MEMORANDUM

To: Licensees & Interested Parties

From: Maryland Board of Pharmacy

Date: March 19, 2020

Re: COVID-19 Guidance Information

To prevent the spread of COVID-19 (Coronavirus), Governor Hogan declared a State of Emergency on March 5, 2020. The Governor subsequently issued Executive Orders on March 12 and 16, 2020, which contain provisions affecting the Board and its licensees. Currently, all pharmacies should remain open if able. As this situation evolves, pharmacists and pharmacies should continue to provide services in a manner that assures access and safety.

The Maryland State Board of Pharmacy (the “Board”) would like to provide the following information and guidance regarding compliance with the Maryland Pharmacy Act during the declared State of Emergency:

All Pharmacies

- Review or create interim emergency policies to anticipate and react to this emergency and disseminate to all staff. It is recommended to incorporate recommendations in the CDC’s Interim Guidance for Employers and additional guidance and information for pharmacies on the APHA and ASHP websites.
- Keep up to date with the state of conditions in Maryland.
- If required by or requested of the pharmacy, the FDA has provided a temporary Guidance Document on a Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency in accordance with USP 795 standards.
- If able, consider facilitating prescription dispensing at curbside or drive-through pickup.
- Consistently monitor the health of pharmacy staff. Any staff member exhibiting flu-like systems or respiratory illness should stay at home.
Remote Processing

- In order to support the Governor and Secretary of Health with their directives to telework and social distance to the extent possible, the Board will not enforce requirements regarding the direct supervision of pharmacy technicians by a licensed pharmacist if the technicians are engaged in remote processing of delegated pharmacy acts. Remote processing of delegated pharmacy acts includes prescription or order entry, other data entry, and may also include insurance processing and other administrative functions.

- Pharmacists currently have the ability to engage in remote processing, which may also include clinical functions such as drug utilization review, authorizing release of medications from automated medication systems, providing drug information, and other similar pharmaceutical services.

- Remote processing does not include the physical handling of any prescription drugs or devices.

Refills

- The Maryland Pharmacy Act, Sec. 12-506(c), allows a pharmacist, during a state of emergency, to refill a prescription for which a refill has not been authorized if: (1) the pharmacist is unable to obtain authorization from the prescriber; (2) the refill is not for a controlled dangerous substance; (3) the quantity dispensed does not exceed a 30-day supply or unit of use; and (4) the pharmacist notifies the prescriber of the refill within 7 days.

Sterile Compounding

- Follow established, recognized guidelines (CDC, CDC on N95 Respirators, FDA, or equivalent) for guidance on conserving garb and alternatives and strategies for managing potential extended use of face masks, gowns, and shoe covers. It is recommended that pharmacies keep a copy of the guidance used to adjust practice and to continue to follow protocols which prohibit the use of contaminated or unusable supplies.

- Please note, at a minimum, weekly surface sampling inside an ISO-5 space is highly recommended when garbing in a manner that is not consistent with USP standards. The Board understands budgetary constraints and suggests following the 2019 USP 797 standards on environmental sampling and organism identification.

- The Board recognizes the need to delay certain activities such as personnel annual competencies or other quality assurance activities in order to reduce supply needs. Inspectors are aware of the challenges being presented to pharmacies and will take these into account when inspecting pharmacies.

- If you use a compounding aseptic isolator, regulation 10.34.19.13(B) states: "The requirements of this regulation [10.34.19.13(A) Garbing] are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with USP 797 Standards and isolator vendor/manufacturer specifications."
Licensing

- Pursuant to an Executive Order issued by Governor Hogan on March 12, 2020, all licenses, registrations, and permits issued by the Board set to expire during the state of emergency and catastrophic health emergency shall be extended to the 30th day after the date the state of emergency is terminated and the catastrophic health emergency is rescinded. No late fees or reinstatement fees will be imposed during this time period. To the extent it is able, the Board will accept and continue to process renewal applications during the state of emergency and catastrophic health emergency.

- In keeping with the Governor’s policy extending expiration dates for licenses, and maintaining the ability of the pharmacist workforce to administer influenza and other CDC-recommended vaccinations, the Board will not take enforcement action based on expired or inactive CPR certifications held by pharmacists registered to administer vaccinations if the CPR certification becomes inactive or expires during the state of emergency. Upon the termination of the state of emergency, the Board will allow affected pharmacists 30 days to update their live CPR certification.

- Pursuant to an Executive Order issued by Governor Hogan on March 16, 2020, any pharmacist or pharmacy technician actively licensed in another state or with an expired license or registration issued by the Board may be able to work in a health care facility (the definition of which does NOT include a pharmacy) in Maryland under certain circumstances.

- The Board will not impose the 30-day notice requirement associated with a change of business hours for a permitted pharmacy or wholesale distributor pursuant to COMAR 10.34.30.05(A). The Board will instead require advanced notice as soon as practicable if an establishment location is forced to change its hours or temporarily close. Please note that all other requirements still apply, such as notice to patients, transfer of prescriptions, and documentation of transfers of any drug inventory.

Any changes to pharmacy practice should only be viewed as short term solutions to deal with the current crisis. All policies should return to normal practice as the crisis begins to resolve. This event is not an excuse to lower quality assurance standards, and the Board expects all of its pharmacies to uphold and follow practices and policies which ensure utmost patient care and safety while aiding in preventing the spread of COVID-19.

If you have any questions or concerns, please contact the Board:
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