REQUEST FOR TECHNICAL CHANGE

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .3101

DEADLINE FOR RECEIPT: April 7, 2016

***NOTE WELL:* This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

This rule appears to use various terms to refer to one particular type of document. Specifically, some or all of the following terms seem to refer to one type of document: "written instructions" (page 1, line 14), "CPP agreement" (page 1, lines 18, 20-21, 24, 27; page 2, lines 12, 17; page 4, lines 3, 14), "supervising physician agreement" (page 2,line 21), "approved physician arrangement" (page 2, line 22), "signed agreement" (page 4, line 1) "approved drug therapy agreement" (page 5, lines 6-7) and "agreement" (page 5, line 12). Please consistently use a single term to refer to one particular type of document. Consider adding a definition of this term.

Page 1, line 12 – replace "Clinical Pharmacist Practitioner or CPP" with "Clinical Pharmacist Practitioner" or "CPP"

Page 1, lines 13-14 – replace "direction of, or under the supervision of" with "direction or supervision of"

Page 1, lines 14-15 – replace "patient and disease" with "patient, and to provide disease" and insert a comma after "therapy"

Page 1, lines 22 and 25 – It appears that a "Primary Supervising Physician" and a "Back-Up Supervising Physician" are each a type of "Supervising Physician" that is defined in Subparagraph (a)(5). If so, replace "licensed physician" in each of these lines with the defined term "Supervising Physician"

Page 1, line 32 – delete "practice setting" if, as it appears, the phrase adds nothing to the meaning of Subparagraph (a)(10).

Page 2, line 5 – insert a comma after "Pharmacy"

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Page 2, line 6 – delete the comma after "program" if the requirement for Boards-approved clinical experience relates only to the ASHP residency.

Page 2, line 8 – insert a comma after "study" and delete "and"

Page 2, line 9 – insert a comma after "Pharmacy" and delete "and"

Page 2, line 10 – insert a comma after "Boards"

Page 2, line 13 – insert a comma after "study" and delete "and"

Page 2, line 14 – insert a comma after "Pharmacy" and delete "and"

Page 2, line 15 – insert a comma after "Boards"

Page 2, line 18 – delete "the" after "and"

Page 2, line 23 – insert a comma after "days"

Page 2, line 24 – delete "an"

Page 2, line 26 – insert a comma after "curriculum"

Page 2, line 31 – insert a comma after "assessing"

Page 2, line 34 – insert "and" before "ordering"

Page 3, line 1 – insert a comma after "effects"

Page 3, line 5 – insert a comma after "nutritional"

Page 3, line 7 – insert a comma after "remedies"

Page 3, line 8 – delete the comma after "devices"

Page 3, lines 17-22 – consider revising as follows:

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

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Page 3, line 22 – under what circumstances will the Board impose restrictions on an approval? What factors will the Board consider in deciding whether to impose restrictions and what restrictions to place on an approval?

Page 3, line 26 – insert "that he or she has been issued" after "verifying"

Page 3, line 31 – replace "renewed" with "registered as required by Subparagraph (c)(1) of this Rule"

Page 3, line 34 – replace "practice relevant" with "practice-relevant"

Page 3, line 34 – insert a comma after "year"

Page 4, line 5 – insert a comma after "Physician"

Page 4, line 7 – insert a comma after "patient"

Page 4, lines 8-10 – revise (f)(3) as two subparagraphs, as follows:

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

(4) specify any modifications which may be permitted, dosage forms, dosage schedules and tests which may be ordered;

Page 4, line 15 – what does "practice-relevant clinic issues" mean? Is this related to the requirement that a CPP agreement must be "specific with regard to the physician, the pharmacist, the patient, and the disease" (see (f)(2))? Please clarify.

Page 4, line 18 – insert "once" after "least"

Page 4, line 25 – what does "collaborative relationship" mean - relationship between (or among) whom?

Page 4, line 26 – replace "shall be" with "are"

Page 4, line 28 – capitalize the defined term "Supervising Physician"

Page 4, line 35 – insert a comma after "denied"

Page 4, line 35 – replace "Pharmacy Board. The pharmacist" with "Pharmacy Board, and a pharmacist"

Page 5, line 1 – consider revising as follows:

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

Page 5, line 5 – capitalize the defined term "Supervising Physician"

Page 5, line 6 – replace "performed" with "provided"

Page 5, lines 8 and 9 – delete "as determined by the Pharmacy Board" and "as determined by the Medical Board"

Page 5, line 11 – capitalize the defined term "Supervising Physician"

Page 5, lines 11-12 – Hasn't the Board already approved the "agreement" before a modification might be made or proposed? What does this sentence mean?

Page 5, line 15 – add "as a CPP" to the end of this line.

Page 5, line 16 – insert "to practice as a CPP" after "approval"

Page 5, line 20 – replace "90-6" with existing authority – perhaps "90-8.2(b)"

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

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21 NCAC 46 .3101 is amended 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(c) to develop rules to govern the provision of drug therapy management by the Clinical Pharmacist Practitioner in North Carolina.

(4) "Clinical Pharmacist Practitioner or 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 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) "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 ~~physician, patient, pharmacist and disease specific~~ written CPP agreement.

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

(7) "Back-Up Supervising Physician" means a licensed 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 when the Primary Supervising Physician is not available.

~~(6)~~ (8) "Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to practice as a CPP in accordance with this Rule.

~~(7)~~ (9) "Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.

~~(8)~~ (10) "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.

(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, which includes two years of clinical experience approved by the Boards; or

(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 CPP shall notify ~~both Boards~~ the Pharmacy Board in writing within 10 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;

(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 Medical Board upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina.

(A) The application shall be approved and at the time of approval the Medical Board shall issue a number which shall be printed on each prescription written by the CPP; or

(B) The application shall be denied; or

(C) The application shall be approved with restrictions.

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

(f) The written CPP agreement shall:

(1) be approved and signed by ~~both~~ the Primary Supervising Physician, any Back-Up Supervising 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 and the disease;

(3) specify the predetermined drug therapy which shall include the diagnosis and product selection by the patient's physician; 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, include a plan and schedule for monthly meetings to discuss practice-relevant clinic issues and quality improvement measures ~~weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference~~ between the ~~physician~~ Primary Supervising Physician and CPP, and thereafter include a plan and schedule for meetings between the Primary Supervising Physician and CPP at least every six months to discuss practice-relevant clinical issues and quality improvement measures. Documentation of the meetings between the CPP and the Primary Supervising Physician shall: ~~CPP;~~

(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 Primary Supervising Physician and be available for review by members or agents of either Board for five calendar years;

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

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

(g) ~~The~~ A supervising physician of the CPP 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 in accordance with this Subchapter before the CPP supervision occurs; and

(4) supervise no more than three pharmacists.

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

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

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

(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 CPP has performed, or attempted to provide, medical management outside the approved drug therapy agreement or for which the CPP is not qualified by education and training to perform;

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

(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 or CPP shall be grounds for denial of Board approval of the 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.

(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; 90-18; 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.