SECTION .3100 – GENERAL DEFINITIONS

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) "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) 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 two years of Clinical Experience approved by the Boards; or

(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.

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) approve 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 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 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 (c)(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:

(1) be approved and signed by the 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) 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;

(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 the operation of the CPP Agreement 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 CPP at least once every six months to discuss the operation of the CPP Agreement and quality improvement measures. Documentation of the meetings between the CPP and the 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 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 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 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. In addition or in the alternative, 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. The 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 CPP has held himself or herself out as, or permitted another to represent that the CPP is, 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 provided, or attempted to provide, medical management outside the approved CPP Agreement or for which the CPP is not qualified by education and training to provide;

(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 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;*
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