



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

May 3, 2010

Phyllis C. Borzi  
Assistant Secretary of Labor  
Employee Benefits Security Administration  
c/o Office of Health Plan Standards and Compliance Assistance  
Room N-5653  
U.S. Department of Labor  
200 Constitution Ave, NW  
Washington, DC 2010

Attention: RIN 1210—AB30

Dear Assistant Secretary Borzi,

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through employers, insurers, unions, state and local governments, and Medicare Part D.

Our members are working to ensure that they fully support their client insurers and employer health plans in meeting the compliance timeframes for The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). The interim final rule raises a number of questions and concerns that the agencies must address to ensure smooth implementation of the law.

MHPAEA requires health plans to have parity between medical/surgical benefits and any offered benefits for mental health and substance abuse. As you know, the law does not require health plans to cover mental health and substance abuse services, but rather requires those plans that do cover such services to ensure parity.

With respect to prescription drugs, the interim final rule makes clear that PBMs and health plans may continue to use formulary tier structures. Pharmacy benefit managers establish formularies based on Pharmacy and Therapeutic (P&T) Committees' clinical recommendations. Most PBMs have a standard formulary, which includes a range of drugs in classes necessary for there to be appropriate drug therapies available for physicians to prescribe. Many PBMs and health plans use three-tier formularies, with successively more expensive enrollee cost sharing for generics, preferred brand, and other brand drugs, respectively. Thus, many health plans using PBM services cover most drugs at some level, although they may impose prior authorization or step-therapy requirements, or other care management requirements that have a clinical basis.

Many drugs used for the treatment of mental health or substance abuse are also used for other purposes. For example, a drug like Divalproex Sodium (brand name Depakote) can be used for seizure disorder (not mental health) and bipolar disorder (mental health). In some other cases, drugs used to treat mental health or substance abuse have other uses that while “off-label” are nonetheless proven and therefore generally covered by our clients’ plans. However, there are also examples of mental health drugs where the only use would be a mental health use and would not have any non-mental health uses.

PCMA urges the agency to provide clarity that with respect to prescription drugs, not only is formulary tiering allowed, but also that the mere use of a standard formulary with its broad list of drugs does not in and of itself denote coverage of mental health and substance abuse benefits in plans that provide no such coverage. PCMA also urges the agency not to require pharmacy benefit managers to ensure that a given drug, in a plan that does not cover mental health and substance abuse, is being used for a diagnosis unrelated to mental health and substance abuse.

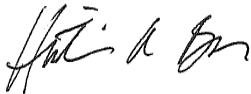
Were the agency to require such a determination, the burden on employers, consumers, pharmacies, and physicians would be very high. In addition, this additional barrier to treatment increases costs without providing any benefit to the plan participants. Currently the system for filling a prescription is relatively streamlined: a person submits the prescription to the pharmacy and then picks up the dispensed medication in person or has it mailed. The information on the prescription does not include a diagnosis. For the most part, a diagnosis is not required. In those limited cases where more information is needed, the patient is generally directed by the pharmacist to call the plan to obtain prior authorization. Were a health plan and PBM required to show that a drug was being used for a specific diagnosis, the pharmacist would have to call the physician’s office to determine the diagnosis, then determine whether the drug was covered for that indication, then alert the patient accordingly. In addition to imposing additional back-office burdens on physicians’ offices, such delays would often result in patients forgoing needed medications. This would be an unfortunate unintended consequence of the mental health and substance abuse parity law.

More broadly, we are concerned that the Interim Final Rule (IFR) introduces certain new concepts, such as “non-quantitative” treatment limitations, that are not based in the legislation and create considerable uncertainty for plans. The IFR does not define the concept, but instead gives a very broad “illustrative list” of examples, with the result that plans have no parameters with which to measure the acceptability of standard formulary management and utilization management tools. In fact, the IFR itself acknowledges the lack of clarity and difficulty in applying the non-quantitative treatment limitation rule to actual health care plan procedures, and admits that the illustrative list of examples do not reflect the reality of the situations.

PCMA does recognize that the IFR includes a special rule for multi-tiered prescription drug benefits, which states that if a plan applies different levels of financial requirements to different tiers of prescription drug benefits based on certain reasonable factors (i.e., cost, efficacy, brand vs. generic, mail order vs. retail pick-up) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance abuse disorder benefits, the parity requirements are satisfied with respect to prescription drug benefits. While this rule on its surface provides some protection for standard PBM drug formulary designs, it becomes essentially meaningless against the complex and confusing non-quantitative treatment limitations rule.

As a result of this uncertainty, many health plans, particularly in the employer market, are considering dropping drug coverage and/or dropping coverage for mental health and substance abuse disorders altogether rather than run the risk of being found to be out of compliance with the requirements of the IFR. We do not believe that this is the outcome that either Congress or the Secretary intended, but we believe that this will be the unintended consequence if the IFR is implemented as currently written. We strongly urge the Secretary to revise the IFR to create a safe harbor for prescription drugs that recognizes that prescription drugs can be used to cover many different conditions, and that it is in the interests of participants that they be allowed to access their drug benefit irrespective of their particular diagnosis.

Sincerely,



Kristin Bass  
Senior Vice President, Policy