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Comments RE: Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

To Whom It May Concern:

I am a research scientist, government contractor for health-related services, and small business owner-operator. I have worked in basic and applied neuroscience and psychology in academia, government, and private industry. I have published extensively in the area of basic and applied human brain electrophysiology.

I am very supportive of most of the provisions of the interim final rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. These rules address many of the inequities in health insurance coverage of mental health care when compared to medical/surgical care that I have observed in over 28 years of mental health practice. However, in my opinion, two areas have not been sufficiently clarified. I am quite concerned that unless these points are more clearly specified in the final regulations, loopholes will remain that will permit widespread violation of the legislative intent of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008:

1. In my opinion, the interim final rules do not define clearly enough the rules regulating the comprehensive scope of services parity between mental health/substance abuse services and medical/surgical services. Given the language of the Act and the positions already taken by the Departments in the interim final regulations, I request that the Final Rules clarify that benefits for MH/SUD must be comparable in scope to the benefits provided in medical/surgical care both across and within each classification. Unless parity in scope of services is required in the final regulations, the intent of the Act will not be achieved.

2. I strongly support the application of parity requirements to both QTLs and NQTLs as being consistent with the Act and allowing for broad application of the parity requirement with regard to treatment limitations. However, in order to implement the intent of the Act, the regulations must specify more clearly that any NQTLs that are applied by plans must be comparable for MH/SUD and medical surgical benefits, and that any NQTLs for MH/SUD must be no more restrictive than NQTLs that are predominant across the broad range of medical/surgical benefits.

The importance of the question of parity of scientific review criteria is well illustrated by experience with EEG biofeedback for the treatment of acute and chronic mental fatigue and stress-related impairments of memory and cognition. As with many mental health conditions, clinicians and neuroscientists cannot sharply define mental fatigue in terms of specific physiological processes. So mental fatigue is usually defined as a subjective assessment that is associated with various behavioral and physiological symptoms. Although mental fatigue is largely assessed subjectively by mental health practitioners, there is a pressing practical need for objective measures to estimate, monitor, and treat it. Changes in the EEG clearly signal the onset and stages of sleep, but more recent studies have shown that EEG patterns can also signal the recurrence of mental fatigue states in awake patients. This state of affairs motivated us to rigorously test the accuracy and robustness of EEG-based estimation of mental fatigue instead of further analyzing its underlying physiology. We used a two-pronged approach: first we assessed the common across-subjects pattern of changes in power spectral density of multichannel EEG over extended periods of mental arithmetic performance. Second, we tested the feasibility of using EEG power spectral densities or PSDs to classify mental fatigue states at a sub-minute time scale in individual subjects. The results have been highly

successful and are now being incoporated in experimental trials on human subjects in studies sponsored by the US Army and the University of California, Losa Angeles.

Our research is laying the groundwork for drug-free treatment of a wide range of fatigue-related conditions including chronic fatigue syndrome, symptoms of sleep disorders, narcolepsy, and cognitive deficits associated with fatigue in children. However, despite this rigorously controlled research, EEG biofeedback is not covered by most health insurers due to claims that there is insufficient scientific evidence. When our research comes to fruition, it will not be available to anyone but those wealthy enough to afford uninsured benefits. In addition the lack of support for insurance-based models for coverage of EEG biofeedback discourages the kind of private investment needed to translate new research such as ours into effective and affordable treatments. If insurers supported this extremely powerful and safe approach to mental health treatment as much as they do other options, patients would benefit from new and drug-free alternatives to lasting treatments of fatigue-related disorders.

These same insurers, however, cover many medical surgical services with far inferior scientific support. Much more stringent and restrictive criteria are employed in scientific review of mental health and substance abuse treatments than are met for the preponderance of medical surgical treatment. The result is an egregious violation of the principles of parity and equality. To give just one of many possible examples: The Journal of the American Medical Association (JAMA) recently published a review of the evidence base supporting the joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA). (Tricoci P, Allen J, Kramer J, Califf R, Smith S (2008) Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines, JAMA, February 25, 2009—Vol 301, No.8). In this review, the 16 current practice guidelines that reported levels of scientific evidence were reviewed and the degree of scientific support for 2711 specific practice recommendations was assessed and paced into one of three categories:

• Level of evidence A: recommendation based on evidence from multiple randomized trials or metaanalyses

• Level of evidence B: recommendation based on evidence from a single randomized trial or nonrandomized studies

• Level of evidence C: recommendation based on expert opinion, case studies, or standards of care.

The results show that only 11% of the 2711 recommendations are based on level of evidence A – multiple randomized trials. Of the remaining recommendations, 41% are based on level of evidence B – a single randomized trial or non-randomized studies, and 48% are based on level C – expert opinion or case studies.

This makes it clear that at least in cardiology, the actual scientific review criteria currently in use in the predominant body of medical surgical practice, at least in cardiology, are less restrictive than those routinely employed for scientific review of mental health and substance abuse treatment and include anecdotal evidence (expert opinion), case studies, non-randomized studies, or a single randomized trial. Specifically, health insurers routinely limit reimbursement of EEG biofeedback as lacking scientific evidence, despite the fact that there is stronger evidence than for many covered services in cardiology.

For this reason, it is critically important, in order to implement the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, that the regulations specify more clearly that any NQTLs that are applied by plans must be comparable for MH/SUD and medical surgical benefits, and that any NQTLs for MH/SUD must be no more restrictive than NQTLs that are predominant for all medical/surgical benefits.

Thank you for your careful consideration of these requests.

Sincerely,

Digitally signed by Leonard J. Trejo
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