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INDEPENDENT REGULATORY REVIEW COMMISSION

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

December 2, 1999

Daniel B. Kimball, Jr., M.D., Chairman
State Board of Medicine
116 Pine Street
Harrisburg, PA 17105

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

Dear Chairman Kimball:

Enclosed are our Comments on the subject regulation. They are also available on our website at http://www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact John Jewett at 783-5475.

Sincerely,

Robert E. Nyce

Robert E. Nyce
Executive Director

REN:kcg
Enclosure
cc: Herbert Abramson
Gerald Smith
Honorable Kim Pizzingrilli
Dorothy Childress
Office of General Counsel
Office of Attorney General
Lee Ann Labecki

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INDEPENDENT REGULATORY REVIEW COMMISSION

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

December 2, 1999

M. Christine Alichnie, Ph.D., R.N., Chairperson
State Board of Nursing
116 Pine Street
Harrisburg, PA 17105

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

Dear Chairperson Alichnie:

Enclosed are our Comments on the subject regulation. They are also available on our website at http://www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact John Jewett at 783-5475.

Sincerely,

Robert E. Nyce
Executive Director

REN:kcg
Enclosure
cc: Herbert Abramson
Gerald Smith
Honorable Kim Pizzingrilli
Dorothy Childress
Office of General Counsel
Office of Attorney General
Lee Ann Labecki

COMMENTS OF THE INDEPENDENT REGULATORY REVIEW COMMISSION

ON

STATE BOARD OF NURSING & STATE BOARD OF MEDICINE
JOINT REGULATION NO. 16A-499

CERTIFIED REGISTERED NURSE PRACTITIONERS PRESCRIPTIVE AUTHORITY

DECEMBER 2, 1999

We have reviewed this joint proposed regulation from the State Board of Nursing and the State Board of Medicine (Boards) and submit for your consideration the following objections and recommendations. Subsections 5.1(h) and 5.1(i) of the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) specify the criteria the Commission must employ to determine whether a regulation is in the public interest. In applying these criteria, our Comments address issues that relate to protection of the public health, safety and welfare, reasonableness, implementation procedures and clarity. We recommend that these Comments be carefully considered as you prepare the final-form regulation.

1. **Sections 18.53 and 21.283 Prescribing and dispensing drugs. – Protection of the Public Health, Safety and Welfare, Implementation Procedures and Clarity.**

Collaborative Agreements

Under existing regulations, a certified registered nurse practitioner (CRNP) works in collaboration with and under the direction of a physician. Collaborative agreements establish the conditions of the working relationship.

We have three concerns. First, the term "collaborative agreement" as used in this regulation should be defined. Second, Sections 18.53 and 21.283 should specifically require a collaborative agreement to be established and signed by the physician and CRNP before the CRNP can prescribe and dispense drugs. Finally, the regulations should also specify the required content of a collaborative agreement.

Subsection (1)

Subsection (1) allows a CRNP to prescribe and dispense drugs if the CRNP has completed an equivalent CRNP program in another state. However, how equivalency will be determined is not clear. The regulation should provide the criteria or standards the Board will use to establish reciprocal equivalency.

Subsection (2)

Subsection (2) requires a CRNP to complete an advanced pharmacology course. We have two concerns with this requirement.

First, some CRNP programs have specific advanced pharmacology courses while others integrate the course material into the overall curriculum. It is unclear what qualifies as an advanced pharmacology course.

Second, how will practicing CRNPs meet this requirement if their formal education did not specifically include an advanced pharmacology course? The Boards should specify the training required before a CRNP can prescribe and dispense drugs.

2. Sections 18.54 and 21.284 Prescribing and dispensing parameters. - Protection of the Public Health, Safety and Welfare, Reasonableness, Consistency with Existing Regulations and Clarity.

General

Physicians, hospitals and CRNPs have expressed concerns with the inclusion and exclusion of certain types of drugs. The Preamble does not provide background information concerning how the Boards developed the lists of drugs to be permitted, restricted or excluded. The enabling statutes do not specify the types of drugs that CRNPs can prescribe. Instead, the statutes direct the Boards to jointly promulgate regulations authorizing CRNPs to perform medical diagnosis and prescription. For this reason, the Boards should explain the basis for restrictions and prohibitions of certain drugs in this proposed regulation.

Subsection (a)

This subsection states that the *American Hospital Formulary Service Pharmacologic-Therapeutic Classification* will be used to identify drugs that the CRNP may prescribe and dispense. The statement seems to contradict the subsections that follow.

Subsection (a) seems to incorporate by reference a document listing the drugs that a CRNP is allowed to prescribe and dispense. Yet, the following subsections specifically list those drugs. It is our understanding that the purpose of this subsection is to provide a reference document for the types of drugs discussed in this section. If this is the case, the words "which the CRNP may prescribe and dispense subject to the parameters identified" should be deleted.

Subsection (b)

This subsection states that a CRNP may prescribe and dispense a drug from the following categories "without limitation." What is the purpose of the phrase "without limitation"? What impact will it have on collaborative agreements?

In existing regulations at 49 Pa. Code §§ 18.21 and 21.251, the Boards state that a CRNP:

> ... 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.

Depending on how it is implemented, the phrase "without limitation" could be seen as inconsistent with existing regulations. The Boards should clarify their intent.

Subsection (c)

This subsection states that a CRNP may prescribe and dispense a drug from the following lists or categories if that authorization is documented in the collaborative agreement. What documentation will be required to meet this requirement?

Subsection (e)

This subsection sets forth the procedures to follow when a collaborating physician discovers that a CRNP is prescribing or dispensing a drug inappropriately. There are two concerns with this subsection.

First, why does the regulation use the word "learn" to describe a physician's method of determining that a CRNP is prescribing or dispensing a drug inappropriately? What is required of a physician under a collaborative agreement?

Second, when a collaborating physician finds that a CRNP has inappropriately prescribed a drug, this subsection directs the CRNP to stop prescribing the drug and immediately advise the patient to stop taking the drug. This is the only course of action available under the regulation. Is it appropriate in all instances for a patient to immediately stop taking a drug? For example, some drug prescriptions come with warnings that abruptly stopping the therapy is dangerous and should only be done in consultation with a physician. Shouldn't the regulation require corrective action on behalf of the patient rather than simply requiring the CRNP to end the therapy?

Subsection (f)

The second sentence of Subparagraph (1) is confusing. When a CRNP writes a prescription for a Schedule II controlled substance, the CRNP must notify the collaborating physician "immediately (within 24 hours)." The subsection is unclear on whether the notice must be immediate or within 24 hours.

Subsection (g)

Subparagraph (g)(2) states that a CRNP may not prescribe a drug for a use not "permitted" by the United States Food and Drug Administration (FDA). The FDA does not prohibit or regulate the use of drugs once they are approved and released for general clinical practice. Therefore, the Boards intent in using the word "permitted" is unclear. The Boards should explain the purpose of this subparagraph.

Subsection (h)

This subsection requires that the prescription blank bear the name and certification number of the CRNP and also identify the collaborating physician. The House Professional Licensure Committee expressed the concern that a CRNP who prescribes medications should also provide a clear and conspicuous notice to patients that he or she is a CRNP. The Boards should review what additional CRNP identification requirements are needed in the regulation.

INDEPENDENT REGULATORY REVIEW COMMISSION

To: Joyce McKeever
Agency: Department of State
Licensing Boards and Commissions
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Fax: 7-0251

From: Kristine M. Shomper
Deputy Director for Administration
Company: Independent Regulatory Review Commission
Phone: (717) 783-5419 or (717) 783-5417
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Date: December 2, 1999
# of Pages: 9

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Nursing/State Board of Medicine's regulation #16A-499 (#2064). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Kristine J. Hoy **Date:** 12/2/99