, et al. (2003) Mild Disorders Should Not Be Eliminated From the DSM-V. *Archives of General Psychiatry*, 60(11), 1117-1122.

[3] Walker, Tracey. (2006, May) Top 25 drug classes involved in step therapy. *Managed Healthcare Executive*, 16(5). Retrieved from http://managedhealthcareexecutive.modernmedicine.com/

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Once again, we thank you for standing firmly with patients seeking access to needed healthcare, in keeping with the goals of the Wellstone-Domenici Mental Health Parity and Addiction Equity Act in drafting the proposed rules. We hope that final revisions will continue in the same spirit.

Sincerely,

John Brockman
President, American Medical Student Association (AMSA)

Andrew Hsieh
Coordinator, AMSA Mental Health Interest Group

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Reston, VA 20191-1502
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703-620-6531 Fax
www.amsa.org