

21 NCAC 46 .3101 is amended with changes as published in 30:12 NCR 1289 as follows:

21 NCAC 46 .3101 CLINICAL PHARMACIST PRACTITIONER

(a) 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) "Joint Subcommittee" means the subcommittee composed of four members of the Pharmacy Board and four members of the Medical Board to whom responsibility is given by G.S. 90-6(e) to develop rules to govern the provision of drug therapy management by the Clinical Pharmacist Practitioner in North Carolina.~~

~~(4)~~ (3) "Clinical Pharmacist Practitioner" ~~Practitioner~~ or "CPP" ~~CPP~~ means a licensed pharmacist who is approved to provide drug therapy management, including controlled substances, under the direction of, or ~~under the~~ supervision of a Supervising Physician pursuant to a CPP Agreement. ~~licensed physician who has provided written instructions for a patient and disease specific drug therapy which may include ordering, changing, substituting therapies or ordering tests.~~ Only a pharmacist approved by the Pharmacy Board and the Medical Board may legally identify himself as a CPP.

~~(5)~~ (4) "Supervising Physician" means a licensed physician who, by signing the CPP Agreement, ~~agreement,~~ is held accountable for the on-going supervision and evaluation of the drug therapy management performed by the CPP as defined in the ~~physician, patient, pharmacist and disease specific written CPP Agreement, agreement.~~ This term includes both the Primary Supervising Physician and any Back-Up Supervising Physician.

~~(6)~~ (5) "Primary Supervising Physician" means the ~~licensed physician~~ Supervising Physician who shall provide on-going supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in ~~written~~ the CPP Agreement. ~~[agreement.]~~

~~(7)~~ (6) "Back-Up Supervising Physician" means a ~~licensed physician~~ Supervising Physician who shall provide supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the ~~written~~ CPP Agreement ~~[agreement]~~ when the Primary Supervising Physician is not available.

~~(8)~~ ~~(8)~~ (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.

~~(9)~~ ~~(9)~~ (8) "Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.

~~(10)~~ ~~(10)~~ (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) has an unrestricted and current license to practice as a pharmacist in North Carolina;

(B) meets one of the following qualifications:

(i) has earned Certification from the Board of Pharmaceutical 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 program, which includes two years of clinical experience Clinical Experience approved by the Boards; or

(ii) has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy, Pharmacy and has three years of clinical experience Clinical Experience approved by the Boards, 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; agreement; or

(iii) has successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy, Pharmacy and has five years of clinical experience Clinical Experience approved by the Boards, 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; agreement;

(C) submits the required application and the fee to the Medical Pharmacy Board;

(D) submits any information deemed necessary by the Medical Pharmacy Board in order to evaluate the application; and

(E) has a signed CPP Agreement supervising physician agreement.

If for any reason a CPP discontinues working under an approved CPP Agreement, in the approved physician arrangement, the CPP shall notify both Boards the Pharmacy Board in writing within 10 days days, and the CPP's approval shall automatically terminate or be placed on an 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 curriculum, including the following components:

- 1 (A) communicating with healthcare professionals and patients regarding drug therapy,
2 wellness, and health promotion;
- 3 (B) designing, implementing, monitoring, evaluating, and modifying or recommending
4 modifications in drug therapy to insure effective, safe, and economical patient care;
- 5 (C) identifying, ~~assessing~~ ~~assessing~~, and solving medication-related problems and providing a
6 clinical judgment as to the continuing effectiveness of individualized therapeutic plans and
7 intended therapeutic outcomes;
- 8 (D) conducting physical assessments, evaluating patient problems, ~~and~~ ordering and
9 monitoring medications and laboratory tests;
- 10 (E) referring patients to other health professionals as appropriate;
- 11 (F) administering medications;
- 12 (G) monitoring patients and patient populations regarding the purposes, uses, ~~effects~~ ~~effects~~,
13 and pharmacoeconomics of their medication and related therapy;
- 14 (H) counseling patients regarding the purposes, uses, and effects of their medication and related
15 therapy;
- 16 (I) integrating relevant diet, ~~nutritional~~ ~~nutritional~~, and non-drug therapy with pharmaceutical
17 care;
- 18 (J) recommending, counseling, and monitoring patient use of non-prescription drugs, herbal
19 ~~remedies~~ ~~remedies~~, and alternative medicine practices;
- 20 (K) using, ordering, and instructing on the use of ~~devices,~~ ~~devices~~ and durable medical
21 equipment;
- 22 (L) providing emergency first care;
- 23 (M) retrieving, evaluating, utilizing, and managing data and professional resources;
- 24 (N) using clinical data to optimize therapeutic drug regimens;
- 25 (O) collaborating with other health professionals;
- 26 (P) documenting interventions and evaluating pharmaceutical care outcomes;
- 27 (Q) integrating pharmacy practice within healthcare environments;
- 28 (R) integrating national standards for the quality of healthcare; and
- 29 (S) conducting outcomes and other research.
- 30 (3) The completed application for approval to practice as a CPP shall be reviewed by the ~~Medical~~
31 ~~Pharmacy~~ Board upon verification of a full and unrestricted license to practice as a pharmacist in
32 North Carolina. ~~The Pharmacy Board shall:~~
- 33 (A) ~~The approve the~~ application ~~shall be approved and~~ ~~and~~, at the time of ~~approval,~~ ~~approval~~
34 ~~the Medical Board shall~~ issue a number which shall be printed on each prescription written
35 by the CPP; ~~or~~
- 36 (B) ~~The application shall be denied;~~ ~~deny the application:~~ or

(C) ~~The approve the~~ application ~~shall be approved~~ with ~~restrictions, 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 in the CPP application in~~
~~Subparagraph (b)(1) of this Rule.~~

(c) Annual Renewal.

(1) Each CPP shall register annually on or before December 31 ~~the anniversary of his or her birth date~~
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 ~~Medical Pharmacy~~ Board's renewal form; and

(D) reporting continuing education credits as required by Paragraph (d) of this Rule. ~~specified~~
~~by the Medical Board.~~

(2) If the CPP has not renewed the CPP's annual registration pursuant to Subparagraph (c)(1) of this
Rule within ~~30~~ 60 days of December 31, the anniversary of the CPP's birth date, the approval to
practice as a CPP shall lapse.

(d) Continuing Education.

(1) Each CPP shall earn 35 hours of ~~practice-relevant~~ practice-relevant CE each year, 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) ~~The A~~ Supervising Physician ~~supervising physician~~ who has a CPP Agreement ~~signed agreement~~ with the a CPP
shall be readily available for consultation with the CPP and and, at the meetings required by Subparagraph (f)(6) of
this Rule. ~~shall review and countersign each order written by the CPP. CPP within seven days.~~

(f) The ~~written~~ CPP Agreement ~~agreement~~ shall:

(1) be approved and signed by ~~both~~ the Primary Supervising Physician, any Back-Up Supervising
Physician, [Physician] ~~supervising physician~~ and the CPP 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, patient and the disease;

(3) specify the predetermined drug therapy therapy, which shall include the diagnosis and product
selection by the patient's physician; 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;

(5) include a pre-determined plan for emergency services;

(6) for the first six months of the CPP Agreement [agreement,] include a plan and schedule for monthly
meetings to discuss [practice relevant clinic issues] the operation of the CPP Agreement and quality
improvement measures ~~weekly quality control, review and countersignature of all orders written by~~

- 1 the CPP in a face-to-face conference between the ~~physician~~ Primary Supervising Physician and CPP,
2 and thereafter include a plan and schedule for meetings between the Primary Supervising Physician
3 and CPP at least once every six months to discuss [practice relevant clinical issues] the operation of
4 the CPP Agreement and quality improvement measures. Documentation of the meetings between
5 the CPP and the Primary Supervising Physician shall: ~~CPP~~;
- 6 (A) identify clinical issues discussed and actions taken;
7 (B) be signed and dated by those who attended; and
8 (C) be retained by both the CPP and Primary Supervising Physician and be available for review
9 by members or agents of either Board for five calendar years;
- 10 (7) require that the patient be notified of the collaborative relationship under the CPP Agreement;
11 relationship; and
12 (8) be terminated when patient care is transferred to another physician and new orders shall will be
13 written by the succeeding physician.
- 14 (g) ~~The A~~ Supervising Physician ~~supervising physician of the CPP~~ shall:
- 15 (1) be fully licensed with the Medical Board and engaged in clinical practice;
16 (2) not be serving in a postgraduate medical training program;
17 (3) be approved in accordance with this Subchapter before the CPP supervision occurs; and
18 (4) supervise no more than three pharmacists.
- 19 (h) The CPP shall wear a nametag spelling out the words "Clinical Pharmacist Practitioner".
- 20 (i) A CPP may be censured or reprimanded, and his or her approval may be restricted, suspended, revoked, annulled,
21 ~~denied denied~~, or terminated by the Medical Board or the Pharmacy Board. In addition or in the alternative, the ~~The~~
22 pharmacist may be censured or reprimanded, and the pharmacist's license may be restricted, suspended, revoked,
23 annulled, denied, or terminated by the Pharmacy Board, in accordance with provisions of G.S. ~~150B~~ 150B. The
24 Pharmacy Board or the Medical Board may take the actions set forth in this paragraph with respect to the pharmacist,
25 the CPP approval, or the pharmacist's license, if either Board finds one or more of the following:
- 26 (1) the CPP has held himself or herself out as, out, or permitted another, another to represent that the
27 CPP is, as a licensed physician;
28 (2) the CPP has engaged, or attempted to engage, in the provision of drug therapy management other
29 than at the direction of, or under the supervision of, a physician licensed and approved by the
30 Medical Board to be that CPP's Supervising Physician; supervising physician;
31 (3) the CPP has provided, performed, or attempted to provide, medical management outside the
32 approved CPP Agreement drug therapy agreement or for which the CPP is not qualified by education
33 and training to provide; perform;
34 (4) the CPP commits any act prohibited by G.S. 90-85.38 as determined by the Pharmacy Board or G.S.
35 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical Board; or
36 (5) the CPP has failed to comply with any of the provisions of this Rule.

Any modification of treatment for financial gain on the part of the ~~supervising physician~~ Supervising Physician or
CPP shall be grounds for denial of Board approval of the CPP Agreement. ~~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. ~~practice.~~
- (2) The fee for annual renewal of approval, due at the time of annual renewal pursuant to Paragraph (c)
of this Rule, on the CPP's anniversary of birth date is fifty dollars (\$50.00).
- (3) No portion of any fee in this Rule is refundable.

History Note: Authority G.S. ~~90-6;~~ 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.