SENATE
STATE OF MINNESOTA
NINETY-FIRST SESSION

S.F. No. 3970

(SENATE AUTHORS: BENSON and Draheim)

DATE	D-PG	OFFICIAL STATUS
03/04/2020	5235	Introduction and first reading Referred to Health and Human Services Finance and Policy
05/11/2020	6453a	Comm report: To pass as amended and re-refer to State Government Finance and Policy and Elections Joint rule 2.03, referred to Rules and Administration

A bill for an act

relating to health; authorizing incentives for manufacturers that choose to import certain drugs pursuant to "Pathway 2" of the safe importation action plan; proposing coding for new law in Minnesota Statutes, chapter 62J.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62J.85] PRESCRIPTION DRUG MANUFACTURER IMPORTATION PATHWAY PLAN.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following terms have the meanings given.

(b) "Drug product" or "drug" means a brand name drug or biological product that is regulated as a drug and is intended for human use. The biological product must be licensed pursuant to section 351 of the federal Public Health Act, United States Code, title 42, section 262, and does not include biological products such as blood and blood products that are intended for transfusion or allogenic-, cellular-, or tissue-based products.

(c) "FD&C Act" means the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 301, et seq.

(d) "Manufacturer" means an entity that:

(1) engages in the manufacture of a drug product; and

(2) sets or changes the wholesale acquisition cost of the drug product it manufactures.

(e) "Multimarket-approved product" or "MMA product" means a federal Food and Drug Administration (FDA)-approved drug product that:

(1) was manufactured outside the United States and originally intended to be marketed and authorized for sale in a foreign country;

(2) is subject to a new drug application or biologics license application supplement;

(3) is authorized by the manufacturer to be marketed in the United States;

(4) continues to meet the quality standards for marketing in its originally intended foreign market; and

(5) differs only from the FDA-approved drug or FDA-licensed biological product with regard to the labeling statement.

(f) "Safe importation action plan" means the plan released by the Department of Health and Human Services and the FDA allowing for the importation of drug products originally intended for foreign markets.

Subd. 2. **Application.** This section applies to any MMA product in which the manufacturer of the product has obtained a new National Drug Code (NDC) for the MMA product and has imported the MMA product in compliance with the FD&C Act and any regulations adopted by the FDA.

Subd. 3. **Labeling.** In addition to any FDA-approved labeling requirements, the label on any MMA product imported and sold in Minnesota must identify that the product was originally manufactured for sale in a country other than the United States.

Subd. 4. **Incentives.** (a) In order to facilitate importation of drugs pursuant to "Pathway 2" of the safe importation action plan, any MMA product offered for sale in Minnesota at a cost that is at least ... percent lower than the wholesale acquisition cost for the FDA-approved product manufactured in the United States shall be:

(1) included on the uniform preferred drug list and covered under the medical assistance and MinnesotaCare programs; and

(2) a covered drug under the state employee health plan pursuant to chapter 43A.

(b) Each health plan company must provide coverage for the MMA product that meets the requirements in paragraph (a) if the FDA-approved drug product is covered by the health plan company and must not impose any cost-sharing requirements for the MMA product.