



Senate Fiscal Agency
P.O. Box 30036
Lansing, Michigan 48909-7536



Telephone: (517) 373-5383
Fax: (517) 373-1986

Senate Bill 219 (as enacted)
Sponsor: Senator Sylvia Santana
Senate Committee: Health Policy
House Committee: Health Policy

PUBLIC ACT 97 of 2023

Date Completed: 8-25-23

RATIONALE

On May 11, 2023, Federal emergency orders related to the COVID-19 pandemic that authorized pharmacists to administer vaccines without the supervision of a doctor expired. Pharmacists are a common healthcare professional in many communities around Michigan and are often the only such professional that are easily accessible to patients in rural areas. Additionally, pharmacists are well-trained, typically having at least 20 hours of training for administering immunizations to at-risk populations. Some believed that allowing pharmaceutical authority to expire and returning to a system of doctoral supervision may have caused vaccine rates to decline in the State, and so it was suggested that the authority be established in statute.

CONTENT

The bill amended Parts 92 (Immunizations) and 177 (Pharmacy Practice and Drug Control) of the Public Health Code to do the following:

- **Allow a pharmacist to order or administer an immunizing agent without direction of a physician if the pharmacist is administering to an individual three years old or older and is administering an immunizing agent that is approved or emergency ordered by the Food and Drug Administration (FDA).**
- **Allow a pharmacist to order or administer a diagnostic laboratory test if the test is waived by the FDA, does not require the use of specimen collected from specific tools, and is used to screen for specific illnesses.**
- **Prescribe requirements for a pharmacist ordering or administering immunizing agents and diagnostic laboratory tests.**
- **Prescribe requirements for the Michigan Board of Pharmacy (Board) in administrating the content of the bill, including the training program used to train pharmacists.**

The bill took effect July 19, 2023.

Definitions

Under the bill, "health professional" means an individual who is licensed, registered, or otherwise authorized to engage in a health profession under Article 15 (Occupations) of the Public Health Code.

"Immunizing agent" means that term as defined in Section 9201 of the Code: a vaccine, antibody preparation, or other substance used to increase an individual's immunity to a disease or infectious agent.

"Qualified immunizing agent" means an immunizing agent that meets the following requirements:

- Is a vaccine that is recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC).
- Is a vaccine that is approved or authorized for use by the FDA or has been authorized for emergency use by the FDA.

"Qualified laboratory test" means a laboratory test that meets the following requirements:

- The laboratory test is classified as waived by the FDA.
- The laboratory test requires only the use of a specimen collected by a nasal or throat swab or a finger prick.
- The laboratory test is used to detect or screen for COVID-19, influenza, or a respiratory infection.

"Practice of pharmacy" means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness and the maintenance and management of health. The Code specifies certain professional functions associated with the practice of pharmacy, including the interpretation and evaluation of a prescription. Under the bill, the following are also professional functions associated with the practice of pharmacy:

- Ordering and administering qualified immunizing agents in accordance with the bill's provisions.
- Ordering and administering qualified laboratory tests in accordance with the bill's provisions.

Ordering and Administering Immunizing Agents

Part 92 of the Code allows a health care professional other than a physician to administer an immunizing agent if the agent is being administered under the direction of a physician. Under the bill, a pharmacist may order and administer, without acting under the direction of a physician, an immunizing agent to an individual who is three years of age or older. Before ordering or administering an immunization, a pharmacist must do all the following:

- Complete a training program with a course on the administration of vaccines developed by the Board.
- If ordering or administering a vaccine to a person less than 19 years of age and the pharmacy does not participate in the Vaccines for Children Program administered by the CDC, inform the individual that he or she may qualify for the Program and notify the individual of local providers that participate in the Program; this does not apply if a third party covers the cost of the immunization.

In addition to the provisions described above, a pharmacist who administers a qualified immunizing agent must do all the following:

- Comply with rules established by the Board in addition to any other requirement established by law.
- If administering to an individual 20 years of age or older, report the vaccination to the Michigan Care Improvement Registry (MCIR) within 72 hours.

The bill requires the Board to promulgate rules for the bill's implementation, including providing standards for the training program which must be provided by an entity accredited by the Accreditation Council for Pharmacy Education.

The bill specifies that it does not prohibit a pharmacist from ordering or administering an immunizing agent pursuant to Federal law or an emergency order.

The bill deletes the authority of pharmacists to dispense and administer a drug as needed to treat an individual with COVID-19.

Ordering and Administering Qualified Laboratory Tests

Under the bill, a pharmacist may order for or administer to an individual a qualified laboratory test if the qualified laboratory test meets all the following requirements:

- It is classified as waived by the FDA.
- It requires only the use of a specimen collected by a nasal or throat swab or finger prick.
- It is used to detect or screen for COVID-19, influenza, or a respiratory infection.

Before ordering or administering a qualified laboratory test, a pharmacist must complete a training program approved by the Board.

A pharmacist who orders a qualified laboratory test for or administers a test to an individual must advise the individual of the test result and refer the individual to a physician, or another health professional, designated by the individual.

A pharmacist who orders or administers a qualified laboratory test for the purposes of detecting or screening for COVID-19 or influenza may dispense without a prescription a drug to an individual if all the following are met:

- The pharmacist determines the drug is needed to treat an individual for COVID-19 or influenza based on the individual's test result.
- The drug is an antiviral drug and is available at the pharmacy.
- The drug is provided pursuant to protocols established by the CDC or public health guidelines established by the Department of Health and Human Services (DHHS).
- The pharmacist complies with the rules above and any other rules promulgated by the Board.

The Board must promulgate rules for the implementation of the bill, including providing standards for the training program which must be provided by an entity accredited by the Accreditation Council for Pharmacy Education.

The bill specifies that it does not prohibit a pharmacist from doing the following:

- Ordering or administering a lab test other than a qualified lab test as a delegated act under a physician or other health professional.
- Ordering or administering a lab test, including a qualified lab test, pursuant to Federal law or emergency order.
- Dispensing a drug without a prescription pursuant to Federal law or emergency order.

Notice to Consumers About Prescription Drugs

The Code requires a pharmacist to provide certain information to the purchaser of a prescription drug, including the brand name, the strength of the drug, and the quantity

dispensed. Under the bill, if a prescription drug is dispensed pursuant to the bill's provisions, the name of the pharmacist dispensing the prescription drug also must be included.

MCL 333.9204 et al.

PREVIOUS LEGISLATION

(Please note: This section does not provide a comprehensive account of all previous legislative efforts on the relevant subject matter.)

The bill is a reintroduction of House Bill 6469 of the 2021-2022 Legislative Session. Senate Bill 219 is a companion bill to House Bill 4316. House Bill 4316 was referred to the House Committee on Health Policy but received no further action.

BACKGROUND

During the COVID-19 pandemic, the Federal Public Readiness and Emergency Preparedness (PREP) Act gave the Secretary of Health and Human Services the ability to provide immunity from liability to medical practitioners. The Secretary later issued declarations under the PREP Act authorizing licensed pharmacists and qualified pharmacy technicians to administer certain vaccines. This authority extended beyond just the COVID-19 vaccine in Michigan and included all vaccines licensed for use in the United States to adults.¹ This authority expired at the end of the Federal Public Health Emergency on May 11, 2023.²

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Pharmacies are more accessible to the public than conventional doctor's offices. Reportedly, more than 90% of individuals in the United States live within 5 miles of a pharmacy, and 87% of Michigan residents say that it is easy to access pharmacies, ranking their accessibility the highest among healthcare destinations tested.³ Additionally, pharmacies appear to be better at reaching vulnerable populations than conventional doctor's offices. For example, 70% of pharmacy sites during the COVID-19 pandemic were in areas with moderate to severe social vulnerability, suggesting a particularly rapid increase in vaccinations among poor and racial-minority communities.⁴ Pharmacies have more locations and longer operating hours for vaccination than physician practices in low-income communities.⁵ Finally, vaccine services at pharmacies were essential to resolving the COVID-19 pandemic because Michigan communities trust pharmacies. In 2021, 80% of Michigan residents got their vaccines at a pharmacy.⁶ Over 40% of individuals vaccinated at pharmacies were a member of a minority racial/ethnic group.⁷ Allowing pharmacists to administer vaccinations and laboratory tests will further the positive impact pharmacies have on public health.

Legislative Analyst: Alex Krabill

¹ National Alliance of State Pharmacy Associations, *Pharmacist Immunization Authority Report – April 2023 Update*, 2023.

² United States Department of Health and Human Services, *Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap*, 2023.

³ *Id.*

⁴ White House, *FACT SHEET: Biden Announces Historic \$10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence In Hardest-Hit and Highest-Risk Communities*, March 2021.

⁵ Popovian, Robert et al., *Accessibility of adult immunizations in pharmacies compared to physician offices in low-income communities*, March 2022.

⁶ IQVIA Institute, *Trends in Vaccine Administration in the United States*, January 2023.

⁷ United States Governmental Accountability Office, *Federal Efforts to Provide Vaccines to Racial and Ethnic Groups*, February 2022.

FISCAL IMPACT

The bill will have no fiscal impact on State or local government.

Fiscal Analyst: Jonah Houtz

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.