GUIDANCE TO NEW RULES GOVERNING LIMITED-SERVICE PERMITS

On November 1, 2021, new rules and standards governing limited-service permits ("LSP") become effective. LSPs have long been available in certain circumstances where a pharmacist-manager's division of time and effort across multiple pharmacies raises a low risk of harm to the public health and safety. (A pharmacist-manager is limited to serving in that capacity for only one pharmacy unless any additional pharmacy is a limited service permit.)

Over the years, however, a lack of precision concerning the types of pharmacy practice that may operate under a LSP, as well as a pharmacist-manager's specific responsibilities for a LSP, have proved challenging.

This FAQ guidance details the new rules and standards designed to provide better clarity on LSP eligibility and operation.

* * *

Q. What pharmacy practices are eligible to operate under a limited-service permit (LSP)?

A. Nine (9) types of pharmacy practice are eligible to operate under an LSP:

(1) a health-care facility where there is only an auxiliary medication inventory maintained under Board Rule 1414(d). "Health-care facility" is defined at Board Rule 1317.

(2) a health-care facility where there is only an automated dispensing or drug supply device operating under Board Rule 1419"Health-care facility" is defined at Board Rule 1317.

(3) direct-to-patient dispensing systems that are not located at the home pharmacy's facility under Board Rule .1821.

(4) alternate delivery sites authorized under Board Rule .1822.

(5) facilities where drugs are dispensed only by nurse practitioners or physician assistants under Section 1700 of the Board's rules. ***NOTE*** The presence of a dispensing physician at a facility does not eliminate the need to obtain a pharmacy permit. PAs and NPs may only dispense from a place holding a pharmacy permit, and may do so only under the supervision of a pharmacist.

(6) county health departments or other governmental entities providing local health services under G.S. 130A-34 and where drugs are dispensed only by registered nurses pursuant to G.S. 90-85.34A and Section 2400 of the Board's rules.

(7) county health departments or other governmental entities providing local health services under G.S. 130A-34 and that engage in dispensing beyond that allowed for registered nurses.

(8) free or charitable clinics as defined in G.S. 90-84.44(a)

(9) critical access hospitals, as defined in G.S. 131E-76

Q. Is there a "catch-all" provision under which other types of pharmacy practices may obtain (or maintain) an LSP?

A. No. Permit applicants who wish to obtain an LSP will be required to attest that their proposed practice meets one of the categories above and identify that category as part of the online permit application process.

Q. If my pharmacy practice is one of the types that qualify for an LSP, am I required to operate it as a LSP?

A. No. LSP eligibility provides the pharmacist-manager ("PM") with an option. If the PM prefers to maintain the practice as a full-service permit, the PM may do so.

Q. If my full-service pharmacy maintains auxiliary medication inventories or operates an automated dispensing device, must I obtain an additional LSP permit?

A. No. A pharmacy holding a full-service permit is not required to obtain an additional, separate LSP for an in-house auxiliary medication inventory or automated dispensing device.

Similarly, an auxiliary medication inventory or automated dispensing device located in a health-system satellite that, under Board Rule 1401(c), is not required to obtain permit separate from the main health-system facility permit is likewise not required to obtain an LSP.

Finally, Board Rule 1419 notes that "an automated dispensing . . . device that is used solely as an Auxiliary Medication Inventory as defined Board Rule 1414(d) shall be governed by the requirements of that rule." Board Rule 1414(d) defines auxiliary medication inventories to include "emergency kits" and specifies the PM's responsibilities for them. The Board takes the position that the mere presence of an "emergency kit" provided by a pharmacy to another facility does not require that facility to obtain a pharmacy permit. The determinative factor is the use to which the kit is put. Emergency kits are only used for the immediate administration of a drug to a patient. Their presence, therefore, does not turn the facility housing the kit into a pharmacy. Other types of auxiliary medication kits, however, are used for dispensing. In that case, a facility housing one is a pharmacy and must obtain a permit.

Q. May a pharmacist-manager of a full-service permit still serve as a pharmacist manager of a LSP as well?

A. Yes.

Q. May an LSP pharmacist-manager designate an assistant pharmacist-manager?

A. Yes. The PM may, but is not required to, designate one assistant pharmacist-manager ("APM"). The APM may fulfill the PM's attendance responsibilities when the PM is not present. (See below for details on the PM's attendance responsibilities for the different types of LSPs.) The PM must notify the Board upon designating an APM, and any APM change must be reported to the Board within 15 days. The PM maintains overall responsibility for the LSPs compliance with all applicable statutes, rules, and standards.

Q. May a PM designate an APM for a full-service permit?

A. No. The APM position is a specific accommodation for LSP in-person presence requirements (detailed below).

Q. Are there differences in a PM's attendance responsibilities among the different types of LSPs?

A. Yes. But first, a reminder. For all pharmacy permits, the PM is "the person who accepts responsibility for the operation of a pharmacy in conformance with statutes and rules pertinent to the practice of pharmacy and distribution of drugs . . . ." 21 NCAC 46.1317(27). Board Rule 2502 sets forth pharmacist-manager responsibilities in more detail. These, and other, overall responsibilities apply to LSP PMs, except as specifically modified in these new LSP rules and standards.

The new LSP rules and standards modify the PM's in-person attendance requirements, and those modifications depend on the type of LSP.

Q. What are a PM's attendance requirements for an LSP to operate an auxiliary medication inventory, automated dispensing device, direct-to-patient dispensing system, or alternate delivery site (categories 1, 2, 3, and 4 above)?

A. The PM or APM must perform an in-person, on-site visit at least once per calendar quarter to inspect the permit, review its operations, and ensure that the permit is operated in compliance with all applicable laws, rules, and standards.

Q. What are a PM's attendance requirements for an LSP to operate a facility where dispensing occurs only by NPs or PAs, or a health department where dispensing occurs only by RNs (categories 5 and 6 above)?

A. The PM or APM must perform an in-person, on-site visit at least once per week to inspect the permit, review its operations, and ensure the permit is operated in compliance with all applicable laws, rules, and standards.

Q. What are a PM's attendance requirements for an LSP to operate a health department where pharmacists dispense, a free or charitable clinic pharmacy, or a critical access hospital pharmacy (categories 7, 8, and 9 above)?

A. The PM or APM may have a flexible attendance schedule, but shall be present for at least one-half of the hours the pharmacy is open or 20 hours per week, whichever is less.

For health department or free/charitable clinic pharmacies (categories 5 and 6), a licensed pharmacist must, of course, be present whenever the pharmacy is open.

For critical access hospital pharmacies (category 7), the LSP may operate in the absence of a pharmacist only as permitted by Board Rule 1413

* * *

Any pharmacist with further questions about LSP eligibility, LSP permit application or renewal, or LSP operation is encouraged to contact Board staff.