SUBSTITUTE FOR HOUSE BILL NO. 4890

A bill to amend 1984 PA 270, entitled "Michigan strategic fund act,"

(MCL 125.2001 to 125.2094) by adding chapter 8F.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

CHAPTER 8F

Sec. 90t. (1) The legislature finds tha

Sec. 90t. (1) The legislature finds that the cost of insulin medications, including rapid-acting and long-acting insulins, has risen to an unacceptable level, and that this increase has resulted in reduced access to life-sustaining medications for many residents of this state with diabetes.

- (2) It is the intent of the legislature that the insulin production program will do all of the following:
- (a) Create a strategic partnership between this state and a



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- 1 private sector contractor for the production and distribution of 2 insulin medications in this state.
- 3 (b) Foster the creation of skilled biopharmaceutical4 manufacturing jobs in this state.
- 5 (c) Ensure that residents of this state have access to
 6 affordable generic or biosimilar forms of long-acting insulin and
 7 other insulin medications.
- 8 (3) The legislature finds that the insulin production program
 9 is a public purpose and of paramount concern in the interest of the
 10 health, safety, and general welfare of the residents of this state.
 11 It is the intent of the legislature that the economic benefits
- 12 resulting from this chapter occur substantially within this state.
- 13 Sec. 90u. As used in this chapter:
- 14 (a) "CFIUS" means the Committee on Foreign Investment in the 15 United States.
- 16 (b) "CFIUS clearance" means either of the following as 17 reflected by a written notice from CFIUS:
- 18 (i) CFIUS has determined that the transaction is not a covered 19 transaction or covered real estate transaction subject to review 20 under the DPA.
- (ii) CFIUS has completed its review or investigation of the transaction, determined that there are no unresolved national security concerns with respect to the transaction, and advised that all action under the DPA has concluded with respect to the transaction.
- 26 (c) "Covered real estate transaction" means that term as 27 defined in 31 CFR 802.212.
- 28 (d) "Covered transaction" means that term as defined in 31 CFR 29 800.213.



- 1 (e) "DPA" means section 721 of the defense production act of 2 1950, 50 USC 4565, and the implementing regulations at 31 CFR parts
- 3 800 to 802.
- 4 (f) "Foreign person" means that term as defined in 31 CFR 800.224 or 802.221.
- 6 (g) "Insulin distribution facility" means 1 or more facilities 7 or operations that store and distribute insulin for medical use.
- 8 (h) "Insulin facilities" means facilities that include both an 9 insulin production facility and an insulin distribution facility.
- 10 (i) "Insulin production facility" means 1 or more facilities
 11 or operations that manufacture insulin for medical use.
- 12 (j) "Insulin production fund" means the insulin production 13 fund created in section 90w.
- 14 (k) "Insulin production program" means the insulin production
 15 program created in section 90v.
- 16 (*l*) "Pharmacy benefit manager" means that term as defined in 17 section 7 of the pharmacy benefit manager licensure and regulation 18 act, 2022 PA 11, MCL 550.817.
 - (m) "Private sector contractor" means an entity in the private sector that develops generic or biosimilar insulin for medical use.
 - (n) "Temporary private sector contractor" means a private sector contractor with an insulin product that has already received approval from the United States Food and Drug Administration.
 - Sec. 90v. (1) The fund shall create and operate the insulin production program to partner with a private sector contractor to establish insulin facilities in this state that manufacture and distribute, at a minimum, long-acting insulin. Under the insulin production program, the private sector contractor selected as a partner shall own the real property where the insulin facilities

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- 1 are located and operate and maintain the insulin facilities.
- 2 (2) To select a private sector contractor as a partner for the
- 3 insulin production program as described in subsection (1), the
- 4 fund, in consultation with the department of health and human
- 5 services, shall issue a request for proposal and receive bids from
- 6 private sector contractors. In evaluating the proposals submitted
- 7 under this subsection, the fund and the department of health and
- 8 human services shall give priority to a private sector contractor
- 9 that meets the following requirements:
- 10 (a) Has an insulin product that has already received or is in
- 11 the process of receiving approval by the United States Food and
- 12 Drug Administration.
- 13 (b) Proposes to manufacture rapid-acting insulin in addition
- 14 to long-acting insulin.
- 15 (c) Is able to establish the insulin facilities in this state
- 16 in an expedient time frame.
- 17 (3) Subject to the requirement in subsection (1) that the
- 18 private sector contractor own the real property where the insulin
- 19 facilities are located, all of the following apply:
- 20 (a) The fund may provide a grant of not more than
- \$50,000,000.00 to the private sector contractor selected under this
- 22 section for the construction of new insulin facilities or
- 23 renovation of existing facilities into insulin facilities.
- 24 (b) The insulin facilities must be located at a location
- 25 jointly determined by the fund, in consultation with the department
- 26 of health and human services, and the private sector contractor.
- 27 (c) The insulin distribution facility must be constructed or
- 28 renovated before the insulin production facility is constructed or
- 29 renovated.



- (4) The fund and the department of health and human services 1 shall not select a private sector contractor under this section 3 unless the private sector contractor does all of the following:
- 4 (a) Demonstrates that it has a development plan in place to bring to market the insulin products, including rapid-acting and 5 6 long-acting insulins, proposed for manufacture in both vials and 7 prefilled pens.
 - (b) Demonstrates it has sufficient available funding to implement the development plan described in subdivision (a). The sufficient available funding may include the amount of any grant provided under subsection (3).
- (c) Obtains any necessary license under part 177 of the public 12 health code, 1978 PA 368, MCL 333.17701 to 333.17780. 13
- 14 (d) Agrees to contract with this state in accordance with 15 subsection (5).
 - (5) Subject to subsection (6), the fund, in consultation with the department of health and human services, shall enter into a written agreement with the private sector contractor selected under this section that includes in a clear and concise manner all of the terms and conditions related to the partnership, as determined by the fund, in consultation with the department of health and human services, including, but not limited to, all of the following:
 - (a) The amount of any grant award under subsection (3).
 - (b) The location of the insulin facilities, a provision that the real property where the insulin facilities are located is owned by the private sector contractor, and, if applicable, a requirement that this state execute all necessary documents to vest ownership of the real property in the private sector contractor.
 - (c) The types of insulin to be produced.

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- 1 (d) Applicable milestones.
- 2 (e) A requirement that the private sector contractor make 3 insulin available at a transparent price, including a description 4 of any price caps.
- 5 (f) A requirement that the private sector contractor sell the 6 insulin without rebates to a pharmacy benefit manager and a 7 provision that, if the private sector contractor cannot meet this 8 requirement, this state may subcontract with another entity to 9 distribute the insulin if that entity is able to distribute the 10 insulin safely and comply with the terms of the written agreement.
 - (g) A requirement that the private sector contractor make insulin available in such a manner as to facilitate insulin availability to and benefit the residents of this state, including any applicable distribution requirements.
- 15 (h) A requirement that the private sector contractor make
 16 insulin available for purchase in this state, including a
 17 description of any minimum quantities to be produced for purchase
 18 in this state.
- (i) A requirement that the private sector contractor assume all liability for, and indemnify this state against, any and all claims arising from the manufacturing, marketing, distribution, sale, or use of the insulin.
 - (j) A repayment provision that requires the private sector contractor to repay all or a portion of the grant award due to a breach of the written agreement under this subsection, a failure to meet applicable milestones, or another misuse of the money, unless both of the following conditions are met:
- 28 (i) The breach, failure, or other misuse is caused by
 29 circumstances beyond the control of the private sector contractor,

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- 1 including, but not limited to, acts of God, wars, strikes, riots,
- 2 catastrophes, acts of government, or other conditions beyond the
- 3 control of the private sector contractor.
- 4 (ii) The private sector contractor did not have reason to know
- 5 of the circumstances described in subparagraph (i) when the written
- 6 agreement was executed.
- 7 (k) The term of the written agreement, which must not be less
- 8 than 15 years.
- 9 (1) Periodic reporting requirements to ensure compliance with
- 10 the agreement under this subsection and facilitate the fund's
- 11 report under section 9.
- 12 (6) If the private sector contractor selected by the fund is a
- 13 foreign person, the fund shall not enter into a written agreement
- 14 under subsection (5) unless the fund files a declaration or notice
- 15 of the transaction with CFIUS under the DPA and receives CFIUS
- 16 clearance.
- 17 Sec. 90w. (1) The insulin production fund is created in the
- 18 state treasury.
- 19 (2) The state treasurer shall deposit money and other assets
- 20 received from any source in the insulin production fund. The state
- 21 treasurer shall direct the investment of money in the insulin
- 22 production fund and credit interest and earnings from the
- 23 investments to the insulin production fund.
- 24 (3) Money in the insulin production fund at the close of the
- 25 fiscal year remains in the insulin production fund and does not
- 26 lapse to the general fund.
- 27 (4) The fund is the administrator of the insulin production
- 28 fund for audits of the insulin production fund.
- 29 (5) The fund shall expend money from the insulin production

- 1 fund, on appropriation, only for 1 or more of the following
 2 purposes:
- 3 (a) Administering the insulin production program.
- 4 (b) Awarding a grant to a private sector contractor under the insulin production program.
 - (c) Purchasing insulin from a private sector contractor or temporary private sector contractor.
- 8 (d) Taking any other action that is necessary to achieve the 9 purposes of the insulin production program.
- Sec. 90x. (1) Until the insulin production facility is
 completed, the fund shall annually issue a request for proposal and
 receive bids from temporary private sector contractors to sell
 generic or biosimilar insulin for medical use in this state,
 subject to both of the following requirements:
- 15 (a) The temporary private sector contractor must make insulin 16 available for purchase in this state.
- 17 (b) The temporary private sector contractor must sell the 18 insulin without rebates to a pharmacy benefit manager.
 - (2) The fund shall enter into a written agreement with a temporary private sector contractor selected under this section that includes the requirements described in subsection (1), the quantities of insulin to be provided, the purchase price of the insulin, the term of the agreement, which must not exceed 1 year, and any other terms the fund considers necessary.
 - (3) The fund shall not contract for insulin under this section unless the insulin distribution facility is completed or the fund has another state facility that can be used for the storage and distribution of the insulin.
- 29 Enacting section 1. This amendatory act does not take effect

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- 1 unless House Bill No. 5519 of the 102nd Legislature is enacted into
- **2** law.

