

Legislative Analysis



INSULIN PRODUCTION PROGRAM

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<http://www.house.mi.gov/hfa>

House Bill 4890 as introduced
Sponsor: Rep. Curt S. VanderWall

Analysis available at
<http://www.legislature.mi.gov>

House Bill 5519 as introduced
Sponsor: Rep. Jennifer A. Conlin

Committee: Health Policy
Revised 2-28-24

SUMMARY:

Taken together, House Bills 4890 and 5519 would amend the Michigan Strategic Fund Act to require the Michigan Strategic Fund (MSF) to create and operate a program to make and distribute insulin in partnership with a private sector entity. The bills would provide requirements for contractors selected to be partners under the program, prescribe provisions to be included in contractor agreements, allow MSF to make grants related to the program, create the Insulin Production Fund, provide for a temporary insulin distribution program while a production facility is being built, and require MSF to include information about the program in its annual report.

House Bill 4890 would require MSF to create and operate an insulin production program under which it would partner with a *private sector contractor* to establish facilities in Michigan that make and distribute (at a minimum) long-acting insulin. Under the program, the state would own the property where the insulin production and distribution facilities are located and the contractor would operate and maintain the facilities. The location of the facilities would have to be jointly determined by MSF and the contractor, and the insulin storage and distribution facility would have to be built or renovated before the insulin production facility is. MSF could provide a grant to the contractor of up to \$150.0 million for the renovation of existing facilities into insulin production and distribution facilities or for the construction of new facilities.

Private sector contractor would mean an entity in the private sector that develops generic or biosimilar insulin for medical use.

Contractor selection

To select a partner for the program, MSF would have to issue a request for proposal and receive bids from private sector contractors. Priority would have to be given to a contractor that meets the following requirements:

- It has an insulin product that has already received or is in the process of receiving approval by the United States Food and Drug Administration (FDA).
- It proposes to manufacture rapid-acting insulin in addition to long-acting insulin.
- It is able to establish the insulin facilities in an expedient time frame.

To be eligible for selection, a private sector contractor would have to do all of the following:

- Demonstrate that it has a development plan in place to bring to market the insulin products proposed for manufacture in both vials and prefilled pens.

- Demonstrate that it has sufficient available funding to implement its development plan. (This could include any grant provided by MSF as described above.)
- Obtain any necessary license under Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code.
- Agree to contract with the state as described below.

Written agreement

MSF would have to enter into a written agreement with the selected private sector contractor. However, if the selected contractor is a *foreign person*, MSF would have to file a declaration or notice of the transaction with the Committee on Foreign Investment in the United States (CFIUS) under the *DPA* and receive *CFIUS clearance* before it could enter into an agreement. The agreement would have to clearly and concisely include all of the terms and conditions related to the partnership, as determined by MSF, including at least all of the following:

- The amount of any grant award as described above.
- The location of the insulin facilities.
- A provision that the real property where the insulin facilities are located is owned by the state and, if applicable, a requirement that the contractor execute all necessary documents to vest ownership of the property in the state.
- The types of insulin to be produced.
- Applicable milestones.
- The following requirements:
 - That the contractor make insulin available at a transparent price (with a description of any price caps).
 - That the contractor sell the insulin without rebates to a *pharmacy benefit manager* (with a provision that, if the contractor cannot meet this requirement, the state could distribute the insulin on behalf of the contractor).
 - That the contractor facilitate insulin availability to the residents of Michigan (with any applicable distribution requirements).
 - That the contractor make insulin branded with State of Michigan labels available for purchase by the state (with a description of any minimum quantities to be produced for state purchase).
 - That the contractor repay all or part of a grant award due to a breach of the written agreement, failure to meet applicable milestones, or another misuse of the money—unless it was caused by circumstances beyond the contractor’s control (such as acts of God, wars, strikes, riots, catastrophes, or acts of government) and the contractor did not have reason to know of those circumstances when the agreement was executed.
- The term of the written agreement (which would have to be at least 15 years).
- Periodic reporting requirements to ensure compliance with the agreement and facilitate the MSF report described below.

DPA would mean section 721 of the federal Defense Production Act of 1950, 50 USC 4565, and the implementing regulations at 31 CFR parts 800 to 802.¹

¹ 31 CFR Part 800: <https://www.ecfr.gov/current/title-31/subtitle-B/chapter-VIII/part-800>
 31 CFR Part 802: <https://www.ecfr.gov/current/title-31/subtitle-B/chapter-VIII/part-802>
 50 USC 4565: <https://www.law.cornell.edu/uscode/text/50/4565>

Foreign person would mean that term as defined in 31 CFR 800.224 or 802.221.²

CFIUS clearance would mean either of the following as reflected by a written notice from CFIUS:

- CFIUS has determined that the transaction is not a covered transaction or covered real estate transaction subject to review under the DPA.
- 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.

Covered real estate transaction would mean that term as defined in 31 CFR 802.212.³

Covered transaction would mean that term as defined in 31 CFR 800.213.⁴

Pharmacy benefit manager means⁵ an entity (except for the Department of Health and Human Services, a carrier, or an insurer) that contracts with a pharmacy or a pharmacy services administration organization on behalf of a health plan or carrier to provide pharmacy health services to individuals covered by the health plan or carrier or administration that includes any of the following:

- Contracting directly or indirectly with pharmacies to provide drugs to enrollees or other covered persons.
- Administering a drug benefit.
- Processing or paying pharmacy claims.
- Creating or updating drug formularies.
- Making or assisting in making prior authorization determinations on drugs.
- Administering rebates on drugs.
- Establishing a pharmacy network.

Temporary contractors

Until the insulin production facility is completed, MSF would have to annually issue a request for proposal and receive bids from **temporary private sector contractors** to sell generic or biosimilar insulin for medical use to the state, subject to both of the following requirements:

- The temporary private sector contractor must make insulin branded with State of Michigan labels available for purchase by the state.
- The temporary private sector contractor must sell the insulin without rebates to a pharmacy benefit manager.

Temporary private sector contractor would mean an entity in the private sector that develops generic or biosimilar insulin for medical use and that has an insulin product that has already received approval from the FDA.

² <https://www.ecfr.gov/current/title-31/section-800.224> or <https://www.ecfr.gov/current/title-31/section-802.221>

³ <https://www.ecfr.gov/current/title-31/section-802.212>

⁴ <https://www.ecfr.gov/current/title-31/section-800.213>

⁵ Defined in the Pharmacy Benefit Manager Licensure and Regulation Act: <http://legislature.mi.gov/doc.aspx?mcl-550-817>. Sections 5 to 9 of that act define other terms used in this definition, such as *carrier*, *insurer*, and *pharmacy services administration organization*. See <http://legislature.mi.gov/doc.aspx?mcl-Act-11-of-2022>

MSF would have to enter into a written agreement with a temporary private sector contractor selected under these provisions that includes the requirements described above, the quantities of insulin to be provided, the purchase price of the insulin, the term of the agreement (which could be up to one year), and any other terms MSF considers necessary.

However, MSF could not purchase insulin under these provisions unless the insulin distribution facility is completed or MSF has another state facility that can be used for the storage and distribution of the insulin.

Insulin Production Fund

The bill would create the Insulin Production Fund in the state treasury and require the state treasurer to deposit assets received from any source in the fund, direct the investment of money in the fund, and credit to the fund interest and earnings from those investments. Money in the fund at the close of the fiscal year would remain in the fund and not lapse to the general fund. MSF would be the fund administrator for audit purposes. MSF could expend money from the fund, upon appropriation, only for one or more of the following purposes:

- Administering the insulin production program.
- Awarding a grant to a contractor under the program.
- Purchasing insulin from a contractor or temporary contractor.
- Taking any other action necessary to achieve the purposes of the program.

Finally, the bill as introduced includes provisions that are identical to those in HB 5519, below.

MCL 125.2009 and proposed MCL 125.2090t et seq.

House Bill 5519 would require MSF to include the insulin production program in the annual report MSF must transmit by April 10 of each year, describing its activities in the immediately preceding state fiscal year, to each member of the legislature, the governor, the clerk of the House of Representatives, the secretary of the Senate, and the Senate and House Fiscal Agencies. The bill would require this report to include the following information about the insulin production program:

- The name of the private sector contractor selected as a partner for the program.
- The amount of any grant award to the contractor.
- The location and status of the insulin facilities.
- The types and amounts of insulin produced.
- The retail price of the insulin produced.
- The percentage of insulin produced that was sold to the state.
- The percentage of insulin produced that was sold in Michigan.
- The names of any temporary contractors selected to provide insulin to the state and the amount of insulin purchased by the state from each temporary contractor.

The bill cannot take effect unless HB 4890 and another bill identified by its request number are also enacted.

MCL 125.2009

FISCAL IMPACT:

House Bills 4890 and 5519 would have an indeterminate fiscal impact on the state and no fiscal impact on local units of government. As written, HB 4890 would require the Michigan Strategic Fund (MSF) to create and operate an insulin production program and would allow the MSF to provide a grant of up to \$150 million to a private sector contractor. The bill would also establish the Insulin Production Fund. The language regarding the grant is permissive and does not identify a fund source that would be utilized. Furthermore, the language creating the Insulin Production Fund does not specify a revenue stream for the fund. The state would likely incur significant costs for the insulin production program, but the magnitude of those costs is currently indeterminate, and would depend on the specifics of any agreement entered by the MSF and a private sector contractor.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.