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BILL ANALYSIS

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Senate Bill 219 (Substitute S-4 as passed by the Senate)
Sponsor: Senator Sylvia Santana
Committee: Health Policy

Date Completed: 5-18-23

INTRODUCTION

The bill would amend the Public Health Code to allow pharmacists to order and administer immunizing agents and qualified laboratory tests without the supervision of a physician provided they follow certain criteria. In addition, the bill prescribes requirements for the training of pharmacists, the eligibility of immunizing agents and qualified laboratory tests, and the administration of the bill's provisions through the Michigan Board of Pharmacy (Board).

BRIEF 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 and accessible medical professional in many communities around Michigan. Some believe that allowing this authority to expire and returning to a system of doctoral supervision would cause vaccine rates to decline in Michigan communities, and so it has been suggested that the authority be established in statute.

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.

FISCAL IMPACT

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

MCL 333.9204 et al.

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CONTENT

The bill would amend 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 were administering to an individual three years old or older and was administering an immunizing agent that was 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 were waived by the FDA, did not require the use of specimen collected from specific tools, and was used to screen for specific illnesses.**
- Prescribe requirements for a pharmacist ordering or administering immunizing agents and diagnostic laboratory tests.**
- Prescribe requirements for the Board in administering the content of the bill, including the training program used to train pharmacists.**

Definitions

"Health professional" would mean 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" would mean 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" would mean 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" would mean 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 also would be 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 could order and administer, without acting under the direction of a physician, an immunizing agent to an individual who was three years of age or older.

Before ordering or administering an immunization, a pharmacist would have to 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 did not participate in the Vaccines for Children Program administered by the CDC, inform the individual that he or she could qualify for the Program and notify the individual of local providers that participate in the Program; this would not apply if a third-party covered the cost of the immunization.

In addition to the provisions described above, a pharmacist who administered a qualified immunizing agent would have to 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 21 years of age or older, report the vaccination to the Michigan Care Improvement Registry within 72 hours.

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

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

The bill would delete 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 could order for or administer to an individual a qualified laboratory test if the qualified laboratory test met all the following requirements:

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

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

A pharmacist who ordered a qualified laboratory test for or administered a test to an individual would have to 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 ordered or administered a qualified laboratory test for the purposes of detecting or screening COVID-19 or influenza could dispense without a prescription a drug to an individual if all the following were met:

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

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

The bill specifies that it would 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 were dispensed pursuant to the bill's provisions, the name of the pharmacist dispensing the prescription drug also would have to be included.

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

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.

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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.