Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

Due to the current Coronavirus Disease 2019 (COVID-19) pandemic, the Iowa Board of Pharmacy is informing its licensees and registrants that it intends to *exercise risk-based enforcement discretion* for non-compliance with rules related to the practice of pharmacy for the period of time as established by the Governor's State of Public Health Disaster Emergency, or until such time that the Board determines the need no longer exists. The Board recognizes that pharmacists are well-suited to assist the public during this national emergency. While the Board expects that each licensee will make every reasonable effort to comply with existing laws, rules, and regulations, the Board recognizes that the unique challenges posed by COVID-19 and the resulting disruption to the drug/garb supply chain, normal activities of daily living, etc., may force a licensee to adjust their practice in order to meet patient care needs while protecting the public and employees from exposure to the novel Coronavirus.

On March 22, 2020, Governor Kim Reynolds issued a Proclamation of Disaster Emergency in which she temporarily suspended certain licensing requirements relating to continuing education, license/registration renewal, internships, background checks, and examinations. The Board will be releasing additional guidance in the coming days relating to this proclamation.

In addition to the Governor's Proclamations, **the Board does not intend to take enforcement action against a licensee or registrant if the standard of care in any given scenario is met.** "Standard of care" means the level of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience. **However, this period of discretionary enforcement does not extend to violations stemming from 657 Iowa Administrative Code 10, which governs controlled substances.** Licensees and registrants shall continue to ensure compliance with all federal and state laws, rules, and regulations related to the distribution and handling of controlled substances.

Below are two examples of situations in which the Board would likely exercise discretion in instituting an enforcement action. The Board will also publish a FAQ document, which provides more detailed responses and recommendations to various situations that have been presented to the Board in recent days.

As an example, Board rules specifically prohibit pharmacists from compounding preparations for retail sale unless the compound is dispensed pursuant to a prescription. However, the Food and Drug Administration released a Final Guidance Document for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency indicating that it does not intend to take action against pharmacists in State-licensed pharmacies or Federal facilities, for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, for violations of sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355). The Board intends to exercise enforcement discretion in this area when pharmacies are following the guidance provided by FDA and the standard of care in the specific circumstance is met.

Another example relates to garb for compounding and personal protective equipment (PPE) for hazardous drug handling. As the garb and PPE supply chain may become limited, if it is not already

limited, your pharmacy may simply not have the necessary garb or PPE as identified in USP General Chapters 797 and 800. The Board intends to exercise risk-based enforcement discretion for licensees who are required to make adjustments in procedures in response to a garb or PPE shortage. Licensees must still employ best practices to ensure product quality, patient safety, and personnel protection.

Additionally, the Board would like to caution pharmacies as it relates to drug supplies and possible rogue suppliers that may contact your pharmacy to offer drug products that are unavailable from your regular supplier(s). These suppliers may be part of the gray or black market engaged in the distribution of counterfeit products. Please ensure your pharmacy exercises due diligence in vetting new suppliers for your pharmacy. The Board provides online Business License Verification that you can utilize to verify that a supplier is licensed to engage in distribution in this state before purchasing from a new supplier.

Further, with respect to drug supplies, the Board has received questions relating to the possible hoarding or new prescribing of hydroxychloroquine to potentially treat COVID-19. Pharmacies are strongly encouraged to assess their current and potential supply and implement policies that will ensure adequate supply for patients who were previously established on the drug. As an example, another state has implemented a limitation on new prescriptions to no more than 14 days, unless the patient was previously established on the drug.

During this extraordinary time, the Board will continue routine enforcement activities as necessary to ensure Iowa patients are receiving the appropriate standard of care. The Board encourages licensees and registrants to reach out to Compliance Staff for assistance with any questions related to Board enforcement.

Dated this 23rd day of March, 2020.