MARIO J. CIVERA, JR., MEMBER
HOUSE POST OFFICE BOX 202020
MAIN CAPITOL BUILDING
HARRISBURG, PENNSYLVANIA 17120-2020

232 LONG LANE
UPPER DARBY, PENNSYLVANIA 19082

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House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

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June 13, 2000

John R. McGinley, Jr., Chairman
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

Dear Chairman McGinley:

I am writing to inform you that the House Professional Licensure Committee held a meeting on June 13, 2000, and voted to approve Regulation 16A-499 and Regulation 16A-612.

Please feel free to contact my office if any questions should arise.

Sincerely,

Mario J. Civera

Mario J. Civera, Chairman
House Professional Licensure Committee

MJC/sms
Enclosures
cc: Charles D. Hummer, Jr., M.D., Chairman
State Board of Medicine
K. Stephen Anderson, M.Ed., CRNA, Chairman
State Board of Nursing
James W. Pashek, Chairman
State Board of Landscape Architects
Honorable Kim H. Pizzingrilli, Secretary of the Commonwealth
Department of State

Regulation 16A-499

State Board of Nursing and State Board of Medicine

PROPOSAL: Regulation 16A-499 amends 49 PA Code, Chapter 18, regulations of the State Board of Medicine, and Chapter 21, regulations of the State Board of Nursing. Section 15(b) of the Medical Practice Act of 1985, 63 P.S. Sec. 422.15(b), authorizes the boards to promulgate regulations which would authorize Certified Registered Nurse Practitioners to prescribe medications. The proposal would add five new sections to existing regulations regarding CRNPs, who are jointly regulated by the two boards. The first section sets forth the minimum requirements a CRNP must meet in order to prescribe and dispense drugs. The second section specifies which drugs a CRNP may prescribe and dispense, which drugs may be prescribed with restrictions, and drugs which may not be prescribed. The third section provides for a written collaborative agreement between a physician and a CRNP who prescribes drugs. The fourth section requires CRNPs to affirmatively identify themselves as CRNPs, and the fifth section limits a physician to collaborating with no more than two CRNPs who prescribe drugs.

Regulation 16A-499 is Final Rulemaking which was delivered to the Professional Licensure Committee on June 6, 2000. The Professional Licensure Committee has until June 26, 2000 to approve or disapprove the regulation.

ANALYSIS: Proposed Sections 18.53 and 21.283 provide that a CRNP may prescribe and dispense drugs if the CRNP has completed a CRNP program which is approved by the Boards, and if the CRNP has completed a specific course in advanced pharmacology of not less than 45 hours. The course, which must be at a more advanced level than a normally required nursing pharmacology course, may be either part of the CRNP education program, or an additional course taken from a board approved educational program. A CRNP with prescriptive authority would be required to complete 16 hours of board approved continuing education in pharmacology per biennium. A prescribing CRNP would be required to comply with standards of the State Board of Medicine relating to prescribing, administering and dispensing controlled substances, and packaging and labeling of dispensed drugs. A prescribing CRNP would also be required to comply with standards of the Department of Health relating to prescriptions and labeling of drugs, devices, cosmetics and controlled substances.

Pursuant to paragraph (a) of proposed Sections 18.54 and 21.284, the Boards would adopt the American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which a CRNP may prescribe and dispense, subject to other regulatory parameters.

Paragraph (b) lists 21 classes of drugs which a CRNP may prescribe so long as the drug is relevant to the practice of the CRNP and authorized in the collaborative agreement. Paragraph (c) lists four classes of drugs which a CRNP may not prescribe. The full list of these drugs is set forth in Annex A of the Boards' proposed rulemaking package.

Paragraph (d) of proposed Sections 18.54 and 21.284 provides that a collaborating physician who determines that a CRNP is prescribing or dispensing inappropriately shall immediately take corrective action of behalf of the patient, notify the patient of the reason for the action, and advise the CRNP as soon as possible. The action shall be noted by the CRNP or the physician in the patient's medical record.

Paragraph (e) would permit a CRNP to prescribe a Schedule II controlled substance for up to a 72 hour dose. The CRNP would be required to notify the collaborating physician of the prescription within 24 hours. A CRNP would be permitted to prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription would not be subject to refills unless authorized by the collaborating physician. Paragraph (f) would prohibit a CRNP from prescribing a Schedule I controlled substance, from prescribing a drug for a use not approved by the U.S. Food and Drug Administration without approval of the collaborating physician, and from delegating his or her prescriptive authority to another health care provider.

Paragraph (g) would require that the name and certification number of the CRNP be in printed format at the top of the prescription blank, and a space for the entry of the DEA registration number, if appropriate. The collaborating physician would also be identified as required by Medical Board regulation 16.91. Paragraph (h) would require that the CRNP to document in a patient's medical record the name, amount and dose of the drug prescribed, the number of refills, the date of the prescription and the CRNP's name.

Proposed Sections 18.55 and 21.285 would require a written collaborative agreement between a CRNP and a physician, and set forth what must be included in a collaborative agreement when a CRNP will prescribe drugs. In summary, this would include the identity of the parties, including a substitute physician who will provide direction for up to 30 days if the collaborating physician is unavailable. It must also identify the area of practice in which the CRNP is certified, and the categories of drugs from which the CRNP will prescribe. The collaborating physician must attest that he or she has knowledge and experience with any drug that the CRNP will prescribe. The collaborative agreement must be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupational Affairs. The agreement must be updated whenever it is changed substantially, and specify the amount of professional liability insurance carried by the CRNP.

Proposed Sections 18.56 and 21.286 would require a patient to be informed at the time of making an appointment that he or she will be seen by a CRNP. A CRNP must where a nametag with the title "Certified Registered Nurse Practitioner." A CRNP who holds a doctorate must inform patients that he or she is not a doctor of medicine or osteopathic medicine.

Proposed Sections 18.57 and 21.287 would limit a physician to collaborating with no more than two CRNPs who prescribe drugs. A physician may apply for a waiver of this limitation for good cause, as determined by the Boards. The limitation does not apply to CRNPs who do not prescribe drugs.

In submitting the regulations in final form, the Boards have adopted all of the House Professional Licensure Committee's recommendations as to core pharmacology education requirements, continuing education in pharmacology, requirement and contents of a written collaborative agreement, and conspicuous CRNP identification.

RECOMMENDATIONS: It is recommended that the Professional Licensure Committee approve the regulation.

House of Representatives
Professional Licensure Committee
June 9, 2000