Maryland

Board of Pharmacy

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

Jennifer L. Hardesty, Board President – Deena Speights-Napata, Executive Director

March 14, 2022

The Honorable Shane E. Pendergrass
Chair, House Health and Government Operations Committee
Room 241, House Office Building
Annapolis, MD 21401-1991

RE: HB 1084 – COVID-19 Response Act of 2022 - Letter of Opposition

Dear Chair Pendergrass and Committee Members:

The Maryland Board of Pharmacy (the Board) is submitting this Letter of Opposition for House Bill (HB) 1084 – COVID-19 Response Act of 2022. HB 1084 will amend certain provisions of the Health Occupations Article for Pharmacists and Pharmacies.

HB 1084 will remove the administration of an influenza vaccination from the list of tasks that cannot be delegated by a pharmacist to a pharmacy technician. HB 1084 will also change the definition of "direct supervision" to remove the requirement that a pharmacist be onsite at the pharmacy, and allow a pharmacist to supervise a pharmacy technician via "technological means." Furthermore, HB 1084 will change the requirements to refill an unauthorized prescription, will authorize vaccine orders from a pharmacist, delete the vaccine-specific written protocol requirement, and eliminate the Board's entire vaccine registration program. Lastly, HB 1084 will allow a pharmacist to delegate the administration of a vaccine to a pharmacy technician that has completed certain requirements.

Below, the Board has identified several issues of concern and offered suggestions to amend or modify HB 1084:

1. HB 1084 will expand the tasks that a pharmacist may delegate to a pharmacy technician to include administration of a FDA-approved, ACIP-recommended vaccine. As pharmacy interns and pharmacy technicians have been successfully administering COVID-19 vaccines, as well as FDA-approved, ACIP-recommended vaccines pursuant to PREP Act authorizations, the Board supports the expansion of duties that a pharmacist may delegate to a pharmacy technician. The Board is supportive of HB 1084's requirement that a pharmacy technician complete an ACIP-approved practical training program of at least six hours that includes hands-on injection techniques, and the recognition and treatment of emergency reactions to vaccines. The Board would like to suggest that HB 1084 be **amended** to include a mandatory requirement that a pharmacy intern or pharmacy technician obtain ***a current certificate in basic cardiopulmonary***

resuscitation (CPR) through in-person classroom instruction prior to receiving authorization to administer a vaccine.

2. HB 1084 will eliminate the current definition of "direct supervision" in favor of a much lighter standard that requires a "pharmacist who is readily and immediately available at all times the delegated tasks are being performed; is aware of the delegated tasks being performed; and provides personal assistance, direction, and approval throughout the time the delegated tasks are being performed." Additionally, HB 1084 clarifies that "direct supervision" includes supervision by "technological means." In practice, this will mean a pharmacy stocked with inventory consisting of regulated pharmaceutical drugs and devices, including controlled dangerous substances, could operate without supervision by the responsible licensed pharmacist. Such a wholesale change to the current definition of "direct supervision" is not supported by the Board. A licensed pharmacist charged with responsibility for every medication dispensed, every vaccine administered, every patient counseled, and all other pharmaceutical services provided in a pharmacy. It is the Board's position that such clinical services should only be offered with the responsible healthcare practitioner, i.e., the pharmacist, onsite. Furthermore, an absence of the responsible supervising pharmacist may lead to an increase in pharmacy technician diversion of controlled dangerous substances, such as Oxycontin, Percocet, and Suboxone, which are highly addictive and have significant street value. The Board's current disciplinary docket is replete with examples of pharmacy technicians who have been disciplined by the Board for diverting controlled dangerous substances; these are cases in which a pharmacist was present on the premises. The Board's enforcement actions will undoubtedly increase, and public health and safety may be at unnecessary risk should pharmacies operate without onsite supervision of a pharmacist. Removing the responsible supervising licensed pharmacist from the pharmacy establishment, particularly without any increase in requirements for security, drug auditing, or drug reporting, may create a tempting environment for unsupervised pharmacy technicians who will have ready access to a pharmacy's entire store of inventory. During a time when the opioid epidemic in Maryland is escalating, it is not advisable to allow a pharmacy to operate without the onsite supervision of a responsible licensed pharmacist. The Board is amenable to a **revision** to the "direct supervision" definition that will make an exception for the supervision of ***non-drug handling tasks*** such as prescription data entry, which will permit a pharmacy technician to work remotely at home or other location outside the pharmacy.

3. HB 1084 will make substantial changes to the laws and regulations that govern a pharmacist's ability to refill a prescription that has not been authorized by a patient's health care provider. Currently, a pharmacist may only provide a "14-day supply" of an unauthorized refill to a patient that will experience a "life" altering impact, but for receiving the prescription. HB 1084 proposes allowing a pharmacist to provide a "30-day supply" (extended to a "90-day supply" during a state of emergency declared at the federal or state level) of an unauthorized refill to a patient that will experience any negative impact to their "well-being," but for receiving the prescription. The Board is supportive of providing pharmaceutical services to patients during temporary emergency situations; however, the Board is concerned the term "well-being" may be open to many interpretations and create unnecessary friction when a pharmacist uses their clinical

judgment to deny or approve a refill. The Board would like to suggest that HB 1084 be **amended** to **define "well-being."**

4. HB 1084 will eliminate the Board's existing vaccine registration program and enforcement efforts. Currently, the Board requires a Maryland-licensed pharmacist to register with the Board prior to administering any vaccine. The Board does not collect a fee to register a pharmacist and the process serves as an initial check to ensure that the individual has completed the required CDC training in vaccinations and obtained an in-person CPR certification. Additionally, the Board requires a pharmacist to renew their registration biennially with proof of a current CPR certificate and four continuing education credits related to vaccinations. Since HB 1084 is expanding the authority of a pharmacist to include ordering vaccinations in addition to administering vaccinations, including childhood immunizations, it is the Board's position that it is not responsible to allow such an expansion while simultaneously removing all vetting and monitoring of vaccinating pharmacists by the Board. The Board would like to suggest that HB 1084 be **amended** to **restore the Board's registration program**.

5. HB 1084 will authorize a pharmacist to order and administer an FDA-approved, ACIP-recommended vaccine to an individual who is at least three years old without a prescription and without performing a preliminary check in ImmuNet to review a patient's immunization record to ensure that the individual has not previously received the vaccine. While the Board is supportive of the expanded scope of practice, it has severe concerns with the blanket authorization to order and administer a vaccine to individuals, especially children, without a mandatory review of a patient's immunization record in ImmuNet to ensure that the individual has not already received the vaccine. Previously, a pharmacist could only vaccinate children ages 11-17 with a prescription from the child's healthcare provider; thus, the assumption was that the child's healthcare provider was knowledgeable about the child's immunization history when issuing the prescription. By eliminating the prescription requirement, it is integral to the safe delivery of healthcare that a pharmacist check ImmuNet prior to ordering and administering a vaccination, particularly to a child. The Board would like to suggest that HB 1084 be **amended** to include that a pharmacist **must check ImmuNet prior to ordering and administering a vaccine**.

6. HB 1084 will remove the Board's requirement that a pharmacist develop or adopt a protocol prior to administering a vaccine. Currently, a pharmacist is required to develop or adopt a vaccine-specific written protocol prior to administering any vaccine. The criteria for an appropriate protocol was developed by the Board in consultation with the Maryland Department of Health, the Board of Nursing, and the Board of Physicians. It is the Board's position that these regulations are necessary for awareness, education, and patient safety. The Board would like to suggest that HB 1084 be **amended** to restore the Board's regulations regarding a **vaccine-specific written protocol**.

The Board is opposed to HB 1084 and recommends an unfavorable report, unless the proposed amendments are incorporated.

I hope this information is useful. If you would like to discuss this further, please do not hesitate to contact me at deena.speights-napata@maryland.gov or 410-764-4753.

Sincerely,

Deena Speights-Napata, MA
Executive Director

Jennifer L. Hardesty,
PharmD, FASCP
President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.