

ASSEMBLY, No. 2270

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED FEBRUARY 1, 2018

Sponsored by:

Assemblywoman VALERIE VAINIERI HUTTLE

District 37 (Bergen)

SYNOPSIS

Prohibits substitution of prescribed epilepsy medication without notification and written consent of physician and patient; requires prescription to include notation of epilepsy diagnosis.

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT concerning epilepsy medications and supplementing
2 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. A practitioner who prescribes an anti-epileptic drug or
8 formulation for the treatment of seizures associated with epilepsy
9 shall, when issuing the prescription, include in the prescription a
10 notation or other appropriate indication that the patient has been
11 diagnosed with epilepsy.

12 b. Notwithstanding any law to the contrary, a pharmacist shall
13 not interchange an anti-epileptic drug or formulation of an anti-
14 epileptic drug, brand or generic, for the treatment of seizures
15 associated with epilepsy without providing prior notification to, and
16 obtaining the signed informed consent of, the prescribing
17 practitioner and the patient, or the patient's parent, legal guardian,
18 or spouse, as applicable.

19 c. As used in this act:

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

22 "Epilepsy" means a neurological condition characterized by
23 recurrent seizures.

24 "Interchange" means the substitution of one version of the same
25 anti-epileptic therapeutic product, including a generic version for
26 the prescribed brand, a brand version for the prescribed generic
27 version, a generic version by one manufacturer for a generic version
28 by a different manufacturer, a different formulation of the
29 prescribed anti-epileptic drug, or a different anti-epileptic
30 therapeutic drug product for the anti-epileptic product originally
31 prescribed.

32 "Practitioner" means an individual currently licensed, registered,
33 or otherwise authorized by this State or another state to prescribe
34 drugs in the course of professional practice.

35 "Seizure" means an acute clinical change secondary to a brief
36 disturbance in the electrical activity of the brain.
37

38 2. This act shall take effect on the first day of the fourth month
39 following the date of enactment.
40
41

42 STATEMENT

43

44 This bill revises the requirements for prescribing and dispensing
45 anti-epileptic drugs. Specifically, when issuing a prescription for
46 an anti-epileptic drug or formulation for the treatment of seizures
47 associated with epilepsy, the practitioner issuing the prescription
48 will be required to include in the prescription a notation or other

1 appropriate indication that the patient has been diagnosed with
2 epilepsy. Pharmacists will be prohibited from substituting brand or
3 generic anti-epileptic drugs prescribed to treat seizures without
4 prior notification to, and the signed informed consent of, the
5 prescribing practitioner and the patient or the patient's parent, legal
6 guardian, or spouse, as applicable.

7 Different patients respond differently to seizure control
8 medications. For anticonvulsant drugs, small variations in
9 concentrations between drugs rated equivalent by the federal Food
10 and Drug Administration can cause toxic effects or seizures when
11 taken by patients with epilepsy.

12 Anticonvulsant drugs for the treatment of epilepsy differ from
13 other classes of drugs in several ways that make therapeutic or
14 generic interchange of agents problematic. In most patients,
15 controlling seizures with medication requires a slow and precise
16 dosage regulation of one or several medications. Changing from
17 one formulation of a drug to another can usually be accomplished,
18 and risks minimized, if health care providers and patients monitor
19 blood levels, seizures, and toxicity.

20 Pharmacists do not have access to a patient's complete medical
21 history and may not know why a particular drug product was
22 prescribed. It is the sponsor's belief that requiring prescriptions for
23 anti-epileptic drugs to include a notation of the epilepsy diagnosis,
24 and establishing additional notification and consent requirements
25 for substitutions, will help ensure that patients with epilepsy receive
26 the care that is most appropriate to their condition.

27 This bill is based on certain recommendations included in the
28 November 2016 final report issued by the New Jersey Epilepsy
29 Task Force, "Addressing the Needs of Persons with Epilepsy:
30 Recommendations for a Plan of Action for the State of New
31 Jersey."