EPILEPSY FOUNDATION®

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March 14, 2006

Medicaid Commission Members
Health and Human Services Medicaid Commission
c/o Nancy Barnes, Executive Secretary
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

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RE: Page B. Pennell, MD's Testimony to Medicaid Commission

Dear Sirs & Mesdames:

Good afternoon. Thank you for the opportunity to provide comments regarding the Commission's recommendations. I am a Neurologist and Director of the Epilepsy Program at Emory University School of Medicine, here in Atlanta. I also serve on the National Professional Advisory Board for the Epilepsy Foundation. We ask that you reconsider the recommendation to raise co-payments for beneficiaries who must use brand name drugs versus generic medications for treatment of their epilepsy.

I come to you as a physician who treats many persons with epilepsy, a chronic disorder characterized by recurrent, unprovoked seizures. My concern is that limitations placed by Medicaid on the affordability of certain medications to our patients will place them in a precarious situation. My special area of expertise is pregnancy in women with epilepsy. Since we are all really here for the welfare of our patients, our constituents, and members of our community, I would like to tell you about recent patient situations I encountered in my practice that illustrates the impact of limiting medication accessibility on a financial basis to our patients.

Patient XY is a 22 year old African American woman with epilepsy, who presented to my clinic for management during pregnancy. At the time her seizures were well controlled on a single "newer" anticonvulsant medication. In the past, she had suffered failure of many of the older anticonvulsant medications. She was eligible for both Medicare and Medicaid, but with the recent changes in drug coverage and her being assigned to a new Medicare D plan, she fell through the cracks as many patients did. The new plan would not cover her particular anticonvulsant medication, she could not afford the cost, and thus she went two days without any doses. She experienced three convulsive grand mal seizures in one day, which mandated an

emergency room visit with fetal monitoring. The obstetricians were able to sustain her pregnancy another few weeks, but with her higher risk of seizures on an older seizure medicine decided to induce labor early with the child being born 4 weeks premature with its associated complications including prolonged hospitalization. In early 2006, another 3 pregnant patients of mine had to be admitted for intravenous loading of phenytoin because the state Medicaid program no longer covered the brand name, and I could not keep their levels therapeutic during pregnancy with oral generic phenytoin.

When a woman is pregnant the risk of seizures to her developing child is tremendous and should be avoided at all costs. Seizures cause fetal hypoxia and acidosis, fetal distress; seizures can lead to premature labor, can result in miscarriage and stillbirths. Recent studies have also demonstrated that if a woman has convulsive seizures during pregnancy, that her child has lower verbal IQ. Developmental delay in the offspring results in another cycle, another generation of dependents for financial assistance and medical care.

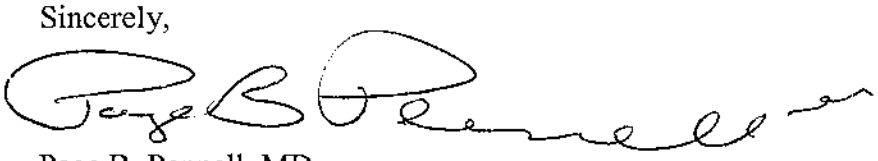
To limit comprehensive coverage of medications to those few antiepileptic drugs that are available in generic form is unacceptable. Many of these older medications are known significant teratogens, increasing the risk substantially for birth defects (major congential malformations). For instance, one of the few available medications in generic form is valproic acid. The risk to the developing child of valproic acid exposure is four times higher that the child will be born with a major congenital malformation (such as spina bifida), compared to exposure to other anticonvulsant medications. Unfortunately, the early timing of spinal cord formation just a few weeks after conception and the need to alter seizure medications slowly, does not afford us the opportunity of providing costlier medications only after pregnancy is diagnosed. Another medication available in generic form, phenobarbital, is also associated with higher risk of birth defects. To be able to practice the best medicine to keep these mothers-to-be safe, but also to improve fetal outcomes, we need to be able to use the best medications possible to achieve these goals.

Many of our patients, whether pregnant or not, certainly have an increased risk of seizures if they miss their prescribed medication for one week, one day, or sometimes even one dose. Any gap in affordability of their medicine places them at substantial risk. Seizure occurrence adversely impacts our patients with risk of trauma, loss of driving privileges, and often loss of any potential or sustainable employment and income. A single seizure results in loss of driving privileges for a full 6 months in Georgia, and is similar in most states. In all patients with epilepsy we need to provide the best medication options for both seizure control and to minimize side effects. The "therapeutic window" for our medications is very tight; with an increased concentration causing toxicity with imbalance, falling, sleepiness, inability to function in daily life, and lower concentrations causing loss of seizure control. For those few antiepileptic drugs that are available in a generic form, bioequivalency and bioavailability may differ by as much as 10-15% and easily push the patient outside of his particular therapeutic window of safety and tolerability. In 2004 the American Academy of Neurology published evidence based reviews of anticonvulsant drugs in patients with epilepsy. The data showed that these drugs are effective and have fewer side effects than the older antiepileptic drugs. Most of these drugs are not available as generic medications. It would create an undo burden to impoverished Medicaid patients to increase their co- payments for drugs that are not available as generics.

We hope that the Medicaid programs will recognize the importance of making available to patients that qualify, all FDA approved drugs for conditions such as epilepsy when they are medically necessary. The cost of emergency room visits, hospitalization and re-visits to their physicians due to failed ability to tolerate a drug, or due to poorly controlled seizures, in the long run will result in higher health care cost to the Medicaid program. Therefore, in certain neurologic conditions such as epilepsy, substitutions are not medically acceptable or financially responsible.

I appreciate the opportunity to submit these comments and your time and attention.

Sincerely,



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