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 45 hours of course work 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 4 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.

Prescribing CRNPs 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. At least 60% of the current CRNP population has taken a 45 hour course in advanced pharmacology and meet the requirement. The great majority of the remaining CRNPs (approximately 1866, or 40%) will be able to demonstrate that they have completed course work totaling 45 hours. A small number who do not have 45 hours of course work but want to prescribe drugs will bear the one-time cost of completing additional course work to bring their total to 45-hours. The cost of a single 45-hour course in advanced pharmacology is between approximately $630 and $1875. A course of fewer hours will be less. 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.

(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 courses 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 additional course work 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.

Regulatory Analysis Form

(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 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.

SRL - 9/26/00
OE

REPORT OF THE STATE BOARDS OF MEDICINE AND NURSING PERTAINING TO PRESCRIPTIVE AUTHORITY FOR CERTIFIED REGISTERED NURSE PRACTITIONERS (16A-499)

To the Honorable Members of the House Committee on Professional Licensure:

To the Honorable Members of the Senate Committee on Consumer Protection and Professional Licensure:

To the Honorable Members of the Independent Regulatory Review Commission:

This report of the State Boards of Medicine and Nursing (Boards) is submitted under Section 7(c) of the Regulatory Review Act, Act of June 30, 1989, P.L. 73, as amended, 71 P.S. § 745.7(c).

On July 13, 2000, the Independent Regulatory Review Commission (IRRC) voted to disapprove a final-form regulation of the Boards pertaining to prescriptive authority for Certified Registered Nurse Practitioners (CRNPs) (16A-499). The regulation had been approved by the House Committee and deemed approved by the Senate Committee. IRRC's order disapproving the final-form regulation was received by the Boards on September 11, 2000.

Following IRRC's vote to disapprove the final-form regulation, the Boards determined that they would attempt to revise or modify the final-form regulation in order to respond to objections raised by IRRC and adopt the regulation with revisions or modifications. The Boards notified the Governor, the House Committee, the Senate Committee, and IRRC on September 11, 2000, that they would proceed further with the final-form regulation under Section 7(c) of the Regulatory Review Act, 71 P.S. § 745.7(c).

The purpose of the final-form regulation is to give CRNPs the authority to prescribe and dispense drugs within specified parameters. The rulemaking established (1) the educational requirements a CRNP must meet in order to prescribe and dispense (§§18.53(1)-(2) and 21.283(1)-

(2); (2) a biennial continuing education requirement that a prescribing CRNP must meet in order to renew his or her certification to prescribe or dispense (§§18.53(3) and 21.283(3)); (3) the categories of drugs from which a CRNP might prescribe and dispense and limits and prohibitions on prescribing and dispensing (§§18.54 and 21.284); (4) a definition of a collaborative agreement between a supervising physician and CRNP (§§18.55(a) and 21.285(a)); (5) the contents of a collaborative agreement between a supervising physician and a CRNP who prescribes and dispenses drugs (§§18.55(b) and 21.285(b)); (6) a requirement that the CRNP identify himself or herself as a CRNP (§§18.56 and 21.286); and (7) a limit on the number of prescribing and dispensing CRNPs that a physician may supervise (§§18.57 and 21.287).

The disapproval of IRRC focused on two principal areas: the educational requirements of a prescribing CRNP and the limit on the number of CRNPs that a physician could supervise.

The Educational Requirement (§§18.53(2) and 21.283(2)).

Under the final-form regulation which had been submitted to and disapproved by IRRC, a CRNP could prescribe and dispense drugs only if he or she completed a specific course in advanced pharmacology of not less than 45 hours. IRRC's order of disapproval stated that the course requirement did not reasonably allow existing CRNPs to comply, would impose unnecessary costs on them, would impose adverse effects on competition, and would allow more favorable treatment for out-of-state equivalency for CRNP certification, but would foreclose the opportunity for Pennsylvania CRNPs to demonstrate an equivalency of the 45 hour advanced pharmacology course.

In responding to IRRC's objection, the Boards revised the final-form regulation to eliminate the requirement of a specific 45 hour course, while seeking to assure that a CRNP who prescribes has had not less that 45 hours of course work in advanced pharmacology. Under the revised final-

form regulation a CRNP who wishes to prescribe and dispense drugs will be required to have successfully completed not less than 45 hours of course work specific to advanced pharmacology. Under the revised final-form regulation a CRNP could fulfill the requirement in several ways. A CRNP might demonstrate that he or she fulfilled the requirement either with a single course, or with two or more courses adding up to 45 hours. If the advanced pharmacology had been integrated into other non-pharmacology courses, the CRNP could apply the advanced pharmacology hours of the integrated course to the 45 hour requirement. The CRNP could also meet the requirement by demonstrating that he or she had a combination of 45 hours of advanced pharmacology taken in integrated courses and courses specific to advanced pharmacology. Under this scheme a CRNP who completed his or her CRNP education program prior to 1992 (when a specific 45 hour course became the norm) could reasonably comply with little or no additional cost.

Neither the final rulemaking which had been disapproved nor the revised final rulemaking treats out-of-state applicants more favorably than Commonwealth applicants. Out-of-state applicants always have to demonstrate that they have the same educational qualifications as Commonwealth applicants.

Supervision of the CRNP (§§18.57 and 21.287)

Under the final-form regulation which had been submitted to and disapproved by IRRC, a physician could not serve as the collaborating physician for more than two prescribing CRNPs at any one time. The final-form regulation did not place any limit on the number of non-prescribing CRNPs whom a physician could supervise. The physician could apply to the Boards for a waiver of the limit of two prescribing CRNPs for good cause.

IRRC's order of disapproval stated that the 2:1 ratio raised questions concerning protection

of the public health, need, and reasonableness, that the ratio would unnecessarily restrict the availability of healthcare, and required part-time CRNPs to meet the same ratio as full-time CRNPs. IRRC pointed out that the preamble did not explain how the 2:1 ratio was determined. IRRC also stated that the waiver process lacked clarity and 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 a waiver.

In responding to IRRC's objection, the Boards revised the final-form regulation to change the ratio of one physician to four prescribing CRNPs at any time. (§§18.57(a) and 21.287(a)) This is the number recommended by the Pennsylvania Medical Society in their comment of October 18, 1999. The Boards further clarified the meaning of the phrase "at any one time" by means of an example. Under the example a physician might supervise four prescribing CRNPs who worked in the morning and four other CRNPs who worked in the afternoon. Thus, part-time prescribing CRNPs will be accommodated. The final rulemaking which IRRC disapproved did not address the issue of a physician who supervised a number of part-time CRNPs. The Boards believe that the revised final rulemaking adequately addresses this issue. The original ratio of not more than two prescribing CRNPs to one physician was obtained from the physician assistant regulations. (See, 49 Pa. Code §18.153(b)(2)) The revised final-form regulation also specifies that the general limit of not more than four prescribing CRNPs to one physician at the same time does not apply to CRNPs who do not prescribe. (§§18.57(c) and 21.287(c)) The Boards do not limit the number of non-prescribing CRNPs whom a physician may supervise. The Boards illustrate this by an example of a physician who collaborates at the same time with four prescribing CRNPs and one or more CRNPs who do not prescribe. The ratio also does not apply to the number of CRNPs with whom a

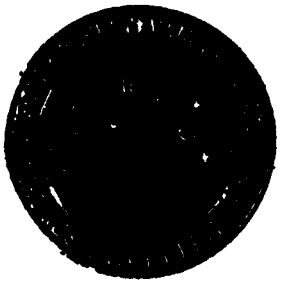
physician might have collaborative agreements. A physician may have any number of collaborative agreements with both prescribing and non-prescribing CRNPs. The ratio only applies to the number of prescribing CRNPs whom the physician is actually supervising at any time.

Further, the Boards keep the waiver provision so that a physician who wishes to collaborate with more than four prescribing CRNPs at the same time could ask the Boards for a waiver for good cause. (§§18.57(b) and 21.287(b)) The Boards do not believe that further elaboration of the waiver process is necessary. Under the revised final rulemaking a physician could, at any time, supervise four prescribing CRNPs in addition to non-prescribing CRNPs. It is therefore not anticipated that there will be many requests for a waiver. If a physician believes that it is necessary to supervise more than four prescribing CRNPs at a time, the physician will be able to apply for the waiver on a simple form that is already being developed. In determining whether to grant a waiver the Boards would look at such factors as the demonstrated need to supervise more than four prescribing CRNPs at a time, the ability of the physician to provide reasonable supervision, the complexity of the practice, etc.

Very truly yours,

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

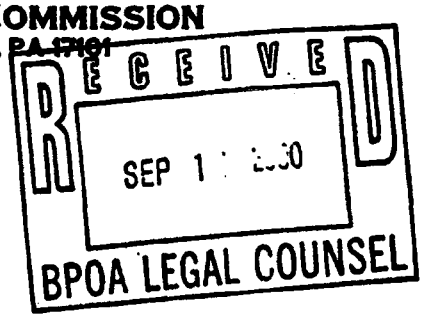
Stephen K. Anderson, R.N., C.R.N.A., Chairperson
State Board of Nursing



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

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

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 work 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 four CRNPs who prescribe and dispense drugs at any one time 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.

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 supported 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.

In response to these comments, the Boards have adopted a 45-hour course work 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. A 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] Forty-five hours of course work in advanced pharmacology 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 forty-five hours of course work as part of his or her CRNP education program will be able to take additional course work from a program or programs approved by the Boards. Advanced pharmacology which has been "integrated" into other courses will be acceptable, provided it can be verified through means such as a course syllabus or catalog which identifies the hours devoted to advanced pharmacology.

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, 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

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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.

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 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

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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.

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 maintaind 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 physican might collaborate. Sections 18.57 and 21.287 would permit a physician to collaborate with four CRNPs who prescribe and dispense drugs at any one time. Under these sections a physician could supervise a total of more than four prescribing and dispensing CRNPs, but not at the same time. Moreover, the regulation 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 four 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 courses 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). A CRNP who wishes to prescribe but who has not already taken 45 hours of advanced pharmacology will have to bear the costs of taking a course or courses in advanced pharmacology. Prescribing CRNPs will also have to bear the costs of continuing education courses. 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 disapproved by IRRC at its meeting of July 13, 2000. IRRC's order of disapproval was received by the Boards on September 11, 2000. On that date the Boards, under Section 7(a) of the Regulatory review Act, submitted written notice of their intention to modify the final rulemaking in accordance with Section 7(c) of the Regulatory Review Act, to the Governor, IRRC, and the House and Senate Committees.

On October 2, 2000, the Boards delivered final revised rulemaking and the 7(c) report to the Governor, IRRC, and the House and Senate Committees.

The final form amendments were approved by the House Committee on _____,2000, the Senate Committee on _____,2000, and by IRRC on _____, 2000.

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

K. Stephen Anderson CRNA

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 OF ~~SPECIFIC~~ COURSE WORK ~~IN~~ SPECIFIC TO ADVANCED PHARMACOLOGY IN ACCORDANCE WITH THE FOLLOWING:

A. THE COURSE ~~OR COURSES~~ WORK IN ADVANCED PHARMACOLOGY MAY BE EITHER PART OF THE CRNP EDUCATION PROGRAM OR, IF COMPLETED OUTSIDE OF THE CRNP EDUCATION PROGRAM, AN ADDITIONAL COURSE OR COURSES TAKEN FROM AN EDUCATIONAL PROGRAM OR PROGRAMS APPROVED BY THE BOARDS.

B. THE COURSE ~~OR COURSES~~ WORK IN ADVANCED PHARMACOLOGY 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) AT ANY TIME A PHYSICIAN ~~SHALL NOT SERVE AS THE COLLABORATING PHYSICIAN FOR MORE THAN TWO~~ MAY NOT SUPERVISE MORE THAN FOUR CRNPS WHO PRESCRIBE AND DISPENSE DRUGS ~~AT ANY ONE TIME.~~ THIS REGULATION, HOWEVER, DOES NOT LIMIT THE NUMBER OF COLLABORATIVE AGREEMENTS THAT A PHYSICIAN MAY HAVE WITH PRESCRIBING CRNPS. ~~HOWEVER,~~ BY WAY OF EXAMPLE, A PHYSICIAN MAY SUPERVISE FOUR PRESCRIBING CRNPS WHO WORK IN THE MORNING AND FOUR OTHER

PRESCRIBING CRNPS WHO WORK IN THE AFTERNOON AS LONG AS THE PHYSICIAN HAS A COLLABORATIVE AGREEMENT WITH EACH CRNP.

(b) A PHYSICIAN MAY APPLY FOR A WAIVER OF ~~THIS SECTION~~ THE SUPERVISION REQUIREMENTS EXPRESSED IN SUBSECTION (a) FOR GOOD CAUSE, AS DETERMINED BY THE BOARDS.

~~(b)~~ (c) THE LIMIT OF THE GENERAL RULE OF NOT MORE THAN ~~TWO~~ FOUR 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~~ SUPERVISE AT THE SAME TIME FOUR CRNPS WHO PRESCRIBE AND DISPENSE DRUGS AND ONE OR MORE CRNPS WHO DO NOT PRESCRIBE AND DISPENSE DRUGS.

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 OF ~~SPECIFIC~~ COURSE WORK ~~IN~~ SPECIFIC TO ADVANCED PHARMACOLOGY IN ACCORDANCE WITH THE FOLLOWING:

A. THE COURSE ~~OR COURSES~~ WORK IN ADVANCED PHARMACOLOGY MAY BE EITHER PART OF THE CRNP EDUCATION PROGRAM OR, IF COMPLETED OUTSIDE OF THE CRNP EDUCATION PROGRAM, AN ADDITIONAL COURSE OR COURSES TAKEN FROM AN EDUCATIONAL PROGRAM OR PROGRAMS APPROVED BY THE BOARDS.

B. THE COURSE ~~OR COURSES~~ WORK 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.

~~(hh)~~(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).

~~(ii)~~(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) AT ANY TIME A PHYSICIAN ~~SHALL NOT SERVE AS THE COLLABORATING PHYSICIAN FOR MORE THAN TWO~~ MAY NOT SUPERVISE MORE THAN FOUR CRNPS WHO PRESCRIBE AND DISPENSE DRUGS ~~AT ANY ONE TIME~~. THIS REGULATION, HOWEVER, DOES NOT LIMIT THE NUMBER OF COLLABORATIVE AGREEMENTS THAT A PHYSICIAN MAY HAVE WITH PRESCRIBING CRNPS. ~~HOWEVER,~~ BY WAY OF EXAMPLE, A PHYSICIAN MAY SUPERVISE FOUR PRESCRIBING CRNPS WHO WORK IN THE MORNING AND FOUR OTHER PRESCRIBING CRNPS WHO WORK IN THE AFTERNOON AS LONG AS THE PHYSICIAN HAS A COLLABORATIVE AGREEMENT WITH EACH CRNP.

(b) A PHYSICIAN MAY APPLY FOR A WAIVER OF ~~THIS SECTION~~ THE SUPERVISION REQUIREMENTS EXPRESSED IN SUBSECTION (a) FOR GOOD CAUSE, AS DETERMINED BY THE BOARDS.

~~(b)~~ (c) THE LIMIT OF THE GENERAL RULE OF NOT MORE THAN ~~TWO~~

FOUR 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~~ SUPERVISE AT THE SAME TIME FOUR CRNPS WHO PRESCRIBE AND DISPENSE DRUGS AND ONE OR MORE CRNPS WHO DO NOT PRESCRIBE AND DISPENSE DRUGS.

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**

October 2, 2000

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

RE: Revised Final Form Regulations of the State Boards of Medicine and Nursing Pertaining to CRNP Prescriptive Authority (16A-499); Report of the State Boards of Medicine and Nursing

Dear Chairman McGinley:

Attached for review by your Commission is a copy of the revised final form regulations of the State Boards of Medicine and Nursing (16A-499 CRNP Prescriptive Authority). Also accompanying this package is the report of the Boards as required by Section 7(c) of the Regulatory Review Act (Act), Act of June 30, 1989, P.L. 73, 71 P.S. § 745.7(c).

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

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
Martha Brown, Counsel
State Board of Nursing
Lee Ann Murray, Regulatory Counsel
State Board of Medicine
State Board of Nursing

RECEIVED
2000 OCT -2 AM 11: 27
INDEPENDENT REGULATORY
REVIEW COMMISSION

TRANSMITTAL SHEET FOR
REPORT PURSUANT TO SECTION 7(b) OR SECTION 7(c)
OF THE REGULATORY REVIEW ACT

ID NUMBER: 16A-499

DEPARTMENT : DEPARTMENT OF STATE, STATE BOARD OF MEDICINE; STATE BOARD OF NURSING

SUBJECT: CRNP Prescriptive Authority

PA CODE CITE: Pa. Code, Chs. 18 and 21

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Type of Report:

Agency report contains final-form regulation without revision, the findings of the Commission and agency response and recommendation regarding the final-form regulation, filed pursuant to Section 7(b) of the Regulatory Review Act.

Agency report containing revised final-form regulation, the findings of the Commission and agency response and recommendation regarding the final-form regulation, filed 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.)
10-2-00	_____	HOUSE PROFESSIONAL LICENSURE COMMITTEE
OCT 02 2000	_____	SENATE CONSUMER PROTECTION AND PROFESSIONAL LICENSURE
10/2/00	_____	INDEPENDENT REGULATORY REVIEW COMMISSION

September 27, 2000