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INDEPENDENT REGULATORY
REVIEW COMMISSION

American Academy of Pediatrics

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Child Death Review Program
David Turkewitz, M.D.

Child Abuse Education Program
Cindy Christian, M.D.

November 2, 1999

Ms. Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

Re: CRNP Prescriptive Authority

Dear Ms. Warner,

I am writing as President of the Pennsylvania Chapter of the American Academy of Pediatrics to comment on the proposed regulations providing for prescriptive authority for Certified Registered Nurse Practitioners under the joint sponsorship of the Board of Medicine and Board of Nursing. Specifically, we have concerns in four significant areas. First, while we support prescriptive powers for nurse practitioners, we strongly believe not only that the certified registered nurse practitioner must have certain pharmacological and other education documented but also must clearly state that she or he is a CRNP and as such is noted for the record.

Second, collaborative agreements must be spelled out publicly and in writing for all patients as well as professional organizations to see the relationship and agreement between the nurse practitioner and collaborating physician in order to prescribe and dispense medications. The CRNP must notify the physician promptly and obtain approval prior to dispensing or prescribing certain medications of Class II drugs which need extra safeguards.

Third, all collaborative agreements must be on file with the State of Pennsylvania and identify the collaborative physician involved. Fourth, malpractice insurance must be appropriate to this new level of liability exposure for the nurse practitioner.

We hope this proves useful as we continue the dialogue around this important issue. Thank you.

Sincerely,

Bradley J. Bradford, MD
President, Pennsylvania Chapter
American Academy of Pediatrics

"Advocates For Children"

June 1, 2000

Dear Mr. Weldon,

As both your constituent and a supporter of the Nurse Practioner (NP) profession in Pennsylvania, I am writing to urge you to use your influence regarding the new regulations on NP practice that were recently agreed to by the state Boards of Nursing and Medicine. I am very concerned that the proposed regulations will further restrict NP's already hampered practice in Pennsylvania.

Specifically, the required ratio of 2 NP's to 1 physician has the potential for threatening the operation of a number of clinics in the state that serve primarily disadvantaged populations. Additionally, none of the crafters of this mandate have been able to offer any rationale or precedent for it, and of the merely 3 other states in the country that require ratios, the lowest is 5:1. The ratio, along with the attendant physician-only waiver right, should be eliminated.

The requirement for documentation of one specific 45-hour pharmacology course may keep some veteran NP's from retaining the prescriptive authority they now have and safely employ. A significant minority of NP's in current practice, many of whom are among Pennsylvania's most experienced clinicians, obtained their formal pharmacology education through other than discreet courses. Instead the teaching of pharmacotherapeutics was integrated and woven into all of their advanced coursework. These NP's can easily show a TOTAL of 45 hours or more of pharmacology education, but may not be able to document one specific course. To require them to do so now would impose an extreme financial and work related hardship for which there is no defensible foundation.

The requirement that an individual collaborating physician take over the present statutory Board authority for CRNP acts of medical prescription is not only a substantive change since the public comment period, but also represents a potentially very costly liability for the collaborating physician. Statutory Board authority is proper and should be maintained.

Lastly, the earlier verbal agreement between the Nursing and Medical Boards to allow CRNP prescription of unclassified therapeutic agents, medical devices and pharmaceutical aids should be honored and maintained as well. To renege on the agreement at this late date and without the input of public comment borders on the unethical.

I do not want to see Pennsylvania further erode and restrict the ability of this competent, proven group of health care professionals to practice to the full extent of their education, training and experience. I know first hand that NP's provide much needed primary care services of the highest quality to ALL citizens of Pennsylvania, including those who have historically had less than open access to quality health care. If we insist on tying their hands even more than is already - deplorably - the case, we will lose them to the vast majority of states that recognize their worth and value their affordable comprehensive patient care.

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Thank you.

Sincerely,

The Rev. Judy Ray *The Rev. Judy Ray*

The Rev. Judy Ray
163 Colket Lane
Devon, PA 19333

J.E. Wood Clinic
Internal Medicine

BENJAMIN FRANKLIN CLINIC
An Affiliate of
Pennsylvania Hospital
University of Pennsylvania Health System

Valerie Weber, MD
Medical Director
Patricia D. Walters
Implementation Manager

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2000 JUL 10 PM 12: 22
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Original: 2064

July 10, 2000

Robert Nyce, Executive Director
Independent Regulatory Review Commission
333 Market St., 14th Floor
Harrisburg, PA 17101

Dear Mr Nyce,

I am writing you regarding the Joint Regulations for Nurse Practitioner prescriptive privileges The final form regulations contained some provisions, which were not included in the version, which were not previously proposed. Some of these changes are particularly troublesome to my practice and the practices of many of my nursing colleagues

In reference to section 21.283, the requirement of a specific 45-hour course in advanced pharmacology This regulation was not included in previous drafts. Most masters level stand alone pharmacology courses in the past have not been 45 hours in length. The hours vary depending on the university or have been integrated in to the program throughout the coursework. Because of this, many experienced CRNPs would not be eligible to apply for prescriptive rights in Pennsylvania. Numerous practicing CRNPs would have to spend several thousand dollars and take time away from their practices to fulfill this requirement Other disciplines that prescribe medications do not require such a specific course. Consider adjusting the requirement to require a 45 hours course or its equivalent so that the hours can be cumulative and not be a hardship to the practicing CRNP or his or her patients.

In regard to section 21.287, no physician may serve as a collaborating physician for more than two CRNPs Only a physician may apply for a waver. This was also not noted in previously proposed regulations This causes a disadvantage to the many nurse managed health centers and clinics caring for underserved clients. No other state has limitations on the number of CRNPs a physician may supervise It will cause barriers to access to care for many citizens in need of quality health care. Consider removing the requirement, increasing the number of CRNPs per physician or allowing CRNPs to apply for a waver. I currently work in a clinic which serves as the residency training clinic for the medical residency program at Pennsylvania Hospital There doesn't appear to be a limitation on the number of residents an attending physician may supervise in their training program. There should not be a double standard for CRNPs in this regard, especially if access to care will be effected.

I have been in practice for six and one half years as an adult nurse practitioner, providing quality health care for many of the underserved citizens of Pennsylvania. Please do not allow these regulations to hamper the access to quality care that many of these people have struggled to obtain.

Sincerely,

Leni S. Dillon CRNP

Leni Sternbach Dillon, CRNP
797 Darby-Paoli Rd.
Bryn Mawr, PA 19010

J.E. Wood Clinic
Internal Medicine

BENJAMIN FRANKLIN CLINIC
An Affiliate of
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Valerie Weber, MD
Medical Director
Patricia D. Walters
Implementation Manager

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Date: 7/10/00 **Number of Pages:** 2

To: Robert Nyce - IRRC

Destination Fax #: 717-783-2664

From: Leni Dillon CRNP

Office #: 215 829 6981

Message

Re: CRNP Regulations

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April 18, 2000

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Mr. Robert Nyce
Executive Director
Independent Regulatory Review Commission
333 Market St., 14th floor
Harriburg, PA 17101

Dear Mr. Nyce;

Original: 2064

I am writing to you in regards to regulations proposed by the Board of Medicine and the Board of Nursing concerning prescriptive privileges for Certified Registered Nurse Practitioners. While I applaud the efforts of both Boards to address this issue I have several concerns about the proposed regulations.

I am concerned that the section which requires "a specific course...of not less than 45 hours" in Advanced Pharmacology" is unnecessarily restrictive. I would request that the regulations be revised to allow a summation of 45 hours of Advanced Pharmacology and that the requirement that the course be specifically Advanced Pharmacology be omitted.

I would recommend that the Boards follow the language of the American Hospital Formulary to list each and every drug category in the book. The missing categories must be inserted as drugs we can prescribe. These categories are "eye, ear, nose, and throat preparations, hormones and synthetic substitutes; oxytocics; unclassified therapeutic agents; medical devices; pharmaceutical aids."

The restriction which limits a collaborating physician to working with only 2 NPs is a concern for providers in a variety of settings. This is likely to have a negative impact on access to care. In other states such limitations are not common and in the two states which do set such ratios the ratios are 1:5.

The March 30 version of the proposed regulations, approved by both Boards, shifts the authority for CRNP acts of medical prescription to the collaborating physician and expands the categories of medications which must be specifically listed in the collaborative agreement from 5 to 21. These changes will result in a serious and costly liability issue for a collaborating physician. I urge you to review this section closely and return the regulatory authority to the Boards.

Overall we are pleased with the progress made on these regulations. We know that Nurse Practitioners provide important access to care in our state. Please make sure that the regulations adopted are thoughtful, comprehensive and assure on-going quality access for our patients.

Sincerely,

[signature], CRNP

CC: Governor Ridge
Senator Clarence Bell
Representative Mario Civera

2064

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

Forthcoming:
Nyce
Sandusky
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Fax Rec'd 8/31/98

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August 31, 1998

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

Dear Mr. McGinley:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its members (more than 225 acute and specialty hospitals and healthsystems in the commonwealth), appreciates the opportunity to comment on the State Boards of Medicine and Nursing draft certified registered nurse practitioner (CRNP) regulations.

§ 18.55(b) CRNP Identification

This regulation states that the CRNP shall inform each patient regarding their right to be treated by a physician. CRNPs are required to wear identification tags which properly identify themselves and their position. It is not being argued that a patient has the right to be treated by a physician if preferred. This requirement should only apply if the CRNP is in a joint practice arrangement. Unlike physician assistants, who are dependent on physicians for scope of practice. CRNPs have independent practices with collaborative physician arrangements.

§ 18.56 Responsibilities of the collaborating physician

- **§1856(a)(1)**

This regulation states that the collaborating physician shall be responsible for the extent and direction of the CRNP for acts of medical diagnosis and prescription of the CRNP. As this section is currently worded, the language implies that the physician has the responsibility to define the practice for the CRNP. HAP recommends that this section focus on the collaboration between the physician and the CRNP, rather than on the extent and direction related to acts of the CRNP which are within the CRNPs recognized scope of practice.

4750 Lindle Road
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Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
http://www.hap2000.org

- **§ 18.56(a)(3)**

HAP requests clarification regarding the definition of a quality assurance review.

- **§ 18.56(b)**

The proposed regulation states that the CRNP cannot perform any procedure that the health care facility prohibits any medical member from performing. This inhibits CRNPs with specialty training from performing procedures which they were specifically trained to perform.

HAP recommends that the wording be changed as follows:

"When practicing in a *licensed* health care facility, the collaborating physician shall not authorize a CRNP to perform any procedure that the *licensed* health care facility prohibits the *collaborating physician* from performing."

By amending this language you will permit CRNPs to mirror their collaborating physician's scope of practice, so long as the CRNP is appropriately trained to perform those procedures.

§ 18.57 Registration as collaborating physician regarding prescriptive authority

HAP believes that the regulations as proposed take away from the intent of the law. As currently drafted, these regulations single out activity related to the prescribing and dispensing of drugs. HAP feels the intent of this section is to indicate the requirements with regard to registration. Additionally, with regard to § 18.57(b), the proposed regulations do not require approval of any type, thus there is not a need to require any "date of approval". HAP recommends that this section be amended as follows:

"(a) A physician who collaborates with a CRNP ~~to authorize the CRNP to prescribdispense drugs~~ shall register with the State Board of Medicine."

***

"(c) The board will keep a current register of physicians who collaborate with the CRNP, who prescribe or dispense drugs. The register will include the physician's name, current address, ~~the date of approval~~ and the name of each current CRNP with whom he or she collaborates."

§ 18.58 Collaborative agreements regarding prescriptive authority

This section, as proposed again singles out prescriptive authority. HAP believes that this section should reflect the components of the collaborative agreement. As a result, HAP recommends that this section be amended as follows:

§ 18.58 Collaborative agreements ~~regarding prescriptive authority~~

(a) The collaborative agreement between the CRNP and collaborating physician ~~authorizing the CRNP to prescribe and dispense drugs~~ shall:

***

§ 18.58(a)(3) This requirement is very restrictive with regard to time, place and manner of meetings. The requirement should state that the collaborating physician and CRNP have scheduled meetings.

§ 18.58(b) HAP requests clarification regarding whether the intent of this requirement is to have the collaborative agreement filed with the State Board of Nursing, State Board of Medicine, or both boards.

§ 18.59. Biennial renewal of CRNP prescriptive and dispensing authority

HAP requests clarification regarding the intent of this section. If the intent is to have a separate registration apply, then there should not be a reference to procedures in 21.331.

If the intent is to establish and validate an "eight (8) hour formal education" standard for renewal related to pharmacology (prescriptive and dispensing), then this section is not necessary. The eight (8) hour standard can be incorporated into § 18.41 of the State Board of Medicine and
§ 21.271 of the State Board of Nursing requirements related to license renewal.

§ 18.60(b) Prescribing and dispensing parameters

The permitted drugs that may be prescribed and dispensed in § 1860(b) do not include hyperglycemic agents (i.e., Insulin). HAPrecommends that Hyperglycemic agents be added to the list in § 1860(b).

HAP also recommends that § 18.60(c) be amended as follows:

"A CRNP may prescribe and dispense a drug from the following categories if the collaborating ~~physician~~ ***agreement*** specifically ~~authorizes prescribing and dispensing and that authorization is documented in the collaborative agreement.~~ ***includes those categories of drugs***."

- **§ 18.60(h)(4)**

***

HAP recommends that this requirement be amended as CRNP's are licensed to prescribe and dispense medications without any "assignment" from the collaborating physician.

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

§ 18.60(i)(1)

This section addresses the requirements for prescription blanks. HAP requests clarification regarding the use of the phrase *"if appropriate"* as opposed to "*as appropriate*", related to the DEA registration number. HAP questions when there would be an appropriate time NOT to have the DEA registration number. Further, the regulations related to Physician Assistants state *"as appropriate"*. As a result, HAP recommends "as appropriate" be used for consistency purposes.

Again, thank you for the opportunity to comment on these regulations. If you should have any questions, please feel free to contact me at (717)561-5544 or by email at pbussard@hap2000.org or Lynn Gurski-Leighton at (717)561-5308 or by email at lgleighton@hap2000.org.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President
Policy & Regulatory Services

PAB/mns

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October 26, 1999

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2639

Dear Ms. Warner:

This correspondence will provide the Pennsylvania State Nurses Association's position on the proposed rulemaking for Certified Registered Nurse Practitioners Prescriptive Authority, published in the Pennsylvania Bulletin, Volume 29 Doc. No. 99-1668.

The PSNA has reviewed these regulations and believe they would improve accessibility and availability to quality health care for all residents of the Commonwealth. We recommend approval of the regulations.

PSNA supports CRNPs having prescriptive authority. A majority of other states and the Federal government have regulated prescriptive authority to Nurse Practitioners.

In regards to Section 18.53(2), PSNA recognizes that earlier CRNP curriculums may have integrated advanced pharmacology content into clinical courses rather than requiring a designated course. We would recommend for these individuals that alternative criteria be used to meet this standard. These include but would not be limited to: grandfathering, continued education course in advanced pharmacology or requiring the CRNP to provide documentation of cumulative advanced pharmacology content.

PSNA would request that a negative formulary be used rather than a listing of acceptable categories as in the proposed amendments. We believe this would simplify the future and prevent the exclusion of certain classes of drugs that would be appropriate for the CRNP to prescribe.

PSNA appreciates the opportunity to review the proposed amendments. We fully support the amendments and commend both the Pennsylvania State Board of Nursing and the Pennsylvania State Board of Medicine for their efforts to provide quality health care to Pennsylvanians.

Respectfully,

Jessie F. Rohner, DrPH, RN
Executive Administrator

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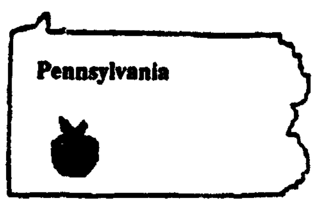
Health Licensing Boards



The Nurse Practitioner Association of Southwestern Pennsylvania

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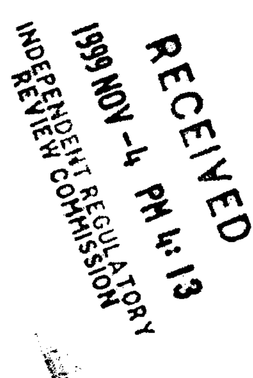

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 171105-2649

Dear Ms Warner,

I am writing to support the proposed Certified Registered Nurse Practitioners Prescriptive Authority recently published in the Pennsylvania Bulletin.

I am president of the Nurse Practitioner's Association of Southwestern Pennsylvania and represent more than 200 CRNP's who are members of the organization. We have discussed the proposed regulations and would like to offer our support in favor of them.

It has been twenty five years since CRNP regulations were first established in PA and many times over those years there have been subcommittees of the BON and BOM who have endeavored to establish an agreement. We are glad that the current Boards have finally been able to do so. We want to thank the members of both Boards for their diligence, hard work, and ability to compromise.

Sheila Gealey

Sheila Gealey, MSN, CRNP
President, Nurse Practitioner's Association of Southwestern Pennsylvania
314 Old Plank Road
Butler, PA 16002

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Stay Healthy - See A Nurse Practitioner

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820
Tel: 717-558-7750
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Pennsylvania
MEDICAL SOCIETY

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Executive Vice President

October 18, 1999

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Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

I am writing as President of the Pennsylvania Medical Society to comment on the proposed regulations, providing for prescriptive authority for certified registered nurse practitioners (CRNPs), which have been jointly promulgated by the State Board of Medicine and the State Board of Nursing. Those regulations were published for public comment in the October 2, 1999 (Vol. 28, No. 40) issue of *Pennsylvania Bulletin.*

The Pennsylvania Medical Society does not object to allowing nurse practitioners to prescribe medication in accordance with the Medical Practice Act of 1985. We do think that portions of the proposed regulations are acceptable as published. However, adjustments need to be made to the regulations in order to make the regulations more clear as to the responsibilities and accountabilities of both the nurse practitioner and the collaborating physician, as well as to provide added patient safeguards and an oversight responsibility for both Boards. The Medical Society has therefore commented on the areas needing clarification and has suggested language to address our concerns. In the Society's recommended language changes, brackets around language indicate deletions while underlined language indicates additions. Section numbers correspond to those in the State Board of Medicine's version of the regulations.

18.53 Prescribing and Dispensing Drugs

At 18.53 (2) lists a requirement for a CRNP who prescribes to have completed a CRNP program that includes a core course in advanced pharmacology. However, this provision does not specify a number of hours for such a course. The Medical Society believes that such a course must, at a minimum, include 30 hours of training.

In addition, pharmacology changes so rapidly that continuing education is a necessity for the CRNP who prescribes. While a general continuing education requirement appears in 18.41 (c) of the existing regulations, it is not specific and does not focus solely on pharmacology. Therefore, the Medical Society recommends the following modifications:

> 18.53 (2)- The CRNP program includes a core course, of at least 30 hours in length, in advanced pharmacology. The CRNP who prescribes medicine shall, at the time of each certification renewal, demonstrate continuing education in advanced pharmacology.

The Medical Society also believes that the CRNP who prescribes medication should identify himself or herself clearly to the public. We believe this is very important given the many types of health care practitioners a patient may encounter and those that might be prescribing

for the patient. Without identification, most patients would not be able to readily recognize whether the prescriber is a physician, physician assistant, or nurse practitioner. The Medical Society believes that the following new section should be added to 18.53 in the proposed regulations.

18.53 (4)- The CRNP who prescribes medication must provide a clear and conspicuous notice to patients that he or she is a CRNP. This notice must contain the practitioner's name and the title "Certified Registered Nurse Practitioner" or the abbreviation "CRNP." The notice may take one of many forms such as a notice placed on a wall or door of a practice site, a nametag, or embroidered on a lab coat or jacket as long as it is visible to patients being treated. The identification may also include any academic credentials or specialties as long as the CRNP does not use abbreviations that are not recognizable to the public. However, a doctorate level nurse practitioner is prohibited from using only the title "Doctor" or its abbreviation followed by the name.

Collaborative Agreements

The Medical Society believes that the regulations should include a section that addresses the collaborative agreements between the nurse practitioners and their collaborating physicians. While we understand that these regulations do not change the existing requirement to have a collaborative agreement, when a CRNP begins writing prescriptions, much more detail is required. First, the agreement should be in writing so there are no doubts or ambiguities concerning its content, and it must be available at the practice site for appropriate persons to review. It must also specify the collaborating physician and any substitute collaborating physician by name so that the lines of responsibility are clearly defined for everyone. In addition, the regulations should limit each collaborating physician to responsibility for no more than four CRNPs who prescribe since it would be very difficult for any physician to carefully monitor more than that number.

The agreement should contain the entire list of drugs for which the CRNP can prescribe so that pharmacists or others can easily confirm the CRNP's ability to prescribe any given drug. Physicians should, however, not be permitted to authorize any drug by including it in the collaborative agreement unless he or she has the expertise required to prescribe that medication so that the physician can easily recognize any inappropriate prescribing or adverse reaction.

The agreement must outline when the collaborating physician must see the patient so that it is clear what occurrences in the course of drug therapy necessitate the physician's intervention. The agreement must also specify the frequency of record review by the physician but it must be at least once every sixty days so that this will allow for review of all Schedule III and IV prescriptions after the initial thirty-day prescription and one authorized refill.

Finally, the Medical Society believes that if the collaborative agreement includes Schedule II controlled substances, it should be filed with the State Board of Medicine so that the Board can identify who is authorized to prescribe these potentially addictive drugs.

The Medical Society believes that in order to upgrade the collaborative agreement requirements when a CRNP prescribes, it will be necessary to add another new section to 18.53 that reads as follows:

18.53 (5)- The collaborative agreement between a CRNP and collaborating physician authorizing the CRNP to prescribe and dispense drugs:

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Health ... Boards

(i) Shall be in writing.
(ii) Shall be available at the practice site and provided to any person requesting to see the agreement such as, but not limited to, patients, other health care practitioners, and professional licensing board investigators.
(iii) Identifies, by name, the physician who serves as the collaborating physician.
(a) Each collaborating physician shall be limited to serving as the collaborative physician for no more than four CRNPs who prescribe.
(iv) Provides for a named substitute collaborating physician for up to thirty days when the collaborating physician is not available.
(v) Contains a list of the classes of medication from 18.54 that the collaborating physician authorizes for dispensing and prescribing by the CRNP.
(a) No collaborating physician may authorize a CRNP to dispense or prescribe any category of medication unless that collaborating physician has the expertise to prescribe that medication.
(vi) Describes the circumstances under which the physician must see the patient.
(vii) Establishes the frequency of record review at a minimum of once every 60 days.
(viii) Shall be filed with the State Board of Medicine if it contains the authorization for the CRNP to write for Schedule "II" controlled substances.

18.54 Prescribing and Dispensing Parameters

The Medical Society believes that in order to write for Schedule II controlled substances, the CRNP should be required to obtain authorization from the collaborating physician prior to issuing the prescription. Schedule II drugs are highly addictive and should only be used under limited circumstances. While the CRNP may have the expertise to write independently for many medications, the nature of Schedule II drugs necessitates an extra safeguard for the public that brings the physician's expertise into the prescribing decision. To accomplish this, we suggest that 18.54 (f-1) be revised as follows:

18.54 (f-1) CRNP may write for a Schedule II controlled substance for up to a 72-hour dose. The CRNP shall [notify the collaborating physician immediately (within 24 hours)] contact the collaborating physician and obtain approval prior to dispensing or prescribing these medications.

Professional Liability Insurance Coverage

Another section should be added to 18.53 that mandates a minimum professional liability coverage requirement of $400,000, the current level of mandatory basic liability coverage under the Health Care Services Malpractice Act. The reason that the Medical Society seeks this provision is that with an increased scope of practice, a CRNP will also have increased liability exposure. We fear that without at least some minimum level of coverage, the collaborating physician will become the only "deep pocket" in a malpractice suit. We suggest adding another section to 18.53 that reads:

18.53 (6)- The CRNP carries a malpractice insurance policy that provides at least a total of $400,000 in liability coverage.

Notice of Collaborative Agreement

After reviewing these regulations, the Medical Society has become aware that at present, neither the Medical Board nor the State Board of Nursing have any way of knowing what collaborative agreements between physicians and nurse practitioners exist, or any knowledge

of who is party to those agreements. If a patient complains, for example, about a nurse practitioner who is not practicing properly, neither board could tell who is the collaborating physician who is perhaps not fulfilling his or her obligations or whether the nurse practitioner is practicing within his or her scope of practice or performing a medical function appropriately obligated to him or her by the collaborating physician. The Medical Society believes, therefore, that the two boards should create a mechanism to require at least notification when any collaborative agreement exists and who is involved in that agreement.

The Medical Society recommends the addition of amendments after our proposed Section 18.53 (5) to read as follows:

(6) The nurse practitioners who enter into such a collaborative agreement shall notify the State Board of Nursing of

- (a) The existence and location of the agreement;
- (b) The name(s) of the collaborating physician(s);
- (c) The effective date and duration of the agreement, not to exceed two years.

(7) The Board of Nursing shall maintain a listing of all current collaborative agreements, identifying all parties to the agreement, and the effective date and duration of the agreement. The State Board of Nursing shall make this listing available to the State Board of Medicine and to the public upon request. In those instances where the collaborative agreement authorizes the nurse practitioner to write for Schedule "II" controlled substances, a copy of such agreement shall be filed with the State Board of Medicine.

The Pennsylvania Medical Society appreciates this opportunity to comment on the proposed nurse practitioners prescribing regulations. The Society believes that the regulations, together with the modifications suggested by the Society, will provide a workable standard for expansion of the scope of practice of advanced practice nurses, specifically for certified registered nurse practitioners.

Sincerely,

John W. Lawrence, MD
President

Cc: State Board of Nursing
Independent Regulatory Review Commission
Chair, Professional Licensure Committee, PA House of Representatives
Chair, Consumer Protection & Professional Licensure Committee, PA Senate

P/Ed and Sci/Final Comments on CRNP Prescribing

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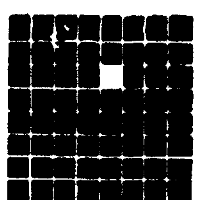

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November 2, 1999

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Ref: CRNP Prescriptive Authority

Dear Ms. Warner:

On behalf of the Pennsylvania Chapter, American College of Emergency Physicians (PaACEP), I am writing to comment on the proposed regulations, providing for prescriptive authority for certified registered nurse practitioners (CRNPs), which have been jointly promulgated by the State Boards of Medicine and Nursing, and published for public comment in the October 2, 1999 (Vol. 28, No. 40), issue of the *Pennsylvania Bulletin.*

PaACEP believes that the proposed regulations should be clarified regarding the responsibilities and accountabilities of both the nurse practitioner and the collaborating physicians. In addition, the regulations should include oversight responsibility by both Boards and provide additional patient safeguards.

To preserve the quality of patient care in Pennsylvania, it is essential that regulations addressing prescriptive authority for nurse practitioners be in accordance with the Medical Practice Act of 1985. Nurse practitioners should act in collaboration with and under the direction of a physician in the performance of acts of medical diagnosis and treatment.

We concur with all of the recommendations made by the Pennsylvania Medical Society, with the following suggested changes.

18.53 Prescribing and Dispensing Drugs:

Regarding Section 18.53, **Prescribing and Dispensing Drugs**, in addition to the amendment suggested by the Medical Society, we would add that specific continuing education in pharmacology should be subject to approval by the physician participating in the collaborative agreement.

INTERNATIONAL HEADQUARTERS: P.O. BOX 619911, DALLAS, TEXAS 75261-9911

Collaborative Agreement:

When CRNPs begin writing prescriptions, a clearly **written collaborative agreement** should be in place, available on request, identifying the nurse practitioners and all physicians and substitutes working in collaboration, including any restrictions on the relationship. The collaborative agreement must be agreed upon by all participating in the relationship. It should contain the entire list of drugs which the CRNP can prescribe.

The agreement for the emergency department and related settings should reflect the high acuity of patients presenting to these settings. Written protocols must be in place addressing the types of different scenarios which present to the emergency department or related setting such as a "Fast Track," or "Urgent-Care Center," delineating those circumstances in which a supervising physician's immediate involvement is required.

Patients in the emergency department often have life-threatening conditions, which require the expertise of a physician for appropriate care. Research has shown that at least 10% of patients presenting to the emergency department, who on initial assessment were thought to have minor problems, were found to have serious illness necessitating admission to the hospital. A recent study by the RAND Corporation noted that nurses triaging patients under-estimated the severity of a patient's illness a substantial percentage of the time.

We agree with the suggestions of the Medical Society delineating the contents of the collaborative agreement, with the following changes for those collaborative agreements pertaining to practice in the emergency department or urgent-care setting. Changes from the Medical Society recommendations are in **bold** face and <u>underlined</u> below.

<u>18.53 (5)- The collaborative agreement between a CRNP and collaborating physician authorizing the CRNP to prescribe and dispense drugs</u> <u>**in an emergency department or urgent-care setting**</u>:

> <u>(v) Contains a list of the classes of medication from 18.54 that the collaborating physician authorizes for dispensing and prescribing by the CRNP</u> <u>**and specific conditions for which they may be prescribed.**</u>
>
> (vi) <u>Describes the circumstances under which the physician must see the patient,</u> <u>**including those circumstances in which the physician must see the patient immediately, prior to the prescribing or dispensing of medication.**</u>
>
> <u>(vii) Establishes the frequency of record review at a minimum of once every</u> <u>**twenty-four hours**</u>.

18.54 Prescribing and Dispensing Parameters:

Many toxicologic problems and polypharmacy drug overdoses occur in the group of drugs listed in 18.54(b). In addition, there are relative contraindications to their prescription based on certain underlying medical conditions. There are many factors to consider in prescribing, more than could be addressed in an "advanced

pharmacology course." The formulary from which a CRNP could prescribe should not include agents beyond those in 18.54(b). We suggest the following amendments to the proposed regulations (deleted text in [brackets], new text underlined).

18.54(b) A CRNP may prescribe and dispense a drug from the following categories [without limitation unless the drug is limited or excluded under other subsections)] if that authorization is documented in the collaborative agreement:

18.54(c) A CRNP may [prescribe and dispense a drug from the following categories if that authorization if documented in the collaborative agreement] not prescribe or dispense a drug from the following categories:

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

1. (1) CRNP may write for a Schedule II controlled substance for up to a 72-hour dose. The CRNP shall notify the collaborating physician immediately (within 24 hours).
2. (2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription may not be refilled unless the collaborating physician authorizes refills.]

18.54(f) A CRNP may write for a Schedule II, III, IV, or V controlled substance for up to a 72-hour dose. The CRNP shall contact the collaborating physician and obtain approval prior to dispensing or prescribing these medications.

Professional Liability Insurance Coverage:

With an increased prescribing authority, a CRNP will have increased liability exposure. There should be a level of coverage equivalent to physicians. Without this coverage requirement for CRNPs, the physician would be the only "deep pocket" in a malpractice suit. Currently, physicians are required to have $400,000 coverage from the primary carrier, and $800,000 from the Medical Professional Liability Catastrophic Loss Fund. We would recommend the following:

Section 18.54(6)-The CRNP carries a malpractice insurance policy that provides liability coverage, including a requirement to participate in the Medical Professional Liability Catastrophic Loss Fund, equal to that which is required of physicians practicing in Pennsylvania, according to the Health Care Services Malpractice Act.

Again, other than our suggested recommendations, we concur with the comments offered by the Pennsylvania Medical Society.

PaACEP appreciates this opportunity to comment on the proposed nurse practitioners prescribing regulations. We believe that the regulations, together with the modifications suggested above will provide a workable standard for certified registered nurse practitioners, while ensuring safeguards for quality patient care in Pennsylvania. Thank you for your consideration.

Sincerely,

Marilyn J. Heine, MD

Marilyn J. Heine, MD
Co-chairperson Governmental Affairs Committee
Member, PaACEP Board of Directors

PENNSYLVANIA SOCIETY OF ANESTHESIOLOGISTS

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November 1, 1999

Ms. Cindy Warner
Health Licensing Division
State Board of Medicine
Bureau of Professional & Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

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RE: Proposed Regulations - Certified Registered Nurse Practitioners Prescriptive Authority

Dear Ms. Warner:

I would like to comment on the proposed amendments to the regulations of the State Board of Medicine governing certified registered nurse practitioners (CRNP) published in the Pennsylvania Bulletin on October 4, 1999.

The Medical Practice Act includes provisions for prescriptive authority for CRNP's. It is time that regulations were promulgated to establish this authority. Therefore, I would support the proposed regulations. However, to be effective, the regulations must be modified to include specific reporting requirements, and very specific responsibilities of, physicians collaborating with nurse practitioners who are prescribing medications. The specific responsibilities of the collaborating physician, and how they are to be discharged, would need to be specified in written collaborative agreements. Only in this way can both the prescribing CRNP, and collaborating physician, both fully discharge their responsibility to the patient for whom CRNP is performing this medical function.

Thank you very much for this opportunity to comment regarding these very important regulations.

Sincerely,

Donald E. Martin, MD
Secretary/Treasurer

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Pennsylvania Podiatric Medical Association

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Ms. Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
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IN RE: CRNP Prescriptive Authority

Dear Ms. Warner,

I am writing this letter in order to comment on the proposed regulations that would affect the ability of Certified Registered Nurse Practitioners to extend the prescriptive and dispensing rights under the Laws and Regulations of the Commonwealth. I reference the publication at Pennsylvania Bulletin Volume 29, Number 40, Page101, et seq. These proposals affect Chapter 18, and Chapter 21 of the Pennsylvania Code, governing the State Board of Medicine, and the State Board of Nursing respectively.

The Pennsylvania Podiatric Medical Association represents over eighty percent of the Doctors of Podiatric Medicine who are licensed to practice within the Commonwealth. The scope of practice that a Doctor of Podiatric Medicine operates within will, by definition, prevent any great intersection of interest between the CRNP and the DPM as it relates to patient care; however, I wish to point out a number of issues that cause concern in the proposal:

1. The role of the treating physician and the CRNP is "presumed" in the proposed regulation, and not explicitly required under the proposed regulation. The proposal should require a collaborating agreement with a physician or podiatrist.
2. The proposal presumes that the CRNP is in the midst of a relationship with the patient. There is no issue relating to the History and Physical of the patient, which should be mandated to be taken or reviewed prior to any prescription being issued. Pharmacology courses alone do not invest the CRNP with the depth of knowledge necessary to medically treat a patient in the manner in which that term is used in the licensing acts.
3. The structure of the proposed regulations are "parallel" in nature with one set affecting the terms of Chapter 18, under the Board of Medicine, and one affecting the

terms of Chapter 21 under the Board of Nursing. It is unclear, given that power within the Board of Nursing, as to whether that Board alone could amend the future regulations, or whether any future regulations must continue to be made in parallel with the two boards.

4. The structure of the proposed regulation indicates a type of regulatorily approved game of "Go Fish" when it proposes that a physician that learns that a CPNR is "prescribing or dispensing a drug inappropriately."... may take action. This indicates that the Commonwealth is authorizing a system through which it is assumed that some inappropriate activity is going to take place, and then it is placing the physician in the position of being the party whose responsibility it is to remedy the situation. It is respectfully submitted that this situation only arises because the CPNR is allowed to practice independently. This should be avoided.
5. To the extent that these regulations allow the CRNP a license to prescribe and dispense "without limitation" (regulatory wording), the CRNP is then in a position of independently practicing medicine. This is not a result that is contemplated by any statute that relates to the medical, podiatric or nursing profession.
6. The proposed regulations now make the CRNP the "captain of the ship" for at least a portion of the time within which the patient is in the care of the treating physician or podiatrist. For that time, and for those events, the treating physician or podiatrist remains professionally liable to the patient. It is respectfully submitted that the proposed regulations now place the CRNP squarely within that group of persons that should participate in the Medical Catastrophe Fund. The "risk" of the fund, which our members jointly and severally underwrite with every licensed physician in the Commonwealth, will be increased through the direct actions of the CRNP, and it is only fair that any licensee who increases the risk be required to participate in the joint liability. This is a legislative matter that should be addressed BEFORE the regulations granting the ability to practice medicine independently are passed.

It is our request that the proposal be withdrawn until these important regulatory and statutory issues are addressed.

Very truly yours,

Michael Q. Davis
Executive Director

Cc: State Board of Nursing
Independent Regulatory Review Commission
Chair, Professional Licensure Committee, PA House of Representatives
Chair, Consumer Protection & Professional Licensure Committee, PA Senate

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Ms. Cindy Warner
Health Licensing Division
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P.O. Box 2649
Harrisburg, PA 17105-2649

IN RE: CRNP Prescriptive Authority

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1. The role of the treating physician and the CRNP is "presumed" in the proposed regulation, and not explicitly required under the proposed regulation. The proposal should require a collaborating agreement with a physician or podiatrist.
2. The proposal presumes that the CRNP is in the midst of a relationship with the patient. There is no issue relating to the History and Physical of the patient, which should be mandated to be taken or reviewed prior to any prescription being issued. Pharmacology courses alone do not invest the CRNP with the depth of knowledge necessary to medically treat a patient in the manner in which that term is used in the licensing acts.
3. The structure of the proposed regulations are "parallel" in nature with one set affecting the terms of Chapter 18, under the Board of Medicine, and one affecting the

757 Poplar Church Road • Camp Hill Pennsylvania • 17011
Phone 717-763-7665 • Fax 717-761-4091

terms of Chapter 21 under the Board of Nursing. It is unclear, given that power within the Board of Nursing, as to whether that Board alone could amend the future regulations, or whether any future regulations must continue to be made in parallel with the two boards.

4. The structure of the proposed regulation indicates a type of regulatorily approved game of "Go Fish" when it proposes that a physician that learns that a CPNR is "prescribing or dispensing a drug inappropriately."... may take action. This indicates that the Commonwealth is authorizing a system through which it is assumed that some inappropriate activity is going to take place, and then it is placing the physician in the position of being the party whose responsibility it is to remedy the situation. It is respectfully submitted that this situation only arises because the CPNR is allowed to practice independently. This should be avoided.
5. To the extent that these regulations allow the CRNP a license to prescribe and dispense "without limitation" (regulatory wording), the CRNP is then in a position of independently practicing medicine. This is not a result that is contemplated by any statute that relates to the medical, podiatric or nursing profession.
6. The proposed regulations now make the CRNP the "captain of the ship" for at least a portion of the time within which the patient is in the care of the treating physician or podiatrist. For that time, and for those events, the treating physician or podiatrist remains professionally liable to the patient. It is respectfully submitted that the proposed regulations now place the CRNP squarely within that group of persons that should participate in the Medical Catastrophe Fund. The "risk" of the fund, which our members jointly and severally underwrite with every licensed physician in the Commonwealth, will be increased through the direct actions of the CRNP, and it is only fair that any licensee who increases the risk be required to participate in the joint liability. This is a legislative matter that should be addressed BEFORE the regulations granting the ability to practice medicine independently are passed.

It is our request that the proposal be withdrawn until these important regulatory and statutory issues are addressed.

Very truly yours,

Michael Q. Davis
Executive Director

Cc: State Board of Nursing
Independent Regulatory Review Commission
Chair, Professional Licensure Committee, PA House of Representatives
Chair, Consumer Protection & Professional Licensure Committee, PA Senate

Pennsylvania Coalition of Nurse Practitioners
893 Stone Jug Road, Biglerville, PA 17307

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Bucks/Mont. Counties NPs

Central Pennsylvania NP Association

Ches./Mont. NP-PA Group

DelVal NAPNAP

Lehigh Valley NP Group

Mid State NP Association.

Northeast Pennsylvania Coalition of Primary Care NPs

Northwestern Pennsylvania NP Association

NPs of South Central Pennsylvania

NP Association of Southwest Pennsylvania

Philadelphia Area NP Association.

Three Rivers Chapter of NAPNAP

November 1, 1999

Dear Sirs,

Enclosed please find the comments of the Pennsylvania Coalition regarding CRNP Prescriptive authority (PA B. DOC. NO 99-1668) proposed regulations published in the Pennsylvania Bulletin October 2, 1999.

The Pennsylvania Coalition consists of the Nurse Practitioner organizations of Pennsylvania. They are:

Berks County NPs
Bucks/Mont. Counties NPs
Central PA NP Association
Ches./Mont. NP-PA Group
DelVal NAPNAP
Lehigh Valley NP Group
Mid State NP Association
Northeast PA Coalition of Primary Care NPs
Northwest PA NP Association
NPs of South Central PA
NP Association of Southwest PA
Philadelphia Area NP Association.
Three Rivers Chapter of NAPNAP

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Sincerely,

Jan Towers

Jan Towers, PhD, CRNP
Chair

JFT/mln

The Pennsylvania Coalition of Nurse Practitioners has reviewed the proposed CRNP prescriptive authority regulations and have expressed a willingness to compromise and therefore endorse the regulations as they have been developed. While the Coalition has been advocating for the use of a negative formulary in these regulations, because of its clarity and ability to accomplish what has been accomplished with the proposed formulary approach, it is willing to accept the proposed formulary based on the most current American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which the CRNP may prescribe and dispense.

It has been noted however, that two categories of drugs, listed in the earlier drafts of the proposed rules: EENT drugs and Hormones and Synthetic substitutes have inadvertently been omitted from the published rule. Most of the drugs in these categories are commonly used in primary care settings and we note that exceptions to these categories are listed in the consulting categories, hence we feel this was an oversight that occurred when the formatting for category (b) and category (c) was restructured in the current proposed regulation.

While the limitations set forth in the controlled substance appear unduly restrictive given the safe track record of nurse practitioners in other states where prescribing controlled substances is more liberal, we are willing to work within these parameters in the interest of compromise and forward movement of these regulations.

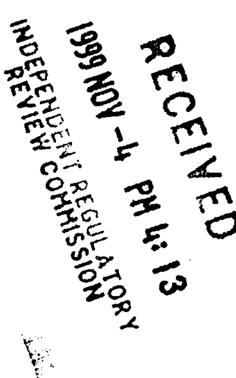
The Coalition wishes to thank both the Board of Medicine and the Board of Nursing for their efforts in behalf of the citizens of the Commonwealth of Pennsylvania to create a safer and more accessible environment for patients to receive care from nurse practitioners. We hope that their efforts will not be further thwarted either internally or externally in the coming months and that this can be a final resolution to the disagreement over the ability of nurse practitioners to sign their own prescriptions for the patients under their care. We feel that the proposed rules suggested here should alleviate concerns regarding liability and safety for all participants both patients and providers in the state to everyone's satisfaction.

Nurse practitioners have an excellent track record regarding the safety and quality of their care. We need to move forward with these regulatory amendments so that the people of Pennsylvania may better benefit from the care they have to offer.

PENNSYLVANIA ASSOCIATION OF NURSE ANESTHETISTS

908 NORTH SECOND STREET ✦ HARRISBURG, PA 17102
(800) 495-7262 ✦ (717) 441-6046 ✦ FAX (717) 236-2046

November 1, 1999



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Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

We are writing to you representing the Pennsylvania Association of Nurse Anesthetists to comment on the proposed joint regulations of the State Board of Nursing and the State Board of Medicine regarding prescriptive authority of CRNPs. As you know, Pennsylvania is on e of the few states that still lacks regulation or law regarding prescriptive authority for CRNPs. We are very much in favor of the action to finally move forward with these regulations, however, we feel we must comment on some of the aspects of these proposed regulations that we see as shortcomings.

The proposed amendment allowing CRNPs to prescribe and dispense drugs, in the first section 21.283(2), limits prescriptive authority to CRNPs in whose current didactic program are included core courses in advanced pharmacology. Although today's current programs actually meet or exceed this requirement, prior program curricula often integrated these courses in such a way that these privileges would be denied to their graduates under these regulations. An amendment is necessary to permit these individuals the right to prescribe and dispense.

In section 21.284 citing use of the American Formulary Service Pharmacologic Therapeutic Classification as the reference for the permitted prescribed drugs, the wording "current published version" is necessary so that prescriptive authority may keep stride with the changing formulary.

Section 21.284(C) limits the prescription of very common drugs to those authorized by collaborative agreements. Under current law, CRNP authorization is derived from the boards, and this would severely limit certain drug categories under the collaborative agreements.

Each of the nursing groups has been consistent in requesting that a negative formulary be utilized, not a list of categories as this proposal suggests. The current proposal would eliminate some entire classes of commonly prescribed drugs, such as common antibiotics for ear infections. Should categories rather than

a negative formulary continue to be used, in order to avoid extended discussion about such categories in the future, a provision should be added to the regulations allowing the State Board of Nursing to add categories of new drugs as they are approved.

As you know, it has taken nearly 25 years to bring these regulations to fruition. We believe that the very least we can expect is that these regulations reflect the progress made in those 25 years, as well as the knowledge, experience, and expertise of the CRNPs affected by them.

Sincerely,

Fred Ackler

Frederick Ackler, CRNA, MS
President, Pennsylvania Association of Nurse Anesthetists

Joan Joyce Cahill, CRNA JJC
President-Elect, Pennsylvania Association of Nurse Anesthetists
Co-Chair, Alliance of Advanced Practice Nurses

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PACDS

PENNSYLVANIA ASSOCIATION OF CHAIN DRUG STORES, INC.

SUITE 300
717 NORTH SECOND STREET
HARRISBURG, PA 17102

PHONE: (717) 238-1222
FAX: (717) 238-9512

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Cindy Warner
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PO Box 2649
Harrisburg, PA 17105-2649

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Dear Ms. Warner:

On behalf of the Pennsylvania Association of Chain Drug Stores (PACDS) whose member firms operate more than 1,500 community retail pharmacies in Pennsylvania, we herein express our ***strong opposition*** to proposed rulemaking by the State Boards of Medicine and Nursing which would authorize certified registered nurse practitioners (CRNPs) to ***prescribe*** and ***dispense*** legend prescription drugs as such rulemaking was published in October 2, 1999 issue of the ***Pennsylvania Bulletin***.

Our opposition is based on the following considerations:

1) The provisions of the Medical Practice Act and Professional Nursing Law authorizing the proposed regulations are limited to "acts of diagnosis and prescription of medical, therapeutic or corrective measures." The provisions do not extend to the dispensing of prescriptions which has heretofore been an act limited to licensed prescribers (with limitations) and to pharmacists. The proposed regulations authorize CRNPs to prescribe ***and*** dispense drugs ***without limitation***.

2) The education requirements for CRNPs to prescribe and dispense legend prescription drugs are to include "a core course in advanced pharmacology." How is this limited training or study capable of preparing a CRNP to perform functions which a licensed pharmacist must spend five or six years of education and training in order to become similarly qualified?

3) As stated in the introductory comments to the proposed regulations, among the states authorizing prescriptive authority to CRNPs, 32 require prescriptive activities under a collaborative practice arrangement with a physician, 13 permit prescriptive

authority for non-controlled substances and 27 allow for prescription of controlled substances with "varying degrees of regulation or limitation." Although the statement itself is confusing and might lead one to assume that there are 72 state jurisdictions where CRNPs are authorized to prescribe, the compelling conclusion is that the Pennsylvania regulations which propose prescription and dispensing by CRNPs ***without limitation*** (other than the expansive list of categories of drugs which may be prescribed or dispensed), would give Pennsylvania the dubious distinction of allowing its CRNPs prescriptive and dispensing privileges the scope of which would be **the most expansive** in any of the states now authorizing such activities.

In today's rapidly changing health care delivery environment, PACDS and other organizations of health care providers recognize the need for qualified practitioners to assume expanded responsibilities in patient care. We believe that pharmacists, for example, are capable of limited prescriptive activities but only if they have received special training and work in direct collaboration with a licensed physician.

These proposed regulations for prescriptive and dispensing activities by CRNPs fail to provide adequate parameters in both necessary training and in supervision or collaboration to ensure a level of quality care to which patients are entitled.

Sincerely,

Bruce E. Johnson
Executive Director

pc: PACDS Board of Directors

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Ralph E. Progar
Vice President of Pharmacy Relations

November 1, 1999

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Ms. Cindy Warner
Health Licensing Division
Bureau of Professional
And Occupational Affairs
Box 2649
Harrisburg, Pennsylvania 17105-2649

RE: **Certified Registered Nurse Practitioners: Prescriptive Authority**
***Pennsylvania Bulletin*, October 2, 1999**

Dear Ms. Warner:

As the Vice President of Pharmacy Relations for Eckerd Corporation (355 pharmacies and over 6,500 associates serving the pharmacy needs of the citizens of this Commonwealth), and a former member of the Board of Pharmacy, I must respectfully oppose the intention of the State Boards of Medicine and Nursing to jointly promulgate regulations permitting Certified Registered Nurse Practitioners (CRNP's) to dispense prescription medications.

It is my strong opinion that the "dispensing" provision noted in *Pennsylvania Bulletin* Vol. 29, No. 40, Pages 5101-5104 should be deleted. I offer the following:

1. *Medical Practice Act* - 422.15 (b) Even in the broadest interpretation, this statutory language does not authorize the dispensing of prescription medications by a CRNP.

2. Reference Section 8 (2) Unlawful Acts of the Pharmacy Practice Act, which prohibits "any person not duly licensed as a pharmacist to engage in the practice of pharmacy including the ... dispensing ... to any person any drug ...", but it permits "a duly licensed medical practitioner to dispense ... any drug to his own patients ... if such dispensing is done by said licensee himself". This provision does not allow for delegation of dispensing to medical staff or in the case of the *Register Notice*, to a CRNP.

3. If a CRNP is permitted to "prescribe and dispense" drugs, there will be no checks and balances to prevent errors and drug interactions. Drug Utilization Review and Patient Counseling will also be negatively effected.

Address: 615 Alpha Drive, Pittsburgh, PA 15238
Phone: 412.967.8735 *Fax:* 412.967.8609

4. How will the CRNP dispense drugs? Will they stock their car or their office with a complete mix of prescription drugs, vials, labels, etc.? How will these be ordered, maintained and stored? Will they have a license to order controlled drugs? Will this become an opportunity for diversion? Who will inspect their pharmaceutical stock to insure quality? What will be stocked? Will the patient get what is stocked or what is needed?

5. The Medical Society was opposed to Collaborative Agreements for pharmacists (five - six years of education) to manage drug therapy, but the Board of Medicine intends to give the same responsibility to a professional who "has completed a course of study of at least one academic year ...". Consistency should be a strong consideration here. If CRNP's can dispense, then pharmacists should be allowed to manage drug therapy regimens through the same Collaborative Care Agreements.

Call me at • 412/967-8735 if more information or comment is needed.

Sincerely,

Ralph E. Progar, R.Ph.
Vice President of Pharmacy Relations

REP/dm

CC: PA Board of Pharmacy
PACDS
PPA

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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October 29, 1999

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Health Licensing Boards

Ms. Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: CRNP Prescriptive Authority

Dear Ms. Warner:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its members (more than 225 acute and specialty hospitals and health systems in the commonwealth), appreciates the opportunity to comment on the State Board of Medicine's and State Board of Nursing's jointly developed and proposed regulations dealing with Certified Registered Nurse Practitioner (CRNP) prescriptive authority. HAP commends both Boards' efforts and commitment to develop regulations addressing CRNP prescriptive authority as enabled in the Medical and Nursing Practice Acts since 1974. HAP offers the following comments as a means of ensuring regulatory clarity in guaranteeing that these regulations provide sufficient public accountability for quality health care.

Elimination of Unnecessary Provisions from Stakeholder Draft Regulations

HAP applauds the Board of Nursing and Board of Medicine for streamlining the proposed regulations by eliminating a number of provisions that were originally included in the set of draft regulations released for stakeholder comment by both boards in the summer of 1998. Specifically, the sections that were dropped from the draft circulated for stakeholder comment are: §18.53 (§21.283). Role of the CRNP; §18.54 (§21.284). Relaying medical regimens; §18.55 (§21.285) CRNP identification; §18.56 (§21.286). Responsibilities of the collaborating physician; §18.57 (§21.287) Registration as collaborating physician regarding prescriptive authority; §18.58 (§21.288) Collaborative agreements regarding prescriptive authority; and §18.59 (§21.289) Biennial renewal of CRNP prescriptive and dispensing authority. We believe that these changes improve the regulations.

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HAP believes that the relationship between a CRNP and a physician licensed to practice medicine in Pennsylvania is already addressed in §18.21. definitions, in the definition of a CRNP and in the definition of direction. The CRNP definition clearly states that, "A CRNP is a registered nurse who while functioning in the expanded role as a professional nurse, 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." Within this same section is a definition of direction that requires the "incorporation of physician supervision to the certified registered nurse practitioner's performance of medical acts," which includes such things as ensuring that a physician is available to the CRNP for consultation/referral, establishing and updating standing orders and drug and other medical protocols within the practice setting, periodic updating in medical diagnosis and therapeutics and the cosigning of records when necessary to document the accountability by both the physician and the CRNP.

Therefore, HAP believes that many of the requirements that were included in the draft (see sections named above) released for stakeholder comment were unnecessary given the definitions that already exist in the Board of Nursing and Board of Medicine regulations.

In addition, HAP also would argue that both Boards already have the authority to review a collaborative agreement whenever they believe that the practice of a CRNP endangers the safety or welfare of a Pennsylvania citizen.

Collaborative Agreement

However, to assure public accountability, HAP would recommend that collaborative agreement be defined in §18.21 (§21.251), particularly since the regulations reference a collaborative agreement in the proposed regulation in §18.54 (§21.284) (c). We also believe that this will strengthen the understanding and appreciation of these regulations. HAP would suggest the following change in §18.21 (§21.251).

Collaborative Agreement - A signed written agreement between a CRNP and a collaborating physician(s) in which they agree to the details of the collaborative relationship. Elements identified under the definition of Collaboration and Direction should be addressed in the collaborative agreement.

CRNP Prescription of Medications without Limitation

HAP agrees with the drugs that are listed in this subsection, §18.54 (§21.284) (b), that defines those drug categories that CRNPs may prescribe and dispense without limitation, unless the drug is specifically limited or excluded under other subsections in the regulations. This list mirrors the list of drugs that physician assistants may prescribe or dispense without limitation with the exception of endocrine replacement agents and hypoglycemic agents. HAP believes that given the additional education and preparation of CRNPs, it is entirely appropriate to include these two additional classifications of drugs in this subsection. HAP also would recommend adding hyperglycemic agents (insulin, glucophage, rezulin, etc.) to this list since primary care of elderly patients with diabetes is a common group of patients that are seen and treated by CRNPs.

CRNP Prescription of Medications within the Context of a Collaborative Agreement

Again, HAP has no disagreement with the drugs listed in this subsection, §18.54 (§21.284) (c), if such authorization were identified in the collaborative agreement with the collaborating physician. To assure clarity, HAP would suggest that 18.54 (c) be changed to read as follows:

A CRNP may prescribe and dispense a drug from the following categories if [that authorization is documented in the collaborative agreement] the collaborating agreement specifically includes those categories of drugs.

Prescription of Medications Reserved Exclusively for Physicians

In comparing subsection § 18.54 (§21.284)(d) with the existing physician assistant regulations, there are a number of drug categories that have not been included in any of the previous subsections of the CRNP proposed regulations or in this subsection. HAP offers the following comments for consideration by both Boards:

- **Dental agents** - HAP believes that CRNPs, particularly those in pediatric practice, should have the authority to prescribe and/or dispense fluoride treatments/supplements for children. HAP recommends that this be addressed in the regulations.

- **Oxytocics** - The prescription of oxytocics is not addressed in the CRNP regulations, but should probably be listed in §18.54 (§21.284) (d). It is highly unlikely that a CRNP would prescribe or dispense this drug given the type of patient eligible for the receipt of this classification drug and the fact that this medication is most likely administered in hospitals. We believe, however, it should be clear that this drug can only be prescribed by a physician.

- **Pharmaceutical Aids and Medical Devices** - HAP questions whether prescription of pharmaceutical aids and medical devices needs to be explicitly stated in the regulations. It is unclear whether these classifications only apply to those medications that are listed in the American Hospital Formulary Service Pharmacologic-Therapeutic Classification under pharmaceutical aids and medical devices or to those items that are traditionally thought of as medical devices and pharmaceutical aids. HAP requests that the Boards clarify why these formulary drug categories were specifically omitted from the CRNP regulations. Finally, HAP requests that the Boards clarify whether it would be appropriate for CRNPs to prescribe and/or dispense devices that promote mobility such as canes, walkers or crutches; devices that immobilize body parts such as splints or slings; or aids that are necessary to administer or enhance the delivery of medication such as pumps, syringes and metered dose inhalers.

HAP also would suggest that §18.54 (§21.284) (d) be amended to include total parenteral nutrition, lipids and agents used as part of experimental treatment. Prescribing or dispensing of these agents should be reserved for physicians.

Omission of Medications and/or Drug Categories

The Boards did not address the prescription of blood products, blood derivatives or intravenous solutions listed in the proposed CRNP regulations. HAP is unclear as to how this should be interpreted by physicians and CRNPs when a specific item is not addressed in the regulations. HAP requests that the Boards clarify what it means to the practice of CRNPs and physicians when a certain drug or classification of drugs is not specifically addressed in the regulations.

General Restrictions on Prescription of Medications by a CRNP

Again in comparing this subsection, §18.54 (§21.284) (g), with a similar subsection in physician assistant regulations, it appears that certain generic restrictions around the prescribing and dispensing of medications were omitted in the CRNP proposed regulations. There are certain provisions in the physician assistant regulations that would also seem appropriate to include in the CRNP regulations for purposes of regulatory clarity. These include the following:

The practitioner may not: (1) prescribe or dispense a pure form or combination of drugs listed unless the drug or class of drug is listed as permissible for prescription or dispension; (2) prescribe or dispense a generic or branded preparation of a drug that has not been approved by the Food and Drug Administration; (3) compound ingredients when dispensing a drug, except for adding water; and (4) issue a prescription for more than a 30-day supply, except in cases of chronic illness where a 90-day supply may be prescribed.

HAP recommends that the Boards add further clarity to §18.54 (§21.284) (g) (3) to indicate that the a CRNP shall not delegate prescriptive authority to another CRNP not covered under the collaborative agreement or to any other health care provider.

In summary, HAP remains confident that both Boards can reach agreement on the CRNP prescriptive authority regulations to bring resolution to this issue. It is evident that the prescription of medications can be done safely and effectively by CRNPs, as demonstrated in 42 other states across the country. CRNPs should be able to fully utilize their skills, consistent with their practice act and these regulations, to serve and treat the citizens in the Commonwealth. HAP urges the Boards to consider our comments as they move forward in firmly establishing prescriptive authority regulations for CRNPs.

Again, thank you for the opportunity to comment on these regulations. If you should have any questions, please feel free to contact Lynn Gurski-Leighton, Director, Clinical Services, HAP at 717-561-5308 or by email at lgleighton@hap2000.org.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

Pennsylvania Psychiatric Society

The Pennsylvania District Branch of the American Psychiatric Association

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Oct. 29, 1999

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Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P. O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

I am writing as President of the Pennsylvania Psychiatric Society to comment on the regulations proposed by the State Board of Medicine and the State Board of Nursing, as published in the October 2, 1999 (Vol. 28, No. 40) issue of *Pennsylvania Bulletin.*

We believe that the proposed regulations adequately address some of the issues which concern our members, who are psychiatric physicians. In other areas, we believe that further detail is essential to clarify the prescribing CRNP's and the physician's roles, responsibilities, and limitations.

I. First, we believe it is imperative to clarify in the regulations that the prescribing of drugs which are listed in § 18.54 (b) is subject to the terms of § 18.21 and additional, related terms which we suggest as subsection (4) under § 18.53. The proposed regulation states that CRNPs may prescribe and dispense a long list of drugs "without limitation." Does this refer to the duration of time limits and refills? Does it mean that these drugs are prescribed outside the collaborative agreement, and are essentially exempt from the collaboration requirement? Does this mean that the nurse can prescribe <u>any</u> drug within the listed categories, giving the collaborating physician no voice in determining which particular drugs can be prescribed, or under what conditions?

We request that the term "without limitation" be deleted, and that the proposed regulations clarify that all drugs must be dispensed in the context of the collaborative agreement. To accomplish this, we suggest that the text of subsection (b) of § 18.54 be deleted, and that the list of drug categories contained in subsection (b) be included in what is now subsection (c). Such a change, of course, would require re-lettering of all the subsections in 18.54, as well as the re-numbering of the combined lists of drug types from (b) - 17 types - and (c) - 3 types.

§18.54 Prescribing and dispensing parameters

* * * *

(b) ~~A CRNP may prescribe and dispense a drug from the following categories without limitation (unless the drug is limited or excluded under other subsections). (c)~~ A CRNP may prescribe and dispense a drug from the following categories if that authorization is documented in the collaborative agreement:

(1) Antihistamines

(2) Anti-infective agents

* * * * * * * * * * * * * * * * *

(17) Endocrine replacement agents.

~~(1)~~ (18) Autonomic drugs.

~~(2)~~ (19) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.
~~(3)~~ (20) Central nervous system agents, except that the following drugs are excluded from this category:

- **(i) General anesthetics.**
- **(ii) Monoamine oxidase inhibitors.**

~~(4)~~ (21) Myotics and mydriatics.
~~(5)~~ (22) Antineoplastic agents originally prescribed by the collaborating physician and approved for ongoing therapy.
~~(d)~~ (c) A CRNP may not prescribe. . ..

The remaining lettered subsections would then have to be renumbered appropriately.

II. We also believe that the proposed regulations should be amended to provide much more detail about the nature of the collaboration between the prescribing CRNP and the physician. The existing regulations, at 49 § 18.21, contain a definition of "Certified Registered Nurse Practitioner" and "Direction" which, taken together, provide a good framework for the collaboration between a CRNP providing medical services and the collaborating physician. This section contains inadequate detail, however, for the regulation of prescription-related activities of the CRNP.

The regulations need to be amended, in § 18.53 (Prescribing and Dispensing Drugs) to specify that the collaborative agreement be in writing, so that both parties understand the responsibilities and protocols to which they have each agreed. A written agreement also allows a mechanism for ensuring that the agreement conforms to state law and regulation, including the regulations currently under consideration. In addition, § 18.53 needs to more specifically define the conditions which must be met in any collaborative agreement which includes the writing of prescriptions. We suggest the following amendments:

18.53 (4) The collaborative agreement between a CRNP and a physician authorizing the CRNP to prescribe and dispense drugs:
(i) shall be in writing
(ii) shall be available at the practice site and provided upon request to others, including, but not limited to, patients, other health care practitioners, professional licensing board investigators, and other regulatory and review agencies.
(iii) identifies, by name, the physician who serves as the collaborating physician. Physicians shall be limited to serving as the collaborative physician for no more than four CRNPs who prescribe.
(iv) provides the name of a substitute collaborating physician, who may serve in the collaborating physician's role for up to thirty days when the collaborating physician is not available.
(v) contains a list of the classes of medication from 18.54 that the collaborating physician authorizes for dispensing and prescribing by the CRNP. No collaborating physician may authorize a CRNP to dispense or prescribe any category of medication unless that collaborating physician has the expertise to prescribe that medication.
(vi) describes the circumstances under which the physician must see the patient.
(vii) establishes protocols for records review by the collaborating physician.

III. Third, although we recognize that the proposed regulations limit a CRNP's authority to prescribe a Schedule II drug, we believe a safer practice would be to restrict all Schedule II prescribing to physicians. These drugs are frequently abused, are frequently diverted for other purposes, have a high

street value, and are often dangerous in themselves. As psychiatrists, we are particularly concerned about the danger when the drugs are prescribed for a depressed or suicidal patient. We therefore suggest the elimination of current subsection (f) (1) of § 18.54, and adding a prohibition against prescribing Schedule II drugs in current subsection (g):

> **§ 18.54 (f) Restrictions on CRNP prescribing and dispensing practices are as follows:**
>
> **~~(1) A CRNP may write for a Schedule II controlled substance for up to a 72-hour dose. The CRNP shall notify the collaborating physician immediately (within 24 hours).~~**
> **~~(2)~~ (1) A CRNP may prescribe a Schedule III or IV...**
> * * * * * * * * * * * * * * * * * *
>
> **(g) A CRNP may not:**
> * * * * * * * * * * * * * * * *
>
> **(4) Prescribe or dispense a Schedule II drug.**

IV. In addition, we generally support the suggestions of the Pennsylvania Medical Society in its October 18 letter to the Bureau, and some of the amendments we suggest above adopt their language. We would specifically note our support for the following:

- We share the Medical Society's view that the regulations should contain a continuing education requirement specific to advanced pharmacology. Rapid changes in the number and types of pharmaceutical agents available, and the evolution of our understanding of various disease processes and their relation to those agents, make this an important requirement.

- We share the Medical Society's view that any CRNP who exercises prescriptive authority must include a core course in advanced pharmacology.

- We believe that CRNPs who prescribe should be required to carry malpractice insurance commensurate with their expanded scope of practice, conferred by the state, into areas of greater risk.

- We share the Medical Society's recommendations requiring CRNPs to notify the Board of Nursing regarding specific information within their collaborative agreements.

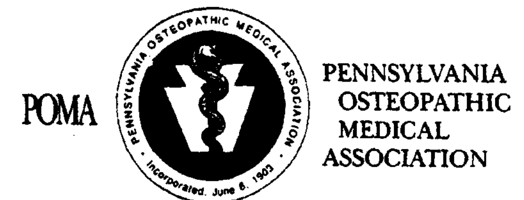
We appreciate the opportunity to comment on these regulations, and hope that both the Board of Nursing and the Board of Medicine will be responsive to our concerns. We believe that the existing and proposed regulations, with the important modifications we have suggested, will provide a workable standard for both physicians and CRNPs.

Sincerely yours,

Lee C. Miller, MD
President

cc: State Board of Nursing
Independent Regulatory Review Committee
Chair, Professional Licensure Committee, PA House of Representatives
Chair, Consumer Protection & Professional Licensure, PA Senate

gvt/CRNP Regs



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October 29, 1999

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Ms. Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

The Pennsylvania Osteopathic Medical Association (POMA) has reviewed the proposed regulations regarding Certified Registered Nurse Practitioner's (CRNP's) prescriptive authority and still strongly believe that CRNP's are to be under the jurisdiction of a physician.

Our concern is that the CRNP's are not adequately trained to practice independently with prescriptive authority. They are an invaluable asset to the overall medical care by their collaborative work under the jurisdiction of the physician.

In order not to be repetitious and for your perusal, we are attaching our testimony given on HB 50 which includes CRNP request for prescriptive authority.

If you have any questions or require additional information, please contact us.

Sincerely,

Leonard V. Limongelli D.O.

Leonard V. Limongelli, D.O.
President

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Enclosure

c: State Board of Nursing
Independent Regulatory Review Commission
Chair, Professional Licensure Committee, PA House of Representatives
Chair, Consumer Protection & Professional Licensure Committee, PA Senate

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TESTIMONY FOR THE HOUSE PROFESSIONAL LICENSURE COMMITTEE ON HOUSE BILL 50 PENNSYLVANIA OSTEOPATHIC MEDICAL ASSOCIATION

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OCTOBER 27, 1999

Chairman Representative Civera, members of the Professional Licensure Committee.

My name is Dr. Ulana Klufas-Ryall, a board certified family physician practicing at the Industrial Resource Center in York, Pennsylvania.

With me is Dr. Ernest Gelb, a certified family physician practicing in West Pittston.

I received a BS degree in nursing from the State University of New York as well as a Masters in Nursing from Syracuse University and a Doctor of Osteopathic Medicine from the University of Osteopathic Medicine and Surgery, Des Moines, Iowa. I practiced as a Registered Nurse for 7 years prior to entering osteopathic medical school. I completed a 1 year rotating internship, a 1 year residency in emergency medicine and 2 years residency in family practice at Memorial Hospital in York. Upon completion of my family practice residency, I worked at Med York and thereafter joined the Industrial Resource Center. I also am a Family Practice Clinic faculty member teaching students, interns and family practice residents.

I arrived at the decision to enroll in a medical school after working as a clinical nurse specialist, functioning as a nurse practitioner (NP), at the time. I worked in New York state, where NP's do have prescription writing privileges, and a great deal of autonomy was allowed (to practice as an NP). What prompted my decision to pursue medicine was that I felt ill prepared to function as an independent practitioner, based on my nursing education.

To reiterate, my nursing background included 4 years of undergrad as well as 2 years of graduate education.

I am here today, representing the POMA and the osteopathic physicians in Pennsylvania. Thank you for giving me the opportunity to present and express our concerns regarding House Bill 50. This bill would give nurses independent practice rights without supervision of a physician.

As proposed, this legislation would indeed create a new category of nurses called "Advanced Practice Registered Nurses". This bill would have the Advanced Practice Registered Nurses (APRN) practice medicine without a license. They would have unsupervised authority to prescribe narcotics and other controlled substances, as well as the legal ability to diagnose, treat, and perform invasive procedures on people in the Commonwealth.

My extensive experience as a nurse cannot compare with the education received in medical school. Intensive studies and extensive clinical experience, in addition to my post graduate residency programs, have proven to me that if you want practice rights and want to practice medicine, one must attend and complete medical school and a residency program.

10/20/99

In lieu of extending my testimony, previous testimonies have demonstrated that a physician, prior to beginning practice independently, currently requires 3 to 7 years of residency following their completion of medical school.

It is not that we question the capability and dedication of nurses as Advanced Practice Registered Nurses (APRN's). They are valuable, essential links in the health care continuum. Because of their lack of training the APRN's qualifications and competency to pursue independent practices is what is brought into question.

In previous testimonies you have been presented with requirements to be met in order to become an APRN, which includes the Nurse Practitioner, Certified Nurse Midwife, Certified Nurse Anesthetist, and Clinical Nurse Specialist. These requirements are achieved after "basic nurse education" (two, three or four year programs) and involve nine months to 2 years of additional education.

A physician, for example, must complete 4 years of basic sciences (undergraduate) as well as 4 years of medical education, before even starting a residency program. In other words, APRN's complete at most 6 years, whereas physicians complete a minimum of 11 years.

How then, can APRN's understand and fully take advantage of a new radiograph imaging technique with no background in the physics of energy transmission? How can one understand and explain to the patient a new chemical therapy for cancer with no solid basic knowledge of cell biology and organic chemistry?

In the vast majority of states where APRN's have prescriptive rights and practice rights, they also have required physician supervision and limited formularies. This fact has not generally been expressed to the public here in Pennsylvania in the latest round of debates. The aforementioned studies, as well as others from the Public Health Service, National Health Service Corporation, and the Military Corp demonstrate that the most effective modules of practice involve physicians and nurses working together to improve quality care and outcome. There are no verifiable quality studies available to substantiate the opinion expressed that nurses give better quality, and more personal care than that of a physician, nor are there any studies quotable that this care is less expensive or more appropriate. There are no direct studies to verify the claim that APRN's can independently provide 60 to 80 percent of primary care in replacement of a physician, and, in fact, studies reflect utilization of a collaborative and supervisory role of physicians working in conjunction with APRN's in structured situations. The claims that APRN's will be willing to work in underserved rural or inner city areas cannot be substantiated by experience or statistical evidence.

I would also argue that the primary care providers located in the most rural or underserved areas should be our most highly trained professionals. This is because the citizens using these providers have less health care choices, and these professionals must be able to do much more because of the lack of a local diagnostic and specialist referral system. It makes little sense to put our least trained into areas that need our best trained.

One cannot appreciate how much is lacking in nursing curricula until one attends medical school and subsequently a medical residency program.

I did not realize how much vital knowledge was lacking in my nursing education until the start of my medical residency. In other words, an excellent nursing educational background did not prepare me to function as an independent practitioner. What I can say to my nursing colleagues is "you do not know this unless you've been there. I have been in your shoes, you haven't been in mine."

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The driving force for my medical education was the desire to deliver the best quality health care and do no harm.

It certainly was not a financial force that prompted me. Not only did I not receive a salary for 4 years while in medical school, but I incurred a $75,000 student loan debt as well.

In conclusion, the quality and economic issues surrounding medical care delivered by physicians, as compared to non-physicians, can be best explained by the wide disparity in the education of these professionals. Physician care is based on cognitive and technical skills, shaped by a minimum eleven years of education and experience. This forms a strong foundation of clinical knowledge and skills that cannot be replaced by lesser degrees of training. To imply that a less trained and less experienced individual can deliver the same quality of care, or can provide more economic care, is illogical and cannot be substantiated. The current models demonstrate that collaborative situations, where nurses in Advance Practice are under the medical supervision of physicians, are the strongest models for quality health care and efficient health care delivery.

Again, thank you for this opportunity to express our concerns and we will be glad to answer any questions you may have.

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October 28, 1999

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: CRNP Prescriptive Authority (49PA Code CHS §18 & 21)

Dear Ms. Warner:

Being the only non-physician provider with prescriptive privileges in the Commonwealth, we believe it is necessary for us to comment on the proposed regulations governing prescriptive privileges for Certified Registered Nurse Practitioners. We note that these regulations are quite different from those approved for our privileges over 6 years ago. We assume that the difference in the restrictive qualities between the regulations is due to the positive history of our prescriptive authority.

Upon reviewing the proposed regulations, we note that this current version deals specifically with the act of prescribing without discussing in detail the definition and nature of the collaborative agreement and oversight of the CRNP. Although this is addressed in the current State Board of Nursing Regulations (49 § 21.251), this area needs further definition and clarification. No such area currently exists within the Medical Practice Act. Overall, we noted that these regulations are far different from the Board recommended revisions of 1995 and 1998.

With that in mind, we offer these general comments:

Section 18.53. Prescribing and dispensing drugs

(1) Under this section, it is noted that the Board will be responsible for the approval of CRNP programs within, and outside of Pennsylvania. This would seem to be a great undertaking for the Board. It would require a greater staff and different expertise than now exists in order to review curriculum, as well as, site visit programs in and out of the State. It has been the experience of our profession that this requires an agency with particular expertise in determining educational curriculum. This would appear to be beyond the intentions of a practitioner licensing board.

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(2) In this same section, the programs are required to include a core course in pharmacology. Will the instructor for this course be a clinical pharmacist or physician, or will that be determined by the Board upon review of the program? Would the minimum number of classroom hours of pharmacology be specified?

C. Background and Purpose

It is stated in the background and purpose that "almost all nurse practitioner programs grant a masters degree and include a course in advanced pharmacology." Would this mean that a nurse practitioner graduating from a program not granting a masters degree and not offering an advanced pharmacology course be unable to prescribe? If so, would a remedial education mechanism be developed to allow them to meet the minimum degree and pharmacology requirement? Considering that CRNP's are specialty trained versus primary care trained as in the case of physician assistants, would their formulary be defined based on their area of specialty?

Likewise, in the absence of national standards for nurse practitioners, what criteria will need to be met by CRNP's graduating from programs outside of Pennsylvania prior to being able to prescribe in the Commonwealth?

Section 18.54. (c):

(1) Autonomic Drugs
(2) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.
(3) Central Nervous System Agents

Under this section, the provision for the prescribing of these medications authorized in the collaborative agreement is outlined. We consider specific, documented authorization in the collaborative agreement to be an efficient manner of dealing with prescribing medications. We are hindered from assisting physicians who provide care for patients requiring the above listed drug categories, because of the lack of a similar regulation for our profession. This would enhance the delegatory authority of physicians.

Section 18.54 (e):

This section deals with the physicians' oversight of the CRNP's prescribing and dispensing. Quality assurance measures need to be incorporated into the agreement for review of prescribing activities. Monitoring compliance to the collaborative agreement is the responsibility of both the CRNP and the collaborating physician. Add to this process periodic chart review, and you have a meaningful process of ongoing education and assurance of quality care.

Section 18.54 (f) : Provides for prescribing of Schedule II controlled substances for up to 72 hours.

This would certainly facilitate their ability to complete prescriptions for patients being discharged from the hospital or emergency care facility. We have certainly discovered that we could help make health care systems more efficient if we were provided this privilege.

However, we do have some concern about the need to prescribe these medications without the immediate knowledge of the collaborating physician. Illnesses or injuries requiring such medications, (i.e., morphine, dilaudid, demerol, percocet etc...), are certainly worthy of physician notification.

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The first and foremost concern in changing any regulations in health care is the safety and welfare of the public. Access to affordable quality healthcare is paramount. Our profession over the last thirty years has shown that through a clearly defined, interdependent relationship with a supervising physician, we can provide quality health care to our citizens. These proposed regulations, in their present form, do not clearly define such a relationship and leave to question an appropriate system of checks and balances.

We would be happy to provide further information and commentary in the future.

Sincerely,

Mark S. DeSantis, PA-C
Chairman, Governmental Affairs

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Pennsylvania Society of Health-System Pharmacists

Pharmacists dedicated to safe and proper medication use in organized health-care settings

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October 28, 1999

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

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Dear Ms. Warner,

The Executive Committee of the Pennsylvania Society of Health System Pharmacists has had an opportunity to review the proposed amendments to the regulations of the States Boards of Medicine and Nursing governing Certified Registered Nurse Practitioners (CRNPs), 49 PA. Code, Chapters 18 and 21, respectively.

PSHP represents over 1500 members, primarily pharmacists who work in health care systems and other practice settings in Pennsylvania. The PSHP supports broadening the scope of health care providers in order to enhance patient access to care, improve the quality of care, and to allow more efficient allocation of resources. It is in the best interest of the patients to assure that physicians play an active and informed role in the care of each patient. The specific role of physician extenders involved in the care and treatment patients must be identified, including allowed procedures and practices, and limitations of their scope with respect to prescription and dispensing of medications. Furthermore, regulations governing the role of certified registered nurse practitioners must provide for appropriate oversight and a description of the necessary checks and balances in the prescribing and dispensing process to assure that the patients needs are met, and adverse events avoided. The pharmacy community believes that a team approach to patient health care assures optimal outcomes. With that in mind, our specific comments on particular sections follow.

Section 18.53 / 21.283 Paragraph (2) One core course in advanced pharmacology does not provide for adequate training for independent prescriptive authority or dispensing of the agents listed in Section 18.54 (b) / 21.284 (b). The regulations should specify a minimum number of course hours, state who will provide the instruction, and describe how competency in the subject area will be assessed. Furthermore, the term "core" must be clarified: does this imply that CRNPs must complete one course for each class of drugs for which they will prescribe and dispense?

As a basis for comparison, it should be noted that pharmacists are required to complete at least 120 hours (8-credit hours) in pharmacology and an additional 150 hours (10-credit

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hours) in "therapeutics", which is the application of drug therapy to specific disease states. Additionally, both physicians and pharmacists are required to complete a stated number of hours of continuing education to assure ongoing knowledge and familiarity with new drug products as they become available. Current requirements for CRNP continuing education are not specific and do not address continuing *drug* education.
Section 18.53 / 21.283 Paragraph (3) The identified regulations in this paragraph (State Board of Medicine 16.92 -16.94) refer to labeling and dispensing. Because requirements for labeling and dispensing generate from Pharmacy Board Regulations, it would be more appropriate to reference these (PA Code Title 49, Chapter 27, Section 27.18), including the reference to the Poison Prevention Packaging Act of 1970 (15 U.S.C.A. §1471—1476) which includes the use of child resistant containers).

Much concern exists that the proposed regulations permit the prescribing <u>and</u> dispensing of medication to a patient with no required check or review by a pharmacist or other third party. One of the strongest sets of checks and balances in our health system is the review and dispensing of prescriptions by a pharmacist. This mechanism plays a key role in avoiding errors, drug interactions, adverse events and allergic reactions in patients that may otherwise be unable to tolerate a medication. This important role has been given by the legislature to pharmacists after completion of a six-years of study in pharmacy which includes required courses in the basic sciences, pharmacology, therapeutics, drug preparation and dispensing activities, in addition to 48 weeks of practical training in pharmacy and patient care. It is difficult to imagine that patient safety can be maintained after the completion of only one core course in pharmacology. Moreover, it is recommended that at least on core course in medication dispensing, at a minimum, be required, along with necessary continuing education components in both dispensing and pharmacology.

Section 18.54/ 21.284 Paragraph (b) The phrase "without limitation" is unclear, implies that there is no oversight from the physician and must be clarified. PSHP, and the entire pharmacy community, recognize the cooperative relationships which physicians enjoy with various physician extenders and other health care practitioners. Furthermore, it is the statutory prerogative of physicians to delegate their authority to extenders for the management of patients, including the prescribing and dispensing of drugs. Such delegation allows the physician to rely on the knowledge and expertise of the respective practitioner.

However, to allow for *independent* authority of CRNPs to prescribe and dispense drugs in any category removes the ability for the delegating physician to determine the competence of the CRNP. A written agreement between the CRNP and the physician would recognize the dependent authority of the CRNP to carry out these duties, and restrict this authority to the drug class or classes with which that practitioner has the most experience and is most qualified to prescribe and dispense, as assessed by the collaborating physician, and / or by the "core pharmacology course".

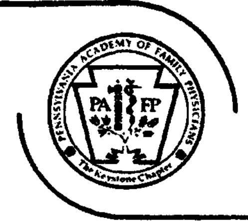
Section 18.54/ 21.284 Paragraph (c) Are the "collaborative agreements" referred to in this section the same as those referenced and described in the Physician Assistant regulations (PA Code Title 49, Chapter 18, Section 18.142)? If so, then they should be referenced, or described as such. Furthermore, these regulations do not identify how the patient or other health care professionals are to be notified of the contents of the written agreement and thus be assured that the drug(s) is (are) included in the agreement.

Section 18.54/ 21.284 Paragraph (g) (2) implies that CRNPs may not prescribe drugs for uses "not permitted by the U.S. Food and Drug Administration." This language requires revision, because the FDA does not prohibit or regulate the uses of approved drugs once they are released into general clinical practice. After a drug has been approved by the FDA for a single indication, a prescriber is free to use that agent for any indication that he or she chooses. Such uses are more properly termed "unlabeled" or "off label" uses, since they are not included in the FDA-approved labeling for the drug. Based on your use of the language "permitted", it is not clear if the intent is to disallow CRNPs from prescribing approved drugs for non-approved or off-label uses, or, if like prescribing physicians, the intent is to disallow the prescribing of drugs not permitted for use in the United States. Use of the terminology "not approved", in lieu of "not permitted" may better clarify the intent of this section.

We appreciate your consideration of our comments and trust they adequately convey our concern with the proposed regulations as they are currently written. Should you require clarification, please do not hesitate to contact me at 215.596.8997.

Sincerely,

Victoria E. Elliott, R.Ph., MBA
Executive Vice President



PENNSYLVANIA ACADEMY OF FAMILY PHYSICIANS

October 28, 1999

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Harrisburg, PA 17105-2649

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INDEPENDENT REGULATORY REVIEW COMMISSION

Re: CRNP Prescriptive Authority;
Jointly Proposed Regulations of the State Board of Medicine and State Board of Nursing
No. 16A-499

Dear Ms. Warner:

The Pennsylvania Academy of Family Physicians has reviewed the jointly proposed regulations of the State Board of Medicine and State Board of Nursing related to CRNP prescriptive authority and appreciates the opportunity to offer the following comments.

The Academy wholly supports the extension of prescriptive authority to CRNPs within the context of a collaborative arrangement with a licensed physician or physicians. CRNPs have been and will continue to be valuable participants in the delivery of medical care in Pennsylvania. With respect to the proposed regulations, however, we do have several concerns and suggested revisions which we trust will strengthen and clarify the scope of CRNP prescriptive authority as well as protect the patients we all serve.

I. **SECTIONS 18.53 and 21.283 (PRESCRIBING AND DISPENSING DRUGS)**

A. **Concerns with Proposed Language**

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1. CRNP Education /Continuing Education

These sections permit a CRNP to prescribe and dispense drugs if the CRNP has (1) completed a CRNP program approved by the Boards or an equivalent program in another state, and (2) the program includes a "core course in advanced pharmacology." The parameters of such a pharmacology course are not defined.

Inasmuch as CRNPs would be permitted to prescribe a virtually unlimited range of drugs that, if improperly prescribed, can have devastating effects, including antineoplastic agents (cancer drugs), coagulation and anticoagulation drugs (clotting agents and blood thinners), and the full range of scheduled controlled substances with highly addictive properties, an appropriate quantum of training needs to be defined. Similarly, because drug choices and treatments change considerably from day to day, the Academy believes it essential that CRNPs be required to remain up to date on advances in the prescribing and administration of drugs for diagnostic and therapeutic purposes.

2. CRNP Examination

There is no requirement under the proposed sections or under current regulations governing CRNP practice that a CRNP pass a standard examination for certification, much less to prescribe a wide range of drugs. The Academy notes that all other professional licensees in the Commonwealth who engage in aspects of medical practice are required to take and pass an examination qualifying them to hold the level of license under which they will be practicing in an expanded fashion. Physicians pass an extensive examination prerequisite to licensure testing medical diagnostic, pharmacological and treatment knowledge and clinical skills; optometrists pass a separate examination to be certified to prescribe therapeutic drugs; nurses pass a separate examination to practice midwifery; and physician assistants pass an examination to prescribe drugs and perform other medical activities. CRNPs should not be exempted from examination requirements to which other similarly situated practitioners are held.

3. Medical Records Documentation

Under the proposed sections, CRNPs would be required to comply with §§ 16.92-16.94 of the State Board of Medicine's regulations related to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs. Nowhere, however, would a CRNP be required to comply with § 16.95 (related to medical records) of the Medical Board's regulations which specifies the information that must be contained in a patient's medical record, including diagnoses, medical treatment plans and therapeutic procedures. The Academy suggests

that CRNPs should also be required to comply with medical records requirements, particularly with respect to the charting of prescriptions issued by the CRNP.

4. Collaborative Agreements

Although reference is made to a "collaborative agreement" throughout current and proposed regulatory provisions, nowhere is such an agreement defined. The expansion of CRNP practice to include wide-ranging prescriptive authority requires that the parameters of collaborative practice be memorialized in writing and signed by all parties involved so that all are clear on their respective responsibilities to their patients. Appropriate direction as defined in §§ 18.21 and 21.251 of the Medical Board and Nursing Board, respectively (relating to definitions) must be set out in the agreement. Parties who need to know the scope of the collaboration, particularly the scope of prescriptive authority of the CRNP (such as pharmacists and regulatory authorities) must have access to the agreement.

B. Suggested Revisions

In light of the foregoing concerns, the Academy suggests that the language of §§ 18.53 and 21.283 be amended to read:

> A CRNP may prescribe and dispense drugs if:
>
> (1) The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.
>
> (2) The CRNP program includes a core course in advanced pharmacology including the appropriate prescription and administration of pharmaceutical agents for diagnostic and therapeutic purposes consisting of a minimum of fifty (50) hours.
>
> (3) The CRNP has obtained a passing score on a CRNP certifying examination approved by the Boards.
>
> (4) The CRNP shall, as a condition for renewal of certification, provide evidence of having completed eight (8) hours of formal education in pharmacology and clinical management of drug therapy within the two-year period immediately prior to the date of renewal.
>
> (5) In prescribing and dispensing drugs, a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92-16.95 (relating to

prescribing, administering and dispensing controlled substances; packaging; labeling of dispensed drugs; and medical records) 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).

(6) The collaborative agreement between the CRNP and collaborating physician(s) shall satisfy the following requirements:

(A) The agreement shall be in writing and shall identify and be signed by the CRNP and each collaborating physician, at least one of whom shall be a medical doctor.

(B) The agreement shall describe the time, place and manner of direction each named physician will provide the CRNP, including the frequency of contact with patients.

(C) The agreement shall describe the frequency with which the collaborating physician will provide medical chart review and consultation, which shall occur at least every thirty (30) days.

(D) The agreement shall list the drugs which the CRNP may prescribe, based on the categories listed in § 18.54 [§ 21.284].

(E) The agreement shall be immediately available to anyone seeking to confirm the scope of the CRNP's prescriptive authority.

(F) The agreement shall be filed with the Boards.

II. SECTIONS 18.54 and 21.84 (PRESCRIBING AND DISPENSING PARAMETERS)

A. Concerns with Proposed Language

1. Unrestricted CRNP Prescribing

Subsection (b) of these provisions permits CRNPs to prescribe seventeen categories of drugs without any apparent restriction, including the requirement that the drugs be identified in a written collaborative agreement with a physician.

All drugs are dangerous, and if improperly prescribed, may have disastrous consequences for patients. For example, antihistamines include many drugs that are available over the counter such as cough syrups and the well-known Benadryl. However, Periactin, a drug under this category, is both an antihistamine and an antiserotonergic agent. The contraindications include newborn or premature infants and nursing mothers. Also contraindicated are patients with hypersensitivity to cyproheptadine and other drugs of similar chemical structure, MAO inhibitors, angle-closure glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction, pyloroduodenal obstruction, elderly and debilitated patients. Warnings on the use of this drug are extensive and the precautions exceed a full column in the Physician's Desk Reference. Central nervous system adverse reactions include sedation and sleepiness, dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, pares thesis, neuritis, convulsions, euphoria, hallucinations, hysteria and fainting. In order to understand adverse reactions, the prescriber needs to understand the normal process, the abnormal process, and the numerous permutations that can occur. Only then can one understand the adverse reactions.

Likewise, an advanced course in pharmacology is not designed to teach the complex medical diagnostic decision-making necessary to choosing the appropriate drug for a particular patient's condition. By way of example, Urispas (flavoxate HCL) is a smooth muscle relaxant (which CRNPs would be permitted to prescribe without limitation and outside the parameters of a collaborative agreement with a physician), indicated for symptomatic relief of dysuria, nocturia, urgency, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis and urethrocystitis/urethrotrigonitis. Urispas is not indicated for definitive treatment, but is compatible with drugs used for the treatment of urinary tract infections. This indication is tied to another indication for the use of antibiotics.

Initially, the correct diagnosis of the patient's condition must be made. The diagnosis includes the determination of the probable microbe responsible: gram positive-aerobe, gram positive-anaerobe, gram negative-aerobe, gram negative-anaerobe, protozoal parasite, mycelial flora or tuberculous flora. Once determined, an anti-infective is chosen based upon the patient's individual allergies and sensitivities, ability to swallow capsule or liquid, drug interactions with other medications prescribed or over-the-counter, recent use of alcohol, and so forth. Having determined the appropriate anti-infective, the physician may choose to use Urispas in conjunction with all of the above. Urispas simply treats the symptoms and not the disease. Indeed, the prescribing of drugs is not properly left to a CRNP who has no medical school training, clinical

medical residency or an appropriate examination to test medical diagnostic, treatment and drug prescription knowledge.[1]

2. Prohibitions on Prescribing Certain Types of Drugs

Subsection (c) of these provisions authorizes CRNPs to prescribe and dispense such drugs as coagulants and anticoagulants (clotting agents and blood thinners, respectively), myotics and mydriatics (capable of blinding patients if not prescribed appropriately) and antineoplastic agents (oncologic or cancer drugs) provided authorization is documented in "the collaborative agreement." Again, the Academy notes that neither current regulations governing the practice of CRNPs nor the proposed language anywhere requires a collaborative agreement to be memorialized in writing or otherwise establish the parameters of the collaboration. CRNPs should certainly not be permitted to prescribe such dangerous drugs, which may, if misprescribed, cause a patient to bleed to death, develop fatal blood clots, become blind or worse, without limitation and without the collaborative oversight of a physician. Even physicians who do not specialize in oncology refrain from prescribing antineoplastic agents. CRNPs should likewise be prohibited from prescribing the foregoing drugs, whether under collaborative agreement or otherwise.

3. Scope of Physician Collaboration

Subsection (e) of the provisions provides:

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

This provision is not only overly simplistic, but falls far short of protecting the patients of both physicians and CRNPs. As noted previously, the prescription of drugs, scheduled or otherwise, involves a complex set of decision-making, beginning with the medical diagnosis of a disease or ailment, which may require testing beyond the scope of merely viewing a patient's symptoms; a knowledge of the patient's history, habits, allergies, lifestyle, and other contraindicators; a treatment plan which may or may not

[1] Indeed, a registered nurse may be certified as a CRNP with as little as two years of nursing training (associate degree or diploma program) and one year of training in advanced practice nursing. Section 5 of the Professional Nursing Law, 63 P.S. § 215; 49 Pa. Code §§ 18.41 and 21.271.

require the prescription of a drug; if a drug is indicated, the appropriate drug among thousands available, for the particular patient, the particular disease or condition.

Such decision-making requires intensive academic and clinical training and examination beyond that required to be certified as a CRNP. Accordingly, it is imperative that a collaborating physician be timely advised of the dispensing of a particular drug and that the physician perform a record review (in accordance with the time frame suggested by the Academy as an additional subsection in §§ 18.53 and 21.283 above). Likewise, the Academy believes that when the physician learns of the misprescription of a drug, the physician be required to resume direct care of the patient and make the appropriate notifications to the patient, pharmacy, and medical records. The current provisions do not provide protection for a patient where a CRNP has improperly diagnosed a condition or prescribed a drug in the first instance.

4. Schedule II Controlled Substances

Paragraph 1 of subsection (f) permits CRNPs to prescribe schedule II controlled substances to include a dose of up to 72 hours, with notification to the collaborating physician within 24 hours of issuing the prescription. The Academy believes that, because schedule II controlled substances are the most highly addictive, CRNPs should not be permitted to prescribe them. The safety of a patient requiring such a drug requires that the patient be evaluated by a physician.

Alternatively, if the Board ultimately decides to allow CRNPs to prescribe schedule II controlled substances, such a prescription should be limited to a very short duration (no longer than 72 hours), and the types of drugs expected to be prescribed should be detailed in the collaborative agreement between the physician and CRNP.

5. Other Prescription Drugs

Paragraph 2 of subsection (f) permits a CRNP to prescribe a schedule III or IV controlled substance for up to a 30-day supply. No limitations, however, are placed on a CRNP's prescription of schedule V controlled substances nor on any other drug, despite the potential for obvious dangerous consequences that may be visited upon a patient as a result of an inappropriate prescription. The Academy therefore suggests that language be included in the regulation establishing definitive parameters for the outside limits of a CRNP's prescriptive authority, that both the collaborating physician and the CRNP understand the parameters and memorialize those parameters in a written collaborative agreement, and that the collaborating physician be timely advised of the prescription of any drug by a CRNP.

6. Parameters for CRNP Prescribing

The prescription of drugs is a serious matter. Determining whether a drug is necessary and, if so, which drug, in what dose, for what period of time, with what instructions for use involves a complex decision-making process. An improperly prescribed drug can effect a fatal response. Even physicians, with extensive academic and clinical training and examination, make mistakes.[2] Practitioners who may be certified as CRNPs with as little as three years of combined training and no examination in medical diagnosis, pharmacology, or appropriate prescribing practices, cannot be expected to recognize medical problems not otherwise apparent, or to even suspect a serious problem not manifest to a less-trained diagnostician, or, more important, the implications of the prescription of a particular drug for that condition.

B. Suggested Revisions

In light of the foregoing, the Academy suggests that the following subsections of §§ 18.54 and 21.284 be amended to read as follows:

* * *

(b) A CRNP may prescribe and dispense a drug from the following categories without limitation if that authorization is documented in the collaborative agreement (unless the drug is limited or excluded under other subsections):

(1) Antihistamines.
(2) Anti-infective agents.
(3) Cardiovascular drugs.
(4) Contraceptives including foams and devices.
(5) Diagnostic agents.
(6) Disinfectants for agents used on objects other than skin.
(7) Electrolytic, caloric and water balance.
(8) Enzymes.
(9) Antitussives, expectorants and mucolytic agents.
(10) Gastrointestinal drugs.
(11) Local anesthetics.
(12) Serums, toxoids and vaccines.

---

[2] To meet minimum requirements for medical licensure in Pennsylvania, a physician will have completed four years of college, four years of medical school (including clinical rotations) and two years of a graduate clinical residency (three years in the case of a foreign medical school graduate), as well as having passed the USMLE testing both academic knowledge and clinical medical skills.

(13) Skin and mucous membrane agents.
(14) Smooth muscle relaxants.
(15) Vitamins.

(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, excluding sympathomimetic (adrenergic) agents.
(2) Blood formation and coagulation drugs with the exception of anti-coagulants and coagulants and thrombolytic agents.
(3) Central nervous system agents with the exception of general anesthetics and monoamine oxidase inhibitors.
(4) Eye, ear, nose and throat preparations with the exception that myotics and mydriatics used as eye preparations require specific approval from the collaborating physician for a named patient.
(5) Hormones and synthetic substitutes with the exception of pituitary hormones and synthetics and parathyroid hormones and synthetics.

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

(1) Gold compounds.
(2) Heavy metal antagonists.
(3) Radioactive agents.
(4) Antineoplastic agents.
(5) Oxytocics.

(e) If, upon consultation with the CRNP or in the course of a record review as required by § 18.53(6)(C) {or §21.283 (6)(C) where appropriate}, the collaborating physician learns that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately advise the patient, notify the CRNP and, in the case of a written prescription, advise

the pharmacy of the inappropriate prescription. The physician shall advise the patient and notify the CRNP to discontinue using the drug, and in the case of a written prescription, shall notify the pharmacy to discontinue the prescription. The order to discontinue use of the drug or prescription shall be noted in the patient's medical record by the physician.

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

(1) A CRNP may not prescribe or dispense schedule I or II controlled substances as defined in § 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

(2) A CRNP may not issue a prescription for more than a 30-day supply of any drug, except in cases of chronic illnesses where a 90-day supply may be prescribed. The CRNP may authorize refills up to six months from the date of the original prescription if not otherwise precluded by law.

(3) A CRNP shall notify the collaborating physician within 12 hours, either orally or in writing, of the prescription or dispensing of any drug and the basis for the decision to prescribe or dispense.

(4) A CRNP may not prescribe or dispense parenteral preparations other than insulin, emergency allergy kits and other approved drugs listed in subsection (b).

(5) A CRNP may not prescribe or dispense a drug for a use not permitted by the U.S. Food and Drug Administration nor may he or she prescribe or dispense a generic or branded preparation of a drug that has not been approved by the U.S. Food and Drug Administration.

(6) A CRNP may not prescribe or dispense a pure form or a combination of drugs listed

in subsections (b) and (c) unless the drug or class of drug is listed as permissible for a prescription or dispensing.

(7) A CRNP may not dispense a drug unless it is packaged in accordance with applicable federal and state law pertaining to packaging by physicians.

(8) A CRNP may not compound ingredients when dispensing a drug, except for adding water.

(9) A CRNP may not delegate prescriptive authority specifically assigned to the CRNP by the collaborating physician to another health care provider.

(g) {The language of proposed subsection (g) should be deleted and subsections (h) and (i) appropriately renumbered as subsections (g) and (h).}

****

Thank you for the opportunity to provide the foregoing comments. We trust that these suggestions will provide a constructive framework for authorizing CRNPs to prescribe drugs and devices consistent with the health and safety of Pennsylvania health care consumers. We look forward to providing the Boards with any assistance they may require in formulating final form regulations.

Sincerely,

Christine M. Stabler, M.D.
President

cc: Hon. John R. McGinley, Jr., Chairman
Independent Regulatory Review Commission
Hon. Mario J. Civera, Jr., Chairman
House Professional Licensure Committee
Hon. Clarence D. Bell, Chairman
Senate Consumer Protection and Professional Licensure Committee
PAFP Board of Directors
PAFP Public Policy Commission
John Jordan, PAFP Executive Vice President
Charles I. Artz, Esq., PAFP General Counsel
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INDEPENDENT REGULATORY REVIEW COMMISSION

Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

I am writing in support of the proposal to include prescriptive privileges in the scope of practice of certified registered nurse practitioners. This is a measure that is long overdue. Lack of prescriptive authority is a major barrier to practice for CRNPs and limits access to care for many patients. Most states in this country provide prescriptive authority to advanced practice nurses. Currently, nurse-practitioners must utilize their consulting physician for any prescription medication , including simple things like prenatal vitamins. This is very burdensome for the nurse-practitioner, her patients and her consulting physician. This change would provide greater accountability for patients and pharmacists and would decrease the liability for physicians who provide consultation for advanced practice nurses.

Nurse-practitioners currently have the educational background to utilize many therapeutic regimes and not being able to do so independently has been sited as an obstacle to practice by both private and publicly funded studies which have looked at improving access to primary care. Nurse-practitioners are on the front lines of our health care system and need to be able to practice effectively. I encourage the Board of Medicine to approve this new regulatory language for advanced practice nurses.

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Sincerely,

Nancy L Hazle CNM.

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829 Spruce Street • Suite 208 • Franklin Medical Building • Philadelphia • PA • 19107 • (215) 829-8000 • Fax (215) 829-8005

Dear Ms. Warner:

I am using this means to expedite my comments on the proposed regulations providing for prescriptive authority for certified registered nurse practitioners, published for comment in the October 2, 1999, *Pennsylvania Bulletin*.

The proposed regulations lack an important patient safeguard—a requirement for a written collaborative agreement between a CRNP and a specific collaborating physician. Such an agreement must identify the CRNP and all physicians who will serve in a collaborating role. It must assure that lines of communication between the CRNP and physician are clear, and that emergency procedures are in place.

CRNPs must have demonstrated training in pharmacology before receiving authority to prescribe.

Patients must be told when a CRNP is providing care and must have the right to see the physician.

The regulations must require adequate professional liability insurance coverage for the CRNP in this expanded role.

Finally, the regulations must retain the joint rule promulgation and oversight responsibilities of the State Board of Medicine.

[signature], MD
Signature

570-275-7698.
Telephone

Ollice Bates, Jr, MD
Print Name

one of approximately 300 cards (form)

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FORM LETTER (300)

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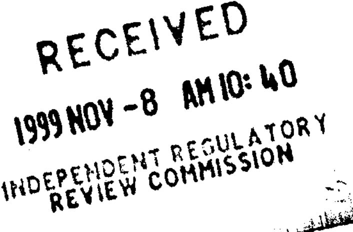

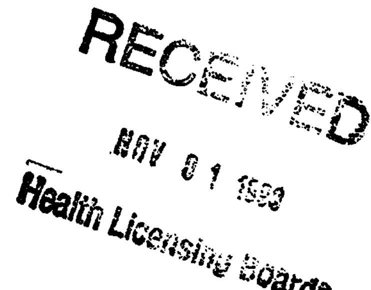

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Finally, the regulations must retain the joint rule promulgation and oversight responsibilities of the State Board of Medicine.

[signature]
Signature

Aaron S. Blom
Print name

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Dear Ms. Warner,

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Finally, the regulations must retain the joint rule promulgation and oversight responsibilities of the State Board of Medicine.

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[signature]
Signature

PHILLIP G. PAINLEY
Print name

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From: <MedDirs@aol.com>
To: PADOS-DOMAIN.GWIA("medicine@pados.dos.state.pa.us"...
Date: Tue, Nov 2, 1999 4:12 PM
Subject: House Bill 50

Sirs: As the Director of the Department of OB-GYN at the Frankford Hospitals in Philadelphia, I am very much in favor of the present role of nurse practitioners. If they are allowed to perform the same clinical functions as physicians, then they should become physicians. Logically, the training necessary to care for patients has been established for tens of decades. It is absurd to abandon this time tested tradition. Just remember what we tell our residents in training: "If this was your mother wouldn't you want the best care possible for her?" The Bill requires a no vote.

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DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

LEGAL OFFICE
COUNSEL DIVISION
(717) 783-7200
FAX: (717) 787-0251

116 PINE STREET
P.O. BOX 2649
HARRISBURG, PA
17105-2649

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

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1999 NOV -4 PM 3:51
INDEPENDENT REGULATORY
REVIEW COMMISSION

RE: Public Comment: Proposed Rulemaking
State Board of Medicine and State Board of Nursing
CRNP Prescriptive Authority: 16A-499

Dear Chairman McGinley:

Pursuant to Section 5(b.1) of the Regulatory Review Act (71 P.S. §845/5(b.1), enclosed are copies of written comments received by the State Board of Medicine and State Board of Nursing regarding Regulation 16A-499. Per discussion between members of our respective staff and in light of the extensive number of comments received we have organized and bound the comments.

Sincerely,

Daniel B. Kimball, Jr., M.D. Chairman
State Board of Medicine

M. Christine Alichnie, Ph.D, RN, Chairperson
State Board of Nursing

DBK/MCA/GSS/RGC:bjd
Enclosures

cc: Joyce McKeever, Deputy Chief Counsel
Department of State

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HERNANDO TRUJILLO, M. D.
5 LAKESIDE DRIVE
LEVITTOWN, PENNSYLVANIA 19054
TELEPHONE (215) 945-1900

November 2, 1999

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Ms. Cindy Warner, Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

As a physician licensed to practice in Pennsylvania, I am writing to comment on the proposed regulations, jointly promulgated by the State Boards of Medicine and Nursing, establishing prescriptive authority for certified registered nurse practitioners (CRNPs).

Nurses provide a vital role as part of the health care team. However, even one with special training, including a CRNP, is not qualified by education and experience to assume a leadership role on that team or to practice independently of the physician. There is no way to equate the training of a nurse practitioner or other advanced practice nurse, even those with a master's level education, with that of a physician.

Regulations regarding prescriptive authority must clearly delineate the provisions of the Medical Practice Act of 1985, stating that nurse practitioners act in collaboration with and under the direction of a physician in the performance of acts of medical diagnosis and treatment.

The currently proposed rulemaking omits several essential provisions. Most critically, the proposed rules lack the specific requirement for a written collaborative agreement between the CRNP and a supervising physician, stating the parties involved and any restrictions on the relationship. The Board should amend the proposed regulations in the following ways:

- Specify the requirements of a *written collaborative agreement* and stipulate that such agreements be available upon request, and that they clearly identify the nurse practitioners and all physicians working in collaboration.

- Identify a minimum *education requirement in advance pharmacology*. Nurses simply do not have the depth and breadth of training and hands-on experience in actual treatment settings dealing with drugs and their interactions. This should be reflected in the regulations.

- Address the issue of *professional liability* for CRNPs with prescriptive authority. The added responsibilities of prescribing and administering of medications, including controlled substances (Schedule II-IV drugs) point to the need for increased liability coverage for this potential increase in exposure for the nurse in this expanded role.

Expanding the scope of practice for advanced practice nurses, without maintaining the requirement for physician supervision, is a threat to the quality of patient care in Pennsylvania. Please revise the proposed rules to ensure appropriate safeguards to regulate the current and future practice of nurse practitioners in the Commonwealth. Thank you for your consideration.

Sincerely,

Hernando Trujillo, M.D.

TEMPLE UNIVERSITY
A Commonwealth University

College of Allied Health Professions

Department of Nursing

3307 N. Broad Street (602-00)
Philadelphia, Pennsylvania 19140
(215) 707-4686
Fax: (215) 707-1599

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Re: The proposed regulations for Nurse Practitioners

October 30,1999

Dear BON- BOM

I support the current regulations for Prescriptive Authority for Nurse Practitioners. I have practiced as a CRNP for 12 years .Prescriptive rights will afford more accessible patient care and acknowledge the competencies of the Certified Registered Nurse Practitioner.

Thank you.
Sincerely,

Kathleen Rowan Mahoney CRNP
Assistant Professor

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From: <djones@yorkhospital.edu>
To: PADOS-DOMAIN.GWIA("medicine@pados.dos.state.pa.us"...
Date: Tue, Nov 2, 1999 3:33 PM
Subject: Advance practice nurse (APN) privileges

The proposed expansion of APN prescriptive authority is ill-advised. This is yet another backdoor avenue for APNs to become physicians without a license. Supervision and oversight for APNs is already too thin in many practice settings; the solution is not to further weaken oversight. A few aggressive members of this group are placing more prudent, but intimidated and silent members of their group, and all of their patient's, in serious jeopardy. Commercial organizations will be happy to push APNs into performing as inexpensive physician surrogates, as a cost-saving measure. I occasionally work side by side with APNs - and the even more reluctant PAs - and they privately express reservations and anxiety about the imcreasing pressure by managed care organizations -- pushing them to exceed the limits of their training and experience to provide high-volume care with inadequate oversight by and consultative availability with physicians. Patients known to us socially complain that it is sometimes difficult to get past the APN to see a physician for persistent unresolved problems -- access to the physicians is discouraged or hindered. The APNs may be concerned about their practice viability in the face of a physician oversupply -- there are now enough, soon more than enough physicians to go around, even to rural areas. Parceling out pieces of medical practice to other providers without the same level of training sets dangerous and unnecessary precedents, and limits patient's access to physician services - they have to settle for the lower cost alternative preferred by payers with their eye on elusive savings.

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Medical Center Clinic, P.C.

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CHARLES H. SRODES, M.D., F.A.C.P.
SIGURDUR R. PETURSSON, M.D., F.A.C.P.
DENNIS J. MEISNER, M.D., F.A.C.P.
CYNTHIA K. EVANS, M.D.
KATHY J. SELVAGGI, M.D.
BACHAR KASSEM, M.D.
WENDY A. BREYER, M.D.

SHADYSIDE OFFICE:
5200 CENTRE AVENUE
SUITE 706
PITTSBURGH, PENNSYLVANIA 15232
(412) 681-4401

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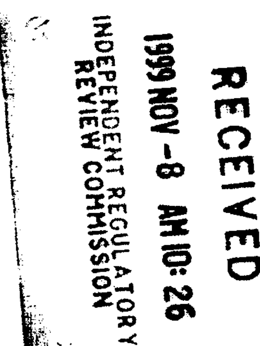

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

October 28, 1999

Dear Ms. Warner,

I am writing to voice my support <u>in favor of</u> the proposed regulations regarding Certified Registered Nurse Prescriptive Authority.

I am one of seven physicians in a busy Hematology/Oncology practice based in Southwestern Pennsylvania. Our practice employs 5 CRNP's who work collaboratively with the physicians in caring for our patients. These nurse practitioners are highly trained, responsible, and offer safe patient care. They are also quite skilled in symptom management. Many of the disease complications and treatment induced side effects are managed pharmacologically. Prescriptive authority if approved, will allow the nurse practitioners to be even more instrumental in providing relief and comfort to our patients.

I am also in favor of CRNP prescriptive authority for controlled substances. Pain management is a common issue with our patients and the nurse practitioners have much experience in recommending narcotic dosing and minimizing side effects.

Giving prescriptive authority to CRNP's in the state of Pennsylvania will enhance quality of patient care.

Sincerely,

Cynthia K Evans

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MONROEVILLE OFFICE:
PROFESSIONAL BUILDING 2 • 2580 HAYMAKER ROAD - SUITE 404 - MONROEVILLE, PENNSYLVANIA 15146 • (412) 373-4411
WEST PENN OFFICE:
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746 Jefferson Avenue
Scranton, Pennsylvania
18501-0990

Charles J. Bannon, M.D.
Chairman of Surgery

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October 27, 1999

Cindy Warner
Health Licensing Division
Bureau of Professional & Occupational Affairs
P.O Box 2649
Harrisburg, PA 17105-2649

Dear Cindy:

I am sure you know my position on certified registered nurse practioners by now, but to put them down in a formal way I feel there needs to be a requirement for a written collaborative agreement between the CRNP and a specific physician. These lines of communication are clear and emergency procedures are in place. CRNP's must have appropriate training and I find the regulations must remain with the Board of the Bureau of Professional Affairs or the State Board of Medicine.

My kindest personal regards to you and my old friends on the Board.

Sincerely,

Charles J. Bannon, M.D., F.A.C.S.

CJB/dmm

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Philadelphia, PA 19131

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27 October 1999

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

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Dear Ms. Warner:

As a nurse practicing in Pennsylvania for the past 29 years and a Board Certified Adult Nurse Practitioner practicing for the past two years, I want to commend the Board of Nursing and the Board of Medicine for their tireless efforts in preparing the proposed amendment to the CRNP regulations as it relates to CRNP prescriptive authority. I am aware of the long process of the negotiations in this matter. The passage of these regulations will enable myself and my colleagues in Pennsylvania to utilize the advanced nursing practice education we achieved more fully and will align more closely with advanced nursing practice in most of the other fifty states. It should slow the flight of advanced practice nurses to other states where there is less restrictive practice.

There are some sections of this amendment that I feel require adjustments. The first is Section 21.283 (2) where no provision is made for "grandfathering" those CRNP's who received their advanced practice education years ago when pharmacology content was integrated into their clinical coursework. They have been certified and practicing in Pennsylvania for many years and are especially valuable colleagues to those of us with less experience. Please provide this "grandfathering" option.

The second is Section 21.284 (Prescribing and Dispensing Parameters). A negative formulary would simplify this section. In lieu of that option, the following adjustments need to be made:

Part b: needs correction in the language so that hypoglycemic agents (16) and endocrine replacement agents (17) are listed as "hormones and synthetic substitutes" as referenced in Part a in the American Hospital Formulary Service Pharmacologic-Therapeutic Classification.

Part b also need to include certain omitted classes of drugs such as Eye, Ear, Nose and Throat preparations (which include antibiotic otic and ophthalmic drops); Unclassified Therapeutic Agents (which include common allergy medications and cromolyn sodium); CNS agents (which include aspirin, acetaminophen, ibuprofen, and antidepressants); Autonomic drugs (which includes pseudoephedrine and albuterol); and, Blood formation drugs (which include iron

preparations).

There also needs to be a provision in Part b for the Board of Nursing to add categories of drugs that will be developed in the future. Any new drugs not acceptable could be added to a negative formulary.

Part c requires a collaborative agreement for certain categories of drugs and would pose considerable administrative and financial burdens on pharmacies, physicians and nurse practitioners and should be eliminated. Many drugs listed in this category are commonly prescribed and are over the counter, except in the Medicaid population, which many of us serve. They include the CNS agents, Autonomic drugs, and Blood formulations listed above.

Section g (3) should be dropped since it infers inaccurately that prescriptive authority is assigned to the CRNP by the collaborating physician, not by the Boards.

I believe these recommendations could be easily adopted by both boards so that this amendment can move through the regulatory process efficiently.

Thank you for hearing my response to these regulations. If you need to discuss my issues or have questions I can answer for you, I can be reached at my work number 215-765-6690, during business hours.

Very truly yours,

Barbara Rideout

Barbara Rideout, MSN, CRNP

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October 26, 1999

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Ms. Cindy Warner
Health Licensing Division
Bureau of Professional & Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

I am using this means to expedite my comments on the proposed regulations providing for prescriptive authority for certified registered nurse practitioners, published for comment in the October 2, 1999, *Pennsylvania Bulletin*.

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Patients must be told when a CRNP is providing care and must have the right to see the physician.

The regulations must require adequate professional liability insurance coverage for the CRNP in this expanded role.

Finally, the regulations must retain the joint rule promulgation and oversight responsibilities of the State Board of Medicine.

Elizabeth J. Homa
Signature

Telephone 215-699-5053

Elizabeth J. Homa
Print Name

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BEAVER VALLEY UROLOGY
1700 THIRD STREET
BEAVER, PENNSYLVANIA 15009
(724) 775-8446 -- (724) 758-3231

DAVID B. PATRICK, M.D.
GEORGE F. DANIELS, JR., M.D.
LORI A. THARP, P.A.-C

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October 26, 1999

Ms. Cindy Warner
Health Licensing Division
Bureau of Professional & Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

I am writing to comment on the proposed regulations establishing prescriptive authority for certified registered nurse practitioners. I have supervised and employed physician assistants and nurse practitioners in my urology practice in excess of fifteen years. I am keenly aware of their role and value in the health care industry. However, they are not qualified by training or experience to practice independently of the direction of a licensed physician.

I do feel that nurse practitioners should be issued prescriptive authority when acting in collaboration with and under the direction of a physician. I also feel this collaboration must be writing. With this appropriate level of direction and the appropriate training in advanced pharmacology, you have the opportunity to better serve patients through the use of CRNPs as physician extenders. This is appropriate. If you wish to grant them privileges granting them the scope of practice as physician replacements, you need to revisit education requirements and make extensive revisions. Advanced pharmacology classes and a prescription pad do not a doctor make.

Thank you for the opportunity to address this issue so vital to the safe and effective practice of medicine in Pennsylvania.

Sincerely,

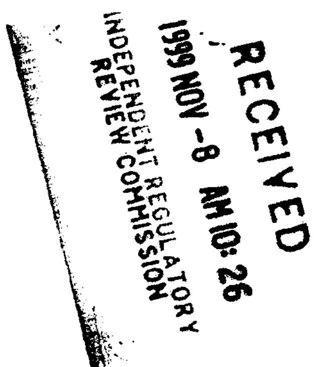
David B Patrick MD

David B. Patrick, M.D.

DBP/fmh

+ CATHOLIC HEALTH INITIATIVES

St. Joseph Hospital



Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

October 6, 1999

Dear Ms. Warner,

I am writing to you to express my support of the ammendments to the regulations, as written, governing certified nurse practitioners (CRNPs). Specifically, I am in support of CRNPs being authorized to prescribe and dispense drugs.

It has been my experience that CRNPs are fully capable of prescribing and dispensing medications. CRNPs are advanced practice nurses who most often hold master's degrees, and have successfully completed a course in advanced pharmacology. CRNPs with Prescriptive Authority would be more fully equipped to utilze their advanced eduation and skills.

I appreciate your support.

Sincerely,

[signature]

Arif Hafiz, MD
Internist

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UNIVERSITY of PENNSYLVANIA

School of Nursing
Nursing Education Building
Philadelphia, PA 19104-6096

215-898-8281

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Nov. 22, 1999

John H. Jewett, Regulatory Analyst
Independent Regulatory Review Commission
333 Market St., 14th floor
Harrisburg, PA 17101

Dear Mr. Jewett,

I very much appreciated meeting with you and your associates last Thursday to discuss the proposed amendment to the CRNP regulations. You are obviously keeping an open mind as you look to balance the positions of vested interests for the sake of all of the citizens of the Commonwealth.

As promised, I am sending you some background material that may be helpful in your review of the CRNP regulations. The most important document, I believe, is the recent Curriculum Guidelines & Regulatory Review Criteria for Family Nurse Practitioners Seeking Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care, that was commissioned by the U.S. Senate and funded by the Health Resources and Services Administration and Agency for Health Care Policy and Research. I was a member of the project advisory committee and was directly involved in its development, as were many groups around the country (see p. 56 & 57). Regulations and statutes of all 50 states plus Puerto Rico were examined in 1995 and are documented beginning on p. 13. "Multiple board authority/regulation of NP practice and prescriptive authority" was found to be a challenge and barrier (p.18) as was lack of standardization across states.

Even so, it is apparent that 38 states require evidence of national certification for prescriptive authority, and 21 to 27 states require some type of description of advanced nursing education (see p. 16). I believe that the current Pennsylvania CRNP regulations under the Board of Medicine section 18.41 b) "education as approved by the Boards" and c)"Evidence shall be given of continuing competency" currently give the Boards authority to review advanced nursing education and continued competency for CRNP practice. Furthermore, Section 18.81 states that the CRNP practice may be terminated if the Board finds "that the registrant has performed a medical task of function which the registrant is not qualified by education to perform."

The Curriculum Guidelines show that 31 states require information about physician collaboration (see p.16). In 33 states, full prescriptive authority is restricted based on a plan of accountability/collaborative agreement (see p.17). Only 2 states restrict prescription to a formulary as is done in the proposed amendment in Pennsylvania. Our current Pennsylvania CRNP regulations delineate the responsibilities of the collaborating

physician as a resource to the CRNP, immediately available for emergencies, and on a regularly scheduled basis for referrals, review of practice standards, updating protocols as well as medical diagnosis and therapeutics, and co-signing records "when necessary". As was pointed out clearly in our discussion Thursday, the common practice today, especially in nurse-managed centers across Pennsylvania, is for the collaborating physician to be a *resource* for the CRNP, *not a gatekeeper* to CRNP services.

Pennsylvania CRNP regulations now require written policies regarding CRNP practice in Section 18.61 a) ..."establish standard policies and procedures, in writing, pertaining to the scope and circumstances of the practice..." And Section 18.71 clearly states that "CRNP shall be responsible for his own professional judgements and is accountable to the individual consumer," the physician, and the employing agency. As the representative for the Pennsylvania Medical Society stated in response to questions after his testimony Oct. 27, 1999 before the House Professional Licensure Committee, requirements for professional liability insurance are a standard part of health care providers' contracts with hospitals, managed care plans, and other agencies. Therefore, liability coverage does not need to be mandated by law. I found no reference in the Curriculum Guidelines regarding liability coverage requirements for prescriptive authority in other states.

You may also want to review the Curriculum Guidelines course content outline, beginning on p. 43, and the end-of-course and end-of-program competencies on p. 41 & 42. In contrast to the proposed Pennsylvania CRNP regulations amendment that limits CRNP prescription to a positive formulary and omits key categories of common drugs, the Curriculum Guidelines includes a comprehensive list of drug groups that Family NPs should be prepared to prescribe. I have reviewed curriculum plans for NP programs across the country seeking Division of Nursing funding; in my judgement, most programs, including ours at Penn, already follow these guidelines for pharmacology content.

I have also enclosed the Nurse Practitioner Board Certification Examination Catalog and information on renewal of certification from the American Nurses Credentialing Center. I marked several pages to highlight the goals of NP certification and the review of NP education that is required to qualify for the certification exam. The certification is valid for 5 years, after which documentation for renewal includes 75 contact hours of continuing education relevant to NP practice, and 1500 hours of practice.

As I discussed in our meeting, I practice at Abbottsford Community Health Center in Philadelphia. I have enclosed a flier on my practice and an abstract of the study I presented at the American Public Health Association convention earlier this month. The study was to describe drug prescriptions given to our patients in a random selection of 250 encounters during 1997. Every one of the prescriptions given was judged to be appropriate to the patient's diagnosis and at the appropriate dose.

For your information, I have also enclosed Nurse Practitioners' Prescribing Reference, a free trade publication that is mailed to many Pennsylvania CRNPs. It will give you an idea of the range of medications prescribed by NPs across the country.

Thank you again for your careful consideration of the issues regarding the proposed amendment to the CRNP regulations. Please do not hesitate to contact me if you need further information.

Sincerely,

Melinda Jenkins

Melinda Jenkins, PhD, CRNP
Assistant Professor of Primary Care
Director, Family Nurse Practitioner Program

Cc: Dean Norma Lang, Rep. Pat Vance

Primary Care Nurse Practitioners' Prescribing Practices
for African American Public Housing Residents

Presented Nov. 9, 1999 at the American Public Health Association convention, Chicago, IL

by
Melinda Jenkins, PhD, CRNP
Assistant Professor of Primary Care
School of Nursing, University of Pennsylvania
Philadelphia, PA 19104-6096

and Family Nurse Practitioner
Abbottsford Community Health Center
3205 Defense Terrace
Philadelphia, PA 19129

While selection of prescriptions is nationally recognized as essential to Nurse Practitioner (NP) education and scope of practice, prescriptive authority for NPs varies by state. Previous studies show that NPs prescribe appropriately, and are more likely than physicians to prescribe less medication and recommend non-pharmacological treatment.

Prescriptions from patient records of 250 randomly selected primary care encounters during 1997 at a nurse-managed Community Health Center in an urban, mostly African American, public housing development were compiled. The average patient age was 23, 76% were female, 80% were in Medicaid managed care. Out of 279 total diagnoses, upper respiratory infections were 16%, well child care 8%, dermatological problems 7%, and hypertension 7%. Out of 293 prescriptions noted, 157 were to children 18 and under. Anti-infectives were 26% of prescriptions, non-narcotic analgesics were 23%, and cold medications were 21%. Dermatologicals were 7% of drugs provided, anti-hypertensives were 5%, other types of medications less than 5%. About 25% of encounters generated no prescription. Common medications appropriate to the diagnosis and at appropriate dosage were selected in each encounter. Over-the-counter medications were selected 51% of the time; they were most likely prescribed in order to obtain Medicaid payment for the drug. With no data to show inappropriate prescribing by NPs, and with many studies documenting safe, effective care by NPs, it appears that upholding current barriers to NP prescribing adversely affects quality by inordinate restriction of patient access to care.

Curriculum Guidelines & Regulatory Criteria for Family Nurse Practitioners Seeking Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care

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Summary Report
1998

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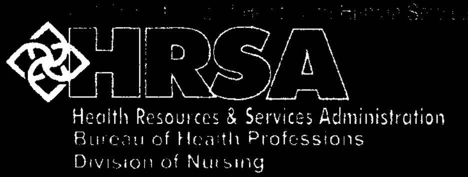

NURSE PRACTITIONERS' PRESCRIBING REFERENCE

NEW THIS EDITION

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OVER 2300 FORMULATIONS IN THERAPEUTIC SECTIONS

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FALL 1999

AMERICAN NURSES CREDENTIALING CENTER
COMMISSION ON CERTIFICATION

Nurse Practitioner
Board Certification Examination Catalog
(COMPUTER-BASED TEST)

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Acute Care Nurse Practitioner

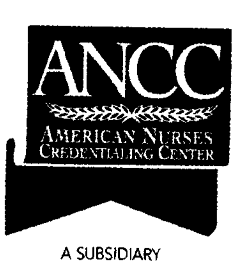
Adult Nurse Practitioner

Family Nurse Practitioner

Gerontological Nurse Practitioner

Pediatric Nurse Practitioner

School Nurse Practitioner



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Includes Application

ABBOTTSFORD COMMUNITY
HEALTH CENTER

Melinda L. Jenkins, Ph.D., CRNP.
Family Nurse Practitioner

3205 Defense Terrace
Philadelphia, PA 19129
(215) 843-9720
FAX (215) 843-7313

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SCHUYLKILL FALLS HEALTH CENTER & ABBOTTSFORD HEALTH CENTER

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P Ellenburger, MD
10/24/99

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ophthalmologists do – for a total of <u>8</u> years of medical training – & because they take a "100 hours of courses", a optom. school are given the privilege of prescribing drugs, etc – dangerous! (you'd want <u>your</u> airline pilot to have more than a 100 hours of book learning – like <u>years</u> of supervised hands-on experience!).

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It is incomprehensible to suggest any consideration of House Bill 50.

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FORM LETTER

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It is incomprehensible to suggest any consideration of House Bill 50.

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OCT 28 1999
Health Licensing Boards

1004 Hampstead Road
Wynnewood, PA 19096

October 25, 1999

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Warner:

As a Pediatric Nurse Practitioner certified in Pennsylvania, I want to commend the Board of Nursing and Board of Medicine for their tireless efforts in preparing the proposed amendment to the CRNP regulations relating to CRNP prescriptive authority. I know this has been negotiated over many years. The passage of these regulations (with some minor adjustments) will enable CRNP's in Pennsylvania to utilize their advanced nursing practice education more fully and more in alignment with practice in most other states.

I have concerns about some sections of this amendment that I feel require adjustments. The first regards section 21.283 (2) where no provision is made for "grand-fathering" those NP's already certified and practicing in Pennsylvania in 1999 who educational programs years ago may have had integrated pharmacology content in their clinical coursework. Please provide this "grand-fathering" option.

Secondly, there are concerns about Section 21.284 (Prescribing and Dispensing Parameters). Basically, a negative formulary would simplify this section tremendously. In lieu of a negative formulary, though, the following adjustments need to be made:

Part b: This section needs correction in the language so that (16) *hypoglycemic agents*, and (17) *endocrine replacement agents* aligns with the American Hospital Formulary Service Pharmacologic-Therapeutic Classification (referenced in Part a) which lists "hormones and synthetic substitutes".

Part b needs inclusion of certain omitted classes of drug such as Eye, Ear, Nose and Throat preparations (which included antibiotic ear and eye drops); Unclassified Therapeutic Agents (which included common allergy meds and cromolyn sodium); CNS agents (which includes aspirin, acetaminophen, ibuprofen, antidepressants); Autonomic drugs (which includes pseudoephedrine, albuterol) and Blood formation drugs (which includes iron prepartions).

Part b needs to have a provision for the Board of Nursing to add categories of future new drugs as they are developed (or as preferred, any new drugs not acceptable to be added to the negative formulary)

Part c requires a collaborative agreement for certain categories of drugs and would pose considerable administrative and financial burdens on pharmacies, physicians and nurse practitioners and should be eliminated. Many drugs listed in this category are commonly prescribed and even over the counter, such as aspirin, acetaminophen, ibuprofen (CNS agents), pseudoephedrine (autonomic drugs) and iron (Blood Formation).

Section g (3) should be dropped since it infers inaccurately that prescriptive authority is assigned to the CRNP by the collaborating physician, not the Boards.

I think these recommendations could be easily adopted by both boards so this amendment can go forward quickly through the regulatory process.

Thank you for giving me the opportunity to respond to these regulations. If you have any questions, please call me at (215) 590-3912.

Very truly yours,

Julie A. Petro, MSN, RN, CRNP

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OCT 28 1999

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OCT 19 1999

Health Licensing Boards

Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

October 14, 1999

Dear Ms. Warner:

I am writing to you regarding the proposed regulations related to CRNP Prescriptive Authority recently published in the Pennsylvania Bulletin October 2, 1999. I encourage both Boards to approve the jointly promulgated regulations as written. These recently published regulations amending the 1974 legislation are long overdue and are reasonable for practice by the CRNPs in the State of Pennsylvania.

You are certainly aware of the fact that Pennsylvania lags behind most of the other States in prescriptive privileges for the CRNP. Pennsylvania is only one of four states in which a CRNP must have prescriptions co-signed by a physician. Here in Pennsylvania, many physicians are anticipating inappropriate/incorrect prescriptions, and are challenging the regulations on this basis. As you are probably aware, the states that have allowed CRNPs to prescribe have had no incidents of liability issues or patient harm related to prescriptive authority. A CRNP's practice is based on scientific principles and includes pharmocology, pharmacotherapeutics and physiology to treat disease and illness. Many CRNPs practice in underserved areas, and currently are at a disadvantage by not being able to prescribe medications as part of the treatment plan. Physician's Assistants are able to prescribe independently, many times with less experience than their CRNP peers.

I feel that the regulations, as amended, are practical and permit me to practice safely and effectively under the law. I am responsible for my own practice, am covered by my own malpractice insurance, and can function independently in areas for which I have received graduate education. I am aware of my limitations, and feel strongly that the doctor-nurse practitioner relationship should be a collaborative one. This also protects the physician with whom I have a collaborative relationship in that he/she is not ultimately responsible for what I do under my own license. Currently under the law, he/she is assuming more liability than necessary, just because the regulations have not been written or approved before now.

Thank you for your prompt attention to this matter.

Sincerely,

Lucinda Harris CRNP, MSN

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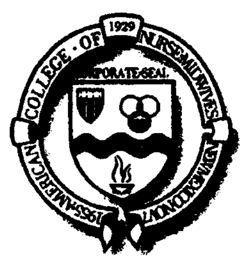

AMERICAN COLLEGE OF NURSE MIDWIVES

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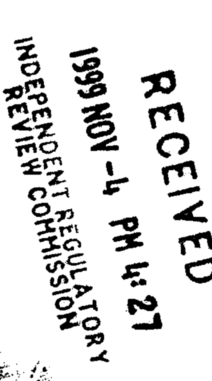


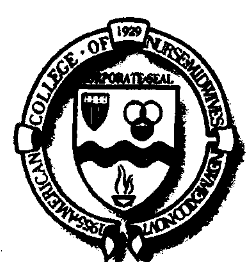
Daniel Kimball Jr. MD
Chairperson
State Board Of Medicine
Harrisburg,Pa. 17105-2649

Dear Dr. Kimball,

Region 2 Chapter

I am writing to comment on the proposed amendment to the CRNP regulations published in the Pennsylvania Bulletin Oct.2, 1999. In the majority of the United States CRNPs have prescriptive authority with a proven track record of excellent care, accountability, and increased access to care for often underserved populations. This amendment will move Pennsylvania into the majority of states who recognize the quality of care and expertise of CRNPs. This amendment will improve access to care for inner city and rural citizens. This amendment will improve accountability for the care rendered by CRNPs. On the whole this amendment is an example of excellent hard work and cooperation between the Boards of Medicine and Nursing. Overall I endorse this amendment. I offer the following suggestions for your consideration as you move this amendment forward.

Section 18.53 This section limits prescriptive authority to CRNPs whose "program includes a core course in advanced pharmacology". Current CRNP programs contain this course. Graduates from courses prior to the late 1980s often had pharmacology content integrated into their other courses. There are many excellent experienced practicing CRNPs who may not be able to demonstrate a core course in advanced pharmacology. I would suggest that a provision be added that allowed an alternative pathway for these current CRNPs to meet requirements for prescribing.



AMERICAN COLLEGE OF NURSE MIDWIVES

Section 18.54 The American Hospital Formulary Service Pharmacologic- Therapeutic Classification is listed as the document to identify drugs CRNPs may prescribe and dispense. Section b then lists drug categories that are labeled differently than the reference formulary. This is a construct issue. I would suggest these categories be consistently labeled. I would also recommend that instead of the current positive listing of drugs and categories, the Boards consider using a negative formulary. This would be less cumbersome and less prone to becoming outdated in this rapidly changing medical environment. If the Boards continue with a positive formulary then attention must be focused to avoid errors of omission(such as the current absence of Eye-Ear-Nose-and Throat preparations).

Region 2 Chapter 4

Section 18.54 (g) (2) This section prohibits off label prescription. This does not allow for current standard of practice in many areas. This section should be eliminated or covered under the collaborative agreement.

Again I thank the Boards for their time and effort with this proposed regulatory change. This new regulation will certainly improve the health, safety, and welfare of the citizens of the Commonwealth of Pa.

Sincerely,

Denise Roy CNM
Chapter Chair, American
College of Nurse Midwives

TEMPLE UNIVERSITY
A Commonwealth University

College of Allied Health Professions

3307 N. Broad Street (602-00)
Philadelphia, Pennsylvania 19140
(215) 707-4686
Fax: (215) 707-1599

Department of Nursing

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28 October 1999

Cindy Warner
Health Licensing Division
Bureau of Professional & Occupational Affairs
PO Box 2649
Harrisburg PA 17105-2649

Dear Ms. Warner:

I am a Family Nurse Practitioner who is excited about the possibility of practicing with prescriptive privileges as my colleagues in ALL the other states in the USA. I have been a nurse practitioner since 1973. In my original state of practice (Massachusetts) and the other states in which I hold licensure (Florida and New Jersey) I have been able to fully practice in my role as a primary health care provider. I relish the opportunity to provide all aspects of primary health care to my clients here in Pennsylvania.

Please accept my commendations for all the effort expended by the members of the task force that has made this proposal a reality. I am truly appreciative and look forward to the final regulations.

I would like to register my concerns about the document (PA Bulletin Doc.No.99-1668).

- There is no mention in the document about 'grandfathering' nurse practitioners currently certified to practice in the Commonwealth.
- The proposal does not address nurse practitioners in solo practice. Will each solo primary care practitioner need a collaborating physician?
- I practice in a nurse practitioner managed primary care center serving the poor who are allowed 'over the counter' medicines to be purchased on their insurance card. Will I continue to need a collaborative physician for these prescriptions?

Please forward my concerns to the boards. Thank you for allowing me to respond to these regulations. If you would like to contact me, I can be reached at (215) 707-4874.

Sincerely,

Janis Davidson

Janis Davidson Ph.D., CFNP
Director Nurse Practitioner Program

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10-28-99
York OB/Gyn
1399 S. Queen St
York, PA 17403

Ms Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

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To Ms. Warner;

This letter is in response to the drafting of new rules and regulations governing nurse practitioner prescriptive authority. I support the propose changes with one area of concern. Prohibiting nurse practitioners to prescribe drugs for indications not approved by the FDA will continue to place a significant barrier to our practice. Off-label use of drugs is a common and accepted practice among medical and nursing professionals. Unfortunately, the FDA is slow to recognize research proven benefits of drugs above what they are approved for. Drug companies will not go to the expense of approaching the FDA for formal approval. Why should our patients be denied the benefits of these therapies?

I propose a compromise. Allow off label use of drugs to be addressed in the collaborative

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list of drugs.

The following is a list of drugs and their off label uses my physician + NP colleagues and I use regularly in our gyn practice

- Provera - To prevent uterine cancer in post menopausal women using estrogen replacement. (MANY Clinicians are unaware of this!) being off-label use!
- Boric acid - resistant vaginal yeast infections
- Various topical compounded drugs
- Temovate for lichens sclerosus
- Spironolactone for hirsutism
- Elavil - recurrent migraines
  vulvodynia
  other chronic pain states
- Tofranil - urinary incontinence
- Bellergal - hot flashes
- Clonidine - hot flashes
- Paxil + effexor - hot flashes

Nurse practioners in other settings have different prescribing needs than those stated above. There are probably other examples than those listed above.

Thank you for your time, energy and effort on this issue.

Sincerely,

Christine [illegible], MSN, CRNP

Paul P. Logan, MSN, CRNP, CS, CCRN
212 Rock Glen Road
Wynnewood, Pennsylvania 19096
(610) 896-2337
LoganCRNP@aol.com

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October 28, 1999

Cindy L. Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
PO Box 2649
Harrisburg, PA 17105-2649

RE: CRNP Prescriptive Authority

Dear Ms. Warner,

When I last wrote to you in the summer, I was concerned that the proposed changes to the rules and regulations for nurse practitioners would make practice for CRNPs in Pennsylvania too restrictive. I am pleased that the Boards of Nursing and Medicine have altered their original proposal. There is, however, one concern that I still have with the draft regulations.

First, sections 18.60(h)(2)/21.290(h)(2) should be amended to allow off-label prescribing by CRNPs, so long as there is documentation in the written collaborative agreement. As I mentioned in my last letter to you, this language prohibits nurse practitioners from prescribing any agent for off-label indications. Although the intent of the language is reasonable, in practice it is not. Heparin, for instance, is an integral component of the therapy for unstable angina and can be life-saving. It's use is ubiquitous among cardiovascular specialists and is well-supported by the medical and nursing literature. Yet, heparin does not have an FDA indication for unstable angina. This language effectively prohibits nurse practitioners from prescribing life-saving therapy for the citizens of Pennsylvania.

I am encouraged by the progress that both Boards have made toward allowing CRNPs in Pennsylvania to practice as nurse practitioners in New York, New Jersey, and most other states in the nation currently practice.

Respectfully,

Paul P. Logan

Cc: Pennsylvania State Nurses Association
Dr. Jan Towers, Pennsylvania Coalition of Nurse Practitioners
Dr. Melinda Jenkins, Pennsylvania Alliance of Advanced Practice Nurses

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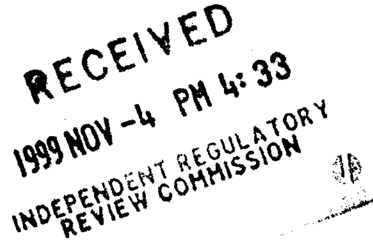

225 Cornell Avenue
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Cindy Warner
Heath Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

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Dear Ms Warner:

On behalf of many Advance Practice Family Nurse Practitioners, I wish to thank you and the Boards of Nursing and Medicine for your tireless efforts in preparing the proposed amendment to the CRNP regulations relating to the prescriptive authority.

I have been in practice as a Family Nurse Practitioner at Project Salud which first began 15 years ago as a primary care service for Mexican migrant farm workers in the Kennett Square area (Chester County). Over the years this primary care health center has evolved to serve the larger underserved community of southern Chester County. My practice is bilingual and bicultural due to the nature of the community I serve. Prescriptive authority would hold me accountable for the medications I now prescribe under my physician preceptor's name and would hold me accountable. This is essential since my prescriptions and patient education tend to be in the language and culture appropriate to my client.

I graduated from the Pennsylvania State Family Nurse Practitioner, Masters Degree Program at Hershey in 1976, and my pharmacology curriculum was well integrated in the clinical studies. Since my graduation I have attended continuing education courses in pharmacology and have continually qualified for certification as an FNP by The American Nurse Association Credentialing Service. It is essential that there be a grandfather clause for those of us who were at the cutting edge of advance clinical nursing practice who attended these early Nurse Practitioner Programs. Indeed many of us were obliged to practice at an advanced level because there was the need and we elected to return to school so that we would get the education to practice safely And legally. We also pushed for accountability in our practice with the development of CRNP regulations. It is now time to allow us to be accountable and responsible for our own prescriptions instead of needing to refer to the authority of a *collaborating physician.* Grant us that prescriptive authority!

The problems with the current formulary is that it cannot take into account all the

medications that are being used in primary care settings now and in the future (say in five years); given that each health maintenance organization caries its own formulary, we can expect many amendments, adjustments, and exceptions. A negative formulary would be easier to administer and would eliminate the need to amend the regulation over and over again.

Thank you for taking these issues into account. I trust that both the Boards of Nursing and Medicine will understand that ultimately it is the patient who we treat, educate and prescribe for and that the Nurse Practitioner needs to be held accountable to the community and patient he/she serves.

Most Sincerely,

Marguerite P. Harris, MS, CRNP

Marguerite P. Harris, M.S., CRNP
Family Nurse Practitioner

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204 Acre Drive
Carlisle, Pennsylvania 17013
October 25, 1999

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Cindy Warner
Health Licensing Division
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, Pennsylvania 17105-2649

Dear Ms. Warner:

As a Women's Health Nurse Practitioner in Carlisle, I feel compelled to comment on House Bill 50. However, I first must commend the Board of Nursing and the Board of Medicine for their continued efforts in preparing the proposed amendment to the CRNP regulations relating to CRNP prescribing authority. The passage of these regulations, with some adjustments, will enable nurse practitioners in Pennsylvania to use their education more fully and more in alignment with practice in most other states.

House Bill 50 states "An APRN is authorized to diagnose and treat illnesses, perform therapeutic and invasive procedures, prescribe, dispense, and administer drugs and devices and order and administer anesthetics, pursuant to the rules and regulations established by the Board consistent with the advanced practice registered nurse scope of practice." This restricts Pennsylvania APRNs to prescriptive authority that is consistent with their respective national scopes of practice. It also restricts Pennsylvania APRNs to procedures for which they are educated and which fall within their respective national scopes of practice.

Multiple research studies have shown the quality of care provided by APRNs to be as good as, or better than, that of physicians. Published medical evidence shows APRNs' care to be safe, appropriate, effective, and highly satisfying to patients.

46 other states have safely provided greater latitude for APRNs for up to 35 years. In the vast majority of states, only the Board of Nursing regulates

APRNs. The Commonwealth already recognizes national standards and scopes of practice for APRNs; House Bill 50 does not expand the scope of practice already given to our group.

Thank you for giving me the opportunity to voice my concerns. If you have any questions, you can reach me at 717-245-0722.

Sincerely yours,

Rita Schlansky

Rita Schlansky, RNC, MSN, CRNP

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