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

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MI

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General Comment

See attached file(s)

Attachments

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Centers for Medicare and Medicaid Service
U.S. Department of Health and Human Services
Attention: CMS-4140-IFC
P.O. Box 8016
Baltimore, MD 21244-1850

To Whom It May Concern:

RE: CMS-4140-IFC, Comments on the Interim Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addition Equity Act of 2008; (Vol. 75, No. 21) issued on February 2, 2010.

Thank you for the opportunity to comment on the Interim Final Regulations regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. I will address many of the areas for which comments were solicited.

The Interim Final Regulations regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) don't adequately address "Scope of Services" or "Continuum of Care". The MHPAEA doesn't provide specific definitions for the terms "mental health conditions" and "substance use disorders." "The regulations state, plans may define mental health conditions or substance use disorders. The definitions must be "consistent with generally recognized independent standards of current medical practice." (Federal Register Vol. 75, No. 21, Tuesday, February 2, 2010 Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Final Rule/ Rules and Regulations 45 CFR Part 146, p. 5412)

The a fore mentioned is too broad and can be subject to many interpretations. Therefore, what is meant by "scope of treatment" requires more specific language in the regulations. It is imperative that the regulations provide further guidance on what is meant by "recognized standards of care" to prevent unmanageable loopholes.

Under the regulations, medical/surgical benefits, mental health benefits and substance abuse disorder benefits are generally defined by reference to the terms of the health plan providing benefits. Mental health benefits and substance use disorder benefits are also defined by reference to applicable Federal and State law, and the benefits must be defined "consistent with generally recognized independent standards of current medical practice."

Specific language in each state's parity laws have been analyzed. States have enacted mental health parity laws that require a health plan, insurer, or employer to provide coverage for mental illness equal to that for physical illness. The study

“An Analysis of the Definitions of Mental Illness Used in State Parity Laws” analyzed definitions of mental illness used in state parity laws, identified factors influencing the development of these definitions, and examined the effects of different definitions on access to care for persons with mental illness. (An Analysis of the Definitions of Mental Illness Used in State Parity Laws_by Marcia C. Peck, M.D., M.P.H. and Richard M. Scheffler, Ph.D. Psychiatr Serv 53:1089-1095, September 2002 American Psychiatric Association)

Policy makers, mental health providers, insurers, and advocates were interviewed to determine factors influencing a state's definition. Definitions of mental illness used in clinical literature and in federal policy were reviewed and compared with definitions used in state parity laws. The definitions of mental illness used in state parity legislation vary significantly and fit into one of three major categories: (1) "broad-based mental illness," (2) "serious mental illness," or (3) "biologically based mental illness." State legislatures didn't rely on clinically accepted definitions or federal mental health policy to define each of these categories. Influenced by political and economic factors, they developed their own definitions. Peck & Scheffler stated that, "Definitions of mental illness in state parity laws have important implications for access, cost, and reimbursement; they determine which populations receive a higher level of mental health services."

Per the National Alliance on Mental Illness (NAMI): "Serious mental illness is used to refer to coverage of major mental illnesses, typically defined in statute[s] as schizophrenia, schizoaffective disorder, psychotic disorders, bipolar disorder, major depression, panic disorders, and obsessive compulsive disorder."; "Broad-based mental health disorders" is used to refer to coverage of a relatively broad range of mental disorders."; and "Substance abuse disorders" is used to refer to coverage of alcoholism and chemical dependency.
(<http://www.nami.org/Template.cfm?Section=Parity1&Template=/ContentManagement/ContentDisplay.cfm&ContentID=45313>)

Per the National Conference of State Legislatures, the definition of "biologically based mental illness" used in state parity legislation varies. It's a list of diagnoses delineated by an individual state.
(<http://www.ncsl.org/IssuesResearch/Health/StateLawsMandatingorRegulatingMentalHealthB/tabid/14352/Default.aspx>)

Mandating coverage for biologically based mental illnesses, while not offering coverage for other mental health conditions and substance use disorders, is not adequate nor moral. For example, the etiology for Post Traumatic Stress Disorder (PTSD) is not biological. PTSD is not limited to war veterans who can receive mental health services through the Veterans Administration. Many people who experienced Hurricane Katrina and the 9/11 (September 11, 2001) tragedy have suffered from PTSD. Per the National Center for PTSD (the world's expert on PTSD and Traumatic Stress), there is evidence-based treatment for PTSD which

includes, psychotherapy, psychoeducation, psychopharmacology and other supportive measures. (<http://www.ptsd.va.gov/public/pages/faq-about-ptsd.asp>)

Although the etiology for PTSD is not biological, it is a mental health condition recognized by the Diagnostic and Statistics Manual of the American Psychiatric Association (DSM). The DSM includes universally accepted definitions and descriptions of mental illnesses and conditions. Andrew Sperling, the director of federal legislative advocacy for the National Alliance on Mental Illness stated that NAMI's research has found that most plans will continue to cover "medically necessary services" for disorders in the Diagnostic and Statistical Manual of Mental Disorders. (<http://articles.latimes.com/2008/oct/13/health/he-parity13>)

The regulations need to clearly state a minimum standard to define the terms "mental health conditions" and "substance use disorders". For example, "Covered mental health conditions and substance use disorders must include, at the *minimum*, the applicable standards of the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)".

One of congress's primary objectives in enacting MHPAEA was to improve access to mental health and substance use disorder benefits by eliminating discrimination that existed with respect to these benefits after the Mental Health Parity Act of 1996. (Federal Register Vol. 75, No. 21, p. 5413) The MHPAEA requires that a plan must provide parity regarding access to services and the continuum of care.

This is substantiated by the language in the regulation:

...Under these regulations, if a plan provides any benefits for a mental health condition or substance use disorder, benefits must be provided for that condition or disorder in each classification for which any medical/ surgical benefits are provided. This follows from the statutory requirement that any treatment limitations applied to mental health or substance use disorder benefits may be no more restrictive than the predominant treatment limitations applied to substantially all medical/ surgical benefits. (Federal Register Vol. 75, No. 21, p. 5413)

However, not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those for medical and surgical conditions.

For example, if a plan limits treatment for major depression to only the use of medications prescribed through a primary care provider, it would restrict access to psychotherapy and other treatment modalities in the benefit design, thus shifting the cost for this benefit to the patient.

Relapse & relapse prevention is another type of treatment. When people seek help for depression and other mental health conditions, hopefully they receive treatment that reduces or eliminates symptoms. However, once they leave treatment, they may revert to old habits and ways of living. This results in a return of symptoms known as relapse. These concepts can be used to describe the

dynamics of any mental illness. (Manderscheid RW, Ryff CD, Freeman EJ, McKnight-Eily LR, Dhingra S, Strine TW. Evolving definitions of mental illness and wellness. Prev Chronic Dis 2010;7(1) [Electronic version] www.cdc.gov/pcd/issues/2010/jan/09_0124.htm)

Any strategies or treatments applied in advance to prevent future symptoms are known as relapse prevention. Prevention of relapse in mental health conditions is crucial because the occurrence of relapse increases chances for future relapses. With each relapse, symptoms tend to be more severe and have more serious consequences. (www.cdc.gov/pcd/issues/2010/jan/09_0124.htm) Relapse prevention aims to teach people strategies that will maintain the wellness skills they learned while in treatment.

The National Institute of Mental Health (NIMH) Collaborative Depression Study delineated desirable clinical outcomes for remission and recovery for persons with depression. The study refers to: (1) Response as a clinically significant reduction in depressive symptoms; (2) Remission as the absence of depressive symptoms after a response; (3) Relapse as a return of depressive symptoms after remission; (4) Recovery as to sustained remission, with or without concurrent treatment; and (5) Recurrence as a return of depressive symptoms after recovery. (Keller MB, Shapiro RW, Lavori PW, Wolfe N. Relapse in major depressive disorder: analysis with the life table. *Arch Gen Psychiatr* 1982;39(8):911-5.)

The term “medical necessity” is the criteria used to determine a beneficiary’s eligibility for treatment and the scope of treatment. Persons who have a mental health condition and/or a substance use disorders often require maintenance treatment to prevent further deterioration, more intensive outpatient treatment and hospitalization. If the treatment is designed to avert deterioration rather than treat illness to a point of significant improvement, it might be considered outside the scope of coverage as defined by medical necessity. Nevertheless, such treatment is a clinical necessity. The regulations need to add the term “clinical necessity” to the language of the MHPAEA. This is important in order to ensure coverage for services which are necessary to sustain or maintain functioning when without the service the patient would deteriorate.

This is supported by William Ford who “proposed the concept of ‘treatment necessity’ or ‘clinical necessity’ to encompass this broader view of the goals of psychiatric services. Treatment necessity requires a service to be: for the treatment of mental illness and substance abuse disorders, or symptoms of these disorders, and impairments in day-to-day functioning related to them; for the purpose of preventing the need for a more intensive level of psychiatric care; for the purpose of preventing relapse of persons with psychiatric disorders; consistent with generally accepted clinical practice for psychiatric disorders ...” (“Medical Necessity and Psychiatric Managed Care” *The Psychiatric Clinics of North America* 23(2):309–317; <http://download.ncadi.samhsa.gov/ken/pdf/SMA03-3790/SMA03-3790.PDF> p. 48.

The Paul Wellstone and Pete Domenici Mental Health Parity and Addition Equity Act of 2008 states that there are six classifications of benefits.

“The MHPAEA regulations specify, in paragraph (c)(2)(ii), that there are six classifications of benefits (i) inpatient/in-network, (ii) inpatient/out-of-network, (iii) outpatient/in-network, (iv) outpatient/out-of-network, (v) emergency care and (vi) prescription drugs. However, the Regulations do not define inpatient, outpatient or emergency care.” Thus, these terms are subject to plan design and their meanings may differ from plan to plan. (Federal Register Vol. 75, No. 21, p. 5413)

However, not all treatments or treatment settings for mental health conditions or substance use disorders correspond to those classifications for medical and surgical conditions. The language in the regulations need to assure adequate access to a full range of settings for patient care. For mental health conditions and substance use disorders, treatment settings should include: outpatient, crisis, hospitalization, partial hospitalization, rehabilitation, detoxification, and residential care. (Often persons who have a mental illness also have a substance use disorder. Thus, it the individual may need concurrent treatment/services for both mental health conditions and substance use disorders.)

Additionally, the regulations must explicitly prohibit exclusions of levels of care. For example, if a plan covers day treatment for programs such as stroke rehabilitation under medical/surgical benefits, it must cover partial hospitalization/day treatment programs for mental health conditions and substance abuse disorders.

Furthermore, the regulations should recognize that the scope of treatment for mental illness and substance use disorders should be no more restrictive than what is covered for other chronic health conditions. For example, if a plan covers preventive services for diabetes, heart disease, and cancer; the plan must cover preventive services for mental health conditions and substance use disorders.

This is substantiated in the MHPAEA.

“The general parity requirement of paragraph (c)(2) of these regulations prohibits a plan (or health insurance coverage) from applying any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation applied to substantially all medical/surgical benefits in the same classification.” (Federal Register Vol. 75, No. 21, p. 5413)

Before ending my public comment, I would like to include some additional remarks regarding access to benefits for mental health and substance use disorders:

1. It's essential that the regulations clarify the terms used for the classification of benefits because “Plans often vary the financial requirements and treatment limitations imposed on benefits based on whether a treatment is

provided on an inpatient, outpatient, or emergency basis; whether a provider is a member of the plan's network . . ." (Federal Register Volume 75, No. 21 pages 5413).

2. The language in the regulations should explicitly state that covered services and levels of care should be appropriate to the covered diagnoses.
3. There must not be a "fail-first" policy. If a service is medically or clinically necessary and appropriate, failure in another service should not be required as a prerequisite to authorization.
4. The regulation must ensure that there are standards that require networks to have sufficient enrolled, participating providers to assure access to treatment/services for mental health conditions and substance use disorders equal to other health services. Some examples of concerns are:
(a) If there are a lot of providers listed who are no longer practicing or accepting new patients, there may not be adequate access to providers.
(b) Plans' whose fee schedules do not entice an adequate supply of providers limit access to treatment/services for mental health conditions and substance use disorders.
5. The regulations must require that plans' utilization management staff include credentialed professionals who have specialized training in mental health *and* substance use disorders.
6. It should be noted that cost effectiveness does not necessarily mean lowest cost.

Thank you for the opportunity to comment on the Interim Final Regulations regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. I have addressed many of the specific areas for which comments were solicited. Please take my comments under careful consideration as the regulations are further developed.