

April 13, 2020

Pennsylvania Issues Additional Pharmacy-Related Waivers During COVID-19 Emergency

Previously, the Department of State sought and received approval for a series of licensing waivers and temporary suspensions related to the State Board of Pharmacy:

- State Board of Pharmacy-Omnibus (Part I): Pennsylvania Suspends Certain
 Licensing and Regulatory Requirements for Pharmacies and Pharmacists During
 Coronavirus Emergency
- Pennsylvania Expands Access to Pharmacy Services

The following additional pharmacy-related waivers have been approved by the Governor:

Signature for Delivery of Pharmaceuticals

Questions have arisen throughout the COVID-19 emergency regarding patient signature requirements for pharmaceuticals and whether pharmacies must obtain proof-of-receipt from patients upon delivery, particularly in the context of home delivery.

The State Board of Pharmacy wishes to clarify that neither the Pennsylvania Pharmacy Act nor any of the State Board's regulations impose signature requirements for delivery/receipt of prescriptions. Pharmacists and pharmacies must, of course, follow all other applicable state and federal laws and rules related to this issue.

Pharmacy Students About to Graduate

Pearson Vue, the company that administers the licensing exams for new pharmacists (NAPLEx and MJPE) is currently closed. Graduations for the seven Pennsylvania pharmacy schools are scheduled to take place beginning in late April and running through early June. Until Pearson Vue reopens, pharmacy graduates will be unable to take licensing exams. Until they take (and pass) their licensing exams, they cannot obtain their pharmacist licenses.

This, of course, comes at a time when healthcare practitioners – including pharmacists – are in great demand. Staff shortages can be particularly critical in the pharmacy setting, because a pharmacy can only be open when a licensed pharmacist is present.

Allowing pharmacy interns who are about to graduate from pharmacy schools the ability to provide greater levels of assistance during the pandemic will provide at least some

level of relief. Therefore, for pharmacy interns who have completed their Advanced Pharmacy Practice Experiences (APPE) rotation and/or are within 90 days of graduating from pharmacy school, the Department has waived the "direct, immediate and personal" supervision requirements. This waiver/suspension shall end 90 days after the emergency has been terminated unless rescinded, superseded, amended or revised by additional orders of the Governor or the Department.

Where direct supervision was called for, pharmacy interns within 90 days of graduation may now be supervised "indirectly." For example, a pharmacist offsite can observe and direct pharmacy activity remotely via live surveillance cameras or other form of remote communication technology to a degree sufficient to: assure the accurate completion of the activities of the pharmacy interns; provide a final verification/check of all aspects of the prepared product; and document the final verification/check before dispensing.

Pharmacy interns and "residents"

Pharmacy intern certificates are only valid for six (6) years and cannot be renewed. This is true for both pharmacy interns who are about to graduate and for all other pharmacy intern certificate holders. **The Department of State has waived the provisions** related to the six-year limit.

Furthermore, while the Board does not recognize "residents" as a separate classification, it is understood that there are in fact "residency" programs in Pennsylvania. Many of these "residents" already hold intern certificates, and to the extent there are "residents" who do not hold intern certificates, the Department recommends that these residents apply for an intern certificate and the Department will do its best to expedite such applications. This waiver/suspension shall end 90 days after the emergency has been terminated unless rescinded, superseded, amended or revised by additional orders of the Governor or the Department.

Pharmacists

To aid in the COVID-19 response effort, it would be helpful to allow pharmacists to administer Point-of-Care testing, e.g., strep throat and other diagnostic tests. Moreover, on April 8, 2020, the <u>U.S. Department of Health and Human Services</u> released critical guidance that authorizes licensed pharmacists to order and administer COVID-19 tests including serology tests.

There is nothing in the Pharmacy Act or the Board's regulations that prohibits pharmacists from ordering and administering tests. A pharmacist is a healthcare practitioner who may administer tests if administration of the test is delegated by a medical doctor. Therefore, for the purposes of preparing for and mitigating any effect of COVID-19 testing, licensed pharmacy practitioners are granted the requisite authority needed to carry out end-to-end COVID-19 testing, including

but not limited to: ordering; testing; and communicating results. This waiver/suspension shall end 90 days after the emergency has been terminated unless rescinded, superseded, amended or revised by additional orders of the Governor or the Department.

This request does not seek to exempt, waive or suspend any requirements of the Clinical Laboratory Act and its corresponding regulations, the Clinical Laboratory Improvement Amendments of 1988 and its corresponding regulations, and may not be interpreted as exempting, waiving, or suspending those requirements. Any person or entity conducting clinical laboratory testing, including Point-of-Care testing and COVID-19 testing, must be authorized by the Pennsylvania Department of Health and the Centers for Medicare & Medicaid Services (CMS) to conduct such testing.

Alternate Care Sites

As hospitals begin to open ancillary or "alternate care" sites, various questions arise as it pertains to pharmacies, pharmacists and dispensing medication at these sites.

Subject to input from the Department of Health, the most efficient way to is to treat these sites as satellite pharmacies under the hospital's permit. The definition of a satellite pharmacy, however, requires the satellite to be located on the premises of the hospital. Since these sites may not be at a hospital, the Department has waived the restrictive definition of "satellite pharmacy" and allows ancillary sites during the COVID-19 emergency to be considered "satellite pharmacies." A further waiver was granted of the requirement that the satellite be dependent upon a centrally located pharmacy, to make it clear that any pharmacy established within an alternate care site or the like during the COVID-19 emergency is permitted to lawfully operate as a satellite pharmacy, provided it is affiliated with a pharmacy holding a current permit issued by the board. This waiver/suspension shall end 90 days after the emergency has been terminated unless rescinded, superseded, amended or revised by additional orders of the Governor or the Department.

Increased Prescribing Amounts

To minimize the number of people going to pharmacies and doctors' offices:

- The Department of State has waived the statutory emergency prescription section to allow pharmacists to issue a 30-day supply for an emergency script as opposed to a 72-hour supply only for nonscheduled legend drugs and schedule V controlled substances.
 - Schedules I, II, III and IV controlled substances are excluded from this waiver.
- Pharmacists may dispense a 90-day supply of a medication (nonscheduled legend drugs) at one time by using the refills on the medication. For example, a prescription for a 30-day supply with two (2) refills could be issued as a 90-day prescription.

These waiver/suspensions shall end 90 days after the emergency has been terminated unless rescinded, superseded, amended or revised by additional orders of the Governor or the Department.

For all licensing-related inquiries, please use the email addresses found here: <u>Board Contact Info.</u>