Regulatory Analysis Form

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REVIEW COMMISSION

(1) Agency
Department of State, Bureau of Professional and Occupational Affairs, State Boards of Medicine and Nursing

(2) I.D. Number (Governor's Office Use)
16A- 499

IRRC Number: 2064

(3) Short Title
CRNP Prescriptive Authority

(4) PA Code Cite

49 Pa. Code, Chapter 18
49 Pa. Code, Chapter 21

(5) Agency Contacts & Telephone Numbers
Primary Contact: Herbert Abramson- 783-7200
Senior Counsel in Charge, Department of State
Secondary Contact: Gerald Smith - 783-7200
Senior Counsel in Charge, Department of State

(6) Type of Rulemaking (check one)

___ Proposed Rulemaking
_X_ Final Order Adopting Regulation
___ Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

X No
__ Yes: By the Attorney General
__ Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

This rulemaking authorizes certified registered nurse practitioners (CRNPs) to prescribe and dispense drugs within specified parameters. CRNPs are advanced practice registered nurses who perform acts of medical diagnosis and prescribe medical, therapeutic, or corrective measures in collaboration with and under the direction of a physician. The regulations define and require a written collaborative agreement between the collaborating physician and the CRNP; require prescribing CRNPs to have successfully completed a 45 hour course in advanced pharmacology and complete 16 hours of continuing education in pharmacology biennially; specify the categories of drugs a CRNP may prescribe based upon the potential for harm and side effects, the need for physician intervention, complexity, categories of exceptional breadth, and the potential for addiction or abuse; require CRNPs to clearly and conspicuously identify themselves; provide for a 2 to 1 ratio of prescribing CRNPs to collaborating physicians and allow physicians to apply for a waiver of the ratio.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Section 15(b) of the Medical Practice Act, Act of Dec. 20, 1985, P.L. 457, as amended, 63 P.S. § 422.15 (b), and Section 2 of the Professional Nursing Law, Act of May 22, 1951, P.L. 317, as amended, 63 P.S. § 212.

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No, the regulation is not mandated by any federal or state law or court order or federal regulation.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

CRNPs perform a vital role in the delivery of health care, especially in medically underserved areas. Working in collaboration with and under the direction of physicians, CRNPs diagnose and prescribe medical interventions. Under the current regulations, CRNPs cannot prescribe and dispense drugs, a function for which they have been educated. Promulgation of these regulations will allow CRNPs to prescribe and dispense drugs, which will fully utilize the advanced education and skills of these advanced practice nurses and positively affect the health and welfare of the citizens of Pennsylvania.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

This rulemaking will increase the availability of quality healthcare without increasing costs to the citizens of Pennsylvania. The risk of nonregulation is that CRNPs will not be able to prescribe and dispense drugs with the result being that the availability of comprehensive, timely, cost-effective health care in the Commonwealth will not be maximized.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The proposed amendments will benefit consumers of health care services, especially those whose initial contact with the health care system is a visit to a CRNP and those who live in medically underserved areas and rely on CRNPs, because the CRNP will be able to provide more comprehensive services. CRNPs will benefit because they will be able to make full use of their advanced education and skills. There are 4,667 licensed CRNPs in the Commonwealth.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Boards have not identified any groups or individuals who will be adversely affected by the regulation.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

There are 4,667 CRNPs registered with the State Board of Nursing. Only CRNPs who prescribe and dispense drugs will be expected to comply with the requirements of a 45 hour pharmacology course and 16 hours of continuing education biennially. All CRNPs will be expected to comply with the requirement of a written collaborative agreement. Each CRNP practicing in Pennsylvania has a collaborating physician who also will be required to comply with the regulation.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Before publishing proposed rulemaking, the Boards solicited input by mailing a preliminary draft of this rulemaking to approximately 54 entities, associations, and individuals. The Boards received approximately 373 separate comments in response to the solicitation. The Boards revised the draft as a result of the responses and published the revised draft as proposed rulemaking. Following publication of proposed rulemaking, the Boards received over 600 separate comments from associations, institutions, groups, practitioners and individuals representing both consumer and professional interests. The Boards reviewed and considered all comments and suggestions received from interested parties during the regulatory development process.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

CRNPs who wish to prescribe drugs and their collaborating physicians will bear a very small cost in revising their collaborative agreements to comply with provisions regarding the content of a collaborative agreement of a CRNP who prescribes. Current approved CRNP programs already provide advanced pharmacology courses and education in drug usage. CRNPs who did not complete a program with a such a course (approximately 1866, or 40% of the CRNP population) and who want to prescribe drugs will bear the one-time cost of completing a 45-hour course in advanced pharmacology. The Boards' research indicates that the cost of a 45-hour course in advanced pharmacology is between approximately $630 and $1875. CRNPs who prescribe drugs will bear the costs of completing 16 hours of continuing education in pharmacology biennially. The Boards' research indicates that the cost of 16 hours of continuing education in pharmacology is between $120 and $960 biennially.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There will be no costs or savings to local governments associated with compliance.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There will be an increase in costs to the Commonwealth, but this increase should not be significant because of the relatively small number of CRNPs and because the increase in costs involves the additional paperwork, filing and review for only those CRNPs who want to prescribe and dispense drugs. (CRNPs make up only 1.8 % of the licensed nursing population in the Commonwealth, and it is unlikely that all of them will want to prescribe and dispense drugs.) The increase in costs to the Commonwealth are due to the Board staff performing additional functions. The additional functions include: receiving and filing the collaborative agreements of prescribing CRNPs; modifying and reviewing the renewal form to verify completion of the continuing education requirements; reviewing and approving programs offering the 45 hour course in advanced pharmacology; and reviewing and approving programs for continuing education. There is no history of these costs, so they have not been ascertained.

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(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$N/A	$N/A	$N/A	$N/A	$N/A	$N/A
Regulated						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated						
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

See item (17) above for the estimate of costs to a CRNP who elects to exercise prescribing authority.

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(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
NA				

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The costs associated with this rulemaking will be small. The initial costs for the group of CRNPs who must take a 45 hour course in advanced pharmacology and the biennial costs of completing 16 hours of continuing education in pharmacology are more than offset by the increased efficiency engendered by having CRNPs who can prescribe and dispense drugs without the prior intervention of a physician. This rulemaking is expected to result in greater availability of quality, cost-effective health care services. All the citizens of the Commonwealth will benefit by increased efficiency and availability of quality health care.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

The Boards did not consider nonregulatory approaches because the Medical Practice Act requires the Boards to promulgate regulations authorizing a CRNP to perform acts of medical diagnosis and prescription of medical, therapeutic, diagnostic or corrective measures. 63 P.S. § 422.15(a).

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

Alternative regulatory schemes had been discussed for some years, but were not found satisfactory by the Boards. It is believed that this proposal adequately addresses the needs of health care consumers, institutions, and practitioners.

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(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No federal standards apply to the issues addressed in this proposal.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

In the current absence of regulations authorizing CRNPs to prescribe, Pennsylvania is likely to be at a competitive disadvantage because CRNP prescribing is the norm in about 42 other states including New York, New Jersey, Ohio, West Virginia, and Maryland. Pennsylvania will benefit from the rulemaking because it will increase the availability of quality, cost-effective health care, and it will make CRNP practice in Pennsylvania more desirable.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulation will not affect existing or proposed regulations of the promulgating agencies or other agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

In light of the extensive public outreach already conducted (an early draft of this rulemaking was sent out for public comment in accordance with Executive Order 1996-1, as noted above at paragraph (16), prior to publication of proposed rulemaking), the over 600 comments received during the public comment period, and the monthly Board meetings where this issue and the comments were discussed by both Boards, no additional public or informational hearings are scheduled. However, the Boards will consider comments from the public during their regularly scheduled meetings. Board meeting dates are posted on the Department of State web page at www.dos.pa.us and are available by calling (717) 783-8200.

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(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

The collaborative agreements of those CRNPs who prescribe drugs will have to be amended to document this authorization. The collaborative agreement will have to be filed with the Bureau of Professional and Occupational Affairs and at the primary practice location of the CRNP. The current renewal forms will have to be modified and reviewed for the continuing education requirement. Application forms to approve 45 hour courses in advanced pharmacology and continuing education courses will have to created, reviewed and filed.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Boards have not identified any groups or persons with particular needs that would be affected by this rulemaking.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will be effective as of the date of publication in the Pennsylvania Bulletin of final rulemaking.

(31) Provide the schedule for continual review of the regulation.

The proposed amendments have not been given a sunset date. The Boards will regularly evaluate the effectiveness of the proposed amendments following their adoption as final rulemaking.

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2064

Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Medicine
State Board of Nursing
(AGENCY)

16A-499

DOCUMENT/FISCAL NOTE NO. _____

DATE OF ADOPTION: _____

BY: _____
Charles D. Hummer, Jr., M.D.

BY: _____
Stephen K. Anderson, R.N., C.R.N.A.

Chairpersons

TITLE: _____
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

6/2/00
DATE OF APPROVAL

Deputy General Counsel
(~~Chief Counsel~~, ~~Independent Agency~~)

(Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable.
No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
STATE BOARD OF NURSING
49 Pa. CODE, CHAPTERS 18 AND 21
CRNP PRESCRIPTIVE AUTHORITY

The State Boards of Medicine and Nursing (Boards) amend their regulations governing certified registered nurse practitioners (CRNPs) at 49 Pa. Code, Chapters 18 and 21, respectively, as set forth in Annexes A and B, relating to CRNP prescriptive authority.

A. Effective Date

The amendments will be effective upon publication of final form regulations in the Pennsylvania Bulletin.

B. Statutory Authority

Section 15(b) of the Medical Practice Act of 1985 (63 P.S. §422.15(b)) authorizes the Boards to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. Section 2(1) of the Professional Nursing Law (63 P.S. §212(1)) similarly indicates that a professional nurse may perform acts of medical diagnosis or prescription of medical therapeutic or corrective measures if the Boards promulgate regulations authorizing such acts.

C. Purpose

Under their statutory authority the Boards have negotiated rulemaking which authorizes CRNPs to prescribe and dispense drugs within specified parameters. CRNPs are advanced practice nurses who are certified by the Boards in a particular clinical specialty area. 49 Pa. Code §§ 18.21 et seq. and 21.251 et seq. This rulemaking will enable Pennsylvania CRNPs to make full use of their advanced education and skills and is consistent with the regulations of 41 other states which authorize CRNPs to prescribe or dispense, or both, with varying degrees of regulation or limitation. A detailed explanation of the purpose and background of the rulemaking may be found in the publication of proposed rulemaking at 29 Pa.B. 5101 (October 2, 1999).

D. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulation the

Boards solicited input and suggestions from the regulated community. The Boards mailed a draft on June 26, 1998, to 54 organizations, entities, and individuals who had an interest in CRNP prescribing. The Boards received 373 responses to the solicitation. The Boards revised the draft as a result of the responses and submitted that revised draft as proposed rulemaking.

E. Summary of Comments and Responses to Proposed Rulemaking

Proposed rulemaking was published at 29 Pa.B. 5101 (October 2, 1999) followed by a 30-day public comment period. The Boards received reports from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) and public comments from more than 600 associations, entities, and individuals. As a result of these reports and comments a number of changes were made to the proposed rulemaking. These changes include specifications regarding the course in advanced pharmacology that will be a prerequisite to prescribing and dispensing; a requirement of continuing education in pharmacology for a CRNP who prescribes or dispenses; a requirement that every category of drugs from which a CRNP might prescribe be identified in the collaborative agreement; greater precision in the listing of the categories of drugs from which a CRNP might prescribe, prescribe with limitations, or not prescribe; a definition of "collaborative agreement"; identification of the contents of a collaborative agreement necessary for a CRNP who prescribes or dispenses; identification of the CRNP by nametag; and limiting a physician to collaborating with not more than two CRNPs who prescribe and dispense drugs unless the physician requests and obtains a waiver of this ratio. The Boards also combined subsections (b) and (c) of §§ 18.54 and 21.284.

The HPLC in its report of November 16, 1999, made recommendations regarding education in pharmacology, continuing education, the collaborative agreement, substitute collaborating physicians, and notice to patients when a patient is treated by a CRNP who prescribes drugs. IRRC in its report of December 2, 1999, made recommendations regarding the collaborative agreement, education in pharmacology, the categories of drugs, action to be taken if a drug is prescribed inappropriately, and the clarity of draftmanship.

The Pennsylvania Coalition of Nurse Practitioners endorsed the

proposed rulemaking but made recommendations for changes. The Nurse Practitioner Association of Southwestern Pennsylvania, individual physicians and nurses, and health care practices and entities supported the proposed rulemaking. The Hospital & Healthsystem Association of Pennsylvania (HAP), the Pennsylvania Academy of Pediatrics, the Pennsylvania Society of Anesthesiologists, the Pennsylvania State Nurses Association (PSNA), and Pennsylvania Academy of Family Physicians (PAFP) generally supported the proposed rulemaking, but made recommendations for changes. The Pennsylvania Medical Society (PMS) did not object to the proposed rulemaking, but also recommended changes. The American College of Emergency Physicians endorsed the recommendations of PMS and made several suggestions of their own.

Several Associations and individuals generally opposed the proposed rulemaking. These associations included the Pennsylvania Podiatric Medical Association, the Pennsylvania Association of Chain Drug Stores and one chain drug store, and the Pennsylvania Osteopathic Medical Association.

The Boards received comments from consumers (individuals who did not identify themselves as physicians or nurses), physicians, and nurses. Of approximately 41 consumer comments, 40 favored the proposed rulemaking, one opposed. Consumers who favored the rulemaking stressed the quality of care received from CRNPs and said that the rulemaking would facilitate access to quality health care. Nurses almost uniformly favored the rulemaking and offered several suggestions which will be addressed below. While a number of physicians opposed prescriptive authority for CRNPs, most physician commentators indicated that they were not opposed to the proposed rulemaking but made recommendations for changes. A large number of physician commentators supported the comments of PMS. The recommendations of physicians and their associations will also be addressed below.

Equivalency of Programs in Other States. §§ 18.53(1) and 21.283(1).

The proposed rulemaking began by indicating that a CRNP might prescribe if he or she, among other things, completed a CRNP program approved by the Board or, if the nurse completed a CRNP education program in another state, the program was equivalent to programs approved by the Boards. IRRC asked how the Boards would determine equivalency. Section 7(b) of the Professional Nursing

Law (63 P.S. § 217(b)), authorizes the State Board of Nursing to issue a certification to registered nurse practitioners who have completed a course of study in another state if the Board considers the program to be equivalent to that required in Pennsylvania. Under §§ 18.42 and 21.272 of the Boards' regulations the Boards may grant certification by endorsement to a CRNP who had been certified in another state if the credentials are equivalent to those required by the Boards. In implementing the statute and regulations the Boards compare the courses of the non-Pennsylvania program with that of Pennsylvania program. If a comparison reveals that the programs are equivalent in course work and hours, the State Board of Nursing certifies the applicant.

The Course in Advance Pharmacology. §§ 18.53(2) and 21.283(2).

The proposed rulemaking would have authorized a CRNP to prescribe and dispense if the "CRNP program include[d] a core course in advanced pharmacology." The HPLC recommended that a minimum number of hours of core education in advanced pharmacology be required in order for a CRNP to be permitted to prescribe and dispense drugs. IRRC, the Pennsylvania Society of Health-System Pharmacists (PSHSP), and others also suggested greater clarity in describing what would qualify as an advanced pharmacology course. PMS, which recommended that the Boards clarify the proposed rulemaking in regard to the responsibility and accountability of both the CRNP and collaborating physician, requested that the course should be at least 30 hours. PAFP recommended a 50-hour course. Individual physicians recommended specific courses of from 30 to 50 hours.

In response to these comments, the Boards have adopted a 45-hour requirement and further refined the education acceptable to the Boards. A course in advanced pharmacology of 45 hours has been standard in Board approved CRNP programs since 1992. Such a course is at a level above the pharmacology courses taught in registered nursing programs. The advanced pharmacology course in a CRNP program provides a level of education necessary for a CRNP to safely prescribe and dispense drugs. This is the standard adopted by the Boards in this rulemaking. The rulemaking has been drafted so that a CRNP who has not taken such a course as part of his or her CRNP education program will be able to take a 45-hour course as additional education from a program approved by the Boards. A separate and distinct course in pharmacology/pharmacotherapeutics of 45 contact hours is recommended in "Curriculum Guidelines & Regulatory Criteria for Family Nurse Practitioners Seeking

Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care: Summary Report 1998" (Curriculum Guidelines), prepared by the Health Resources & Services Administration of the U.S. Department of Health and Human Services recommends.[1]

IRRC and others noted that some programs did not have a specific course but integrated pharmacology into the overall curriculum. Some commentators suggested that boards devise a way to "grandfather" those whose education in pharmacology was not contained in a specific course. Pennsylvania Association of Nurse Anesthetists, PSNA, and numerous individual nurse commentators support this view. PSNA recommended that the Boards consider "grandfathering" and requiring continuing education in advanced pharmacology or requiring the CRNP to provide documentation of cumulative advanced pharmacology. After considerable discussion the Boards rejected "grandfathering," "integrated courses," and piecemeal accumulation of credits. First, it would not be feasible for Boards to determine how much of the "pharmacology-integrated" curriculum covered pharmacology and to equate that with the requirements of a specific course. This would be the case especially if a CRNP education program was taken more than a decade ago. Second, public safety would be enhanced if every CRNP who prescribes or dispenses drugs has met the course requirement. Third, final rulemaking provides a mechanism which will allow CRNPs who do not have a specific 45-hour course in their CRNP education program to complete a course outside of a nursing education program.

The Pennsylvania Association of Physician Assistants expressed the view in regard to section 18.53 that it would be a great undertaking for the Board to approve CRNP programs in Pennsylvania and elsewhere. The Boards, however, have a history and duty and the necessary staff to approve CRNP programs. See, 49 Pa. Code §§ 18.41-18.42 and 21.271-21.272.

Continuing Education. §§ 18.53(3) and 21.283(3).

The HPLC recommended that a minimum number of hours of continuing education in advanced pharmacology be required per biennium for a CRNP to maintain prescriptive authority. PMS, PAFP,

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[1]Of the 42 states which permit CRNPs to prescribe, 21 require that the CRNP have completed a separate pharmacology course. "Curriculum Guidelines," Table 2,page 16.

PSHSP, the Pennsylvania Psychiatric Society (PPS), and numerous physician commentators also recommended continuing education for a CRNP who prescribes drugs. The Boards believe this is a sound recommendation that would help the CRNP to stay current in pharmacological knowledge, would help insure public safety, and would be consistent with the current regulations of the Boards which require a CRNP to provide evidence of continuing competency in the area of medical diagnosis and therapeutics at the time the CRNP renews his or her certification. 49 Pa. Code §§ 18.41(c) and 21.271(d) The Boards determined that 16 hours of continuing education biennially in pharmacology approved by the State Board of Nursing would be appropriate.

The Collaborative Agreement. §§ 18.55 and 21.285.

The HPLC, IRRC, and others made recommendations concerning the collaborative agreement. The proposed rulemaking referred to, but did not define, the collaborative agreement. The HPLC recommended that the collaborative agreement be in writing, contain a list of the classes of medications that the CRNP would be authorized to prescribe, identify the collaborating physician, and provide for an identified substitute collaborating physician for up to 30 days when the collaborating physician is not available. IRRC recommended that the collaborative agreement be defined, that the collaborative agreement be signed by both the physician and CRNP before the CRNP could prescribe drugs, and that the rulemaking specify the contents of the collaborative agreement.

A number of commentators, both individual physicians and associations, recommended that the collaborative agreement be a written document that clarifies the collaborating physician-CRNP relationship. HAP recommended that the collaborative agreement be defined. PAFP, the Pennsylvania Society of Anesthesiologists, PSHP and the Pennsylvania Association of Physician Assistants expressed the view that the proposed rulemaking did not define the collaborative agreement and that the parameters of collaborative practice should be memorialized in writing so that the parties to the agreement will have a clear understanding of their responsibilities to their patients. PAFP recommended that the collaborative agreement be in writing, identify the parties, describe the direction each physician will provide the CRNP, the frequency with which the collaborating physician will provide chart review and consultation, identify the drugs which the CRNP may prescribe, be available to anyone seeking to confirm the scope of the CRNP's prescriptive authority, and be filed with the Board.

The American Academy of Pediatrics (AAP) recommended that the collaborative agreements be spelled out publicly and in writing and kept on file with the state. PMS recommended that the final rulemaking include a section on the collaborative agreement; that when a CRNP prescribes or dispenses drugs, the agreement should be in writing; that it be available at the practice site; that it identify the collaborating physician and any substitute collaborating physician by name; that the agreement contain the list of drugs for which the CRNP might prescribe; that it outline when a physician should see the patient and what occurrences would necessitate physician intervention; and that the collaborative agreement be filed with the State Board of Medicine if it authorized the CRNP to prescribe or dispense Schedule II controlled substances. PMS and the Pennsylvania Psychiatric Society (PPS) recommended that the boards be notified of the existence of every collaborative agreement and who is party to the agreement. PMS and PPS recommended that a physician not be permitted to include any drug in a collaborative agreement unless the physician has the expertise required to prescribe that drug so that he or she would be able to recognize any inappropriate prescribing or adverse reaction.

Final rulemaking contains a definition of the term collaborative agreement and requires that it be in writing.[2] §§ 18.55(a) and 21.285(a). Sections 18.55(b) and 21.285(b) specify the contents of a collaborative agreement between a physician and a CRNP who prescribes and dispenses drugs. These subsections adopt the recommendations of the HPLC and IRRC. Additionally, under the final rulemaking the collaborative agreement of a CRNP who prescribes and dispenses drugs is required to identify the area of practice in which the CRNP is certified, contain attestation that the collaborating physician has knowledge and experience with any drug that the CRNP prescribes, specify the circumstances and how often the collaborating physician will personally see the patient, specify the conditions under which a CRNP may prescribe a Schedule II controlled substance for up to 72 hours, be kept at the primary practice location of the CRNP and a copy filed with the BPOA, be made available for inspection to anyone seeking to confirm the scope of practice of the CRNP, be updated when it is changed substantively, and specify the amount of professional liability

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[2]The definition is based on the definition of the collaborative agreement between a physician and nurse midwife found at 49 Pa. Code § 18.1.

insurance carried by the CRNP.

Professional Liability Insurance. §§ 18.55(b)(10) and 21.285(b)(10). PMS, PPS, AAP, the Pennsylvania Academy of Emergency Physicians, the Pennsylvania Podiatric Medical Association, and both nurse and physician commentators recommended that a CRNP with prescriptive authority should be required to carry malpractice insurance. PMS recommended that the Boards require a CRNP who prescribes and dispenses medications to carry $400,000 in professional liability insurance, the current level of coverage mandated for certain health care practitioners under the Health Care Services Malpractice Act. The Boards support the principle that a CRNP should carry professional liability insurance, but lack the statutory authority to require it by regulation. The Boards, however, can require that the collaborative agreement of a CRNP with prescriptive authority identify the level of insurance that the CRNP carries. This does not require a CRNP to carry any insurance, but will assure that the collaborating physician and anyone with an interest in reviewing the agreement will be aware of the amount of professional liability insurance, if any, carried by the CRNP.

Prescribing and Dispensing Parameters. §§ 18.54 and 21.284.

IRRC and physician and nurse commentators had several recommendations regarding these sections. IRRC requested that the Boards explain the basis for restrictions and prohibitions of certain drugs in the proposed section. These sections authorize, restrict or prohibit prescribing categories or classes of drugs rather than specific drugs. Sections 18.54(a) and 21.284(a) adopt the American Hospital Formulary Service Pharmacologic-Therapeutic Classification (AHFS) and either *(1)* authorize a CRNP to prescribe and dispense from the formulary if the authorization is documented in the collaborative agreement (§§ 18.54(b) and 21.284(b)) or *(2)* authorize a CRNP to prescribe and dispense if the collaborating physician originally prescribed the drug and approved it for ongoing therapy (§§ 18.54(b)(3) and 21.284(b)(3)) or *(3)* authorize a CRNP to prescribe or dispense from a category while prohibiting certain sub-categories (§§ 18.54(b)(7)(i)-(ii) and 21.284(b)(7)(i)-(ii)) or *(4)* prohibit categories of drugs (§§ 18.54(c) and 21.284(c)) or *(5)* establish parameters for prescribing and dispensing controlled substances (§§ 18.54(e) and (f) and 21.284(e) and (f)). The bases for the restrictions and prohibitions include potential for harm and side effects, need for physician intervention, complexity of prescribing, categories of

exceptional breadth, and potential for addiction or abuse.

IRRC suggested that the Boards delete the words "which the CRNP may prescribe and dispense subject to the parameters identified in this section" from sections 18.54(a) and 21.284(a). The Boards have not done so to avoid suggesting that if a classification of drug were in the AHSF a CRNP would automatically be able to prescribe or dispense from it.

Under subsection (b) of the proposed rulemaking a CRNP would have been able to prescribe and dispense any drug within the categories of the subsection "without limitation," that is, without the need to list the category of drug in the collaborative agreement. Moreover, it would have been at best implicit that a CRNP, a practitioner who is certified in a specialty area, would prescribe only in his or her area of practice. Under subsection (c) of the proposed rulemaking a CRNP would have been able to prescribe any drug if the authorization was documented in the collaborative agreement.

PPS requested that subsections (b) and (c) be combined to clarify that all categories of drugs from which a CRNP would be authorized to prescribe must be identified in the collaborative agreement. PAFP also recommended that the collaborative agreement identify every category of drug from which a CRNP might prescribe. Similarly HAP recommended that subsections (c) be modified to authorize a CRNP to prescribe a drug in the subsection if the collaborating agreement specifically included the category. Some commentators, including the Pennsylvania Association of Nurse Anesthetists, PSNA, and a number of nurses, requested that the Boards employ a "negative formulary," and not require the collaborative agreements to list every category of drug from which a CRNP might prescribe. The Boards have not adopted this suggestion.

On final rulemaking the Boards have determined that the collaborative agreement of a CRNP who prescribes should contain a "positive formulary" which specifies every category of drug from which a CRNP might prescribe and dispense. A "positive formulary" assures that the parties to a collaborative agreement have made a conscious determination that the identified categories are appropriate for the CRNP to prescribe. Subsections (b) and (c) have been combined. Subsection (b) makes explicit that the CRNP will be permitted to prescribe and dispense drugs relevant to the CRNP's area of practice.

IRRC, PPS, and several other commentators questioned the phrase "without limitation" in §§ 18.54(b) and 21.284(b). IRRC suggested that the phrase could be interpreted in a way that was inconsistent with the current regulations. The Boards have concluded that the phrase was confusing and susceptible to varying interpretations. The Boards have deleted the phrase on final rulemaking.

Several commentators pointed out that several categories of drugs in the AHFS Pharmacologic-Therapeutic Classification were omitted from the proposed rulemaking: Eye, Ear, Nose, and Throat Preparations, Hormones and Synthetic Substitutes, Devices, Pharmaceutical Aids, and Unclassified Therapeutic Agents. These have been included in final rulemaking. Hypoglycemic agents and endocrine replacement agents, not identified as categories in the AHFS Pharmacologic-Therapeutic Classification, have been removed and are replaced with Hormones and Synthetic Substitutes (into which categories these drugs do fall).

In regard §§ 18.54(c) and 21.284(c) of the proposed rulemaking (now subsection (b) in the final rulemaking) IRRC asked how documentation of categories of drugs would be authorized in the collaborative agreement. The parties to the collaborative agreement would simply identify the categories of drugs in the collaborative agreement.

Inappropriate Prescribing. §§ 18.54(d) and 21.284(d). In regard to §§ 18.54(e) and 21.284(e) (now subsection (d) in final rulemaking), IRRC questioned the use of the word "learn" in regard to a physician's method of determining that a CRNP had prescribed incorrectly and recommended a more general course of corrective action than had been proposed. The Boards have adopted both of IRRC's suggestions. PAFP recommended that if a physician learns that a drug has been wrongly prescribed, the physician should be required to resume direct care of the patient and make the appropriate notifications. Several nurse commentators suggested that the physician should tell the CRNP how to proceed if the physician determines that there has been incorrect prescribing. In final rulemaking the Boards require the physician to immediately take corrective action on behalf of the patient and notify the patient of the reason for the action and advise the CRNP as soon as possible. Further, the action is required to be noted in the patient's medical record.

Controlled Substances. §§ 18.54(e) and (f) and 21.284(e) and (f).

The Boards made two editorial changes recommended by IRRC to clarify CRNP prescribing of controlled substances. In regard to §§ 18.54(f) and 21.284(f) of the proposed rulemaking (now subsection (e) in the final rulemaking), IRRC questioned the clarity of the phrase "immediately (within 24 hours)." The Boards agreed with IRRC's concern that the wording was unclear and replaced the phrase in question with "as soon as possible but in no event longer than 24 hours."

"Off-label" Uses. §§ 18.54(f)(2) and 21.284(f)(2). In regard to §§ 18.54(g)(2) and 21.284(g)(2) of the proposed rulemaking (now subsection (f)(2) in the final rulemaking), IRRC, PSHP, and others questioned the use of the word "permitted," pointing out that the Food and Drug Administration approves drugs for clinical use for a single indication and that after a drug has been approved for a single indication a prescriber is free to use that drug for any indication that the prescriber chooses. These alternative uses are generally referred to as "unlabeled uses" or "off-label uses." The Boards replaced the word "permitted" with "approved," and will authorize a CRNP to prescribe or dispense a drug for a use not approved by the FDA if the collaborating physician approves the use.

Schedule II Controlled Substances. PSS and PAFP recommended that CRNPs not be given the authority to prescribe Schedule II controlled substances at all. PAFP alternatively expressed the view that if CRNPs are permitted to prescribe Schedule II controlled substances, the prescription be limited to 72 hours and the types of drugs be identified in the collaborative agreement. The American Academy of Pediatrics (AAP) recommended that a CRNP be required to notify the collaborating physician promptly and obtain approval prior to dispensing or prescribing "certain" Schedule II drugs, but did not specify which drugs. PMS recommended that a CRNP be permitted to prescribe a Schedule II controlled substance for up to a 72-hour dose only if the CRNP obtains approval from the collaborating physician prior to dispensing or prescribing the medication. The Boards did not adopt these recommendations. Under the final rulemaking the CRNP will be authorized to prescribe a Schedule II controlled substance for up to 72 hours but must inform the collaborating physician as soon as possible, but in no event longer than 24 hours. The rulemaking will, however, require the collaborative agreement to specify the conditions under which a CRNP may prescribe a Schedule II controlled substance. If a physician does not think it appropriate for a CRNP to prescribe Schedule II controlled substances, that limitation could be

included in the collaborative agreement.

Identification of the CRNP. §§ 18.56 and 21.286.

HPLC, IRRC, and others recommended that a CRNP who prescribes medications provide clear and conspicuous notice to patients that he or she is a CRNP. Similar recommendations were made by PMS, AAP, and individual physicians. PMS and others also recommended that a CRNP not use abbreviations that are not recognizable to the public and that a CRNP who possesses a doctorate not use only the title, "Doctor" in a clinical setting.

The final rulemaking requires that a patient be informed at the time of making an appointment that he or she will be seen by a CRNP, that the CRNP wear a nametag that clearly identifies himself or herself with the title "Certified Registered Nurse Practitioner," and that a CRNP with a doctorate should take appropriate steps to inform patients that he or she is not a doctor of medicine or doctor of osteopathic medicine.

Physician Supervision. §§ 18.57 and 21.287.

PMS and PPS recommended that a physician not be permitted to supervise more than four CRNPs who prescribe because it would be, in the view of PMS, very difficult for a physician to carefully monitor more than that number. Other physician commentators noted that the regulations should require strict physician supervision and oversight. Some nurse commentators maintained that CRNPs in "solo practice" should not need a collaborating physician. The legislative scheme, however, requires CRNPs to act in accordance with regulations authorized by Section 15(a) of the Medical Practice Act (63 P.S. § 422.15(a)). Current regulations define a CRNP as a registered nurse certified in a particular clinical specialty area who performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures "in collaboration with and under the direction of a physician. . . ." (49 Pa. Code §§ 18.21 and 21.251) Final rulemaking emphasizes that a collaborating physician is required to provide meaningful direction to a CRNP who prescribes by generally limiting the number of prescribing CRNPs with whom a physician might collaborate. Sections 18.57 and 21.287 would permit a physician to collaborate with two CRNPs who prescribe and dispense drugs, but would not prohibit the physician from further collaborating with other CRNPs who do not prescribe and dispense and would permit the physician to request a waiver of the limit of two prescribing CRNPs for good

cause.

Further Comments.

The Pennsylvania College of Emergency Physicians recommended that the Boards include specific regulatory requirements pertaining to CRNPs prescribing in emergency departments. The Boards decline to do this but point out that the contents of a collaborative agreement could reflect the particular needs of any type of practice, including emergency departments.

PAFP and several commentators, most of whom were physicians, recommended that CRNPs be required to pass a standard examination for certification. While a board examination is not required for certification under the Medical Practice Act and the Professional Nursing Law, §§ 18.41 and 21.271 of the regulations of the State Board of Medicine and Nursing establish educational criteria for certification of nurse practitioners. Moreover the Boards carefully review CRNP education programs and approve only those which offer rigorous course work and assessment of the nurse practitioner students.

PAFP observed that the Boards did not specify that a CRNP must comply with section 16.95 of the regulations of the State Board of Medicine (pertaining to medical records). While these regulations are not specifically cited, every professional nurse is required to document and maintain accurate records under § 21.18(a)(5) of the regulations of the State Board of Nursing. Further, § 18.111 of the regulations of the State Board of Medicine and § 21.351 of the regulations of the State Board of Nursing authorize the Boards to suspend or revoke the certification of a CRNP who violates any provision of the Medical Practice Act, the Professional Nursing Law, or the regulations adopted under those acts.

The Pennsylvania Podiatric Medical Association and a number of physician commentators in their opposition to the proposed rulemaking stated that the proposal did not require a collaborative agreement, that a CRNP lacked the knowledge to medically treat a patient, that the State Board of Nursing could amend future regulations without input from the State Board of Medicine, and that the CRNP was wrongly permitted to practice independently and was now the "captain of the ship." While the proposed rulemaking did not adequately address the collaborative agreement, final rulemaking both requires a written agreement and outlines the contents of the agreement. The General Assembly has given the

Boards the power to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. See above, B. Statutory Authority. The current regulations of both Boards make plain that a CRNP while functioning in the expanded role as a professional nurse, performs acts of medical diagnosis or corrective measures "in collaboration with and under the direction of a physician . . . ." 49 Pa. Code §§ 18.21 and 21.251. Section 15(b) of the Medical Practice Act requires the joint action of both Boards to promulgate regulations regarding medical acts that might be performed by a CRNP.

The Pennsylvania Association of Chain Drug Stores, Inc. and one chain drug store opposed the proposed rulemaking. PACDS and the chain suggested that while the Boards have the statutory authority to implement regulations authorizing a CRNP to prescribe drugs, statutory authority to authorize a CRNP to dispense a drug is lacking. The Boards have the authority to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. See above, B. Statutory Authority. Prescribing drugs is the prescription of a medical measure. Section 8(2) of the Pharmacy Act makes clear that while it is unlawful for someone who is not licensed as a pharmacist to dispense drugs, that prohibition does not extend to "a duly licensed medical practitioner." (63 P.S. § 390-8(2)). Section 2(9) of the Pharmacy Act defines the phrase medical practitioner as "a physician, dentist, veterinarian or other individual duly authorized and licensed by law to prescribe drugs." (63 P.S. § 390-2(9)). Authorization to prescribe drugs includes authorization to dispense drugs.

Finally, the Pennsylvania Osteopathic Medical Association expressed the view that CRNPs should be "under the jurisdiction of a physician" and was concerned that "CRNPs are not adequately trained to practice independently with prescriptive authority." A CRNP performs in an expanded role as a professional nurse and performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures in collaboration with and under the direction of a physician licensed to practice medicine in this Commonwealth. 49 Pa. Code §§ 18.51 and 21.251. This rulemaking does not curtail the responsibility of the collaborating physician to provide collaboration and direction.

F. Fiscal Impact and Paperwork Requirements

There will be an increase in costs to the Commonwealth. Board staff will have to receive and file copies of the collaborative agreements of those CRNPs who prescribe and dispense drugs. Board staff will also have to slightly modify the CRNP renewal application to include a provision which will enable a CRNP with prescriptive authority to certify that he or she has completed the 16 hours of required continuing education courses. Board staff will have to review renewal applications to ascertain that prescribing CRNPs have fulfilled continuing education requirements. The Nurse Board and its staff will have to review programs wishing to offer either a 45-hour course in advanced pharmacology or continuing education, or both. The amount of these costs have not been ascertained because there is no history of these costs. Costs to the regulated community will be increased in that collaborating physicians and CRNPs who wish to prescribe will have to modify their collaborative agreements to include the required content of §§ 18.55 and 21.285 (pertaining to the collaborative agreement). CRNPs who prescribe will have to bear the costs of taking and passing a 45-hour course in advanced pharmacology, if they have not already taken one, and of continuing education. CRNPs who prescribe and their collaborating physicians will bear the costs of forwarding a copy of the collaborative agreement to the Bureau of Professional and Occupational Affairs. The costs of this rulemaking may be passed on to consumers of CRNP services. It is unlikely that these costs will result in significantly increased prices. The costs may be offset by the greater availability of medical services and the increased efficiency engendered by having CRNPs who can prescribe without the prior intervention of a physician. Citizens of the Commonwealth will benefit from having more ready access to cost-effective, quality health care. Revising collaborative agreements and forwarding a copy to the Bureau represent the largest increase in paperwork in regard to this rulemaking.

G. Regulatory Review

Under Section 5.1(a) of the Regulatory Review Act, Act of June 30, 1989, P.L. 73, No. 19 (71 P.S. §§745.1-745.15), the Board submitted a copy of the notice of proposed rulemaking, published at 29 Pa.B. 5101, to the Independent Regulatory Review Commission and to the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee for review and comment. In compliance with section 5(c) of the Regulatory Review Act, the Board also provided IRRC and the Committees with copies of the comments received as well as other

documentation.

In preparing these final-form regulations the Board has considered the comments received from IRRC and the public.

These final-form regulations were (deemed) approved by the House and Senate Committee on , 2000. IRRC met on , 2000, and (deemed) approved the amendments in accordance with section 5(e) of the Regulatory Review Act.

H. Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

I. Contact Person

Further information may be obtained by contacting Ann Steffanic, Board Administrator, State Board of Nursing or Cindy Warner, Board Administrator, State Board of Medicine, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649, (717) 783-7142 and 783-1400, respectively.

J. Findings

The Boards find that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) These amendments do not enlarge the purpose of proposed rulemaking published at 29 Pa.B. 5101.

(4) These amendments are necessary and appropriate for administration and enforcement of the authorizing acts identified in Part B of this preamble.

K. Order

The Boards, acting under their authorizing statutes, order

that:

(a) The regulations of the Boards, 49 Pa. Code Chapters 18 and 21, are amended by adding §§ 18.53-18.57 and 21.283-287 to read as set forth in Annexes A and B.

(b) The Boards shall submit this order and Annexes A and B to the Office of General Counsel and to the Office of Attorney General as required by law.

(c) The Boards shall certify this order and Annexes A and B and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on publication in the Pennsylvania Bulletin.

CHARLES D. HUMMER, JR., MD

STEPHEN K. ANDERSON, RN, CRNA

Chairpersons

ANNEX A
TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS
PART I. DEPARTMENT OF STATE
SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS
CHAPTER 18. STATE BOARD OF MEDICINE
SUBCHAPTER C. CERTIFIED REGISTERED NURSE PRACTITIONERS

CRNP PRACTICE

§18.53. Prescribing and dispensing drugs.

A CRNP may prescribe and dispense drugs if THE FOLLOWING REQUIREMENTS ARE MET:

(1) The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.

(2) The CRNP ~~program includes a core course in advanced pharmacology~~ HAS SUCCESSFULLY COMPLETED A SPECIFIC COURSE IN ADVANCED PHARMACOLOGY OF NOT LESS THAN 45 HOURS IN ACCORDANCE WITH THE FOLLOWING:

A. THE COURSE MAY BE EITHER PART OF THE CRNP EDUCATION PROGRAM OR, IF COMPLETED OUTSIDE OF THE CRNP EDUCATION PROGRAM, AN ADDITIONAL COURSE TAKEN FROM AN EDUCATIONAL PROGRAM APPROVED BY THE BOARDS.

B. THE COURSE MUST BE AT AN ADVANCED LEVEL, THAT IS, ABOVE A PHARMACOLOGY COURSE REQUIRED BY A PROFESSIONAL NURSING (RN) EDUCATION PROGRAM.

(3) A CRNP WHO HAS PRESCRIPTIVE AUTHORITY SHALL COMPLETE AT

LEAST 16 HOURS OF STATE BOARD OF NURSING APPROVED CONTINUING EDUCATION IN PHARMACOLOGY IN THE TWO YEARS PRIOR TO THE BIENNIAL RENEWAL DATE OF HIS OR HER CRNP CERTIFICATION. THE CRNP SHALL SHOW PROOF THAT HE OR SHE COMPLETED THE CONTINUING EDUCATION WHEN SUBMITTING A BIENNIAL RENEWAL.

~~(3)~~(4) In prescribing and dispensing drugs a CRNP shall comply with standards of the State Board of Medicine in §§16.92-94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §25.51 - 25.58, 25.61 - 25.81, and 25.91 - 25.95 (relating to prescriptions and labeling of drugs, devices and cosmetics and controlled substances).

§18.54. Prescribing and dispensing parameters.

(a) The Board adopts the American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.

(b) A CRNP may prescribe and dispense a drug RELEVANT TO THE AREA OF PRACTICE OF THE CRNP from the following categories ~~without limitation~~ IF THAT AUTHORIZATION IS DOCUMENTED IN THE COLLABORATIVE AGREEMENT (unless the drug is limited or excluded under THIS OR ~~other~~ ANOTHER subsection~~s~~):

(1) Antihistamines.

(2) Anti-infective agents.

(3) ANTINEOPLASTIC AGENTS, UNCLASSIFIED THERAPEUTIC AGENTS, DEVICES AND PHARMACEUTICAL AIDS IF ORIGINALLY PRESCRIBED BY THE COLLABORATING PHYSICIAN AND APPROVED BY THE COLLABORATING PHYSICIAN FOR ONGOING THERAPY.

~~(3)~~ (4) AUTONOMIC DRUGS.

(5) BLOOD FORMATION, COAGULATION AND ANTICOAGULATION DRUGS, AND THROMBOLYTIC AND ANTITHROMBOLYTIC AGENTS.

~~(3)~~ (6) Cardiovascular drugs.

(7) CENTRAL NERVOUS SYSTEM AGENTS, EXCEPT THAT THE FOLLOWING DRUGS ARE EXCLUDED FROM THIS CATEGORY:

(i) GENERAL ANESTHETICS.

(ii) MONOAMINE OXIDASE INHIBITORS.

~~(4)~~ (8) Contraceptives including foams and devices.

~~(5)~~ (9) Diagnostic agents.

~~(6)~~ (10) Disinfectants for agents used on objects other than skin.

~~(7)~~ (11) Electrolytic, caloric and water balance.

~~(8)~~ (12) Enzymes.

~~(9)~~ (13) Antitussive, expectorants and mucolytic agents.

~~(10)~~ (14) Gastrointestinal drugs.

~~(11)~~ (15) Local anesthetics.

(16) EYE, EAR, NOSE AND THROAT PREPARATIONS.

~~(12)~~ (17) Serums, toxoidS and vaccines.

~~(13)~~ (18) Skin and mucous membrane agents.

~~(14)~~ (19) Smooth muscle relaxants.

~~(15)~~ (20) Vitamins.

~~(16) Hypoglycemic Agents.~~

~~(17) Endrocrine replacement agents.~~

(21) HORMONES AND SYNTHETIC SUBSTITUTES.

~~(c) A CRNP may prescribe and dispense a drug from the following categories if that authorization is documented in the collaborative agreement:~~

~~(1) Autonomic drugs.~~

~~(2) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.~~

~~(3) Central nervous system agents, except that the following drugs are excluded from this category:~~

~~(i) General Anesthetics.~~

~~(ii) Monoamine oxidase inhibitors.~~

~~(4) Myotics and mydriatics.~~

~~(5) Antineoplastic agents originally prescribed by the collaborating physician and approved for ongoing therapy.~~

~~(d)~~ (c) A CRNP may not prescribe or dispense a drug from the following categories:

(1) Gold compounds.

(2) Heavy metal antagonists.

(3) Radioactive agents.

(4) OXYTOCICS

~~(e)~~ (d) If a collaborating physician ~~learns~~ DETERMINES that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately TAKE CORRECTIVE ACTION ON BEHALF OF THE PATIENT AND NOTIFY THE PATIENT OF THE REASON FOR THE ACTION AND advise the CRNP AS SOON AS POSSIBLE ~~and the CRNP will stop prescribing or dispensing the drug and will advise the pharmacy to stop dispensing the drug. The CRNP shall immediately advise the patient to stop taking the drug.~~ This action shall be noted by the CRNP OR THE COLLABORATING PHYSICIAN, OR BOTH, in the patient's medical record.

~~(f)~~(e) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 72 hour dose. The CRNP shall notify the collaborating physician ~~immediately (within~~ AS SOON AS POSSIBLE BUT IN NO EVENT LONGER THAN 24 hours~~)~~.

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription shall not be subject to refills unless the collaborating physician authorizes refills FOR THAT PRESCRIPTION.

~~(g)~~(f) A CRNP may not:

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §780-14).

(2) Prescribe or dispense a drug for a use not ~~permitted~~ APPROVED by the U.S. Food and Drug Administration WITHOUT APPROVAL OF THE COLLABORATING PHYSICIAN.

(3) Delegate prescriptive authority specifically assigned to him or her by the collaborating physician to another health care provider.

~~(h)~~(g) A prescription blank shall bear the certification number of the CRNP, name of the CRNP in printed format at the top of the blank, and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

~~(i)~~(h) The CRNP shall document in the 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.

§18.55. THE COLLABORATIVE AGREEMENT

(a) A COLLABORATIVE AGREEMENT IS THE SIGNED WRITTEN AGREEMENT BETWEEN A CRNP AND A COLLABORATING PHYSICIAN IN WHICH THEY AGREE TO THE DETAILS OF THE COLLABORATIVE ARRANGEMENT BETWEEN THEM WITH RESPECT TO THE CARE OF CRNP PATIENTS.

(b) THE COLLABORATIVE AGREEMENT BETWEEN A PHYSICIAN AND A CRNP WHO WILL PRESCRIBE DRUGS SHALL SATISFY THE FOLLOWING REQUIREMENTS. THE AGREEMENT SHALL:

(1) IDENTIFY THE PARTIES, INCLUDING THE COLLABORATING

PHYSICIAN, THE CRNP, AND A SUBSTITUTE PHYSICIAN WHO WILL PROVIDE COLLABORATION AND DIRECTION FOR UP TO 30 DAYS IF THE COLLABORATING PHYSICIAN IS UNAVAILABLE.

(2) IDENTIFY THE AREA OF PRACTICE IN WHICH THE CRNP IS CERTIFIED.

(3) IDENTIFY THE CATEGORIES OF DRUGS FROM WHICH THE CRNP MAY PRESCRIBE OR DISPENSE IN ACCORDANCE WITH § 18.54.

(4) CONTAIN ATTESTATION BY THE COLLABORATING PHYSICIAN THAT HE OR SHE HAS KNOWLEDGE AND EXPERIENCE WITH ANY DRUG THAT THE CRNP WILL PRESCRIBE.

(5) SPECIFY THE CIRCUMSTANCES AND HOW OFTEN THE COLLABORATING PHYSICIAN WILL PERSONALLY SEE THE PATIENT, BASED ON THE TYPE OF PRACTICE,SITES OF SERVICE, AND CONDITION OF THE PATIENT, WHETHER THE TREATMENT IS FOR AN ONGOING OR NEW CONDITION, AND WHETHER THE PATIENT IS NEW OR CONTINUING.

(6) SPECIFY THE CONDITIONS UNDER WHICH THE CRNP MAY PRESCRIBE A SCHEDULE II CONTROLLED SUBSTANCE FOR UP TO 72 HOURS.

(7) BE KEPT AT THE PRIMARY PRACTICE LOCATION OF THE CRNP AND A COPY FILED WITH THE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS.

(8) BE MADE AVAILABLE FOR INSPECTION TO ANYONE SEEKING TO CONFIRM THE SCOPE OF PRACTICE OF THE CRNP.

(9) BE UPDATED BY THE COLLABORATING PHYSICIAN AND THE CRNP WHENEVER IT IS CHANGED SUBSTANTIVELY.

(10) SPECIFY THE AMOUNT OF PROFESSIONAL LIABILITY INSURANCE CARRIED BY THE CRNP.

(c) THE CRNP SHALL NOTIFY THE BUREAU WHENEVER A COLLABORATIVE AGREEMENT OF A CRNP WHO PRESCRIBES AND DISPENSES DRUGS IS UPDATED OR TERMINATED.

§18.56. IDENTIFICATION OF THE CRNP.

(a) A PATIENT SHALL BE INFORMED AT THE TIME OF MAKING AN APPOINTMENT THAT HE OR SHE WILL BE SEEN BY A CERTIFIED REGISTERED NURSE PRACTITIONER.

(b) A CRNP SHALL WEAR A NAMETAG THAT CLEARLY IDENTIFIES HIMSELF OR HERSELF WITH THE TITLE "CERTIFIED REGISTERED NURSE PRACTITIONER."

(c) A CRNP WHO HOLDS A DOCTORATE SHOULD TAKE APPROPRIATE STEPS TO INFORM PATIENTS THAT HE OR SHE IS NOT A DOCTOR OF MEDICINE OR DOCTOR OF OSTEOPATHIC MEDICINE.

§18.57. Physician supervision.

(a) A PHYSICIAN SHALL NOT SERVE AS THE COLLABORATING PHYSICIAN FOR MORE THAN TWO CRNPs WHO PRESCRIBE AND DISPENSE DRUGS AT ANY ONE TIME. HOWEVER, A PHYSICIAN MAY APPLY FOR A WAIVER OF THIS SECTION FOR GOOD CAUSE, AS DETERMINED BY THE BOARDS.

(b) THE LIMIT OF THE GENERAL RULE OF NOT MORE THAN TWO PRESCRIBING CRNPS TO ONE PHYSICIAN SHALL NOT APPLY TO CRNPS WHO DO NOT PRESCRIBE OR DISPENSE DRUGS. BY WAY OF EXAMPLE, A PHYSICIAN MAY COLLABORATE WITH TWO CRNPS WHO PRESCRIBE AND DISPENSE DRUGS AND ONE OR MORE CRNPS WHO DO NOT.

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS
PART I. DEPARTMENT OF STATE
SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS
CHAPTER 21. STATE BOARD OF NURSING
SUBCHAPTER C. CERTIFIED REGISTERED NURSE PRACTITIONERS

CRNP PRACTICE

§21.283. Prescribing and dispensing drugs.

A CRNP may prescribe and dispense drugs if THE FOLLOWING REQUIREMENTS ARE MET:

~~(1)~~ The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.

(2) The CRNP ~~program includes a core course in advanced pharmacology~~ HAS SUCCESSFULLY COMPLETED A SPECIFIC COURSE IN ADVANCED PHARMACOLOGY OF NOT LESS THAN 45 HOURS IN ACCORDANCE WITH THE FOLLOWING:

A. THE COURSE MAY BE EITHER PART OF THE CRNP EDUCATION PROGRAM OR, IF COMPLETED OUTSIDE OF THE CRNP EDUCATION PROGRAM, AN ADDITIONAL COURSE TAKEN FROM AN EDUCATIONAL PROGRAM APPROVED BY THE BOARDS.

B. THE COURSE MUST BE AT AN ADVANCED LEVEL, THAT IS, ABOVE A PHARMACOLOGY COURSE REQUIRED BY A PROFESSIONAL NURSING (RN) EDUCATION PROGRAM.

(3) A CRNP WHO HAS PRESCRIPTIVE AUTHORITY SHALL COMPLETE AT

LEAST 16 HOURS OF STATE BOARD OF NURSING APPROVED CONTINUING EDUCATION IN PHARMACOLOGY IN THE TWO YEARS PRIOR TO THE BIENNIAL RENEWAL DATE OF HIS OR HER CRNP CERTIFICATION. THE CRNP SHALL SHOW PROOF THAT HE OR SHE COMPLETED THE CONTINUING EDUCATION WHEN SUBMITTING A BIENNIAL RENEWAL.

~~(3)~~(4) In prescribing and dispensing drugs a CRNP shall comply with standards of the State Board of Medicine in §§16.92-94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §25.51 - 25.58, 25.61 - 25.81, and 25.91 - 25.95 (relating to prescriptions and labeling of drugs, devices and cosmetics and controlled substances).

§21.284. Prescribing and dispensing parameters.

(a) The Board adopts the American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.

(b) A CRNP may prescribe and dispense a drug RELEVANT TO THE AREA OF PRACTICE OF THE CRNP from the following categories ~~without limitation~~ IF THAT AUTHORIZATION IS DOCUMENTED IN THE COLLABORATIVE AGREEMENT (unless the drug is limited or excluded under THIS OR ~~other~~ ANOTHER subsection~~s~~):

(1) Antihistamines.

(2) Anti-infective agents.

(3) ANTINEOPLASTIC AGENTS, UNCLASSIFIED THERAPEUTIC AGENTS, DEVICES AND PHARMACEUTICAL AIDS IF ORIGINALLY PRESCRIBED BY THE COLLABORATING PHYSICIAN AND APPROVED BY THE COLLABORATING PHYSICIAN FOR ONGOING THERAPY.

~~(3)~~ (4) AUTONOMIC DRUGS.

(5) BLOOD FORMATION, COAGULATION AND ANTICOAGULATION DRUGS, AND THROMBOLYTIC AND ANTITHROMBOLYTIC AGENTS.

~~(3)~~ (6) Cardiovascular drugs.

(7) CENTRAL NERVOUS SYSTEM AGENTS, EXCEPT THAT THE FOLLOWING DRUGS ARE EXCLUDED FROM THIS CATEGORY:

(i) GENERAL ANESTHETICS.

(ii) MONOAMINE OXIDASE INHIBITORS.

~~(4)~~ (8) Contraceptives including foams and devices.

~~(5)~~ (9) Diagnostic agents.

~~(6)~~ (10) Disinfectants for agents used on objects other than skin.

~~(7)~~ (11) Electrolytic, caloric and water balance.

~~(8)~~ (12) Enzymes.

~~(9)~~ (13) Antitussive, expectorants and mucolytic agents.

~~(10)~~ (14) Gastrointestinal drugs.

~~(11)~~ (15) Local anesthetics.

(16) EYE, EAR, NOSE AND THROAT PREPARATIONS.

~~(12)~~ (17) Serums, toxoidS and vaccines.

~~(13)~~ (18) Skin and mucous membrane agents.

~~(14)~~ (19) Smooth muscle relaxants.

~~(15)~~ (20) Vitamins.

~~(16) Hypoglycemic Agents.~~

~~(17) Endrocrine replacement agents.~~

(21) HORMONES AND SYNTHETIC SUBSTITUTES.

~~(c) A CRNP may prescribe and dispense a drug from the following categories if that authorization is documented in the collaborative agreement:~~

~~(1) Autonomic drugs.~~

~~(2) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.~~

~~(3) Central nervous system agents, except that the following drugs are excluded from this category:~~

~~(i) General Anesthetics.~~

~~(ii) Monoamine oxidase inhibitors.~~

~~(4) Myotics and mydriatics.~~

~~(5) Antineoplastic agents originally prescribed by the collaborating physician and approved for ongoing therapy.~~

~~(d)~~ (c) A CRNP may not prescribe or dispense a drug from the following categories:

(1) Gold compounds.

(2) Heavy metal antagonists.

(3) Radioactive agents.

(4) OXYTOCICS

~~(e)~~ (d) If a collaborating physician ~~learns~~ DETERMINES that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately TAKE CORRECTIVE ACTION ON BEHALF OF THE PATIENT AND NOTIFY THE PATIENT OF THE REASON FOR THE ACTION AND advise the CRNP AS SOON AS POSSIBLE ~~and the CRNP will stop prescribing or dispensing the drug and will advise the pharmacy to stop dispensing the drug. The CRNP shall immediately advise the patient to stop taking the drug~~. This action shall be noted by the CRNP OR THE COLLABORATING PHYSICIAN, OR BOTH, in the patient's medical record.

~~(f)~~(e) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 72 hour dose. The CRNP shall notify the collaborating physician ~~immediately (within~~ AS SOON AS POSSIBLE BUT IN NO EVENT LONGER THAN 24 hours~~)~~.

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription shall not be subject to refills unless the collaborating physician authorizes refills FOR THAT PRESCRIPTION.

~~(g)~~(f) A CRNP may not:

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §780-14).

(2) Prescribe or dispense a drug for a use not ~~permitted~~ APPROVED by the U.S. Food and Drug Administration WITHOUT APPROVAL OF THE COLLABORATING PHYSICIAN.

(3) Delegate prescriptive authority specifically assigned to him or her by the collaborating physician to another health care provider.

~~(h)~~(g) A prescription blank shall bear the certification number of the CRNP, name of the CRNP in printed format at the top of the blank, and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

~~(i)~~(h) The CRNP shall document in the 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.

§21.285. THE COLLABORATIVE AGREEMENT

(a) A COLLABORATIVE AGREEMENT IS THE SIGNED WRITTEN AGREEMENT BETWEEN A CRNP AND A COLLABORATING PHYSICIAN IN WHICH THEY AGREE TO THE DETAILS OF THE COLLABORATIVE ARRANGEMENT BETWEEN THEM WITH RESPECT TO THE CARE OF CRNP PATIENTS.

(b) THE COLLABORATIVE AGREEMENT BETWEEN A PHYSICIAN AND A CRNP WHO WILL PRESCRIBE DRUGS SHALL SATISFY THE FOLLOWING REQUIREMENTS. THE AGREEMENT SHALL:

(1) IDENTIFY THE PARTIES, INCLUDING THE COLLABORATING

PHYSICIAN, THE CRNP, AND A SUBSTITUTE PHYSICIAN WHO WILL PROVIDE COLLABORATION AND DIRECTION FOR UP TO 30 DAYS IF THE COLLABORATING PHYSICIAN IS UNAVAILABLE.

(2) IDENTIFY THE AREA OF PRACTICE IN WHICH THE CRNP IS CERTIFIED.

(3) IDENTIFY THE CATEGORIES OF DRUGS FROM WHICH THE CRNP MAY PRESCRIBE OR DISPENSE IN ACCORDANCE WITH § 21.284.

(4) CONTAIN ATTESTATION BY THE COLLABORATING PHYSICIAN THAT HE OR SHE HAS KNOWLEDGE AND EXPERIENCE WITH ANY DRUG THAT THE CRNP WILL PRESCRIBE.

(5) SPECIFY THE CIRCUMSTANCES AND HOW OFTEN THE COLLABORATING PHYSICIAN WILL PERSONALLY SEE THE PATIENT, BASED ON THE TYPE OF PRACTICE,SITES OF SERVICE, AND CONDITION OF THE PATIENT, WHETHER THE TREATMENT IS FOR AN ONGOING OR NEW CONDITION, AND WHETHER THE PATIENT IS NEW OR CONTINUING.

(6) SPECIFY THE CONDITIONS UNDER WHICH THE CRNP MAY PRESCRIBE A SCHEDULE II CONTROLLED SUBSTANCE FOR UP TO 72 HOURS.

(7) BE KEPT AT THE PRIMARY PRACTICE LOCATION OF THE CRNP AND A COPY FILED WITH THE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS.

(8) BE MADE AVAILABLE FOR INSPECTION TO ANYONE SEEKING TO CONFIRM THE SCOPE OF PRACTICE OF THE CRNP.

(9) BE UPDATED BY THE COLLABORATING PHYSICIAN AND THE CRNP WHENEVER IT IS CHANGED SUBSTANTIVELY.

(10) SPECIFY THE AMOUNT OF PROFESSIONAL LIABILITY INSURANCE CARRIED BY THE CRNP.

(c) THE CRNP SHALL NOTIFY THE BUREAU WHENEVER A COLLABORATIVE AGREEMENT OF A CRNP WHO PRESCRIBES AND DISPENSES DRUGS IS UPDATED OR TERMINATED.

§21.286. IDENTIFICATION OF THE CRNP.

(a) A PATIENT SHALL BE INFORMED AT THE TIME OF MAKING AN APPOINTMENT THAT HE OR SHE WILL BE SEEN BY A CERTIFIED REGISTERED NURSE PRACTITIONER.

(b) A CRNP SHALL WEAR A NAMETAG THAT CLEARLY IDENTIFIES HIMSELF OR HERSELF WITH THE TITLE "CERTIFIED REGISTERED NURSE PRACTITIONER."

(c) A CRNP WHO HOLDS A DOCTORATE SHOULD TAKE APPROPRIATE STEPS TO INFORM PATIENTS THAT HE OR SHE IS NOT A DOCTOR OF MEDICINE OR DOCTOR OF OSTEOPATHIC MEDICINE.

§21.287. PHYSICIAN SUPERVISION.

(a) A PHYSICIAN SHALL NOT SERVE AS THE COLLABORATING PHYSICIAN FOR MORE THAN TWO CRNPs WHO PRESCRIBE AND DISPENSE DRUGS AT ANY ONE TIME. HOWEVER, A PHYSICIAN MAY APPLY FOR A WAIVER OF THIS SECTION FOR GOOD CAUSE, AS DETERMINED BY THE BOARDS.

(b) THE LIMIT OF THE GENERAL RULE OF NOT MORE THAN TWO PRESCRIBING CRNPS TO ONE PHYSICIAN SHALL NOT APPLY TO CRNPS WHO DO NOT PRESCRIBE OR DISPENSE DRUGS. BY WAY OF EXAMPLE, A PHYSICIAN MAY COLLABORATE WITH TWO CRNPS WHO PRESCRIBE AND DISPENSE DRUGS AND ONE OR MORE CRNPS WHO DO NOT.

PROPOSED RULEMAKING

STATE BOARD OF MEDICINE

STATE BOARD OF NURSING

[49 PA. CODE CHS. 18 AND 21]

Certified Registered Nurse Practitioners Prescriptive Authority

[29 Pa.B. 5101]

The State Boards of Medicine and Nursing (Boards) propose to amend their regulations governing certified registered nurse practitioners (CRNPs) Chapters 18 and 21 (relating to State Board of Medicine; and State Board of Nursing), to read as set forth in Annex A, relating to CRNP prescriptive authority.

A. Effective Date

The proposed regulations will be effective upon publication of final-form regulations in the *Pennsylvania Bulletin.*

B. Statutory Authority

Section 15(b) of the Medical Practice Act of 1985 (63 P. S. § 422.15(b)) authorizes the Boards to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. Section 2(1) of the Professional Nursing Law (63 P. S. § 212(1)) similarly indicates that a professional nurse may perform acts of medical diagnosis or prescription of medical therapeutic or corrective measures only if the Boards promulgate regulations authorizing these acts. These provisions were originally enacted in the practice acts of 1974. Under the 1974 laws, the Boards jointly promulgated the current regulations which provide for certification of nurse practitioners.

C. Background and Purpose

In accordance with their statutory authority the Boards have negotiated rulemaking which would authorize CRNPs to prescribe and dispense drugs. CRNPs are advanced practice nurses who are certified by the Boards in a particular clinical specialty area. See §§ 18.21 et seq. and 21.251 et seq. An applicant for certification as a CRNP shall be a currently licensed professional or registered nurse who has successfully completed a course of study of at least 1 academic year in a program approved by the Boards. See §§ 18.41 and 21.271. Almost all nurse practitioner programs grant a master's degree and include a course in advanced pharmacology. The proposed regulations will enable Pennsylvania CRNPs to make full use of their advanced education and skills.

At the present time CRNPs in most states have varying degrees of prescriptive and dispensing authority. Only about eight states do not permit CRNPs to prescribe or dispense drugs.[1] The remaining states authorize CRNPs to prescribe or dispense, or both, with

varying degrees of regulation or limitation. Of the states permitting CRNPs to prescribe drugs, 32 states require the authority to be identified in the collaborative agreement, 13 states limit prescribing authority to substances which are not controlled, and 27 allow prescription of controlled substances, but with varying degrees of regulation or limitation.[2]

D. Description of Proposed Regulations

The proposal would add two new sections to the existing regulations regarding CRNPs. The first section, §§ 18.53 and 21.283, of the State Board of Medicine and the State Board of Nursing, would establish the requirements a CRNP shall meet to prescribe and dispense drugs: completion of a CRNP program approved by the Boards, which includes a course in advanced pharmacology, and adherence to standards for prescribing already established by the State Board of Medicine and the Department of Health.

The second sections, §§ 18.54 and 21.284, specify categories of drugs which a CRNP may prescribe and dispense without restriction, those which the CRNP may prescribe and dispense with limitations, and those which the CRNP may not prescribe or dispense. The first category contains those drugs a CRNP will be able to prescribe and dispense without specific limits (§§ 18.54(b) and 21.284(b)). The second category contains those drugs a CRNP will be able to prescribe and dispense only if the collaborative agreement between the physician and CRNP authorizes prescribing and dispensing those drugs (§§ 18.54(c) and 21.284(c)). The third category contains those drugs which a CRNP may not prescribe or dispense (§§ 18.54(d) and 21.284(d)). This section also establishes the parameters for prescribing and dispensing controlled substances (§§ 18.54(f) and (g) and 21.284(f) and (g)). Further provisions would establish procedures to deal with an inappropriately prescribed or dispensed drug (§§ 18.54(e) and 21.284(f)), requirements pertaining to prescription blanks (§§ 18.54(h) and 21.284(h)) and documentation of the prescription in a patient's medical record (§§ 18.54(i) and 21.284(i)).

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the proposed regulations the Boards solicited input and suggestions from the regulated community. The Boards mailed a draft on June 26, 1998, to 54 organizations, entities and individuals who had an interest in CRNP prescribing. The Boards received 373 responses to the solicitation. The Boards revised the draft as a result of the responses.

F. Fiscal Impact and Paperwork Requirements

There will not be an adverse fiscal impact or additional paperwork imposed on the Commonwealth, political subdivisions or the private sector. Citizens of this Commonwealth will benefit from having more ready access to cost-effective, quality health care.

There will be a very slight increase in paperwork to the regulated community in regard to certain categories of drugs because a CRNP would be authorized to prescribe or dispense from these categories only if the authorization is documented in the collaborative agreement.

G. Sunset Date

The Boards continuously monitor their regulations. Therefore, no sunset date has been assigned.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on September 17,

1999, the Boards submitted a copy of these proposed regulations to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposal, the Boards have provided IRRC and the Committees with a copy of a detailed regulatory analysis form prepared by the Boards in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulations, it will notify the Boards within 10 days after the expiration of the Committees' review period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review of objections prior to final publication of the proposed regulations by the Boards, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Cindy Warner, Health Licensing Division, Bureau of Professional and Occupational Affairs, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of the proposed regulations in the *Pennsylvania Bulletin*. Please cite to *CRNP Prescriptive Authority* when submitting comments. Please do not send copies of the same comment to both Boards.

DANIEL B. KIMBALL, Jr., M.D.,
Chairperson
State Board of Medicine
and

CHRISTINE ALICHNIE, Ph.D., R.N.,
Chairperson
State Board of Nursing

Fiscal Note: 16A-499. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 18. STATE BOARD OF MEDICINE--PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

CRNP PRACTICE

§ 18.53. Prescribing and dispensing drugs.

A CRNP may prescribe and dispense drugs if:

(1) The CRNP has completed a CRNP program which is approved by the Boards or, if

completed in another state, is equivalent to programs approved by the Boards.

(2) The CRNP program includes a core course in advanced pharmacology.

(3) In prescribing and dispensing drugs a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92--16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code § 25.51--25.58, 25.61--25.81 and 25.91--25.95 (relating to prescriptions and labeling of drugs, devices and cosmetics and controlled substances).

§ 18.54. Prescribing and dispensing parameters.

(a) The Board adopts the *American Hospital Formulary Service Pharmacologic-Therapeutic Classification* to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.

(b) A CRNP may prescribe and dispense a drug from the following categories without limitation (unless the drug is limited or excluded under other subsections):

(1) Antihistamines.

(2) Anti-infective agents

(3) Cardiovascular drugs.

(4) Contraceptives including foams and devices.

(5) Diagnostic agents.

(6) Disinfectants for agents used on objects other than skin.

(7) Electrolytic, caloric and water balance.

(8) Enzymes.

(9) Antitussive, expectorants and mucolytic agents.

(10) Gastrointestinal drugs.

(11) Local anesthetics.

(12) Serums, toxoid and vaccines.

(13) Skin and mucous membrane agents.

(14) Smooth muscle relaxants.

(15) Vitamins.

(16) Hypoglycemic agents.

(17) Endrocrine replacement agents.

(c) A CRNP may prescribe and dispense a drug from the following categories if that authorization is documented in the collaborative agreement:

(1) Autonomic drugs.

(2) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.

(3) Central nervous system agents, except that the following drugs are excluded from this category:

(i) General anesthetics.

(ii) Monoamine oxidase inhibitors.

(4) Myotics and mydriatics.

(5) Antineoplastic agents originally prescribed by the collaborating physician and approved for ongoing therapy.

(d) A CRNP may not prescribe or dispense a drug from the following categories:

(1) Gold compounds.

(2) Heavy metal antagonists.

(3) Radioactive agents.

(e) If a collaborating physician learns that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately advise the CRNP and the CRNP shall stop prescribing or dispensing the drug and shall advise the pharmacy to stop dispensing the drug. The CRNP shall immediately advise the patient to stop taking the drug. This action shall be noted by the CRNP in the patient's medical record.

(f) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) CRNP may write for a Schedule II controlled substance for up to a 72-hour dose. The CRNP shall notify the collaborating physician immediately (within 24 hours).

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription may not be refilled unless the collaborating physician authorizes refills.

(g) A CRNP may not:

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-14).

(2) Prescribe or dispense a drug for a use not permitted by the United States Food and Drug Administration.

(3) Delegate prescriptive authority specifically assigned to the CRNP by the collaborating physician to another health care provider.

(h) A prescription blank shall bear the certification number of the CRNP, the name of the CRNP in printed format at the top of the blank and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

(i) The CRNP shall document in the 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.

CHAPTER 21. STATE BOARD OF NURSING

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

CRNP PRACTICE

§ 21.283. Prescribing and dispensing drugs.

A CRNP may prescribe and dispense drugs if:

(1) The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.

(2) The CRNP program includes a core course in advanced pharmacology.

(3) In prescribing and dispensing drugs a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92--16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §§ 25.51--25.58, 25.61--25.81 and 25.91--25.95 (relating to prescriptions and labeling of drugs, devices and cosmetics and controlled substances).

§ 21.284. Prescribing and dispensing parameters.

(a) The Board adopts the *American Hospital Formulary Service Pharmacologic-Therapeutic Classification* to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.

(b) A CRNP may prescribe and dispense a drug from the following categories without limitation (unless the drug is limited or excluded under other subsections):

(1) Antihistamines.

(2) Anti-infective agents.

(3) Cardiovascular drugs.

(4) Contraceptives including foams and devices.

(5) Diagnostic agents.

(6) Disinfectants for agents used on objects other than skin.

(7) Electrolytic, caloric and water balance.

(8) Enzymes.

(9) Antitussive, expectorants and mucolytic agents.

(10) Gastrointestinal drugs.

(11) Local anesthetics.

(12) Serums, toxoid and vaccines.

(13) Skin and mucous membrane agents.

(14) Smooth muscle relaxants.

(15) Vitamins.

(16) Hypoglycemic agents.

(17) Endrocrine replacement agents.

(c) A CRNP may prescribe and dispense a drug from the following categories if that authorization is documented in the collaborative agreement:

(1) Autonomic drugs.

(2) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.

(3) Central nervous system agents, except that the following drugs are excluded from this category:

(i) General anesthetics.

(ii) Monoamine oxidase inhibitors.

(4) Myotics and mydriatics.

(5) Antineoplastic agents originally prescribed by the collaborating physician and approved for ongoing therapy.

(d) A CRNP may not prescribe or dispense a drug from the following categories:

(1) Gold compounds.

(2) Heavy metal antagonists.

(3) Radioactive agents.

(e) If a collaborating physician learns that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately advise the CRNP and the CRNP will stop prescribing or dispensing the drug and will advise the pharmacy to stop dispensing the drug. The CRNP shall immediately advise the patient to stop taking the drug. This action shall be noted by the CRNP in the patient's medical record.

(f) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 72-hour dose. The CRNP shall notify the collaborating physician immediately (within 24 hours).

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription may not be refilled unless the collaborating physician authorizes refills.

(g) A CRNP may not:

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-14).

(2) Prescribe or dispense a drug for a use not permitted by the United States Food and Drug Administration.

(3) Delegate prescriptive authority specifically assigned to the CRNP by the collaborating physician to another health care provider.

(h) A prescription blank shall bear the certification number of the CRNP, the name of the CRNP in printed format at the top of the blank and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

(i) The CRNP shall document in the 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.

[Pa.B. Doc. No. 99-1668. Filed for public inspection October 1, 1999, 9:00 a.m.]

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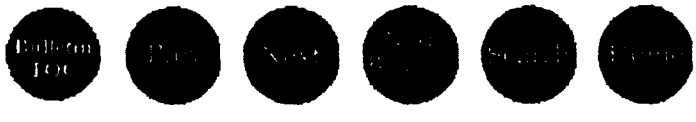
[1] U.S. Department of Health and Human Services, Health Resources & Services Administration, "Curriculum Guidelines & Regulatory Criteria for Family Nurse Practitioners Seeking Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care, Summary Report, 1998 (Curriculum Guidelines)," (Prepared by National Council of State Boards of Nursing and National Organization of Nurse Practitioner Faculties) page 14, Table 1.

[2] Curriculum Guidelines, pages 17-18, Tables 3-4.



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE and STATE BOARD OF NURSING
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400 & (717) 783-7142

June 6, 2000

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2
333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Rulemaking:
State Board of Medicine
State Board of Nursing
CRNP Prescriptive Authority (16A-499)

Dear Chairman McGinley:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine and the State Board of Nursing pertaining to CRNP Prescriptive Authority.

The Boards will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Charles D. Hummer, Jr., M.D.
Chairman
State Board of Medicine

K. Stephen Anderson, M.Ed., CRNA
Chairman
State Board of Nursing

CDH/KSA/HA:bjd
Enclosure

c: John T. Henderson, Jr., Chief Counsel
Department of State
Dorothy Childress, Commissioner
Bureau of Professional and Occupational Affairs
Joyce McKeever, Deputy Chief Counsel
Department of State
Herbert Abramson, Senior Counsel in Charge
Bureau of Professional and Occupational Affairs
Gerald S. Smith, Counsel
State Board of Medicine
Robert G. Cameron, Counsel
State Board of Nursing
State Board of Medicine
State Board of Nursing

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-499
SUBJECT:	State Board of Medicine & State Board of Nursing - CRNP Prescriptive Authority
AGENCY:	DEPARTMENT OF STATE

RECEIVED
2000 JUN -6 AM 9:38
REVIEW COMMISSION

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6-6-00		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
JUN 06 2000		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
6/6/00		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

June 2, 2000

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
POST OFFICE BOX 2649
HARRISBURG, PENNSYLVANIA 17105-2649

STATE BOARD OF MEDICINE (717) 783-1400
STATE BOARD OR NURSING (717) 783-7142

September 11, 2000

The Honorable John R. McGinley, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

RE: Order of Final Rulemaking of the State Boards of Medicine and Nursing Pertaining to CRNP Prescriptive Authority (16A-499)

Dear Chairman McGinley:

Please be advised that the State Boards of Medicine and Nursing intend to proceed with Regulation 16A-499 (CRNP Prescriptive Authority) in accordance with the provisions of Section 7 (c) of the Regulatory Review Act, Act of June 30, 1989, P.L. 73, 71 P.S. § 745.7(c). The required report of the Board under Section 7(c) of the Act will be forthcoming.

Sincerely,

Charles D. Hummer, Jr., M.D., Chairperson
State Board of Medicine

K. Stephen Anderson CRNA

Stephen K. Anderson, R.N., C.R.N.A., Chairperson
State Board of Nursing

HA:dws
cc: The Honorable Kim Pizzingrilli
Secretary of the Commonwealth

Dorothy Childress, Commissioner
Bureau of Professional and Occupational Affairs

PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 11, 2000

K. Stephen Anderson, M.Ed., CRNA, Chairperson
State Board of Nursing
116 Pine Street
Harrisburg, PA 17105

Re: IRRC Regulation #16A-499 (#2064)
State Board of Medicine
State Board of Nursing
Certified Registered Nurse Practitioners
Prescriptive Authority

Dear Mr. Anderson:

The Independent Regulatory Review Commission disapproved the subject regulation at its public meeting on July 13, 2000. Our Order is enclosed and is available on our website at http://www.irrc.state.pa.us.

Section 7(a) of the Regulatory Review Act requires you to notify us within seven days from receipt of this letter if you will: (1) withdraw the regulation; (2) proceed with promulgation under Section 7(b); or (3) proceed with promulgation under Section 7(c).

Sincerely,

Robert E. Nyce
Executive Director

cae
Enclosure
cc: [redacted]
Gerald Smith
Dorothy Childress
Honorable Kim Pizzingrilli

INDEPENDENT REGULATORY REVIEW COMMISSION
DISAPPROVAL ORDER

Commissioners Voting:

John R. McGinley, Jr., Chairman
Alvin C. Bush, Vice Chairman, by proxy
Arthur Coccodrilli, dissenting
Robert J. Harbison, III
John F. Mizner, dissenting

Public Meeting Held July 13, 2000

Regulation No. 16A-499
State Board of Medicine and
State Board of Nursing
Certified Registered Nurse Practitioners
Prescriptive Authority

On September 17, 1999, the Independent Regulatory Review Commission (Commission) received this joint proposed regulation from the State Board of Medicine and the State Board of Nursing (Boards). This rulemaking adds 49 Pa. Code Sections 18.53 to 18.57 and 21.283 to 21.287. The proposed regulation was published in the October 2, 1999 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on June 6, 2000.

This rulemaking will authorize Certified Registered Nurse Practitioners (CRNP) to prescribe and dispense drugs. In order for a CRNP to prescribe and dispense drugs, the regulations establish education requirements, specify categories of drugs CRNPs may and may not prescribe, require collaborative agreements with physicians, specify CRNP identification requirements and specify physician supervision requirements.

The final regulation contains significant amendments to the proposed version of the regulation. There are three areas that do not meet our criteria as explained below.

First, the Boards added a 2:1 ratio of CRNPs to physicians in Sections 18.57 and 21.287 of the final regulation. This ratio raises questions concerning protection of the public health, need and reasonableness (71 P.S. §§ 745.5a(i)(2) and (3)). These provisions were not in the proposed regulation.

Commentators believe the 2:1 ratio will unnecessarily restrict the availability of healthcare, particularly in underserved rural and urban areas. They also observe that the regulation requires part-time CRNPs to meet the same ratio as full-time CRNPs.

The Preamble does not explain how the 2:1 ratio was determined. The Boards state that CRNPs prescribing drugs is the norm in 42 states. Commentators have stated that only two of those states use a ratio, and that the ratio is higher than the 2:1 ratio in this regulation. The Boards should amend or delete this requirement or explain why it is appropriate.

Second, the waiver process in Sections 18.57(a) and 21.287(a) lacks clarity (71 P.S. § 745.5a(i)(3)). The provision allows a physician to "apply for a waiver...for good cause, as determined by the Boards." This is new language added to the final regulation.

Commentators believe the waiver process is not clearly defined in the regulation. The regulation should be amended to state how to apply to the Boards for a waiver, what information is required, and what criteria the Boards will use to evaluate a request for waiver.

Finally, the requirement in Sections 18.53(2) and 21.283(2) for "a specific course in advanced pharmacology of not less than 45 hours" does not reasonably allow existing CRNPs to comply, would impose unnecessary costs on them, and would impose adverse effects on competition (71 P.S. §§ 745.5a(i)(1) and (3)). Prior to 1992, pharmacology was integrated into other courses in the CRNP curricula. Approximately 40% of practicing CRNPs may not be able to document a "specific" course, even though they may have had equivalent education. A further concern is that the Boards will allow more favorable treatment for out-of-state equivalency for CRNP certification under existing Sections 18.42 and 21.272 (relating to Certification by endorsement; currently licensed), but would foreclose the opportunity for Pennsylvania's CRNPs to demonstrate an equivalency of the 45-hour advanced pharmacology course. The regulation should allow all CRNPs the opportunity to demonstrate an equivalency of the 45-hour advanced pharmacology course to the Boards.

We have determined this regulation is consistent with the statutory authority of the State Board of Medicine (63 P.S. § 422.15(b)) and the State Board of Nursing (63 P.S. § 212) and the intention of the General Assembly. However, after considering all of the other criteria of the Regulatory Review Act discussed above, we find promulgation of this regulation is not in the public interest.

BY ORDER OF THE COMMISSION:

This regulation is disapproved.

John R. McGinley, Jr., Chairman

TRANSMITTAL SHEET FOR
NOTICE PURSUANT TO SECTION 7(a)
OF THE REGULATORY REVIEW ACT

DEPARTMENT: DEPARTMENT OF STATE **ID NUMBER:** 16A-499

SUBJECT: Order of Final Rulemaking of the State Boards of Medicine and Nursing Pertaining to CRNP Prescriptive Authority (16A-499)

PA CODE CITE: State Board of Medicine, 49 Pa. Code §§18.53-18.57
State Board of Nursing, 49 Pa.Code §§21.283-21.287

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Type of Notice:

Notice final-form regulation will be promulgated without revision pursuant to Section 7(b) of the Regulatory Review Act.

X Notice that final-form regulation will be revised and promulgated pursuant to Section 7(c) of the Regulatory Review Act.

Notice that final-form regulation will be withdrawn.

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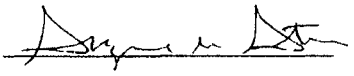
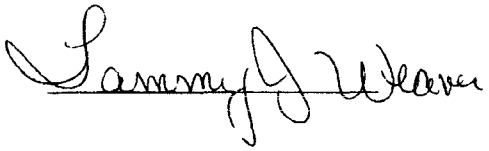
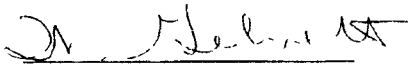
Filing of Notice:

DATE	SIGNATURE	AGENCY
_____	_____	Governor's Office (333 Market St.)
9-13-00		House Committee
9/11/00		Senate Committee
9/14/00		Independent Regulatory Review Commission

Original: 2064

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
Date: 7/11/00

FROM THE DESK OF:

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____ **For your information**

__X__ **Per your request**

____ **Please call me at (717) 783-1959**

____ **See me and discuss**

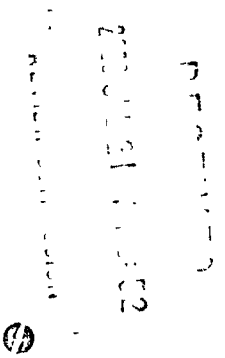
____ **Please distribute to staff**

____ **Please draft a response and return to me by _____.**

TO: Jim Smith
IRRC
14th Floor
333 Market St.

Original: 2064

Mailing list for comments on 16A-499: Certified Registered Nurse Practitioners, Prescriptive Authority.



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September 11, 2000

Re: Regulation #16A-499 (IRRC #2064)
State Board of Nursing
State Board of Medicine
Certified Registered Nurse Practitioners Prescriptive Authority

Dear Commentator:

Section 6(a) of the Regulatory Review Act requires the Independent Regulatory Review Commission (Commission) to notify commentators when a regulation has been disapproved. On July 13, 2000, the Commission voted to disapprove this regulation for the reasons stated in the enclosed Order. However, delivery of the Commission's Order was delayed until September 11, 2000, at the request of the House and Senate standing committees.

Today, the Department informed the Commission that it intends to revise and resubmit this regulation within the 40-day period prescribed by Section 7(c) of the Regulatory Review Act. Therefore, the regulation must be resubmitted to us and the standing committees on or before October 23, 2000.

If you have any questions on this matter, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director
cae

INDEPENDENT REGULATORY REVIEW COMMISSION
DISAPPROVAL ORDER

Commissioners Voting:

John R. McGinley, Jr., Chairman
Alvin C. Bush, Vice Chairman, by proxy
Arthur Coccodrilli, dissenting
Robert J. Harbison, III
John F. Mizner, dissenting

Public Meeting Held July 13, 2000

Regulation No. 16A-499
State Board of Medicine and
State Board of Nursing
Certified Registered Nurse Practitioners
Prescriptive Authority

On September 17, 1999, the Independent Regulatory Review Commission (Commission) received this joint proposed regulation from the State Board of Medicine and the State Board of Nursing (Boards). This rulemaking adds 49 Pa. Code Sections 18.53 to 18.57 and 21.283 to 21.287. The proposed regulation was published in the October 2, 1999 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on June 6, 2000.

This rulemaking will authorize Certified Registered Nurse Practitioners (CRNP) to prescribe and dispense drugs. In order for a CRNP to prescribe and dispense drugs, the regulations establish education requirements, specify categories of drugs CRNPs may and may not prescribe, require collaborative agreements with physicians, specify CRNP identification requirements and specify physician supervision requirements.

The final regulation contains significant amendments to the proposed version of the regulation. There are three areas that do not meet our criteria as explained below.

First, the Boards added a 2:1 ratio of CRNPs to physicians in Sections 18.57 and 21.287 of the final regulation. This ratio raises questions concerning protection of the public health, need and reasonableness (71 P.S. §§ 745.5a(i)(2) and (3)). These provisions were not in the proposed regulation.

Commentators believe the 2:1 ratio will unnecessarily restrict the availability of healthcare, particularly in underserved rural and urban areas. They also observe that the regulation requires part-time CRNPs to meet the same ratio as full-time CRNPs.

The Preamble does not explain how the 2:1 ratio was determined. The Boards state that CRNPs prescribing drugs is the norm in 42 states. Commentators have stated that only two of those states use a ratio, and that the ratio is higher than the 2:1 ratio in this regulation. The Boards should amend or delete this requirement or explain why it is appropriate.

Second, the waiver process in Sections 18.57(a) and 21.287(a) lacks clarity (71 P.S. § 745.5a(i)(3)). The provision allows a physician to "apply for a waiver...for good cause, as determined by the Boards." This is new language added to the final regulation.

Commentators believe the waiver process is not clearly defined in the regulation. The regulation should be amended to state how to apply to the Boards for a waiver, what information is required, and what criteria the Boards will use to evaluate a request for waiver.

Finally, the requirement in Sections 18.53(2) and 21.283(2) for "a specific course in advanced pharmacology of not less than 45 hours" does not reasonably allow existing CRNPs to comply, would impose unnecessary costs on them, and would impose adverse effects on competition (71 P.S. §§ 745.5a(i)(1) and (3)). Prior to 1992, pharmacology was integrated into other courses in the CRNP curricula. Approximately 40% of practicing CRNPs may not be able to document a "specific" course, even though they may have had equivalent education. A further concern is that the Boards will allow more favorable treatment for out-of-state equivalency for CRNP certification under existing Sections 18.42 and 21.272 (relating to Certification by endorsement; currently licensed), but would foreclose the opportunity for Pennsylvania's CRNPs to demonstrate an equivalency of the 45-hour advanced pharmacology course. The regulation should allow all CRNPs the opportunity to demonstrate an equivalency of the 45-hour advanced pharmacology course to the Boards.

We have determined this regulation is consistent with the statutory authority of the State Board of Medicine (63 P.S. § 422.15(b)) and the State Board of Nursing (63 P.S. § 212) and the intention of the General Assembly. However, after considering all of the other criteria of the Regulatory Review Act discussed above, we find promulgation of this regulation is not in the public interest.

BY ORDER OF THE COMMISSION:

This regulation is disapproved.

John R. McGinley, Jr., Chairman

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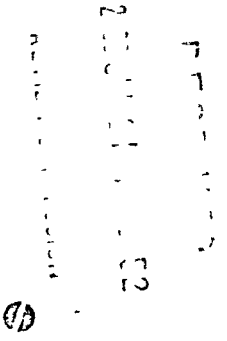
Mailing list for comments on 16A-499: Certified Registered Nurse Practitioners, Prescriptive Authority.



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

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July 7, 2000

Suzanne K. Kelley, D.O., President
Pennsylvania Osteopathic Medical Association
1330 Eisenhower Boulevard
Harrisburg, PA 1711-2995

RE: FINAL RULEMAKING OF THE STATE BOARDS OF MEDICINE AND NURSING PERTAINING TO CRNP PRESCRIPTIVE AUTHORITY (16A-499)

Dear Dr. Kelley:

A copy of your letter of June 29, 2000, to Chairman John R. McGinley, Jr., of the Independent Regulatory Review Commission was forwarded to the Department of State, Bureau of Professional and Occupational Affairs.

In your letter you asked how the final rulemaking pertaining to prescriptive authority (16A-499) would affect an osteopathic physician entering into a collaborative agreement. Please note that the State Boards of Medicine and Nursing are promulgating this rulemaking. The statutory authority under which this rulemaking is being promulgated, Sections 15(b) of the Medical Practice Act and 212(1) of the Professional Nursing Law, authorizes the State Boards of Medicine and Nursing to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnosis and prescription of medical, therapeutic, diagnostic or corrective measures. Neither statute would seem to provide authority to affect osteopathic physicians. As you know, the State Board of

Osteopathic Medicine is the only licensing board with the authority to regulate osteopathic physicians.

Very truly yours,

Herbert Abramson
Senior Counsel in Charge

c: The Honorable John R. McGinley, Jr., Chair
Independent Regulatory Review Commission

The Honorable Clarence Bell, Chair
Senate Consumer Protection and Professional Licensure Committee

The Honorable Mario Civera, Chair
House Professional Licensure Committee

Charles D. Hummer, M.D., Chair
State Board of Medicine

Daniel D. Dowd, Jr., D.O., Chair
State Board of Osteopathic Medicine

Robert S. Muscalus, D.O.
Physician General

Original: 2064

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
HARRISBURG PENNSYLVANIA
17120

July 6, 2000

The Honorable Frank A. Salvatore
Senate Box 203005
Harrisburg, PA 17120-3005

RE: Response to Maureen P. Glendon's Letter Concerning Prescriptive Authority for Certified Registered Nurse Practitioners - Expanding the Scope of Practice Without Impacting Current Practice

Dear Senator Salvatore:

Thank you for your letter dated June 20, 2000, which you wrote on behalf of your constituent, Maureen P. Glendon, a pediatric nurse practitioner. Ms. Glendon expressed concern about the effect of the Certified Registered Nurse Practitioner (CRNP) prescriptive authority regulations on access to essential health care for citizens in the Commonwealth. Ms. Glendon strongly urged that the regulations be disapproved. Ms. Glendon specifically did not approve of the two CRNPs to one physician ratio; the 45 hour course requirement; and the restrictions on some of the drugs from American Hospital Formulary. Ms. Glendon also expressed the belief that the statutory Board authority over CRNP acts of medical prescription was shifted to collaborating physicians.

Ms. Glendon's concerns appear to rely on two premises: (1) that the revisions made to the proposed regulations require further public comment, and (2) that the regulations will restrict the practice of CRNPs and thus, result in reduced access health care for the citizens in the Commonwealth. These premises are incorrect.

1. The revisions to the regulations do not enlarge the purpose of the proposed regulations and thus, conform to the Commonwealth Documents Law.

The purpose of the CRNP prescriptive authority regulations is to give CRNPs the authority to prescribe drugs within specified parameters. Currently, CRNPs are advanced practice registered nurses who work in collaboration with and under the direction of a physician to perform acts of medical diagnosis and prescribe medical, therapeutic, or corrective measures. Pre-draft copies of the regulations were sent to stakeholders, and over 300 comments were received Revisions were made based upon these comments, and then proposed rulemaking was published. Following publication of proposed rulemaking, the State Board of Nursing (SBON) and the State Board of Medicine (SBOM) received over 600 comments from the Senate Committee on Consumer Protection

and Professional Licensure (Senate), the House Committee on Professional Licensure (House), the Independent Regulatory Review Commission (IRRC), and numerous groups, associations, consumers, and individuals. The SBON and SBOM carefully considered all the comments and made well-reasoned revisions which did not enlarge the original purpose of proposed rulemaking. The revisions refined and clarified the parameters within which CRNPs will be authorized to prescribe drugs. This means that the revisions were made in accordance with Section 202 of the Commonwealth Documents Law, Act of July 31, 1968, P.L. 769, No. 240, as amended, 45 P.S. §1202, and additional public comment is not required before the regulations are published as final rulemaking.

2. The regulations broaden the practice of CRNPs, do not restrict current practice, and increase access to health care.

The regulations broaden the practice of CRNPs by giving them prescriptive authority in accordance with the regulations and thus, increase access to health care for the citizens of the Commonwealth. The revised regulations do not restrict the current practice of CRNPs. CRNPs who do not want to prescribe drugs may continue to practice the same way they have always practiced after these regulations are published as final. CRNPs who want to broaden their practice by prescribing drugs will not have the unlimited authority of physicians to prescribe but will have authority to prescribe drugs within the parameters specified for this new practice area.

a. The ratio of two CRNPs to one physician, which pertains only to prescriptive authority, and the opportunity for a physician to request a waiver of the ratio are appropriate safeguards.

Ms. Gendon's letter urged eliminating the two CRNPs to one physician (2:1) ratio because she believed that the 2:1 ration was limiting and arbitrary. The SBOM clarified at its April 25, 2000, meeting that the 2:1 ratio pertains only to CRNPs with prescriptive authority. The 2:1 ratio does not impact current practice. For example, a physician who supervises and collaborates with five CRNPs who do not have prescriptive authority may continue to supervise and collaborate with them. If two of the five supervised nurse practitioners obtain prescriptive authority, that would also be allowed under the regulations. Thus, access to healthcare is increased under the regulations.

The 2:1 ratio has a waiver provision whereby a physician may request a waiver in order to supervise more than two CRNPs with prescriptive authority. For example, if a physician supervises five CRNPs, and all five CRNPs want to prescribe drugs, then the physician must apply for a waiver. The physician applies for the waiver because the physician is in the best position to know how many CRNPs he or she can appropriately supervise. The physician is also in the best position to objectively evaluate the skill, training and ability of the collaborating CRNPs and determine how much supervision they require. Further, as noted above, giving CRNPs prescriptive authority, even with restrictions, increases access to health care because there is no impact on current practice.

The 2:1 ratio is not arbitrary. Prescribing drugs is a new practice area for CRNPs, and the 2:1 ratio is a proven start point that has been used successfully with respect to physician assistants

with prescriptive authority and doctors. It is important to note that CRNPs, in general, have a much broader scope of practice than physician assistants and therefore, would be more difficult to supervise in their new practice area. The 2:1 ratio for prescriptive authority is an appropriate ratio which has been proven effective in protecting the health, safety and welfare of the citizens of the Commonwealth. Additionally, states without ratios have other safeguards built into their regulatory framework. For example, Delaware does not allow CRNPs to prescribe refills (the Pennsylvania regulations do allow refills); Ohio and West Virginia forbid CRNPs to prescribe Schedule II drugs (the Pennsylvania regulations allow Schedule II drugs to be prescribed for 72 hours); Ohio allows CRNPs to prescribe Schedule III, IV, and V drugs for 72 hours with no refills (the Pennsylvania regulations allows Schedule III and IV drugs to be prescribed for 30 days and refills may be authorized in the collaborative agreement). The 2:1 ratio is an appropriate safeguard within Pennsylvania's regulatory framework.

The purpose of the CRNP prescriptive authority regulations is to give CRNPs the authority to prescribe drugs within specified parameters. The 2:1 ratio is a prudent safeguard which allows prescribing CRNPs even greater prescriptive authority than in some surrounding states. Please note that access to health care without a method to insure that quality care is being delivered would be detrimental to the health safety and welfare to the citizens of the Commonwealth. The 2:1 ratio and the waiver provision insures that quality health care is being delivered in this new practice area for CRNPs.

b. The separate 45-hour course is appropriate and reasonable.

Ms. Glendon's letter expressed concern about a separate 45-hour, or three credit course, in advanced pharmacology. She stated that the 45-hour requirement "was not specified in the proposed regulations published for public comment, nor in the comments from the Independent Regulatory Review Commission, nor in the written comments of the Pennsylvania Medical Society," and that the 45-hour requirement was arbitrary. It is important to note that both Boards received over 600 comments. Many commentators, including IRRC, requested that the course requirements be specified. The Pennsylvania Academy of Family Physicians recommended a 50-hour course.

Currently, at least 21 states require a separate and distinct course in pharmacology. Separate and distinct courses are recommended by both the National Council of State Boards of Nursing (NCSBN) and the National Organization of Nurse Practitioner Faculties (NONPF) in their *1998 Summary Report, Curriculum Guidelines & Regulatory Criteria for Family Nurse Practitioners Seeking Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care* (Summary Report). The Summary Report specifically recommends 45 contact hours, or three credit hours, over the course of a semester. Since at least 1992, all CRNP programs approved by the SBON have included a separate 45-hour, or three credit, course. Clearly the 45-hour requirement was not arbitrary.

There are approximately 4,667 CRNPs in Pennsylvania. The SBON estimates that approximately 1,888 CRNPs would be required to take a 45-hour course, if they wanted to prescribe drugs. If they do not want to prescribe drugs, they would not be required to take the course. For

the CRNPs who want to prescribe drugs, Ms. Geldon has estimated that the cost of a 45 hour pharmacology course would be $5,000.00, including time away from work, however, she did not give support for this estimate. The SBON has estimated that the cost of a 45-hour course is between $630.00 and $1,875 for tuition depending upon the educational institution.

Ms. Geldon's letter accurately stated that CRNPs have been safely practicing for years. However, it is important to note that no matter how safe their practice has been, they have not been prescribing drugs. Prescriptive authority is a new practice area for CRNPs. Therefore, based upon the current SBON practice for CRNP program approval, the current practice of 21 states, and the recommendation of the NCSBN, in addition to numerous commentators, the SBON and the SBOM believe that a separate 45-hour, or three credit, course is appropriate and reasonable.

c. The language in the American Hospital Formulary is used for each drug category.

Ms. Geldon's letter suggested that the language in the American Hospital Formulary should be used for each drug category. The language in the American Hospital Forumulary has been used for each drug category. She also noted that the SBON voted on March 30, 2000, to approve the final regulations if some missing categories of drugs were added to the regulations. The Boards have approved the following revisions in final rulemaking: eye, ear, nose and throat preparations and hormones and synthetic substitutes were added to the list of drugs that may be prescribed as long as they are specified in the collaborative agreement. Unclassified therapeutic agents and devices and pharmaceutical aides were added to the list of drugs that may be prescribed as long as they are specified in the collaborative and if they are originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy. Oxytocics were not added. Please note that the addition of these categories of drugs further opens up this new practice area for CRNPs.

d. CRNPs are jointly regulated by the SBON and the SBOM, and the regulations do not partition liability.

Ms. Geldon's letter stated that the Board should maintain the "statutory board authority over CRNP acts of medical prescription instead of shifting to an individual collaborating physician the authorization to identify drug categories that the CRNP may prescribe and dispense." In support of her statement, Ms. Geldon quoted an article written by Barbara Safreit which pertains to the regulation of advanced practice nursing, and postulates that advanced practice nurses should not have physician oversight. The article is inapplicable. The article is about the economics of the healthcare system and the utilization of advanced practice nurses. It is not about protecting the heath, safety and welfare of the citizens of Pennsylvania while giving CRNPs the authority to prescribe drugs. Additionally, the article presents an argument and advocates a position. It does not present a balanced perspective.

It is important to note that CRNPs are jointly regulated by the SBON and SBOM. No statutory authority is abrogated by either Board. Indeed, abrogation of either Board's statutory authority would require an act of the Legislature. It appears that Ms. Geldon is concerned about responsibility and liability for physicians. Regulations and liability are two separate and distinct

issues. These regulations do not and cannot assign civil liability. Having a particular regulation does not make someone automatically civilly liable for something that happens. Liability is heavily fact specific and depends upon what happened in a particular situation.

Finally, Ms. Geldon's letter states, "It is essential for the State Board of Nursing to represent the interest of our profession as they protect the health, safety and welfare of Pennsylvania citizens." The SBON regulates the nursing profession to protect the health, safety and welfare of Pennsylvania citizens. The Board does not represent the interests of professional associations, special interests or groups. The SBON uses its knowledge and expertise to protect the health, safety and welfare of Pennsylvania citizens.

In conclusion, these regulations broaden the practice of CRNPs in Pennsylvania and thus, increase access to health care for citizens in the Commonwealth. The revisions to these regulations do not enlarge the original purpose of the proposed regulations. These regulations represent a successful collaboration of the SBON and SBOM to establish prescriptive authority for CRNPs. These regulations will increase access to health care without placing the health, safety and welfare of the citizens of the Commonwealth in jeopardy.

If you have any additional questions regarding these regulations, please do not hesitate to contact Jeff Cox, Legislative Liaison or myself.

Sincerely,

Kim Pizzingrilli
Secretary of the Commonwealth

KP/CMW/rc/bls

cc: Jeff Cox, Legislative Liaison
Robert C. Nyce, IRRC Executive Director ✓
C. Michael Weaver, Deputy Secretary for Regulatory Programs
Dorothy Childress, Commissioner