PUBLIC SUBMISSION

As of: May 26, 2009
Received: May 25, 2009
Status: Pending_Post
Tracking No. 809b41bc
Comments Due: May 28, 2009
Submission Type: Web

Docket: EBSA-2009-0010
Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

Comment On: EBSA-2009-0010-0001
Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

Document: EBSA-2009-0010-DRAFT-0094
Comment on FR Doc # E9-9629

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General Comment

RE: Comments regarding Regulatory Guidance USCG-2007-27022 page 19157, II B specific areas 1 and 4, specifically with reference to the requirement that “the treatment limitations (including limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment) applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan.”

Introduction
I am a Licensed Professional Counselor and am also a Biofeedback Certification Institute of America Board Certified Neurofeedback Therapist. I have been providing Neurofeedback (aka EEG Biofeedback) for 10 years. However, I cannot count the number of prospective clients who desperately needed and desired Neurofeedback but could not afford this very effective and necessary service because their insurance company refused to pay for Neurofeedback. Because of this, what I have found is that THOSE WHO NEED NEUROFEEDBACK THE MOST CAN ACCESS IT THE LEAST! This is a GROSS injustice and I strongly urge that the MHPAEA be implemented in a way to require that Neurofeedback and/or Biofeedback be covered in the same way as other medical treatments as provided for in the Act.

I am a strong advocate of evidence based practice and pursue this in my practice. My focus on the importance of evidence based practice has resulted in

increasing awareness of the minimal evidence base for much of medical surgical practice, and of the complete absence of parity between limitations placed on mental health and substance abuse treatment in comparison to medical surgical treatment allegedly in the name of evidence based practice.

More restrictive scientific review criteria in mental health and substance abuse treatment.
EEG biofeedback is an approach in several areas of mental health and substance abuse treatment that is safe, non-invasive, widely available, and has an ample evidence base in over thirty years of clinical practice and hundreds of published studies. Like the research supporting cardiovascular treatment, EEG biofeedback research includes randomized controlled studies as well as non-randomized, open trials and case studies. However, most insurers do not cover EEG biofeedback services, usually based on claims of insufficient scientific evidence of efficacy of this treatment. This is the case with most health insurers active in my geographic area, including Blue Cross Blue Shield of Arizona and Aetna Behavioral Health.

This represents a limitation in coverage in mental health care that is not present in medical and surgical benefits, since many medical treatments that are routinely covered have substantially less research evidence of efficacy than biofeedback. In this way, more restrictive scientific review criteria are employed for limiting the coverage of biofeedback in mental and behavioral health care than those employed for review of many medical procedures. This appears to be a violation of the requirements of parity under MHPAEA.

According the the January 2005 issue in Child and Adolescent Psychiatric Clinics of North America, EEG biofeedback was considered to meet the review criteria as a “clinical guideline for treatment of ADHD, seizure disorders, anxiety (eg, obsessive-compulsive disorder, GAD, posttraumatic stress disorder, phobias), depression, reading disabilities, and addictive disorders. This finding suggests that EBF always should be considered as an intervention for these disorders by the clinician. “ This review was published in 2005; many additional studies demonstrating the efficacy of EEG biofeedback have been published since that time. It is without question that there is a substantial research evidence base of documenting the effectiveness of this very safe and widely available treatment in a range of very difficult to treat mental and behavioral health disorders.

Perhaps more importantly, Neurofeedback/EEG biofeedback shows substantial efficacy in many conditions that are quite resistant to treatment by other means. For example, seven studies have been completed evaluating the efficacy of EEG biofeedback for autism spectrum disorders. All have shown substantial benefit in social, emotional, and executive function, in several studies after only 20 sessions, or ten weeks of treatment.

Adequate and practical scientific review criteria The criteria for “gold standard” scientific research methods have increasingly and steadily grown stricter and more demanding. The result is that it is extraordinarily expensive and time consuming to conduct research that meets these strict standards, especially mental health and substance abuse treatment outcome research.

While it is a worthy goal that treatment outcome studies attain this gold standard for all interventions in use, it simply is not practical. For example, many if not most parents of children with autism spectrum disorder recognize the importance of scientific research, but simply cannot afford to wait until all approaches are thoroughly studied with such rigorous methods. Instead they are willing to consider approaches that have preliminary evidence of efficacy as long as they are safe and have few adverse effects.

In using this common sense, these parents are in fact supported by scientific

evidence. It is a legitimate goal of scientific research to determine empirically the type of criteria that are most suitable for use in scientific review. The question of what type of research is needed to provide adequate empirical support for treatment can be answered using the scientific method. Some recent research of this type suggests that the increasing tendency to accept as adequate evidence only results from randomized controlled trials itself represents an opinion unsupported by the evidence base.

Recent meta-analyses comparing the results of observational studies versus randomized controlled trials to assess efficacy of medical treatment reveal that results from the two approaches to research are generally concordant . For example, analyzing data from 136 published reports of efficacy of 19 diverse medical treatments, Benson and Hartz concluded “In only two of the 19 analyses of treatment effects did the combined magnitude of the effect from the observational studies lie outside of the 95% confidence interval for the combined magnitude in the randomized controlled trials’”. (A comparison of observational studies and randomized, controlled trials. N. Engl. J. Med. 342(25), 1878–1886 (2000). These findings suggest that in most instances, observational studies provide adequate data to evaluate treatment outcome. Since observational studies are much less costly and time consuming, scientific review criteria that are both adequate and practical may accept as valid evidence the outcome of less highly controlled observational studies.

A clear violation of parity and equity.
Unquestionably, many if not most insurers employ more restrictive and limiting scientific review criteria in the evaluation of methods in mental and substance abuse treatment than are predominantly employed in medical and surgical treatment. The contrast between guidelines in cardiology and restrictions against EEG biofeedback is only one example. There are many others, such as limitations placed on psychological and neuropsychological assessment for many disorders.

Empirical research suggests that these stricter standards are unnecessarily restrictive, since the findings of uncontrolled observational studies are generally concordant with findings form more controlled research. However, whatever standard is employed for assessing the scientific evidence, parity requires that the same standard is employed for mental health and substance abuse that is employed for most medical surgical treatments. But this is not in fact the case.

Clearly, with regard to the example of EEG biofeedback, a well studied and safe treatment, the treatment limitations applicable to mental health or substance use disorder benefits are much more restrictive than the predominant treatment limitations applied to medical and surgical benefits covered by most plans. Parity requires that the same scientific review criteria be used for coverage of mental health and substance disorder treatment that predominate in coverage of medical and surgical services. However, for most insurers, EEG biofeedback (aka Neurofeedback) is not a covered service, even though there is an empirical evidence-base for EEG biofeedback that is far stronger than that for many covered medical services. True parity, as envisioned in MHPAEA, will only be achieved when regulations require that insurers use the same scientific review criteria that are applied for the preponderance of medical and surgical treatments in providing and limiting access to mental health and substance abuse treatment. By this rule, EEG biofeedback should be covered.

I strongly urge that you write and enforce regulations that require health insurers to use the same scientific review criteria for mental health and substance abuse services such as EEG biofeedback or neurofeedback that they use for most medical procedures.

Thank you for your attention to this very important matter. I would be happy to provide documentation to support the claims made above about the level of

evidence supporting EEG biofeedback.

Sincerely,
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