

1 21 NCAC 32T .0101 is proposed to be amended as follows:

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3 **21 NCAC 32T .0101 CLINICAL PHARMACIST PRACTITIONER**

4 (a) Definitions as used in the Rule:

- 5 (1) "Medical Board" means the North Carolina Medical Board.
- 6 (2) "Pharmacy Board" means the North Carolina Board of Pharmacy.
- 7 (3) "Joint Subcommittee" means the subcommittee composed of four members of the Pharmacy Board and  
8 four members of the Medical Board to whom responsibility is given by G.S. 90-6(c) to develop rules  
9 to govern the provision of drug therapy management by the Clinical Pharmacist Practitioner in North  
10 Carolina.
- 11 (4) "Clinical Pharmacist Practitioner or CPP" means a licensed pharmacist who is approved to provide  
12 drug therapy management under the direction of, or under the supervision of a licensed physician who  
13 has provided written instructions for a patient and disease specific drug therapy which may include  
14 ordering, changing, substituting therapies or ordering tests. Only a pharmacist approved by the  
15 Pharmacy Board and the Medical Board may legally identify himself as a CPP.
- 16 (5) "Supervising Physician" means a licensed physician who, by signing the CPP agreement, is held  
17 accountable for the on-going supervision and evaluation of the drug therapy management performed  
18 by the CPP as defined in ~~the physician, patient, pharmacist and disease specific~~ written CPP  
19 agreement.
- 20 (6) "Primary Supervising Physician" means the licensed physician who shall provide on-going  
21 supervision, collaboration, consultation, and evaluation of the drug therapy management performed by  
22 the CPP as defined in the written CPP agreement.
- 23 (7) "Back-up Supervising Physician" means a licensed physician who shall provide supervision,  
24 collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as  
25 defined in the written CPP agreement when the Primary Supervising Physician is not available.
- 26 ~~(6)~~(8) "Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to  
27 practice as a CPP in accordance with this Rule.
- 28 ~~(7)~~(9) "Continuing Education or CE" is defined as courses or materials which have been approved for credit  
29 by the American Council on Pharmaceutical Education.
- 30 ~~(8)~~(10) "Clinical Experience approved by the Boards" means work in a pharmacy practice setting which  
31 includes experience consistent with the following components as listed in Parts (b)(2)(A), (B), (C),  
32 (D), (E), (H), (I), (J), (N), (O), and (P) of this Rule. Clinical experience requirements must be met  
33 only through activities separate from the certificate programs referred to in Parts (b)(1)(B) of this Rule.

34 (b) CPP application for approval.

- 35 (1) The requirements for application for CPP approval include that the pharmacist:  
36 (A) has an unrestricted and current license to practice as a pharmacist in North Carolina;  
37 (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, which includes two years of clinical experience approved by the Boards;
  - (ii) has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and 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) has successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy and 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 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 supervising physician agreement.

If for any reason a CPP discontinues working in the approved physician arrangement, the clinical pharmacist practitioner shall notify ~~both Boards~~ the Pharmacy Board in writing within ten 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 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, ordering and monitoring medications and laboratory tests;
  - (E) referring patients to other health professionals as appropriate;
  - (F) administering medications;

- 1 (G) monitoring patients and patient populations regarding the purposes, uses, effects and
- 2 pharmacoeconomics of their medication and related therapy;
- 3 (H) counseling patients regarding the purposes, uses, and effects of their medication and related
- 4 therapy;
- 5 (I) integrating relevant diet, nutritional and non-drug therapy with pharmaceutical care;
- 6 (J) recommending, counseling, and monitoring patient use of non-prescription drugs, herbal
- 7 remedies and alternative medicine practices;
- 8 (K) ordering of and educating patients regarding proper usage of devices, and durable medical
- 9 equipment;
- 10 (L) providing emergency first care;
- 11 (M) retrieving, evaluating, utilizing, and managing data and professional resources;
- 12 (N) using clinical data to optimize therapeutic drug regimens;
- 13 (O) collaborating with other health professionals;
- 14 (P) documenting interventions and evaluating pharmaceutical care outcomes;
- 15 (Q) integrating pharmacy practice within healthcare environments;
- 16 (R) integrating national standards for the quality of healthcare; and
- 17 (S) conducting outcomes and other research.

18 (3) The completed application for approval to practice as a CPP shall be reviewed by the Medical Board  
19 upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina.

- 20 (A) The application shall be approved and at the time of approval the Medical Board shall issue a
- 21 number which shall be printed on each prescription written by the CPP; or
- 22 (B) the application shall be denied; or
- 23 (C) the application shall be approved with restrictions.

24 (c) Annual Renewal.

- 25 (1) Each CPP shall register annually on or before December 31 ~~the anniversary of his or her birth date~~ by:
- 26 (A) verifying a current Pharmacist license;
- 27 (B) submitting the renewal fee as specified in Subparagraph (j)(2) of this Rule;
- 28 (C) completing the ~~Medical~~ Pharmacy Board's renewal form; and
- 29 (D) reporting continuing education credits as required by subsection (d) of this Rule. ~~specified by~~
- 30 ~~the Medical Board.~~

31 (2) If the CPP has not renewed within ~~30~~ 60 days of December 31, the anniversary of the CPP's birth date,  
32 the approval to practice as a CPP shall lapse.

33 (d) Continuing Education.

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

1 (e) ~~The~~ A supervising physician who has a signed agreement with the CPP shall be readily available for consultation  
2 with the CPP; and shall review ~~and countersign~~ each order written by the CPP. ~~CPP within seven days.~~

3 (f) The written CPP agreement shall:

4 (1) be approved and signed by ~~both~~ the Primary Supervising Physician, and Back-Up Supervising  
5 Physician ~~supervising physician~~ and the CPP ~~CPP~~, and a copy shall be maintained in each practice site  
6 for inspection by agents of either Board upon request;

7 (2) be specific in regards to the physician, the pharmacist, the patient and the disease;

8 (3) specify the predetermined drug therapy which shall include the diagnosis and product selection by the  
9 patient's physician; any modifications which may be permitted, dosage forms, dosage schedules and  
10 tests which may be ordered;

11 (4) prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed  
12 by the physician without first obtaining written consent of the physician;

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

14 (6) for the first six months of the CPP agreement, include a plan and schedule for monthly meetings to  
15 discuss practice-relevant clinic issues and quality improvement measures ~~weekly quality control,~~  
16 ~~review and countersignature of all orders written by the CPP in a face-to-face conference~~ between the  
17 ~~physician~~ Primary Supervising Physician and CPP, and thereafter include a plan and schedule for  
18 meetings between the Primary Supervising Physician and CPP at least every six months to discuss  
19 practice-relevant clinical issues and quality improvement measures. Documentation of the meetings  
20 between the CPP and the Primary Supervising Physician shall: ~~CPP;~~

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

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

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

25 (7) require that the patient be notified of the collaborative relationship; and

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

28 (g) The supervising physician of the CPP shall:

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

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

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

32 (4) supervise no more than three pharmacists.

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

34 (i) The CPP may be censured or reprimanded or the CPP's approval may be restricted, suspended, revoked, annulled,  
35 denied or terminated by the Medical Board or the Pharmacy Board and the pharmacist may be censured or reprimanded  
36 or the pharmacist's license may be restricted, suspended, revoked, annulled, denied, or terminated by the Pharmacy  
37 Board, in accordance with provisions of G.S. 150B if either Board finds one or more of the following:

- 1 (1) the CPP has held himself or herself out or permitted another to represent the CPP as a licensed  
2 physician;
- 3 (2) the CPP has engaged or attempted to engage in the provision of drug therapy management other than  
4 at the direction of, or under the supervision of, a physician licensed and approved by the Medical  
5 Board to be that CPP's supervising physician;
- 6 (3) the CPP has performed or attempted to provide medical management outside the approved drug  
7 therapy agreement or for which the CPP is not qualified by education and training to perform;
- 8 (4) The CPP commits any act prohibited by any provision of G.S. 90-85.38 as determined by the  
9 Pharmacy Board or G.S. 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical  
10 Board; or
- 11 (5) the CPP has failed to comply with any of the provisions of this Rule.

12 Any modification of treatment for financial gain on the part of the supervising physician or CPP shall be grounds for  
13 denial of Board approval of the agreement.

14 (j) Fees:

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

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21 *History Note Authority G.S. 90-6(c); 90-18(c)3a; 90-18.4;*  
22 *Eff. April 1, 2001;*  
23 *Amended Eff. July 1, 2016; March 1, 2007; October 1, 2001.*

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