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Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D. EXECUTIVE DIRECTOR

Board of Pharmacy Response to Governor's Proclamation

On April 2, 2020, Governor Kim Reynolds issued a new Proclamation of Disaster Emergency. In this Proclamation, Governor Reynolds extends the temporary regulatory relief relating to inactive/lapsed pharmacist licenses, technician trainee registrations, continuing education, license/registration renewal, pharmacist-intern experiential training, and background checks. The Proclamation provides new regulatory relief relating to drug product selection, pharmacist license reciprocity, and initial pharmacist licensure. The suspension of regulatory provisions identified in the Proclamation is effective through April 30, 2020, unless the Governor terminates or extends it in writing prior to that date. As required in the Proclamation, the Board hereby issues this guidance relating to the temporary suspension of administrative rules in these areas which directly impact the Board of Pharmacy and 657 Iowa Administrative Code.

In Section Thirty-Three, Governor Reynolds temporarily suspends the provision in Iowa Code § 155A.32 that otherwise limits drug product selection without prior approval from the prescriber to generically equivalent drug products. For the duration of this disaster emergency, a pharmacist should follow this guidance for drug product selection when presented with drug product shortages. *The temporary suspension of this provision is limited to drug product selection in response to a drug product shortage or for formulary management and, where identified below, only when a substitute prescription or order cannot be obtained from the prescriber after reasonable effort.* This guidance applies to therapeutic substitution of prescription drug products. A pharmacist who engages in therapeutic substitution pursuant to this guidance shall exercise professional judgment when making such substitutions and should consult with scientific literature and/or peer-reviewed drug information resources for dosing equivalencies.

The authority to therapeutically substitute prescription drugs in response to a drug shortage under this guidance shall NOT apply to:

- Controlled substances
- Biological products, with the exception of insulin products
- Drug products with a narrow therapeutic index

For inhaled beta-agonist prescription drug products, a pharmacist may engage in therapeutic substitution with respect to drug and dosage form without prior prescriber authorization when necessary due to a documented drug shortage.

- Prior to the substitution, the pharmacist shall discuss the therapeutic substitution with the patient, including the reason for the substitution and any cost or third-party payor implications.
- Following therapeutic substitution, the pharmacist shall provide notice to the prescriber in writing or by electronic means within 7 days of dispensing.

For other prescription drug products not previously identified which are subject to a drug shortage during this disaster emergency, a pharmacist shall follow this guidance.

- Consider limiting dispensing to no more than a 30 day supply to preserve drug supply.
- Consider assigning one pharmacy staff member with the task of daily review of drug shortage reports (through FDA and wholesaler, etc.).

- As a drug appears on a drug shortage list, identify all current patients with active prescriptions for the drug. For those patients whose supply will run out in the near term (within 15 days, for example), send a request as soon as possible to the patient's prescriber for an alternate prescription in case the medication cannot be procured in time for the patient's prescription to be filled.
- When a prescription *must* be filled, the drug is *not* available, and the prescriber has *not* responded to the pharmacy's request(s) for substitution, the pharmacist may dispense an appropriate alternate drug within the same therapeutic drug class, ensuring a complete prospective drug utilization review is completed, and adjusting the dose and directions accordingly to result in the same therapeutic outcome for the patient.
- Within 7 days of dispensing a therapeutically-substituted prescription, the pharmacist shall notify the prescriber of the substitution in writing or by electronic communication.
- Prescriptions dispensed in this manner should be processed as a new prescription with the name of the prescribing physician on the original prescription for the unavailable drug product. The prescription record shall include the pharmacy's attempts to contact the prescriber for a substitution.
- The pharmacist shall, prior to dispensing, counsel the patient about the alternate product selected to include notification to the patient that the selected drug product does not contain the identical active ingredient present in the originally prescribed drug.

In Section Forty, Governor Reynolds extends the temporary suspension of administrative rules which prohibit the practice of a pharmacist or technician trainee after the license has expired.

- Through April 30, 2020, a pharmacist whose license has been inactive or expired for no more than 5 years may continue to engage in the practice of pharmacy with the inactive or lapsed license. Be reminded that the Governor's action does not permit pharmacists whose licenses have been voluntarily surrendered or revoked to return to practice. A pharmacist returning to practice pursuant to this authorization does not need to contact the Board.
- Technician trainees whose registration expires between March 18, 2020 and May 31, 2020 and who are unable to sit for the national technician certification exam are authorized to continue practicing as a technician through May 31, 2020. The Board will continue to monitor the situation at the testing centers and exercise enforcement discretion for technician trainees subject to this Proclamation who continue to experience difficulty in accessing the exam.

In Section Forty-One, Governor Reynolds extends the temporary suspension of administrative rules which require continuing education as a condition of license renewal when such requirements cannot be satisfied due to the disaster emergency. For pharmacists whose license is due to renew by July 1, the Board will continue to monitor the situation, but does not anticipate the continuing education requirements will be impacted by this disaster.

In Section Forty-Two, Governor Reynolds extends the temporary suspension of administrative rules which apply to license and registration renewal during the period of this disaster emergency. Licensees or registrants whose license or registration expires during this emergency period (March 22 through April 30) may continue to practice through April 30. The Board is continuing to process license and registration renewals and licensees and registrants are encouraged to utilize the Board's <u>online services</u> for renewal. The Board will not assess late penalty fees for licenses and registrations which expire March 31 and April 30 if they are renewed (or a renewal application is received in the Board office) no later than May 31.

In Section Forty-Three, Governor Reynolds extends the temporary suspension of administrative rules which require the completion of clinical, practical, or internship experience as a condition of obtaining pharmacist licensure. As noted in the Board's guidance following the Governor's March 22 Proclamation, Iowa-registered

pharmacist-interns who are unable to complete the college-based clinical program due solely to the COVID-19 pandemic, will continue to be eligible for licensure, if all other licensure requirements are met.

In Section Forty-Four, Governor Reynolds extends the temporary suspension of administrative rules which require the completion of a criminal history background check prior to licensure. As noted in the Board's prior guidance relating to deferred background checks, the Board will continue to process license and registration applications which are otherwise complete and will defer the background check until the expiration of the disaster emergency, currently scheduled to expire on April 30, 2020. Licensees and registrants will be provided with a fingerprint packet to complete and return within 60 days of the expiration of the disaster emergency. Failure to timely return the completed fingerprint packet may result in license or registration rescission. Failure to provide truthful information relating to criminal or disciplinary action history on the license application may result in disciplinary action, including license or registration revocation.

In Section Forty-Five, Governor Reynolds temporarily suspends the administrative rules which prohibit a pharmacist who is licensed in another state from engaging in the practice of pharmacy in Iowa prior to obtaining an Iowa pharmacist license due to requirements which are not able to be satisfied due to this disaster emergency.

- A pharmacist who is actively licensed in another state and who wishes to practice pharmacy in Iowa during this emergency period without first obtaining an Iowa pharmacist license: shall obtain temporary authorization through the National Association of Boards of Pharmacy Passport Program. Authorization to practice pharmacy in Iowa via the NABP Passport program is limited to the duration of the Governor's disaster emergency declaration (currently set to expire on April 30, 2020).
- A pharmacist who is seeking to obtain an Iowa pharmacist license via license transfer: shall complete the National Association of Boards of Pharmacy License Transfer Application. Upon submission of a completed application, the Board will issue a pharmacist license and will temporarily defer the criminal history background check and completion of the MPJE-Iowa edition examination until the expiration of the emergency disaster.
 - O Upon the expiration of the disaster emergency, the Board will provide a licensee who is subject to these provisions with a fingerprint packet to complete the criminal history background check. The licensee shall return the completed fingerprint packet within 60 days of the expiration of the disaster emergency.
 - O Upon expiration of the disaster emergency, the licensee shall successfully complete the MPJE-Iowa edition examination within 120 days of the expiration of the disaster emergency. The Board will continue to monitor the availability of testing opportunities and may extend this deadline if warranted.
 - o Failure of the licensee to submit the completed fingerprint packet or successfully complete the MPJE-Iowa edition examination within the prescribed time may result in license rescission.
 - Failure to provide truthful information relating to criminal or disciplinary action history on the license application may result in disciplinary action, including license or registration revocation.

In Section Forty-Six, Governor Reynolds temporarily suspends the provisions of Iowa Code and administrative rules for candidates for initial pharmacist licensure who have, as determined by the Board of Pharmacy, completed sufficient education, are unable to sit for required examinations due to closure of testing locations, and should be granted an emergency license to practice until such time as the licensee is able to complete the required examinations. The Board will work with applicable Colleges of Pharmacy to ensure candidates for emergency pharmacist licensure in Iowa have sufficiently completed educational components for pharmacy practice. Upon submission of a completed pharmacist license application, the Board will issue a pharmacist license and will defer the completion of the criminal history background check and successful completion of the NAPLEX and MPJE-

Iowa edition examinations until the expiration of the emergency declaration (currently set to expire April 30, 2020).

- Upon the expiration of the disaster emergency, the Board will provide licensees who are subject to these provisions with a fingerprint packet for completion of the criminal history background check which must be returned to the Board within 60 days of the expiration of the emergency declaration.
- Upon the expiration of the disaster emergency, licensees who are subject to these provisions shall successfully pass both the NAPLEX and MPJE-Iowa edition examinations within 120 days of the expiration of the emergency declaration. The Board will continue to monitor the availability of testing opportunities and may extend this deadline if warranted.
- Failure to timely return the completed fingerprint packet for the background check may result in license rescission.
- Failure to provide truthful information relating to criminal or disciplinary action history on the license application may result in disciplinary action, including license or registration revocation.
- Failure to successfully complete both required examinations with 120 days of the expiration date of the emergency declaration may result in license rescission.
- A licensee subject to this provision who takes the NAPLEX examination and fails to receive a passing score shall have their license cancelled until such time as they receive a passing score. The individual will be limited to practicing as a pharmacist-intern if their pharmacist license is cancelled pursuant to this provision. If the individual subsequently takes and passes NAPLEX while the disaster emergency is still in place, the license shall be reactivated and the licensee will continue to be subject to the remainder of the examination and background check provisions at the conclusion of the emergency disaster.

In Section Fifty-One, Governor Reynolds extends the suspension of administrative rules which require a pharmacist licensure candidate to complete all examination components within one year from the date the candidate passed the initial component. Board licensing staff will continue to identify licensure candidates who have completed one component and monitor examination completion during the emergency period.

The Board of Pharmacy will continue to monitor the situation as additional information is available and make necessary adjustments to provide pharmacy professionals with the guidance needed to navigate the current public health emergency.