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Comment On: CMS-2009-0040-0001
Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

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DC

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General Comment

Takeda commends CMS, the Internal Revenue Service (IRS), and the Employee Benefits Security Administration (hereafter referred to as "agencies") for seeking additional information to aid in the development of regulations implementing MHPAEA. Takeda submits these comments in response to issue "Number 2" in the agencies' joint request for information, which asks the following: "What terms or provisions require additional clarification to facilitate compliance? What specific clarifications would be helpful?"
In response to these requests, Takeda believes that it is important to highlight three issues that warrant clarification and that must be addressed to affect the intent of the MHPAEA:
(1) The definition of the term "mental health benefits;"
(2) The law's parity standards for "financial requirements", as applied to prescription medications that treat mental health conditions, including the antidepressant class; and

(3) Treatment limitation provisions that are directed to quantity limits on mental health drugs, including the antidepressant class.

Attachments

CMS-2009-0040-DRAFT-0038.1: DC

May 28, 2009

Acting Administrator Charlene Frizzera
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4140-NC
P.O. Box 8017
Baltimore, MD 21244-8010

Re: Comments on Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 [CMS-4140-NC; Response to Issue #2]

Dear Acting Administrator Frizzera:

Takeda Pharmaceuticals North America, Inc. (Takeda) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to its request for information regarding issues under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).[1] Takeda is one of the nation's leading pharmaceutical companies and is committed to striving toward better health for individuals and progress in medicine by developing innovative pharmaceutical products. We currently market oral diabetes, insomnia, gastroenterology, and hyperuricemia treatments. We seek to bring new pharmaceutical products to patients through a pipeline that includes compounds in development for diabetes, psychiatric conditions such as depression, cardiovascular disease, oncology, gastroenterology, neurology, rheumatology and other conditions.

Takeda commends CMS, the Internal Revenue Service (IRS), and the Employee Benefits Security Administration (hereafter referred to as "agencies") for seeking additional information to aid in the development of regulations implementing MHPAEA. Takeda submits these comments in response to issue "Number 2" in the agencies' joint request for information, which asks the following: "What terms or provisions require additional clarification to facilitate compliance? What specific clarifications would be helpful?" [2]

In response to these requests, Takeda believes that it is important to highlight three issues that warrant clarification and that must be addressed to affect the intent of the MHPAEA:

(1) The definition of the term "mental health benefits;"

[1] 74 Fed. Reg. 19155 (April 28, 2009).
[2] 74 Fed. Reg. 19155, 19157.

(2) The law's parity standards for "financial requirements", as applied to prescription medications that treat mental health conditions, including the antidepressant class; and

(3) Treatment limitation provisions that are directed to quantity limits on mental health drugs, including the antidepressant class.

1. Agencies Are Urged to Clarify the Definition of "Mental Health Benefits" in a Manner Which is Consistent With the Purposes of the Act

Prescription medications have become some of the most efficacious and cost effective treatments for many illnesses and conditions, including mental health conditions such as depression or schizophrenia. Particularly due to their central role in treating mental health conditions, it is important that the regulations implementing MHPAEA spell out clearly how the law's parity requirements apply to prescription medications covered by health plans. This will require that the regulations clearly define "mental health benefits." In the absence of addressing this issue, the reality is that the Act may not achieve its intended goal of ensuring true parity for mental health benefits. This issue quite clearly implicates the fundamental purpose of the MHPAEA.

As specified by the MHPAEA, if a health plan provides mental health benefits, key parity requirements include:

1) The financial requirements for mental health or substance use disorder benefits may not be "more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered under the plan." [3] Financial requirements are defined as including "deductibles, copayments, coinsurance and out-of-pocket expenses. . . ;" [4] and

2) "The treatment limitations applicable to such mental health or substance use disorder benefits can be no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits." [5] Treatment limitation is defined to include "the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." [6]

The law defines "mental health benefits," as "benefits with respect to services for mental health conditions, *as defined under the terms of the plan* and in accordance with applicable Federal and State law." (Emphasis added).[7] Technically, this might mean that "mental health benefits" are those labeled as such by a health plan. However, this reading would not make sense because it would permit a plan to label what would

[3] 29 U.S.C. §1185a(a)(3)(A)(i); 42 U.S.C. §300gg-5(a)(3)(A)(i); 26 U.S.C. §9812(a)(3)(A)(i)
[4] *Id* at 29 U.S.C. §1185a (a)(3)(B)(i); 42 U.S.C. §300gg-5(a)(3)(B)(i); 26 U.S.C. §9812(a)(3)(B)(i)
[5] *Id* at 29 U.S.C. §1185a (a)(3)(A)(ii); 42 U.S.C. §300gg-5(a)(3)(A)(ii); 26 U.S.C. §9812 (a)(3)(A)(ii).
[6] *Id* at 29 U.S.C. §1185a (a)(3)(B)(iii); 42 U.S.C. §300gg-5(a)(3)(B)(iii); 26 U.S.C. §9812 (a)(3)(B)(iii).
[7] *Id* at 29 U.S.C. §1185a(e)(4); 42 U.S.C. §300gg-5(e)(4); 26 U.S.C. §9812 (e)(4).

ordinarily be considered a mental health service as something other than a mental health service or benefit and thereby avoid triggering the law's parity requirements. Likewise, a plan could inadvertently avoid the parity requirements by covering drugs that are used to treat depression or schizophrenia as part of its "pharmacy" benefit (as plans typically do) instead of its "mental health benefit". This scenario is realistic because typically a pharmacy benefit does not differentiate between "mental health" and "medical" drugs.

We are hopeful that CMS and the other agencies will jointly confirm that parity applies to drugs used to treat mental health conditions even if the health benefits are not labeled by the health plan as mental health benefits. These medications can be lifesaving, and they improve the quality of life for millions. In an effort to balance the need for greater clarity to properly effectuate the statute and preserve health plans' decision making authority in formulary development in order to best manage the costs and utilization of prescription drugs, Takeda respectfully proposes the following regulatory definition of "mental health benefits" for the agencies' consideration:

> The term 'mental health benefits' means benefits for items and services (including prescription drugs) that are: (1) covered by the plan, as determined under the terms of the plan and any applicable Federal or State law; and (2) used to treat mental health conditions, meaning conditions listed in the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM).

We believe this definition makes clear that health plans retain the right to determine which, if any, mental health conditions they will cover, while clarifying that coverage of certain conditions, identified by reference to a well-recognized list of mental health conditions, is subject to the parity requirements of the Act (regardless of whether a plan calls the coverage a mental health benefit). At the very least, a definition must recognize that medication is the front line treatment to address mental illness, including depression, and that "items and services" should similarly extend to mental health drugs in the broader definition of "mental health benefits."

2. Agencies Should Provide Guidance on the Application and Calculation of Financial Parity

The MHPAEA provides greater access to mental health treatments and services by eliminating discriminatory cost sharing practices for many Americans already struggling with high health care costs. With passage of the bill, Congress has sent the message that those who suffer from mental illness are on equal footing with those who suffer from other health conditions and that it is necessary to protect their benefits.

To ensure that these mental health treatments are truly attainable, we urge the agencies to provide additional clarification and guidance on the application of the financial parity requirement to prescription drugs, as it remains unclear how the

predominant" financial requirement is determined and/or calculated.[8] For example, it is not clear whether, in the case of medications, the "predominant" co-pay would be based on the single most common co-pay for "medical or "surgical" benefits (and whether "medical" or "surgical" benefits would include prescription drugs that are used for purposes other than mental health) even if that meant mental health drugs ended up with a different co-pay than other drugs, or whether a plan would pick the most common co-pay that applied to medications used for purposes other than mental health. One approach that would meet the statutory goals and be administratively simple to effectuate might be to specify that the most common medical and surgical co-pay would be that for a visit to a physician's office, or (alternatively) the most common co-pay for prescription drugs for purposes other than mental health.

3. Agencies Should Provide Guidance on the Application of the Statute's Treatment Limitation Provisions to Quantity Limits on Mental Health Drugs

MHPAEA requires plans or coverage to ensure that the treatment limitations 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.[9] "Treatment limitations" include "limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." [10] Thus, it would be helpful if the agencies make clear in the regulations that the treatment limitations subject to the parity requirements include quantity limitations on prescription drugs used for mental health conditions.

Our research shows that quantity limits are a significant concern because 55 percent of all plans in 2008 covering brand name anti-depressants used quantity limits. These limitations can have devastating consequences for people already stabilized on mental health medications. Further, studies have shown that current utilization management strategies may significantly increase costs of other services (e.g., emergency room visits, hospitalizations, costs associated with suicidal or violent ideation or behavior, and homelessness) for this population, and that limits on the number or dosing of medications may be problematic for this population.[11] Additionally, patients with more severe depressive or anxiety symptoms are significantly more likely to experience problems accessing clinically indicated medications or are subject to more adverse events when utilization management tools are employed. Our data show that compared to 2008,

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[8] The regulation only notes that a financial or treatment limit is considered "predominant" if it is "the most common or frequent" type of limit or treatment, providing the agencies with clear authority to issue a regulation reflective of our recommendation. 74 Fed. Reg. 19156.

[9] 29 U.S.C. §1185a (a)(3)(A)(ii); 42 U.S.C. §300gg-5(a)(3)(A)(ii); 26 U.S.C. §9812 (a)(3)(A)(ii).
[10] *Id* at 29 U.S.C. §1185a (a)(3)(B)(iii); 42 U.S.C. §300gg-5(a)(3)(B)(iii); 26 U.S.C. §9812 (a)(3)(B)(iii)
[11] American Psychological Association, "Facts about Suicide in Older Adults," available at http://www.apa.org/ppo/issues/oldersuicidefact.html. See also Joyce C. West, Joyce, Wilk, Joshua, et al.: Medication Access and Continuity: The Experiences of Dual-Eligible Psychiatric Patients During the First 4 Months of the Medicare Prescription Drug Benefit. *Am J Psychiatry* 2007; 164:789–796.

in 2009, an even greater percentage of plans will apply quantity limits to select drugs. To that end, we urge the agencies to ensure that the same parity requirements for quantity limits apply equally to prescription drugs, as it would for medical/surgical services.

Summary

Takeda appreciates the opportunity to submit comments in response to provisions that require additional clarification to facilitate compliance. In particular, we believe that greater clarification is needed on the definition of "mental health benefits." Without an adequate definition, patients could potentially experience limits on the quantity, frequency or duration of treatment. Takeda also urges the agencies' for additional clarification and guidance on the application of the financial parity requirement to prescription drugs, as it remains unclear how the "predominant" financial requirement is determined and/or calculated. Without added clarification, it could result in potentially higher co-payments for mental health treatments compared to medical/surgical benefits. Finally, we request guidance on the application of the statute's treatment limitation provisions to quantity limits on mental health drugs in order to ensure that these utilization tools are not inadvertently used to discriminate against patients with mental illness, including depression.

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Thank you for your consideration. If you have any questions or require further information, please contact me at (224) 554-5647.

Sincerely,

Suzanne McDonald
VP Government and External Affairs