STATE OF NEW YORK

10479

IN ASSEMBLY

May 29, 2024

Introduced by COMMITTEE ON RULES -- (at request of M. of A. Blumencranz) -- read once and referred to the Committee on Health

AN ACT to amend the public health law and the education law, in relation to the labeling of prescriptions that are manufactured or compounded in a foreign country and subject to approval by the federal Food and Drug Administration foreign drug inspection program

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Short title. This act shall be known and may be cited as the "foreign drug transparency act".

§ 2. Subdivision 3 of section 280-a of the public health law, as amended by chapter 128 of the laws of 2022, is amended to read as follows

3. Prescriptions. A pharmacy benefit manager may not substitute or cause the substituting of one prescription drug for another in dispensing a prescription, or alter or cause the altering of the terms of a prescription, except with the approval of the prescriber or as explicitly required or permitted by law, including regulations of the department of financial services or the department of health. The superintendent and commissioner, in coordination with each other, are authorized to promulgate regulations to determine when substitution of prescription drugs may be required or permitted. **A pharmacy benefit manager shall disclose to a health plan, pharmacy and patient whether a prescription drug was manufactured or compounded in a foreign country; whether the prescription was approved by the federal food and drug administration foreign drug inspection program; and the date of the last inspection of such prescription drug by the federal food and drug administration foreign drug inspection program.**

§ 3. Subdivision 1 of section 6810 of the education law, as amended by section 2 of part V of chapter 57 of the laws of 2012, is amended to read as follows

1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD15348-01-4

prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription**, and the country in which the drug was manufactured or compounded; whether the drug was approved by the federal food and drug administration foreign drug inspection program; and the date of the last inspection of such prescription drug by the federal food and drug administration foreign drug inspection program. Such label shall be emphasized by being highlighted in yellow color or in bold type or both and printed in a minimum of a twelve-point font; if said drug was not approved by the federal food and drug administration foreign drug inspection program, such information shall be contained within the label with a warning sign and in a minimum size fourteen-point font**. All labels shall conform to such rules and regulations as promulgated by the commissioner pursuant to section sixty-eight hundred twenty-nine of this article. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words "drug" and "prescription required drug" within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision. Nothing in this subdivision shall prevent a pharmacy from furnishing a drug to another pharmacy which does not have such drug in stock for the purpose of filling a prescription.

§ 4. This act shall take effect immediately.