

TITLE 21 - OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

CHAPTER 46 - PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rule cited as 21 NCAC 46 .3101.

Link to agency website pursuant to G.S. 150B-19.1(c): <https://www.ncbop.org/rulemakings.htm>

Proposed Effective Date: April 1, 2027

Public Hearing:

Date: November 10, 2026

Time: 10:00 a.m.

Location: Proximity Hotel, 704 Green Valley Road, Greensboro, NC 27408 (Teams: <https://tinyurl.com/3fjb6fu6>)

Reason for Proposed Action: Session Law 2025-37 implemented changes to the practice of clinical pharmacist practitioners ("CPPs"), most notably (a) to expand the ability of CPPs to provide health care services that are delegated by a supervising physician, and (b) to allow CPPs to enter collaborative practice agreements with multi-provider institutional or group practices. As directed by G.S. 90-18(c)(3a), the Board of Pharmacy and the Medical Board have reviewed and proposed amendments to their respective CPP rules in order to remove inconsistent provisions and accommodate collaborative practice agreements. In addition, a working group proposed streamlining CPP and making the annual continuing education requirements for CPPs analogous to those for physician assistants and nurse practitioners. The boards further propose to reorganize and clean up the rules to be more logical and clear. Furthermore, because this is the only rule in Section .3100, the Board proposes this rule as the readoption of that section, to the extent permitted.

Comments may be submitted to: Jay Campbell, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; email ncboprulemaking@ncbop.org

Comment period ends: December 14, 2026

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit a written objection to the Rules Review Commission. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive letters via U.S. Mail, private courier service, or hand delivery to 1711 New Hope Church Road, Raleigh, North Carolina, or via email to oah.rules@oah.nc.gov. If you have any further questions concerning the submission of objections to the Commission, please review 26 NCAC 05 .0110 or call a Commission staff attorney at 984-236-1850.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

- ☐ State funds affected
- ☐ Local funds affected
- ☐ Substantial economic impact ($\geq$ \$1,000,000)
- ☐ Approved by OSBM
- ☒ No fiscal note required

SECTION .3100 – CLINICAL PHARMACIST PRACTITIONERS

21 NCAC 46 .3101 CLINICAL PHARMACIST PRACTITIONER

(a) A pharmacist may serve as a clinical pharmacist practitioner (or "CPP") pursuant to G.S. 90-18(c)(3a) and 90-18.4 as set forth in this Rule.

Definitions. As used in this Rule:

- (1) "Medical Board" means the North Carolina Medical Board.
- (2) "Pharmacy Board" means the North Carolina Board of Pharmacy.
- (3) "Clinical Pharmacist Practitioner" or "CPP" means a licensed pharmacist who is approved to provide drug therapy management, including controlled substances, under the direction or supervision of a Supervising Physician pursuant to a CPP Agreement. Only a pharmacist approved by the Pharmacy Board and the Medical Board may legally identify himself as a CPP.
- (4) "Supervising Physician" means a licensed physician who, by signing the CPP Agreement, is held accountable for the on-going supervision and evaluation of the drug therapy management performed by the CPP as defined in the CPP Agreement. This term includes both the Primary Supervising Physician and any Back Up Supervising Physician.

- (5) ~~"Primary Supervising Physician" means the Supervising Physician who shall provide on going supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the CPP Agreement.~~
- (6) ~~"Back Up Supervising Physician" means a Supervising Physician who shall provide supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the CPP Agreement when the Primary Supervising Physician is not available.~~
- (7) ~~"Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to practice as a CPP in accordance with this Rule.~~
- (8) ~~"Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.~~
- (9) ~~"Clinical Experience approved by the Boards" means work in a clinical pharmacy practice setting which includes experience consistent with the components listed in Parts (b)(2)(A), (B), (C), (D), (E), (H), (I), (J), (N), (O), and (P) of this Rule. Clinical experience requirements must be met only through activities separate from the certificate programs referred to in Parts (b)(1)(B) of this Rule.~~
- (10) ~~"CPP Agreement" means a written agreement between the CPP, Primary Supervising Physician and any Back Up Supervising Physician by which the Supervising Physician(s) have provided written instructions to the CPP for patient specific and disease specific drug therapy, which may include ordering, changing, or substituting therapies or ordering tests.~~

(b) ~~CPP application for approval.~~

- (1) ~~The requirements for application for CPP approval include that the pharmacist:~~ A pharmacist may serve as a CPP only after the Medical Board and the Board of Pharmacy (collectively, "the Boards") approve a pharmacist who meets each of the following requirements:
 - ~~(A)(1)~~ The pharmacist has an unrestricted and current license to practice as a pharmacist in North ~~Carolina.~~ Carolina;
 - ~~(B)(2)~~ The pharmacist meets one of the following qualifications:
 - ~~(i)(A)~~ has earned ~~Board~~ Certification from the Board of Pharmaceutical ~~Specialties;~~ Specialties, is a Certified Geriatric Pharmacist as certified by the Commission for Certification in Geriatric Pharmacy, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program with two years of Clinical Experience approved by the Boards; or
 - ~~(B)~~ has completed a residency program accredited by the American Society of Health System Pharmacists; or
 - ~~(C)~~ holds an undergraduate professional degree in pharmacy as defined in Rule .1317 of this Section and has acquired two years of full-time practice of pharmacy in a clinical pharmacy practice setting that includes experience consistent with the health care services to be provided under the collaborative practice agreement. This clinical experience must be acquired following graduation with an undergraduate professional degree in pharmacy.
 - ~~(ii)~~ holds the academic degree of Doctor of Pharmacy, has three years of Clinical Experience approved by the Boards, and has completed a North Carolina Center for Pharmaceutical Care (NCCPC) or American Council on Pharmaceutical Education (ACPE) approved certificate program in the area of practice covered by the CPP Agreement; or
 - ~~(iii)~~ holds the academic degree of Bachelor of Science in Pharmacy, has five years of Clinical Experience approved by the Boards, and has completed two NCCPC or ACPE approved certificate programs with at least one program in the area of practice covered by the CPP Agreement;
 - ~~(C)~~ submits the required application and fee to the Pharmacy Board;
 - ~~(D)~~ submits any information deemed necessary by the Pharmacy Board in order to evaluate the application; and
 - ~~(E)~~ has a signed CPP Agreement.
- (3) The pharmacist certifies that he or she is a party to a signed collaborative practice agreement that meets the requirements of G.S. 90-18(c)(3a) and 90-18.4 and this Rule, and identifies the supervising physician and (if applicable) the institution or group practice that is a party to the agreement.
- (4) The pharmacist submits any information required by the Boards in order to evaluate whether the requirements of the Rule have been met.
- (5) The pharmacist pays the required fee. The fee provided in G.S. 90-8.2(b) as the maximum fee that the Boards are entitled to charge and collect for a request for approval is hereby established as the fee. No portion of that fee is refundable.

If for any reason a CPP discontinues working under an approved CPP Agreement, the CPP shall notify the Pharmacy Board in writing within 10 days, and the CPP's approval shall automatically terminate or be placed on inactive status until such time as a new application is approved in accordance with this Subchapter.

- (2) All certificate programs referred to in Subpart (b)(1)(B)(i) of this Rule must contain a core curriculum, including the following components:
 - ~~(A)~~ communicating with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;
 - ~~(B)~~ designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care;
 - ~~(C)~~ identifying, assessing, and solving medication related problems and providing a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;
 - ~~(D)~~ conducting physical assessments, evaluating patient problems, and ordering and monitoring medications and laboratory tests;

- (E) referring patients to other health professionals as appropriate;
 - (F) administering medications;
 - (G) monitoring patients and patient populations regarding the purposes, uses, effects, and pharmacoeconomics of their medication and related therapy;
 - (H) counseling patients regarding the purposes, uses, and effects of their medication and related therapy;
 - (I) integrating relevant diet, nutritional, and non drug therapy with pharmaceutical care;
 - (J) recommending, counseling, and monitoring patient use of non-prescription drugs, herbal remedies, and alternative medicine practices;
 - (K) using, ordering, and instructing on the use of devices and durable medical equipment;
 - (L) providing emergency first care;
 - (M) retrieving, evaluating, utilizing, and managing data and professional resources;
 - (N) using clinical data to optimize therapeutic drug regimens;
 - (O) collaborating with other health professionals;
 - (P) documenting interventions and evaluating pharmaceutical care outcomes;
 - (Q) integrating pharmacy practice within healthcare environments;
 - (R) integrating national standards for the quality of healthcare; and
 - (S) conducting outcomes and other research.
- (3) The completed application for approval to practice as a CPP shall be reviewed by the Pharmacy Board upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina. The Pharmacy Board shall:
- (A) approve the application and, at the time of approval, issue a number which shall be printed on each prescription written by the CPP;
 - (B) deny the application; or

(c) The Boards may deny CPP approval for failure to comply with G.S. 90-18(c)(3a) or 90-18.4 or this Rule, or for any grounds stated in Paragraph (h) of this Rule. In the alternative to either granting or denying CPP approval, the Boards may approve CPP status the application with restrictions, in the event that restrictions are appropriate in order to protect the public health, safety, and welfare in light of the information received and reviewed by the Boards, as part of the CPP application.

(e) Annual Renewal:

- (1) Each CPP shall register annually on or before December 31 by:
 - (A) verifying that the CPP holds a current Pharmacist license;
 - (B) submitting the renewal fee as specified in Subparagraph (j)(2) of this Rule;
 - (C) completing the Pharmacy Board's renewal form; and
 - (D) reporting continuing education credits as required by Paragraph (d) of this Rule.
- (2) If the CPP has not renewed the CPP's annual registration pursuant to Subparagraph (e)(1) of this Rule within 60 days of December 31, the approval to practice as a CPP shall lapse.

(d) Continuing Education:

- (1) Each CPP shall earn 35 hours of practice relevant CE each year, approved by the Pharmacy Board.
- (2) Documentation of these hours shall be kept at the CPP practice site and made available for inspection by agents of the Medical Board or Pharmacy Board.

(e) A Supervising Physician who has a CPP Agreement with a CPP shall be readily available for consultation with the CPP and, at the meetings required by Subparagraph (f)(6) of this Rule, shall review each order written by the CPP.

(f) The CPP Agreement shall:

(d) The CPP may provide health care services pursuant to a collaborative practice agreement so long as both the agreement and the operation of the agreement meet the requirements of G.S. 90-18(c)(3a) and 90-18.4 and this Rule:

- (1) The agreement must specify the health care services that the CPP is authorized to provide.
- ~~(1)(2)~~ The agreement must be approved and signed by the CPP and either the supervising physician or the institutional or group practice through which the CPP provides health care services, Primary Supervising Physician, any Back-Up Supervising Physician, and the CPP, and a copy shall be maintained in each practice site for inspection by agents of either Board upon request.
- (2) be specific in regard to the physician, the pharmacist, the patient, and the disease;
- (3) Any practice site must be within the State of North Carolina, specify the predetermined drug therapy, which shall include the diagnosis and product selection by the patient's physician and any modifications which may be permitted, dosage forms, dosage schedules and tests which may be ordered;
- (4) prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed by the physician without first obtaining written consent of the physician; The agreement must have a supervising physician who:
 - (A) Agrees to perform on-going supervision and evaluation of the health care services performed by the CPP under the agreement and to be held accountable for doing so. The agreement must be in writing, by the supervising physician either signing the agreement or signing a separate acknowledgement of having reviewed the agreement and agreeing to serve as supervising physician. Any acknowledgement must be maintained in the same location as the agreement and must be renewed upon any amendments to the agreement.
 - (B) Has an unrestricted and current license to practice medicine in North Carolina and spends the majority of the physician's time in practice located physically within the State;
 - (C) Is engaged in clinical practice;
 - (D) Is not serving in a postgraduate medical training program;

- (E) Specifies the site or sites to which the collaborative practice agreement applies, and is readily available for consultation with the CPP;
- (F) Possesses a registration for a schedule or schedules of controlled substances equal to or greater than the CPP's DEA registration; and
- (G) If not identified to the Board at the time of any approval or renewal, is identified within 10 days after the physician becomes a supervising physician.

(5) The agreement must include a pre-determined plan for emergency services. ~~services;~~

(6) The agreement must incorporate a policy for oversight and evaluation of the CPP by the supervising physician, including a periodic review and evaluation of the health care services provided by the CPP. For the first six months, months of the CPP Agreement include a plan and schedule for monthly meetings to discuss the CPP and supervising physician must meet at least monthly to review the operation of the CPP Agreement collaborative practice agreement, the health care services provided by the CPP, and measures to improve the health care services provided by the CPP, and quality improvement measures between the Primary Supervising Physician and CPP, and thereafter include a plan and schedule for meetings between the Primary Supervising Physician and Thereafter, the CPP and supervising physician must meet to perform these tasks at least once every six months, months to discuss the operation of the CPP Agreement and quality improvement measures. Documentation of the meetings between the CPP and the supervising physician ~~Primary Supervising Physician~~ shall:

- (A) identify clinical issues discussed and actions taken;
- (B) be signed and dated by those who attended; and
- (C) be retained by both the CPP and supervising physician Primary Supervising Physician and be available for review by agents of either Board for five calendar years. ~~years;~~

(7) The agreement must require that the evaluation and supervision of the CPP remain with the supervising physician, regardless of whether other physicians or advanced practice providers are parties to the collaborative practice agreement, require that the patient be notified of the collaborative relationship under the CPP Agreement; and

(8) be terminated when patient care is transferred to another physician and new orders will be written by the succeeding physician.

(g) A Supervising Physician shall:

- (1) be fully licensed with the Medical Board and engaged in clinical practice;
- (2) not be serving in a postgraduate medical training program;
- (3) be approved with this Subchapter before the CPP supervision occurs; and
- (4) supervise no more than three pharmacists.

~~(h)(c)~~ (e) The CPP shall wear a nametag spelling out the words "Clinical Pharmacist Practitioner". Practitioner" at all times that the CPP provides health care services pursuant to this Rule.

(f) A CPP may be registered only when actively providing services pursuant to a collaborative practice agreement. If for any reason a CPP discontinues practicing under the agreement or the supervising physician no longer serves under the agreement (and no replacement agrees to serve), the CPP shall notify the Board of Pharmacy in writing within 10 days, and the CPP's approval shall automatically be placed on inactive status until such time as a new approval is issued in accordance with this Rule.

(g) A CPP must renew CPP status on annual basis by December 31 as follows:

- (1) The CPP shall earn 25 hours of practice-relevant continuing education each calendar year that has been approved for credit by the American Council on Pharmaceutical Education or the Accreditation Council for Continuing Medical Education. The hours earned for the continuing education required by Rule .2201 may also count toward these hours, if they also qualify under this Rule. A CPP who prescribes controlled substances shall complete at least one hour of continuing education designed specifically to address controlled substance prescribing practices. Documentation of these hours shall be kept at the CPP practice site and made available for inspection by agents of either Board.
- (2) The CPP shall update the information set out in Paragraph (b) of this Rule, certify the required continuing education hours, and submit any information required by the Boards in order to evaluate whether the requirements of the Rule have been met.
- (3) The CPP shall pay the required fee. The fee provided in G.S. 90-8.2(b) as the maximum fee that the Boards are entitled to charge and collect for a request for renewal is hereby established as the fee. No portion of that fee is refundable.
- (4) Any CPP registration that is not renewed by March 1 of the succeeding year lapses, and it is unlawful to practice as a CPP following that date.

~~(i)(h)~~ (h) A CPP may be censured or reprimanded, and his or her CPP approval may be restricted, suspended, revoked, annulled, denied, or terminated or denied by either of the Boards, the Medical Board or the Pharmacy Board. In addition or in the alternative, the pharmacist may be censured or reprimanded, and the pharmacist's license may be restricted, suspended, revoked, annulled, or denied, or terminated or the pharmacist may be required to successfully complete remedial education by the Board of Pharmacy, Pharmacy Board, in accordance with provisions of G.S. 90-85.38, G.S. 150B. The Boards Pharmacy Board or the Medical Board may take the actions set forth in this Paragraph with respect to the pharmacist, the CPP approval, or the pharmacist's license, if either Board finds one or more of the following:

- (1) The the CPP has held himself or herself out as, or permitted another to represent that the CPP is, a licensed physician; physician or other health care provider that the CPP is not.
- (2) the CPP has engaged, or attempted to engage, in the provision of drug therapy management other than at the direction of, or under the supervision of, a physician licensed and approved by the Medical Board to be that CPP's Supervising Physician;

- ~~(3)~~ ~~The the~~ CPP has provided, or attempted to provide, ~~health care services~~ ~~medical management~~ outside the collaborative practice agreement ~~approved CPP Agreement~~ or for which the CPP is not qualified by education and training to ~~provide.~~ provide;
- (3) The CPP has not satisfied the terms of the collaborative practice agreement.
- (4) The the CPP commits any act prohibited by G.S. 90-85.38 as determined by the Board of Pharmacy ~~Pharmacy Board~~ or G.S. 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical Board. ~~Board;~~
- (5) The CPP or anyone else operating under the collaborative practice agreement has modified the CPP's provision of health care services for financial gain.
- ~~(5)(6)~~ The the CPP has failed to comply with any of the provisions of G.S. 90-18(c)(3a) or 90-18.4 or this Rule.

This does not limit the grounds upon which the Board can discipline a pharmacist serving as a CPP on the same basis as it could any other pharmacist.

Any modification of treatment for financial gain on the part of the Supervising Physician or CPP shall be grounds for denial of Board approval of the CPP Agreement.

(j) Fees:

- (1) An application fee of one hundred dollars (\$100.00) shall be paid at the time of initial application for approval and each subsequent application for approval to practice as a CPP.
- (2) The fee for annual renewal of approval, due at the time of annual renewal pursuant to Paragraph (c) of this Rule, is fifty dollars (\$50.00).
- (3) No portion of any fee in this Rule is refundable.

History Note: Authority G.S. 90-8.2; 90-18; 90-18.4; 90-85.3; 90-85.18; 90-85.26A;

Eff. April 1, 2001;

Amended Eff. July 1, 2016; April 1, 2007; March 1, 2004; October 1, 2001;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017~~ 2017;

Amended Eff. April 1, 2027.