



NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2470 – Pharmacists and Pharmacies Should Ensure That Their Pharmacy Interns Hold a Current Registration

Pharmacy intern registrations were due to be obtained or renewed by September 1, 2023. North Carolina pharmacists and pharmacies that host pharmacy interns as part of an academic experiential program or that host/employ pharmacy interns outside of an academic experiential program must verify that the would-be intern is, in fact, currently registered. Interns may print a North Carolina Board of Pharmacy-issued certificate after completing registration. Pharmacists and pharmacies should also use the [Board's License/Permit/Registration Verification tool](#) to confirm intern status. No person may practice in an intern capacity without holding a current pharmacy internship registration. For more information on pharmacy internship registration, see this frequently asked questions ([FAQs](#)) [web page](#).

Item 2471 – License/Permit/Registration Renewal Period Opens November 1

The window to renew licenses, permits, and registrations (other than pharmacy intern registrations – see Item 2470 above) issued by the Board for 2024 opens on November 1, 2023. Board licensing staff will send frequent reminders and instructions electronically. All license, permit, and registration holders should ensure that they have provided the Board with a current email address to receive these reminders and instructions.

All licenses, permits, and registrations (other than pharmacy intern registrations) expire on December 31 annually. State

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statute provides a 60-day period after expiration before a license, permit, or registration holder is deemed to be engaged in the unlicensed practice of pharmacy. That said, there is no need to procrastinate! Get your renewals completed by December 31.

Item 2472 – DTP Dispensing System Rulemaking

The Board has completed its rulemaking on the authorization for and regulation of the use of direct-to-patient (DTP) dispensing systems. **New Rule 21 North Carolina Administrative Code (NCAC) 46.1821** provides that authorization and the standards that apply to the use of DTP systems. **Amended Rule 21 NCAC 46.1616** authorizes limited service permits to be issued for operation of a DTP system when the system is not located at the site of the home pharmacy.

What are the next steps? At the time of this writing (the newsletter items are submitted a month ahead of publication), the new rules are not yet operational. Board staff must complete programming to implement a DTP system “limited service” permit application, as well as make changes to the pharmacy services section of pharmacy permit applications. Board staff is also creating a comprehensive guidance document to take pharmacists through the rules’ requirements and procedures.

Board staff will provide notice to all pharmacists and pharmacies when these implementation activities have been completed. In the meantime, pharmacies wishing to deploy DTP systems should begin familiarizing themselves with the new rules linked above.

Item 2473 – State Health Director Updates Statewide Opioid Antagonist Standing Order

North Carolina State Health Director Betsey Tilson has updated the statewide standing order for opioid antagonists, as well as the associated list of approved products for dispensing under the standing order. The updated order and product list may be found [here](#). More information concerning the state’s opioid antagonist program and pharmacists’ and pharmacies’ roles is located at www.naloxonesaves.org.

Item 2474 – Pharmacy and Medical Boards Adopt Protocols Implementing SL 2021-110

On August 19, 2021, Governor Roy Cooper signed Session Law (SL) 2021-110, which created an authority for immunizing pharmacists to dispense, deliver, and administer certain treatment and medications. These authorities – to dispense, deliver, and administer nicotine replacement therapy, self-administered oral or transdermal contraceptives, prenatal vitamins, post-exposure prophylaxis for the prevention of HIV infection, and glucagon to treat severe hypoglycemia – were previously implemented by standing orders issued by State Health Director Tilson. As required by the statute, the North Carolina Medical Board and the Board of Pharmacy have adopted protocols

to replace the standing orders. Importantly, the protocols are substantively identical to the standing orders.

Detailed guidance for immunizing pharmacists, including links to the protocols, is available [here](#).

Item 2475 – North Carolina DHHS Issues Guidance Allowing Donation of ‘Abandoned’ Long-Acting Antipsychotics

On July 27, 2023, the North Carolina Department of Health and Human Services (DHHS) issued [guidance](#) detailing how long-acting antipsychotics dispensed for a Medicaid beneficiary but “abandoned” by the beneficiary are eligible for donation and redispensing/administration.

The Board’s [FAQs guidance on drug donation has been updated](#) to include this new opportunity.

Item 2476 – DEA Issues Final Rule on One-Time Transfers of Electronic CS Prescriptions for Initial Filling

What a long, strange trip it has been. On July 27, 2023, Drug Enforcement Administration (DEA) published its final rule allowing one-time transfers of electronic prescriptions for controlled substances (EPCS) for initial filling. The new rule (which adds a new paragraph (e) to [21 Code of Federal Regulations \(CFR\) 1306.08](#)) became effective August 28, 2023.

The final rule states that an EPCS in Schedule II-V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a Schedule III, IV, or V controlled substance (CS) are transferred with the original prescription.

The final rule specifies that the following requirements must be met when EPCS are transferred between pharmacies for initial dispensing. The prescription must be transferred in its electronic form and may not be converted to another form (eg, paper, facsimile) for transmission. The information required to be on a CS prescription pursuant to 21 CFR Part 1306 must be unaltered during the transmission. DEA commentary asserts that SCRIPT Standard Version 2017071 enables the transfer of prescriptions between pharmacies. Board staff has received comments, however, that the SCRIPT Standard does not, in fact, have the capability that DEA asserts. In all events, pharmacies should coordinate with their pharmacy technology vendors to determine if and how the SCRIPT Standard may be used to transfer prescriptions between pharmacies.

The transfer must be communicated between two licensed pharmacists. DEA commentary notes that existing regulations include “any other person (e.g., a pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed in such State” in the definition of a pharmacist.

The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing state or other applicable law. Board staff is aware of no provision of North Carolina law that would prohibit transfers performed in compliance with this new rule.

The final rule describes the documentation requirements for pharmacies transferring EPCS for initial filling. A pharmacist transferring an electronic CS prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also update the prescription record with the following information: the name, address, and DEA registration number of the pharmacy to which the prescription was transferred; the name of the pharmacist receiving the transfer; the name of the transferring pharmacist; and the date of the transfer.

Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number; the name of the transferring pharmacist; the date of the transfer; and the name of the pharmacist receiving the transfer.

In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture this required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. However, the transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

The final rule requires the electronic records documenting EPCS transfers to be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the prescription and the pharmacy receiving and filling the prescription. North Carolina law requires the retention of prescription records for three years, and this stricter retention requirement applies.

Note: 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. DEA's commentary does not grapple with the absence of a means to transfer oral prescriptions for initial filling, even though that absence contributes to a problem that DEA cited as a chief reason for this new rule: "the potential for duplicate prescriptions and thus . . . the opportunity for diversion or misuse."

The text of the new rule, as well as DEA's commentary and responses to comments from the public, is [here](#).

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