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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."

I am a Licensed Marriage and Family Therapy and Psycho-physiologist and own a mental health practice servicing over two hundred adults and children monthly. I have been in full time practice for more than 9 years, working with children and adults with neurodevelopmental and neuropsychiatric problems. I have presented on numerous topics in psychology at national and international conferences for Autism and ADHD. I am a strong advocate of evidence based practice and pursue this comprehensively in the clinic I own.

I summarize the relevant research on all forms of treatment available for the particular problem a client presents with and discuss the profile of advantages and disadvantages of each. I offer for every client to provide them with published reviews of the relevant research. I also gather treatment outcome data for every client using well established measures, and provide these data to the client and to all of the treating professionals involved with this client. So I am acutely aware of the importance of the evidence base in providing competent care.

Indeed, 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.

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, medical surgical practice guidelines are very rarely based on the highest level of scientific evidence, and that the actual scientific review criteria currently in use in the predominant body of medical surgical practice, at least in cardiology, are less restrictive and include anecdotal evidence (expert opinion), case studies, non-randomized studies, or a single randomized trial.

More restrictive scientific review criteria in mental health and substance abuse treatment
However, virtually all health insurers employ much more restrictive criteria in their scientific review of treatment practices in mental health and substance abuse. This is a clear violation of the principle of parity and equality, since it results in much more severe limitations in coverage of treatment in mental health and substance abuse care.

An example to contrast with the standard in cardiology: EEG biofeedback, also called neurofeedback. 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 our geographic area, including Blue Cross Blue Shield of RI and Massachusetts, Tufts Health Plan, Harvard Pilgrim Health Plan, 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.

A review of the research on the efficacy of EEG biofeedback was published in 2005 in Child and Adolescent Psychiatric Clinics of North America, a well respected psychiatric journal. This review employed criteria for judging the degree of scientific evidence of treatment efficacy that were employed by the American Academy of Child and Adolescent Psychiatry, the child psychiatry professional organization, for developing practice guidelines for the treatment of ADHD. These criteria specified four levels:

- ‘‘Minimal Standards’’ [MS] are recommendations that are based on substantial empirical evidence (such as well-controlled, double-blind trials) or overwhelming clinical consensus. Minimal standards are expected to apply more than 95% of the time. i.e., in almost all cases. When the practitioner does not follow this standard in a particular case, the medical record should indicate the reason.
- ‘‘Clinical Guidelines’’ [CG] are recommendations that are based on limited empirical evidence (such as open trials, case studies) and/or strong clinical consensus. Clinical guidelines apply approximately 75% of the time. These practices should always be considered by the clinician, but there are exceptions to their applications.
- ‘‘Options’’ [OP] are practices that are acceptable but not required. There may be insufficient empirical evidence to support recommending these practices as minimal standards or clinical guidelines. In some cases they may be appropriate, but in other causes they should be avoided. If possible, the practice parameter will explain the pros and cons of these options.
- ‘‘Not Endorsed’’ [NE] refers to practices that are known to be ineffective or contraindicated.

Based on these scientific review criteria, as advanced by the chief child psychiatry professional organization, EEG biofeedback was considered to be 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, 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. I have been specializing in clinical work with this group for more than 20 years. I have seen at very close hand virtually al of the treatment techniques in use. EEG biofeedback more consistently results in more rapid progress than any other form of intervention I know. The same is true for the use of EEG biofeedback in the treatment of PTSD.

Indeed, using the scientific review criteria that predominate in medical/surgical practice in cardiology, EEG biofeedback meets the predominant criteria for treatment of the following disorders:

- ADHD
- Autism spectrum disorders
- Substance abuse/addictions
- Generalized anxiety disorder
- Obsessive compulsive disorder
- PTSD
- Phobias
- Panic disorder
- Major depression
- Bipolar disorder
- Conduct disorder
- Traumatic brain injury
- Reading disabilities
- Reactive attachment disorder
- Schizophrenia

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 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.

Cordially,

Jamie L. Juarez, Ph.D. Candidate, LMFT
President of Hope Counseling and Family Therapy, Inc.