



NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2424 – Proposed Board Rule Amendments Concerning Remote Medication Order Entry and Limited Service Permits

The North Carolina Board of Pharmacy has published for notice and comment a proposed repeal of 21 North Carolina Administrative Code (NCAC) 46.1417 and amendments to 21 NCAC 46.1816. These rule changes would consolidate two existing rules into one rule that governs situations where two pharmacies provide services with respect to a prescription. The principal substantive changes are to:

1. expand remote medication order processing services from its existing use with health care facility pharmacies so that remote medication order processing services can be used by any pharmacy permitted by the state;
2. expand the pharmacy personnel who may provide remote medication order processing services so that they may be provided by registered technicians in addition to licensed pharmacists; and
3. provide that pharmacies involved in centralized pharmacy services may decide which of those pharmacies provide the required patient counseling for mail-order or other delivered prescriptions.

The Board has published for notice and comment a proposed new rule, 21 NCAC 46.1616, and amendments to 21 NCAC 46.1317, .1703, .1706, and .2502. Under existing rules, the Board may grant limited service permits to pharmacies that operate on limited hours in an institutional setting (ie, pharmacies in health care facilities). The only current distinction in the rules between a limited service permit and a regular permit is that a pharmacist may serve on an ongoing basis as the pharmacist-manager of multiple pharmacy permits only if those permits are limited service permits. As a practical matter, there has been an ad hoc development of the use of limited service permits in other settings where limited pharmaceutical services are provided.

The proposed adoption of Rule .1616 would codify a more expansive view of limited service permits, which would include those pharmacies rendering services where the Board believes that services may be safely provided by pharmacist-managers who serve multiple pharmacies. Proposed Rule .1616 would further allow for the pharmacist-manager to be present at the limited service permit for less time than required at regular pharmacy permits, with the amount of time depending upon the amount necessary to safely

supervise each type of permit. It would also allow the pharmacist-manager to designate an assistant pharmacist-manager to help exercise supervision due to the unique nature of these limited service permits.

Proposed changes to other rules (Rules .1317, .1703, .1706, and .2502) are principally intended to conform those rules to the new Rule .1616.

The comment period is open through Tuesday, July 20, 2021. More details, including instructions for submitting comments, are located on the Board's [Rulemakings in Progress web page](#).

Item 2425 – Board Intends to Sign FDA MOU Concerning Interstate Distribution of Compounded Drug Products

The Board has announced its intention to sign the Food and Drug Administration (FDA) memorandum of understanding (MOU) concerning interstate distribution of compounded drug products upon successful completion of a rulemaking to require certain information to be reported annually by North Carolina compounding pharmacies to the National Association of Boards of Pharmacy® (NABP®) Information Sharing Network.

Section 503A of the Federal Food, Drug, and Cosmetic Act limits the compounding of human drug products in states that have not entered into an MOU with the secretary of the United States Department of Health and Human Services (HHS), with respect to gathering and providing certain information to FDA (21 US Code §353a(b)(3)(B)). The consequence of not entering into the MOU would be to prevent North Carolina compounding pharmacies from shipping compounded human drug products outside of the state if those exceed 5% of the total prescriptions dispensed by the pharmacy.

The MOU provides that, rather than being collected by each state, the data required to be gathered by a signatory state may be collected by NABP through its e-Profile system, in which all North Carolina-permitted pharmacies already participate. At the time of this writing, a proposed amendment to 21 NCAC 46.2801, which will implement the information reporting requirement, is nearing completion. If the rule goes into effect as planned, the Board will sign the MOU.

Item 2426 – Updated Buprenorphine Practice Guidelines – What Do They Mean for Pharmacists?

On April 28, 2021, HHS issued revised [Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder](#). In brief, these new guidelines create an expedited pathway for certain practitioners to obtain an “X-waiver” under the Drug Addiction Treatment Act of 2000 (DATA 2000) to prescribe buprenorphine for the treatment of opioid use disorder to 30 or fewer patients. The guidelines accomplish this by exempting certain practitioners from certification requirements related to training and the provision of psychosocial services.

What does this mean for dispensing pharmacies? In practical terms, very little. Prescriptions for buprenorphine to treat opioid use disorder must still come from a practitioner holding an “X” Drug Enforcement Administration number under DATA 2000. There is simply a more rapid path available for some practitioners to obtain it.

More information can be found by visiting <https://www.samhsa.gov/medication-assisted-treatment/practitioner-resources/faqs>.

Item 2427 – Follow the Board Website for Continual Updates on COVID-Related Matters, Including Vaccination Process and Authority

Staff continue to frequently update the Board [website](#) on general coronavirus disease 2019 (COVID-19)-related matters and specifically on COVID-19 vaccination matters. Updates are posted on the home page of the website, then periodically consolidated in a general COVID-19 updates [section](#) and a COVID-19 vaccination-related updates and resources [section](#). Key updates are also included in a weekly email to all pharmacists.

Among the recent topics addressed:

- State Health Director Elizabeth Tilson updates standing order for COVID-19 vaccine administration to include the Pfizer vaccine for patients ages 12 to 17.
- Upcoming vaccination training opportunities for pharmacists and pharmacy technicians.

Item 2428 – Board Provides Guidance to Pharmacist-Managers Seeking Technician-to-Pharmacist Ratio Increases

The Board has issued a guidance document for pharmacist-managers seeking technician-to-pharmacist ratio increases. The guidance reviews North Carolina law governing technician-to-pharmacist ratios, details the responsibilities of a pharmacist-manager when making a request, describes Board staff authority to approve certain requests, and asks that certain key information accompany any request that must be reviewed by the full Board. The guidance is available [here](#).

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