

# SENATE, No. 961

## STATE OF NEW JERSEY 214th LEGISLATURE

INTRODUCED FEBRUARY 4, 2010

**Sponsored by:**

**Senator JOSEPH F. VITALE**

**District 19 (Middlesex)**

**Senator FRED H. MADDEN, JR.**

**District 4 (Camden and Gloucester)**

**Co-Sponsored by:**

**Senators T.Kean and S.Kean**

**SYNOPSIS**

Prohibits substitution of prescribed epilepsy drugs by pharmacists without prior notification to and written consent of physician and patient.

**CURRENT VERSION OF TEXT**

As introduced.



**(Sponsorship Updated As Of: 3/12/2010)**

1 AN ACT concerning substitution of epilepsy drugs and  
2 supplementing P.L.1977, c.240 (C.24:6E-1 et seq.).  
3

4 **BE IT ENACTED** *by the Senate and General Assembly of the State*  
5 *of New Jersey:*  
6

7 1. a. Notwithstanding any law to the contrary, a pharmacist  
8 shall not interchange an anti-epileptic drug or formulation of an  
9 anti-epileptic drug, brand or generic, for the treatment of seizures  
10 associated with epilepsy without providing prior notification to, and  
11 obtaining the signed informed consent of, the prescribing physician  
12 and the patient, or the patient's parent, legal guardian or spouse, as  
13 applicable.

14 b. As used in this act:

15 "Anti-epileptic drug" means any drug prescribed for the  
16 treatment of epilepsy or a drug used to treat or prevent seizures.

17 "Epilepsy" means a neurological condition characterized by  
18 recurrent seizures.

19 "Interchange" means the substitution of one version of the same  
20 anti-epileptic therapeutic product, including a generic version for  
21 the prescribed brand, a brand version for the prescribed generic  
22 version, a generic version by one manufacturer for a generic version  
23 by a different manufacturer, a different formulation of the  
24 prescribed anti-epileptic drug, or a different anti-epileptic  
25 therapeutic drug product for the anti-epileptic product originally  
26 prescribed.

27 "Seizure" means an acute clinical change secondary to a brief  
28 disturbance in the electrical activity of the brain.  
29

30 2. This act shall take effect on the first day of the second month  
31 following the date of enactment.  
32  
33

#### 34 STATEMENT 35

36 This bill prohibits pharmacists from substituting brand or generic  
37 anti-epileptic drugs prescribed to treat seizures without prior  
38 notification to, and the signed informed consent of, the prescribing  
39 physician and patient, or the patient's parent, legal guardian or  
40 spouse, as applicable.

41 Different patients respond differently to seizure control  
42 medications. For anticonvulsant drugs, small variations in  
43 concentrations between FDA equivalent rated drugs can cause toxic  
44 effects or seizures when taken by patients with epilepsy.

45 Anticonvulsant drugs for the treatment of epilepsy differ from  
46 other classes of drugs in several ways that make therapeutic or  
47 generic interchange of agents problematic. In most patients,  
48 controlling seizures with medication requires a slow and precise

1 dosage regulation of one or several medications. Changing from  
2 one formulation of a drug to another can usually be accomplished,  
3 and risks minimized, if physicians and patients monitor blood  
4 levels, seizures, and toxicity.

5 Pharmacists do not have access to the patient's complete medical  
6 history and may not know why a particular drug product was  
7 prescribed. While pharmacists are a vital part of the health care  
8 team, documented consent should be obtained from both the  
9 treating physician and the patient prior to any substitution in  
10 anticonvulsant medication in the case where the prescribing  
11 physician does not check "do not substitute" on the prescription.