

21 NCAC 32T .0101 is amended, with changes, as published in 30:12 NCR pages 1285-1289 as follows:

21 NCAC 32T .0101 CLINICAL PHARMACIST PRACTITIONER

(a) Definitions as used in the 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(c) 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~~ 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 Primary Supervising Physician and 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 the ~~written~~ 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)(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)(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)(9)~~ "Clinical Experience approved by the Boards" means work in a pharmacy practice setting which includes experience consistent with the following components as 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.

1 (10) "CPP Agreement" means a written agreement between the CPP, Primary Supervising Physician and
2 any Back-Up Supervising Physician by which the Supervising Physician(s) have provided written
3 instructions to the CPP for patient-specific and disease-specific drug therapy, which may include
4 ordering, changing, or substituting therapies or ordering tests.

5 (b) CPP application for approval.

6 (1) The requirements for application for CPP approval include that the pharmacist:

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

8 (B) meets one of the following qualifications:

9 (i) has earned Certification from the Board of Pharmaceutical Specialties, is a Certified
10 Geriatric Pharmacist as certified by the Commission for Certification in Geriatric
11 Pharmacy, or has completed an American Society of Health System Pharmacists
12 (ASHP) accredited residency program, which includes program with two years of
13 clinical experience Clinical Experience approved by the Boards; or

14 (ii) has successfully completed the course of study and holds the academic degree of
15 Doctor of Pharmacy, Pharmacy and has three years of clinical experience Clinical
16 Experience approved by the Boards, Boards and has completed a North Carolina
17 Center for Pharmaceutical Care (NCCPC) or American Council on Pharmaceutical
18 Education (ACPE) approved certificate program in the area of practice covered by
19 the CPP agreement; Agreement; or

20 (iii) has successfully completed the course of study and holds the academic degree of
21 Bachelor of Science in Pharmacy, Pharmacy and has five years of clinical
22 experience Clinical Experience approved by the Boards, Boards and has completed
23 two NCCPC or ACPE approved certificate programs with at least one program in
24 the area of practice covered by the CPP agreement; Agreement;

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

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

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

29 If for any reason a CPP discontinues working under an approved CPP Agreement, in the approved physician
30 arrangement, the clinical pharmacist practitioner shall notify both Boards the Pharmacy Board in writing within
31 ten days 10 days, and the CPP's approval shall automatically terminate or be placed on an inactive status until
32 such time as a new application is approved in accordance with this Subchapter.

33 (2) All certificate programs referred to in Subpart (b)(1)(B)(i) of this Rule must contain a core curriculum,
34 curriculum including the following components:

35 (A) communicating with healthcare professionals and patients regarding drug therapy, wellness,
36 and health promotion;

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

1 information received and reviewed in the CPP application in Subparagraph (b)(1) of this
2 Rule.

3 (c) Annual Renewal.

- 4 (1) Each CPP shall register annually on or before December 31 ~~the anniversary of his or her birth date~~ by:
- 5 (A) verifying that the CPP holds a current Pharmacist license;
 - 6 (B) submitting the renewal fee as specified in Subparagraph (j)(2) of this Rule;
 - 7 (C) completing the Medical Pharmacy Board's renewal form; and
 - 8 (D) reporting continuing education credits as required by subsection (d) of this Rule, specified by
9 the Medical Board.
- 10 (2) If the CPP has not renewed the CPP's annual registration pursuant to Subparagraph (c)(1) of this Rule,
11 within 30 60 days of December 31, the anniversary of the CPP's birth date, the approval to practice as
12 a CPP shall lapse.

13 (d) Continuing Education.

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

18 (e) ~~The A~~ Supervising Physician supervising physician who has a CPP Agreement signed agreement with a the CPP
19 shall be readily available for consultation with the CPP; and CPP and, at the meetings required by Subparagraph (f)(6) of
20 this Rule, shall review ~~and countersign~~ each order written by the CPP, CPP within seven days.

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

- 22 (1) be approved and signed by ~~both~~ the Primary Supervising Physician, and Back-Up Supervising
23 Physician, [Physician] ~~supervising physician~~ and the CPP CPP, and a copy shall be maintained in
24 each practice site for inspection by agents of either Board upon request;
- 25 (2) be specific in regards to the physician, the pharmacist, the patient, patient and the disease;
- 26 (3) specify the predetermined drug therapy, therapy which shall include the diagnosis and product
27 selection by the patient's physician; physician and any modifications which may be permitted, dosage
28 forms, dosage schedules and tests which may be ordered;
- 29 (4) prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed
30 by the physician without first obtaining written consent of the physician;
- 31 (5) include a pre-determined plan for emergency services;
- 32 (6) for the first six months of the CPP Agreement [agreement,] include a plan and schedule for monthly
33 meetings to discuss [practice-relevant clinic issues] the operation of the CPP Agreement and quality
34 improvement measures weekly quality control, review and countersignature of all orders written by the
35 CPP in a face to face conference between the physician Primary Supervising Physician and CPP, and
36 thereafter include a plan and schedule for meetings between the Primary Supervising Physician and
37 CPP at least once every six months to discuss [practice relevant clinical issues] the operation of the

1 CPP Agreement and quality improvement measures. Documentation of the meetings between the CPP
2 and the Primary Supervising Physician shall: CPP;

3 (A) identify clinical issues discussed and actions taken;

4 (B) be signed and dated by those who attended; and

5 (C) be retained by both the CPP and Primary Supervising Physician and be available for review
6 by members or agents of either Board for five calendar years;

7 (7) require that the patient be notified of the collaborative relationship; relationship under the CPP
8 Agreement; and

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

11 (g) The Supervising Physician supervising physician of the CPP shall:

12 (1) be fully licensed with the Medical Board and engaged in clinical practice;

13 (2) not be serving in a postgraduate medical training program;

14 (3) be approved in accordance with this Subchapter before the CPP supervision occurs; and

15 (4) supervise no more than three pharmacists.

16 (h) The CPP shall wear a nametag spelling out the words "Clinical Pharmacist Practitioner".

17 (i) The CPP may be censured or reprimanded or the CPP's approval may be restricted, suspended, revoked, annulled,
18 denied, denied or terminated by the Medical Board or the Pharmacy Board and Board. In addition or in the alternative,
19 the pharmacist may be censured or reprimanded or the pharmacist's license may be restricted, suspended, revoked,
20 annulled, denied, or terminated by the Pharmacy Board, in accordance with provisions of G.S. 150B G.S. 150B. The
21 Pharmacy Board or the Medical Board may take the actions set forth in this paragraph with respect to the pharmacist, the
22 CPP approval, or the pharmacist's license, if either Board finds one or more of the following:

23 (1) the CPP has held himself or herself out as, or permitted another to represent that the CPP is, as a
24 licensed physician;

25 (2) the CPP has engaged or attempted to engage in the provision of drug therapy management other than
26 at the direction of, or under the supervision of, a physician licensed and approved by the Medical
27 Board to be that CPP's supervising physician; Supervising Physician;

28 (3) the CPP has performed provided or attempted to provide medical management outside the approved
29 drug therapy agreement CPP Agreement or for which the CPP is not qualified by education and
30 training to perform; provide;

31 (4) The CPP commits any act prohibited by any provision of G.S. 90-85.38 as determined by the
32 Pharmacy Board or G.S. 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical
33 Board; or

34 (5) the CPP has failed to comply with any of the provisions of this Rule.

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

37 (j) Fees:

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

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7 *History Note* Authority G.S. ~~90-6(e);~~ **90-8.2 (b);** 90-18(c)3a; 90-18.4;
8 *Eff. April 1, 2001;*
9 *Amended Eff. July 1, 2016; March 1, 2007; October 1, 2001.*

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