



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

MARYLAND BOARD OF PHARMACY

2024 SESSION POSITION PAPER

BILL NO.: SB 18 – Health Occupations – Pharmacists – Administration of Vaccines
COMMITTEE: Finance
POSITION: Letter of Support with Amendments

TITLE: Health Occupations – Pharmacists – Administration of Vaccines

POSITION & RATIONALE:

The Maryland Board of Pharmacy (Board) submits this letter of support with amendments for SB 18 – Health Occupations – Pharmacists – Administration of Vaccines (SB 18).

current statutory authority to administer – Md. Code Ann., Health Occ. § 12-508

Vaccine	Age Restriction	Is a prescription required?	Is ImmuNet reporting required?
Influenza	9 – adult.	No.	Yes.
Those listed in the Centers for Disease Control and Prevention’s (CDC) recommended immunization schedule ¹	11 – 18.	Yes. ²	Yes.
Those listed in the CDC’s recommended immunization schedule ³	Adult.	No. ²	Yes.
Those recommended in the CDC’s Health Information for International Travel ⁴	Adult.	No. ²	Yes.

¹ CDC, website, accessed February 7, 2024, <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

² A pharmacist who administers a vaccine in accordance with a prescription is required to document one effort to inform the prescribing practitioner. If the prescribing practitioner is not the patient’s primary care provider, a pharmacist is also required to document one effort to inform the patient’s primary care provider.

³ CDC, website, accessed February 7, 2024, <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>.

⁴ CDC, website, accessed February 7, 2024, <https://wwwnc.cdc.gov/travel>.

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current statutory registration and training requirements – Md. Code Ann., Health Occ. § 12-508

Prior to administering a vaccine, a pharmacist is required to submit a registration form to the Board. On the form, a pharmacist must document (1) proof of completion of a Board-approved course⁵ that includes instruction in the guidelines and recommendations of the CDC regarding vaccinations, and (2) certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

current regulatory requirements to administer a vaccine – COMAR 10.34.32

A pharmacist must complete **4 hours of continuing education credit** per renewal period to maintain the ability to administer a vaccine.

A pharmacist must provide a patient with a **vaccine information statement** issued by the CDC.

A pharmacist must obtain signed **informed consent** from a patient, or the patient's custodial parent, prior to administering a vaccine.

A pharmacist must **observe a patient** for a period of at least 15 minutes after administering a vaccine to detect any adverse effects, including syncope.

A pharmacist must **maintain records** regarding a vaccination for a minimum of 5 years.

A pharmacist must maintain a **written protocol** for any vaccine the pharmacist administers.

⁵ Board-approved programs cover, at a minimum, responses to an emergency situation, administration technique (intramuscular, subcutaneous, and intranasal), record-keeping, and ACIP and CDC guidelines for vaccines. COMAR 10.34.32.04.

expiring federal authority – PREP Act

Authorization for a pharmacist to order and administer any vaccine approved or authorized by the Food and Drug Administration (FDA) that the Advisory Council on Immunization Practices (ACIP) recommends to patients aged 3 – 18.⁶

The authorization is dependent on completion of a training program, possession of a CPR certificate, completion of continuing education hours, maintenance of appropriate records, compliance with reporting requirements, compliance with notification requirements, and receipt of informed consent.

- Completing a 20-hour training program that has received approval from the Accreditation Council for Pharmacy Education (ACPE) which provides instruction on:
 - hands-on injection technique,
 - clinical evaluation of indications and contraindications of vaccines, and
 - the recognition and treatment of emergency reactions to vaccines.
- Maintaining a current certificate in basic cardiopulmonary resuscitation.
- Certifying 2 hours of ACPE-approved continuing education credit per renewal cycle.
- Informing the primary care provider of a patient, when available.
- Reporting vaccine administration to ImmuNet.
- Informing a minor patient and the adult caregiver of a minor patient of the importance of a well-child visit with a pediatrician.
- Referring a patient to a higher level of care as appropriate.

⁶ Third Amendment to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52138 (Aug. 24, 2020) (amending the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19).

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responses to concerns expressed by stakeholders and citizens

signed consent – required

Prior to administering a vaccine, a pharmacist shall obtain a signed consent form from the patient or custodial parent. COMAR 10.34.32.03. Pharmacists are not authorized to administer a vaccine without obtaining consent.

vaccine information statement

A pharmacist is required to provide a vaccine information statement produced by the CDC that explains both the benefits and risks of a specific vaccine to the vaccine recipient, their parent, or their legal guardian. COMAR 10.34.32.02, .06. Pharmacists provide patients with the information necessary to make an informed decision regarding their healthcare.

Vaccines for Children – voluntary participation

Participation in the Vaccines for Children Program (VFC) is voluntary for all eligible providers. A pharmacist may enroll in the VFC program if state law grants them the authority to administer vaccines by prescription, vaccine protocol, or prescribing authority.⁷ SB 18 increases the number of eligible providers who may participate in the VFC program; therefore, more children may benefit from the VFC program.

designated spaces – not necessarily required for safe administration

As stated in the Third Amendment to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (Third Amendment):

Administering vaccinations to children age three and older is less complicated and requires less “training and resources than administering vaccinations to younger children. That is because ACIP generally recommends administering intramuscular injections in the deltoid muscle for individuals age three and older. For individuals less than three years of age, ACIP generally recommends administering intramuscular injections in the anterolateral aspect of the thigh muscle. Administering injections in the thigh muscle often presents additional complexities and requires additional training and resources including additional personnel to safely position the child while another

⁷ CDC, website, accessed February 7, 2024, <https://www.cdc.gov/vaccines/programs/vfc/downloads/operations-guide-508.pdf>.

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healthcare professional injects the vaccine.⁶

notice – well-child visits

An administering pharmacist is required to inform each minor vaccination patient and the minor vaccination patient's adult caregiver who is accompanying the minor of the importance of well-child visits with a pediatric primary care provider. Md. Code Ann., Health Occ. § 12-508.

appropriate referral – pediatrician

An administering pharmacist is required to refer a minor vaccination patient and the minor vaccination patient's adult caregiver who is accompanying the minor to a pediatric primary care provider when appropriate. Md. Code Ann., Health Occ. § 12-508. A pharmacist who notices a potential health care issue while screening a minor patient for indications, precautions, contraindications, and allergies is well-situated to refer the minor patient and the minor patient's accompanying legal guardian to a pediatrician for appropriate care. A recommendation to obtain additional care and a referral to a pediatrician may alert the minor patient and the minor patient's accompanying legal guardian of the seriousness of certain symptoms and behaviors. A referral from a pharmacist may increase the likelihood that symptomatic lapsed pediatric patients will resume annual well-child visits.

bill position – support with amendments

SB 18 permits licensed pharmacists to continue the life-saving work they have been successfully performing since the Secretary of the Department of Health and Human Services published the Third Amendment on August 19, 2020. The Third Amendment authorized Maryland-licensed pharmacists to order and administer any FDA-approved or FDA-authorized vaccine that the ACIP recommended to persons ages three through eighteen, COVID-19 vaccines, and COVID-19 tests.

The impact of pharmacist administration of vaccines has been documented in Health Occupations – Pharmacists – Administration of Children's Vaccines – Study and Temporary Authority⁸. The Maryland Department of Health stated:

Given the overall benefit of illness prevention, the documentation that vaccinations are one of the most effective public health tools available, the recognition that lack of easy

⁸ Study required by HB 1040/SB 736 (Chapters 792 and 793 of the Acts of 2021).

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access to preventative services like vaccinations increases health inequities, and the demonstration that Maryland pharmacists can effectively vaccinate children, MDH strongly recommends making permanent the authority for pharmacists to order and administer CDC recommended vaccinations to children ages 3-18.⁹

The Board concurs with the recommendations put forth in the report, and urges the committee to submit a favorable report for SB 18.

SB 18 will increase the number of qualified healthcare professionals who can administer vaccines to children and adults, and thus make vaccines more accessible. This accessibility is imperative to the goal of public health — promoting and improving the health and safety of all Marylanders through disease prevention, access to care, quality management, and community engagement.

It is important to note that receiving a vaccine from a pharmacist is merely an option for a patient, not a substitution for an annual visit or routine screenings. A patient presented with multiple convenient options to obtain preventative care is more likely to obtain such care. Pharmacists have strong relationships with medical providers and hospitals, and refer patients as appropriate. Services provided by a pharmacist complement, but do not compete with, services provided by physicians, nurse practitioners, physician assistants, and pediatricians.

Amendment 1

Proposed language requires a pharmacist to obtain “a current certificate in basic cardiopulmonary resuscitation” prior to administering a vaccine to an individual who is at least five years old, while current language requires the Board to adopt regulations that require a pharmacist to verify certification “in basic cardiopulmonary resuscitation through in-person classroom instruction” for children and adults. *Compare* § 12-508(a)(1)(iii) with § 12-508(b)(2)(ii). As training obtained through “in-person classroom instruction” is more robust than “a current certificate in basic cardiopulmonary resuscitation,” the Board recommends adoption of an amendment designed to remove the conflicting statutory provision.

On page 2, strike lines 17 – 18 beginning with “THE PHARMACIST HAS” and ending with “RESUSCITATION,” and then insert, “THE PHARMACIST IS CERTIFIED IN BASIC

⁹ Health Occupations – Pharmacists – Administration of Children’s Vaccines – Study and Temporary Authority, Page 12.

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CARDIOPULMONARY RESUSCITATION AND OBTAINED THE CERTIFICATION THROUGH IN-PERSON CLASSROOM INSTRUCTION.”

Amendment 2

Proposed language appears to exclude the administration of vaccines to adults from certain statutory requirements. *Compare* § 12-508(a)(1) with § 12-508(a)(2). To ensure a pharmacist adheres to statutorily mandated immunization practices, trainings, certifications, continuing education, record keeping, and notice requirements, the Board recommends adoption of an amendment designed to apply all statutory requirement administration of both adult and child vaccines.

On page 1, line 21, insert “(2) AND” between “PARAGRAPH” and “(3).”

With the proposed amendments, the Board respectfully requests a favorable report on SB 18.

If you would like to discuss this further, please do not hesitate to contact Deena Speights-Napata, MA, Executive Director, at deena.speights-napata@maryland.gov or (410) 764-4753.

Sincerely,



Deena Speights-Napata, MA
Executive Director
Maryland Board of Pharmacy

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