

# 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:

1 Section 1. Short title. This act shall be known and may be cited as  
2 the "foreign drug transparency act".  
3 § 2. Subdivision 3 of section 280-a of the public health law, as  
4 amended by chapter 128 of the laws of 2022, is amended to read as  
5 follows  
6 3. Prescriptions. A pharmacy benefit manager may not substitute or  
7 cause the substituting of one prescription drug for another in dispens-  
8 ing a prescription, or alter or cause the altering of the terms of a  
9 prescription, except with the approval of the prescriber or as explicit-  
10 ly required or permitted by law, including regulations of the department  
11 of financial services or the department of health. The superintendent  
12 and commissioner, in coordination with each other, are authorized to  
13 promulgate regulations to determine when substitution of prescription  
14 drugs may be required or permitted. A pharmacy benefit manager shall  
15 disclose to a health plan, pharmacy and patient whether a prescription  
16 drug was manufactured or compounded in a foreign country; whether the  
17 prescription was approved by the federal food and drug administration  
18 foreign drug inspection program; and the date of the last inspection of  
19 such prescription drug by the federal food and drug administration  
20 foreign drug inspection program.  
21 § 3. Subdivision 1 of section 6810 of the education law, as amended by  
22 section 2 of part V of chapter 57 of the laws of 2012, is amended to  
23 read as follows  
24 1. No drug for which a prescription is required by the provisions of  
25 the Federal Food, Drug and Cosmetic Act or by the commissioner of health  
26 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.

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1 prescription written by a person legally authorized to issue such  
2 prescription. Such drug shall be compounded or dispensed by a licensed  
3 pharmacist, and no such drug shall be dispensed without affixing to the  
4 immediate container in which the drug is sold or dispensed a label bear-  
5 ing the name and address of the owner of the establishment in which it  
6 was dispensed, the date compounded, the number of the prescription under  
7 which it is recorded in the pharmacist's prescription files, the name of  
8 the prescriber, the name and address of the patient, and the directions  
9 for the use of the drug by the patient as given upon the prescription,  
10 and the country in which the drug was manufactured or compounded; wheth-  
11 er the drug was approved by the federal food and drug administration  
12 foreign drug inspection program; and the date of the last inspection of  
13 such prescription drug by the federal food and drug administration  
14 foreign drug inspection program. Such label shall be emphasized by being  
15 highlighted in yellow color or in bold type or both and printed in a  
16 minimum of a twelve-point font; if said drug was not approved by the  
17 federal food and drug administration foreign drug inspection program,  
18 such information shall be contained within the label with a warning sign  
19 and in a minimum size fourteen-point font. All labels shall conform to  
20 such rules and regulations as promulgated by the commissioner pursuant  
21 to section sixty-eight hundred twenty-nine of this article. The  
22 prescribing and dispensing of a drug which is a controlled substance  
23 shall be subject to additional requirements provided in article thirty-  
24 three of the public health law. The words "drug" and "prescription  
25 required drug" within the meaning of this article shall not be construed  
26 to include soft or hard contact lenses, eyeglasses, or any other device  
27 for the aid or correction of vision. Nothing in this subdivision shall  
28 prevent a pharmacy from furnishing a drug to another pharmacy which does  
29 not have such drug in stock for the purpose of filling a prescription.  
30 § 4. This act shall take effect immediately.