

MINNESOTA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Disciplinary Actions Listed Online

Because of space limitations, information on disciplinary actions is no longer included in the *Minnesota Board of Pharmacy Newsletter*. A document that provides information about recent Board disciplinary actions can be found on the Board's website under the "Resources/FAQs" menu item.

New Online Licensing/Registration Platform

The Board has implemented a new online platform for services such as license application and renewals for prospective and current registrants. The new site is currently open for pharmacy technician and pharmacist applications and renewals. Prior to initiating an application or renewal, individuals must register for an account. Tip sheets are available on the Board's website.

Pharmacy Technician Renewals Overdue

Pharmacy technician registration renewals were due on December 1, 2023. Technicians were then given the month of December as a "grace period." The registrations of technicians who failed to renew by December 31, 2023, have expired. Individuals cannot continue working as technicians if their registrations have expired.

Pharmacists-in-charge (PICs) are encouraged to verify that technicians working under their supervision have current registrations. This can be done by using the "VERIFY License or Registration Status" link on the Board's website. If an unregistered individual performs duties that require a technician registration, the Board can take disciplinary action against that individual, the PIC, and the pharmacy.

National Pharmacy Compliance News

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MN Vol. 45 | No. 1 Minnesota Board of Pharmacy | 1

Pharmacy technicians are reminded they must report any changes in name, residence, or place of employment to the Board within 10 days of the change. The change notification form can be found on the Board's website.

Pharmacist License Renewals Due Soon

Pharmacists who want to renew their license for the license period that starts on March 1, 2024, may do so at this time. To renew your license, go to the Board's website and select the "LOGIN" for online services link. This will take you to the new online services website. All users will need to create an account for this website. The renewal screen will allow you to change your address, update your employment, or change your license status. As a reminder, Minnesota Rule 6800.2500 states that pharmacists "shall notify the Board of Pharmacy immediately of any change in location of employment or change of residence address." There is a change notification form available on the website for changes that occur outside of the renewal period.

The renewal period for pharmacists opened in mid-December, and the deadline for completing the renewal process is **February 1.** The month of February is a grace period during which no late fees are assessed for pharmacists who have missed the February 1 deadline. If your completed application and required fee are not received by the Board office **prior** to March 1, 2024, your license will expire, and the late fee will be imposed. You will not be allowed to practice pharmacy in the state of Minnesota until the Board receives the completed application and fees.

Guidance on 'Essentially a Copy of a Commercially Available Drug Products'

The term "essentially a copy of a commercially available drug product" is described in Minnesota Statute 151.253. A copy "does not include a drug product in which there is a change, made for an identified individual patient, that produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." When evaluating whether a drug is a copy, a pharmacist should utilize the January 2018 final guidance document from Food and Drug Administration (FDA) to help determine whether a drug might be a copy and consider any documentation of individual patient need or significant difference, which may be required.

In August 2022, FDA approved a reconstitutable formulation of omeprazole suspension – Konvomep TM . Prior to this approval, some patients required compounded formulations due to the inability of existing omeprazole formulations to meet the patient's needs.

FIRST Compounding Kits are not FDA-approved drugs, but simply convenience kits containing the bulk ingredients for pharmacists to compound products.

With FDA approval and market availability of Konvomep, pharmacies are prohibited from compounding omeprazole suspensions unless the compound meets the conditions identified in state and federal regulations for compounding essentially copies of commercially available drugs.

Transfer of CS Prescriptions

Recently, Drug Enforcement Administration (DEA) made changes that were implemented in 21 Code of Federal Regulations §1306.08. Those changes state that, upon request from the patient, a pharmacy may transfer an electronic controlled substance (CS) prescription in Schedule II-V to another registered retail pharmacy for initial filling subject to the conditions specified in the rule and its associated subparts. The final rule was published in the *Federal Register* on July 27, 2023, and became effective on August 28, 2023.

One of the provisions in the federal rule requires that the transfer is permissible only if allowable under existing state or other applicable law. Minnesota Rule 6800.3120 is the state law that governs this type of activity. The rule addresses both non-dispensed (initial fill) and refill prescriptions. The rule prohibits the transfer of Schedule II prescription drug orders. Given the federal rule change, the Board intends to propose to strike that restriction from Minnesota Rule 6800.3120 through rulemaking processes to align it with the federal law.

The Board believes that it would be beneficial to public health to ensure that duplicate Schedule II prescriptions are not available to patients across several pharmacies and that pharmacists are able to ensure the appropriate transfer of those prescriptions. As such, the Board does not intend to enforce the restriction within Minnesota Rule 6800.3120, which prohibits the transfer of Schedule II prescriptions, when a pharmacist acts in compliance with all federal provisions of the rule and in accordance with all other requirements in Minnesota Rule 6800.3120. The Board went on record to that regard at the Board meeting on November 1, 2023.

Based on the new federal rule, a pharmacist in the state of Minnesota may transfer a prescription at the request of a patient even if the prescription has not yet been filled but has been profiled, including those in Schedule II-V with enforcement discretion by the Board. A pharmacist (or intern) must do so subject to the conditions and provisions in Federal Rule 1306.08 and all other provisions of Minnesota Rule 6800.3120. Pharmacists should be aware that DEA's new rule does not authorize the transfer of written or oral CS prescriptions for initial filling. DEA's commentary notes that if a pharmacy is unable to fill a written CS prescription, it may return the paper to the patient.

The Minnesota Board of Pharmacy News is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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