As Introduced

136th General Assembly
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Representatives Russo, Abdullahi
Cosponsors: Representatives Cockley, Brennan, Piccolantonio, Synenberg

To enact section 125.62 of the Revised Code to establish the Ohio-Made Medicine Manufacturing Program and to name this act the Ohio-Made Prescription Drug Act.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That section 125.62 of the Revised Code be enacted to read as follows:

Sec. 125.62. (A) As used in this section:

(1) "Generically equivalent drug" has the same meaning as in section 3715.01 of the Revised Code.

(2) "Health plan issuer" has the same meaning as in section 3922.01 of the Revised Code.

(3) "Hospital" means a facility or institution licensed under Chapter 3722. of the Revised Code.

(4) "Pharmacy benefit manager" has the same meaning as in section 3959.01 of the Revised Code.

(5) "State retirement systems" has the same meaning as in section 171.01 of the Revised Code.

(B) Not later than sixty days after the effective date of this section, the department of administrative services, department of health, and department of development shall jointly establish the Ohio-made medicine manufacturing program. The program shall engage in efforts to make essential drugs more affordable, including efforts to support the distribution, manufacture, purchase, or sale of generically equivalent drugs.

The program shall be established within the department of administrative services, with the departments of health and development to provide the program with expertise in the areas of public health, medical care, economic development, or business support and with additional staffing.

(C) As soon as practicable after the program's establishment, the directors of administrative services, health, and development shall jointly appoint an administrator for the program. Subject to available funds, the administrator may hire staff to assist in the program's management and oversight.

(1) Subject to division (D) of this section, and in consultation with appropriate entities if necessary, the administrator shall enter into partnerships for the following purposes:

(a) To increase competition, lower prices, and address shortages in the market for generically equivalent drugs;

(b) To reduce drug costs for public and private purchasers, taxpayers, and consumers;

(c) To increase access to affordable drugs for patients across this state;

(d) To promote and advance the distribution or manufacture of generically equivalent drugs in this state, when viable and

not in conflict with any purpose described in divisions (C)(1)(a) to (c) of this section.

(2) The partnerships described in division (C)(1) of this section may include contractual agreements with payers, state agencies, group purchasing organizations, nonprofit corporations, or other third-party entities for the distribution, manufacture, purchase, or sale of generically equivalent drugs.

(3) Subject to division (E) of this section, the administrator shall develop a list of the generically equivalent drugs to be distributed, manufactured, purchased, or sold through partnerships entered into under this section.

(4) Subject to division (F) of this section, the administrator shall set prices for generically equivalent drugs purchased or sold through partnerships entered into under this section.

(D) Before a partnership is entered into for the distribution, manufacture, purchase, or sale of generically equivalent drugs, all of the following apply:

(1) The administrator shall examine relevant legal, market, policy, and regulatory factors in an effort to determine if viable pathways exist for partnerships for the distribution, manufacture, purchase, or sale of generically equivalent drugs.

(2) In consultation with appropriate entities, the administrator shall determine minimum thresholds for purchasing a partnering entity's expected volume of a targeted drug over a multi-year period.

(3) A partnership shall be entered into only if the administrator and partnering entity do both of the following:

(a) Reasonably determine that the partnership will satisfy, rather than deter, the purposes described in division (C)(1) of this section;

(b) Maintain records demonstrating the administrator's and entity's reasonable determination.

(4) A partnering entity shall be registered with the United States food and drug administration as an owner or operator of a drug manufacturing establishment.

(E) Not later than nine months after the effective date of this section, the administrator shall develop the list of the generically equivalent drugs described in division (C)(3) of this section. In developing the list, all of the following apply:

(1) The administrator shall consider the generically equivalent drugs most likely to lower drug costs for patients, increase competition and address shortages in the prescription drug market, improve public health, or reduce the cost of prescription drugs for public and private purchasers.

(2) The administrator shall prioritize those prescribed to treat chronic and high-cost health conditions, in particular, those available by mail order.

(3) The administrator shall consult with appropriate entities, including all of the following, to assist in developing the list and determining the volume of each generically equivalent drugs that can be distributed, manufactured, purchased, or sold over a multi-year period in order to support a market for lower-cost drugs:

(a) The departments of administrative services, aging, health, insurance, medicaid, rehabilitation and correction, and

youth services, the industrial commission, and the bureau of workers' compensation or any entities acting on their behalf to purchase drugs;

(b) The state retirement systems or any entities acting on their behalf to purchase drugs;

(c) Health plan issuers;

(d) Hospitals;

(e) Pharmacy benefit managers;

(f) The state board of pharmacy.

(F) In the case of a partnership that involves the administrator setting the price of a generically equivalent drug, both of the following apply:

(1) The administrator shall consider the following, if applicable, when setting the drug's price:

(a) United States food and drug administration user fees;

(b) Abbreviated new drug application acquisition costs amortized over a five-year period;

(c) Any rebates mandated by federal or state law;

(d) Total contracting and production costs for the drug, including a reasonable amount for the drug manufacturer's administrative, operating, and rate-of-return expenses;

(e) Research and development costs attributed to the drug over a five-year period;

(f) Other initial start-up costs amortized over a five-year period.

(2) Under the program, each drug shall be made available

to health care providers, patients, and purchasers at a transparent price and without rebates, other than rebates required by federal law, with priority for in-state providers, patients, and purchasers, should supply levels necessitate priority purchasing. No person or governmental entity shall be required to purchase drugs from the administrator or a partnering entity.

(G)(1) Not later than the first day of the first September that occurs on or after the date that is six months after the effective date of this section and every first day of September thereafter, the administrator shall prepare and submit to the governor and general assembly a report that does all of the following:

(a) Describes the status of the drugs that are the program's focus;

(b) Analyzes the program's impact on competition, drug availability, and drug costs, in particular generically equivalent drug costs for public and private purchasers;

(c) Recommends and assesses improvements to the program, including those to ensure that the purposes described in division (C)(1) of this section are met.

(2) The first report required by this section shall describe in detail the plan for administering, managing, and overseeing the program, including the following:

(a) An assessment of measures to feasibly achieve program purposes;

(b) An analysis of governance structure options for manufacturing functions, including chartering a private organization, public-private partnership, or public board of

directors.

(3) As generically equivalent drugs are listed as described in division (E) of this section, each subsequent report shall also include all of the information required in division (G)(2) of this section.

(H) To protect proprietary and confidential information regarding manufacturer or distribution costs and drug pricing, utilization, and rebates, any information or document that the program or its administrator and staff obtain in administering this section shall not be considered a public record under section 149.43 of the Revised Code.

Section 2. This act shall be known as the Ohio-Made Prescription Drug Act.