# ASSEMBLY, No. 3290

# STATE OF NEW JERSEY

## 219th LEGISLATURE

INTRODUCED FEBRUARY 25, 2020

**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.

**AN ACT** concerning epilepsy medications and supplementing P.L.1977, c.240 (C.24:6E-1 et seq.).

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

1. a. A practitioner who prescribes an anti-epileptic drug or formulation for the treatment of seizures associated with epilepsy shall, when issuing the prescription, include in the prescription a notation or other appropriate indication that the patient has been diagnosed with epilepsy.

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

c. As used in this act:

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

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

"Interchange" means the substitution of one version of the same anti-epileptic therapeutic product, including a generic version for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed anti-epileptic drug, or a different anti-epileptic therapeutic drug product for the anti-epileptic product originally prescribed.

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

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

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

STATEMENT

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

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

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

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

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

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