State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-SECOND SESSION

H. F. No. 2004

03/08/2021 Authored by Haley
The bill was read for the first time and referred to the Committee on Commerce Finance and Policy

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 prescription drug or biological product that is intended for human use and regulated as a drug except where specific reference is made to a drug approved under section 505 of the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 355, or biological product approved under section 351 of the federal Public Health Act, United States Code, title 42, section 262. Drug product or drug does not include biological products that are intended for transfusions, including blood or blood products; or allogeneic-, 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(d) "Importation guidance" means the draft guidance released by the FDA titled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for the Industry," which if finalized allows for the importation of MMA products.

(e) "Manufacturer" means the entity that is the holder of the New Drug Application or Biologics License Application for the drug product.

(f) "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 authorized for marketing by another country's regulatory authority;

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

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

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

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 importation guidance finalized by the FDA.

Subd. 3. **Incentives.** (a) In order to facilitate importation of drugs pursuant to importation guidance finalized by the FDA, any MMA product offered for sale in Minnesota at a cost that is at least 23 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 group insurance program pursuant to chapter 43A.

(b) A health plan company must provide coverage for each MMA product that meets the requirements in paragraph (a) if the manufacturer's FDA-approved drug product manufactured in the United States is covered by the health plan company and the health plan company must not impose any enrollee cost-sharing requirements for the covered MMA product.

(c) This subdivision shall not become effective for MMA products that are offered for sale in Minnesota in accordance with paragraph (a) unless affirmative action is taken by the legislature.