GUIDANCE ON EXPANDED SCOPE OF AUTHORITY FOR CLINICAL PHARMACIST PRACTITIONERS

Effective October 1, 2025, changes to clinical pharmacist practitioner ("CPP") scope of practice enacted in <u>SL 2025-37</u> become effective. This guidance document details what changed, what did not change, and how Board staff will approach the CPP application review and approval process come October 1, 2025.

Qualification to Practice As a CPP

The statutory amendments did <u>not</u> change the definition of a clinical pharmacist practitioner: "[A] licensed pharmacist who meets the guidelines and criteria for such title established by the joint subcommittee of the North Carolina Medical Board and the North Carolina Board of Pharmacy and is authorized to enter into drug therapy management agreements with physicians in accordance with the provisions of G.S. 90-18.4."

Accordingly, the three CPP qualification pathways in <u>Board Rule .3101(b)</u> remain in place. Any change would require joint rulemaking by the Pharmacy and Medical Boards. In the coming months, changes to Board Rule .3101 (and its Medical Board mirror rule) may be proposed. Pharmacists should monitor the Board's "Rulemakings in Progress" tab on the website (<u>www.ncbop.org</u>).

CPP Scope of Authority Changes

CPPs may provide "health care services . . . under a collaborative practice agreement with one or more physicians." G.S. § 90-18(c)(3a); see also G.S. § 90-18.4; G.S. § 90-85.3(b2).

"Health care services" are "medical tasks, acts, or functions authorized through a written agreement by a physician and delegated to a pharmacist for the purpose of providing drug therapy, disease, or population health management for patients." G.S. § 90-18(c)(3a). Providing population health management services may include a CPP receiving referrals from health care providers who are not the CPP's supervising physician if the practice agreement specifically authorizes such referrals and the supervising physician accepts responsibility for overseeing the CPP's care of those patients.

CPPs may order "medications, tests, or devices" as part of the medical tasks, acts, or functions authorized by their collaborative practice agreement. G.S. § 90-18.4(c1).

A CPP's collaborative practice agreement may include, if the CPP and supervising physician intend to allow it, a "statement of authorization" allowing the CPP to "conduct drug substitutions within the same therapeutic class or for biosimilar medications based upon the health plan's drug formulary for a patient." G.S. § 90-18.4(e)(5).

A supervising physician may include Physician Assistants and Nurse Practitioners that they also supervise in a CPP collaborative practice agreement. Evaluation and supervision responsibility for the CPP remains with the supervising physician, however. G.S. 90-18.4(f).

A supervising physician may collaborate with "any number of clinical pharmacist practitioners" that the supervising physician "deems can be safely and effectively supervised." G.S. § 90-18.4(e)(3).

Institutional and group practices may implement site-specific, multi-provider practice agreements for care of their patients. The institution must develop an oversight policy and CPPs operating under the agreement must be evaluated by a supervising physician. G.S. 90-18.4(c2).

Collaborative Practice Agreement Content Changes

Specific collaborative practice agreement content required by the revised statute include:

- The CPP must have a "site-specific" supervising physician. G.S. § 90-18.4(e1). The supervising physician shall determine the location at which the CPP may provide health care services, and the CPP may be fully or partially embedded at the site-specific practice. G.S. § 90-18.4(f). The practice agreement should specify each site where the CPP will practice (multiple sites including pharmacies are allowed) and which supervising physician (if there is more than one; a supervising physician may oversee multiple practice sites if doing so provides clinically appropriate oversight) is responsible for CPP supervision at each site.
- The "health care services" (again, defined as "medical tasks, acts, or functions") "such as initiating, changing, or discontinuing drugs, or ordering tests or devices, to assist with drug therapy, disease, or population health management, must be included" in the collaborative practice agreement. G.S. § 90-18.4(e)(4).

Collaborative Practice Agreement content requirements contained in <u>Board Rule</u> .3101(b) that were not superseded by the statute remain in place. Those include:

- Be approved and signed by the supervising physician and maintained at the CPP's practice site for inspection. 21 NCAC 46.3101(f)(1).
- Include a pre-determined plan for emergency services. 21 NCAC 46.3101(f)(5).
- For the first six months of the collaborative practice agreement, include a plan and schedule for monthly meetings to discuss operation of the agreement (i.e., the services provided, and the manner in which the CPP has provided them) with the supervising physician, and thereafter a plan and schedule for such meetings at least once every six months. 21 NCAC 46.3101(f)(6); see G.S. § 90-18.4(e)(2) ("The supervising physician shall conduct periodic review and evaluation of the health care services provided by the clinical pharmacist practitioner.").
- Require that the patient be notified of the collaborative relationship under the practice agreement. 21 NCAC 46.3101(f)(7).

CPP Application

A pharmacist who wishes to practice as a CPP must be eligible to do so (see above), must apply for CPP status with the Board of Pharmacy, and must have that application approved. Detailed instructions on filing an application are found here:

https://www.ncbop.org/clinical-pharmacist-practitioner.html

Board staff are presently updating the CPP application and the CPP landing site at www.ncbop.org to reflect S.L. 2025-37's changes. When complete, staff will provide a step-by-step guide to the revised application.

CPP Application Review

Board staff will continue its present process for reviewing a CPP applicant's qualifications, and that the applicant has entered into a signed practice agreement.

Given the expanded authority conferred upon CPPs and supervising physicians to tailor a practice agreement, the application process will no longer include a detailed review of the practice agreement itself. The CPP and supervising physician(s) are responsible for the practice agreement meeting all legal requirements and restrictions in its form and operation. Board staff can (and will) respond to complaints that a CPP practiced beyond the authority granted by the revised CPP statute and/or engaged in negligent or unprofessional conduct while practicing as a CPP. See generally G.S. § 90-85.38(a).

CPPs and supervising physicians must maintain their agreement at practice site(s) for inspection.