APRIL 2024

NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2484 – Updated Board of Pharmacy Website on the Horizon

In the coming weeks, North Carolina Board of Pharmacy staff will be launching an updated Board website. The URL – *www.ncbop.org* – will remain the same. Improvements to the website include a cleaner, more user-friendly interface; reorganized and more easily searchable frequently asked questions (FAQs) sections; and modules for each type of license, permit, and registration that the Board issues.

As the launch date is finalized and approaches, Board staff will send notices and updates to the regulated community.

Item 2485 – Dispensing Optometrist Registration System Became Effective March 1, 2024

Effective Friday, March 1, 2024, optometrists became eligible to register with the Board of Pharmacy to dispense certain prescription drugs. "Dispensing optometrists may dispense prescription drugs to their own patients only for the diagnosis and treatment of abnormal conditions of the eye and its adnexa," per North Carolina General Statute (GS) §90-127.4(a) and (c). "Dispensing optometrists may not compound medications, nor may they dispense controlled substances (CS)," according to GS §90-127.4(a).

As noted in the *Guidance for Dispensing Optometrists*:

> Dispensing optometrists must register with the Board of Pharmacy prior to beginning dispensing activities and must renew

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that registration annually. GS §90-85.26B. The initial registration fee is $75, as is the annual renewal fee. GS §90-85.24(a)(20).

A dispensing optometrist must comply in all respects with relevant laws and regulations that apply to pharmacists governing the distribution of drugs, including packaging, labeling, and record keeping. GS §90-85.26B. The Board of Pharmacy may discipline a dispensing optometrist's registration for violation of these laws and regulations. The Board of Optometry may discipline an optometrist's license to practice optometry. GS §90-85.25B.

Step-by-step instructions for completing a dispensing optometrist registration are available on the Board's website, *www.ncbop.org.*

Item 2486 – Update: Transfer of Unfilled CS Prescriptions

On July 27, 2023, Drug Enforcement Administration (DEA) issued a final rule governing the transfer of electronic prescriptions for controlled substances prior to initial fill. The rule is available here.

Among other things, the DEA rule provides that for a valid transfer to occur: "The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission." Furthermore, the rule states: "The contents of the prescription required by this part must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid." Refer to 21 Code of Federal Regulations §1306.08(f)(1) and (2).

DEA commentary accompanying the rule asserted that SCRIPT Standard Version 2017071 enables the transfer of CS prescriptions between pharmacies in a way that satisfies these rule requirements. Board staff received several comments that DEA's assertion was fanciful and that SCRIPT Standard Version 2017071 does no such thing. In a February 14, 2024 letter to stakeholders, Surescripts confirmed that SCRIPT Standard Version 2017071 does **not** do what DEA thinks that it does – and never has. Surescripts states that SCRIPT Standard Version 2022011 is capable of transferring CS prescriptions in a way that complies with the DEA rule, but the Centers for Medicare & Medicaid Services must finalize a rule allowing the industry to adopt this updated SCRIPT standard. Surescripts hopes that will happen soon. Until then, friends, questions regarding implementation of the DEA transfer rule should be directed to DEA's Greensboro office at 336/632-4297.

Item 2487 – Update: North Carolina Drug Control Unit Issues FAQs Guidance on Reporting Gabapentin to the CSRS

Last fall, the General Assembly passed, and the governor signed into law, a statute making gabapentin a drug for which dispensing must be reported to the Controlled Substances Reporting System (CSRS). Gabapentin became reportable on March 1, 2024.

The Drug Control Unit, which administers the CSRS, has created and updated an FAQs document with reporting instructions, **including how a pharmacy that does not hold a DEA registration may register for access to the CSRS to report gabapentin dispensing.** Pharmacists with additional questions should contact the Drug Control Unit.

Pharmacists and pharmacies continue to contact Board staff to inquire whether gabapentin has become a CS under North Carolina law. The confusion is entirely understandable. As the Drug Control Unit's FAQs document explains, gabapentin is **not** a CS under North Carolina (or federal) law. Nonetheless, its dispensing must be reported to the CSRS.

Item 2488 – State and Federal Pharmacy Law Applicable to IV 'Hydration Clinic'

Board staff continues to field inquiries from licensed medical professionals (and non-licensed entrepreneurs) concerning clinics that offer walk-in intravenous (IV) therapy services. This is a reminder that this guidance document sets forth North Carolina law governing the need for pharmacy permits and the preparation of sterile drug products.

Item 2489 – FDA Warns Consumers Not to Purchase or Use Neptune's Fix or Any Tianeptine Product

Food and Drug Administration (FDA) has issued a warning that consumers should not purchase or use tianeptine-containing products. Tianeptine is not an FDA-approved substance but is often sold at convenience stores, gas stations, and the like with claims that it will improve mental function and treat anxiety, depression, pain, opioid use disorder, and other conditions. FDA continues to receive severe adverse event reports associated with use of tianeptine products. Pharmacists should be aware of this danger and be prepared to advise patients who indicate they are using tianeptine products or ask about them.

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