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December 4, 2008

Ann Steffanic, Board Administrator
Pennsylvania State Board of Nursing
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

Re: # 16A-5124 CRNP General Revisions

To the Members of the Pennsylvania State Board of Nursing:

Allow this correspondence to serve as the official comments of the Pennsylvania Coalition of Nurse Practitioners (PCNP) relating to recently proposed regulations of the State Board of Nursing (SBON) that appeared in the Pennsylvania Bulletin on November 8, 2008.

The PCNP represents the interests of more than 6,400 Certified Registered Nurse Practitioners (CRNPs), in Pennsylvania. As the proposed regulations relate to practice parameters for CRNPs, we appreciate the opportunity to comment upon the proposed rulemaking.

Background

We believe it is necessary and appropriate to provide some history on how we have arrived at the present opportunity to provide a more hospitable environment for CRNP practice in Pennsylvania. CRNPs and the individual physicians with whom they collaborate generally enjoy excellent working relationships based on mutual respect and a shared commitment to serving the needs of their patients in the best way possible. This is certainly born out in the many supportive comments on these regulations provided by our physician colleagues.

However, there is a significant history of efforts by "organized medicine" to restrict and limit CRNP practice. Generally these are not based on empirical data or evidence of lack of patient safety or bad outcomes. The statutory and regulatory climate in Pennsylvania is more restrictive to CRNP practice than in many other states and has not been conducive to keeping up with the frontline of changes in the medical marketplace. Given the severity of the health care crisis our country is experiencing we believe there are ample opportunities for both physicians and CRNPs to work together to expand access to quality, affordable health care. However, our physician colleagues, as represented by their professional organizations, need to acknowledge and respect the skill, dedication, education and clinical competence achieved by CRNPs. Many of Pennsylvania's current laws and regulations are barriers to CRNP practice. We

believe the current regulations presented by the SBON are a long-awaited attempt to lower some of those barriers.

Historical Perspective

In 1974 the PA General Assembly passed legislation that conferred prescriptive authority on CRNPs in Pennsylvania. However, the legislation required joint promulgation of rules between the State Board of Nursing (SBON) and the State Board of Medicine (SBOM), thereby subjecting nurse practitioners in Pennsylvania to the regulatory oversight of two different boards. CRNPs were the only profession so situated. The net effect of this regulatory scheme was that while Pennsylvania was one of the first states to allow CRNPs to prescribe we became one of the last states to implement prescriptive authority, as final jointly promulgated rules were not agreed to until late in 2000. By and large this was due to the intransigence of the State Board of Medicine. The threat of passage of legislation to rectify this situation in the late 1990s provided an inducement that facilitated joint promulgation of rules. Many of the provisions of the current regulations, which are still in effect, were the result of intense and protracted negotiations between and among the two Boards, the Ridge Administration and affected stakeholders.

In the original version of the 2000 regulations the SBOM insisted on a ratio of 2:1 of CRNPs to collaborating physicians, e.g. that a physician could not collaborate with more than two CRNPs at one time. PCNP protested to the Independent Regulatory Review Commission. IRRC disapproved the regulations. A subsequent version with a 4:1 ratio and ameliorating language was finally approved.

In 2002 the General Assembly passed HB 1208 (Act 206 of 2002), which established the SBON as the sole regulatory authority for CRNPs. This legislation defines collaboration and lays out the framework for how CRNPs may prescribe. It too was the subject of intense and protracted negotiations among stakeholders. Since that time we have awaited publication of the first set of proposed rules that were not subject to the regulatory authority of the SBOM. The SBON's effort to promulgate new rules remained internal through 2006.

In 2007, as part of Governor Rendell's Prescription for Pennsylvania, HB 1253 (Act 48 of 2007) was passed. This legislation addressed issues relating to obsolete, antiquated laws and regulations that prevented CRNPs from practicing to their full scope. Many of the original provisions of HB 1253 that are now at issue in these regulations were removed from the legislation because PCNP and the PA Medical Society could not reach agreement on them. The issues remaining in what is now Act 48 of 2007, such as ordering dietary referrals, occupational therapy, physical therapy, and other similar treatments are not an expansion of the scope of practice of CRNPs, but things we were precluded from ordering because of existing statutes or regulations containing "physician only" language.

The SBON, rather than promulgating two separate packages of regulations, folded the provisions of Act 48 of 2007 into the existing regulatory work product. This is the proposed rulemaking that is finally before us.

The PCNP is fully aware that certain commentators have expressed dissatisfaction with the currently proposed regulations. It is the goal of this correspondence to address both the reasons why these proposed regulations are necessary and to discuss some of the concerns raised by others, which, with respect, are not supported in data, history or logic.

PCNP SUPPORTS THE PROPOSED RULEMAKING FOR CRNPS

With the United States and Pennsylvania in the midst of a health care crisis, and as our population continues to grow older and have more complex needs, it is essential that we fully utilize the highly educated and clinically prepared nurse practitioners to help offset these increasing demands. For over 40 years, research has consistently demonstrated the high quality care provided by the nurse practitioner profession. Nurse practitioners have demonstrated repeatedly that they can provide cost-effective, high-quality primary care for many of the most needy members of society, but their role in providing care has been severely limited by restrictions on their scope of practice, prescriptive authority, and eligibility for reimbursement. Regulations need to be evidence based, consistent, and protective of patients instead of being directed toward serving the economic interest of physicians. Regulations that are "barriers serve no useful purpose and contribute to our healthcare problems by preventing the full deployment of competent and cost effective providers who can meet the needs of a substantial number of consumers."[1]

According to the American Academy of Nurse Practitioners (AANP), Pennsylvania ranks 5th in the nation for having the largest number of CRNPs that are available to remedy the provider shortages felt throughout our nation. In 2007, in conjunction with Governor Ed Rendell and the Office of Healthcare Reform, our organization worked diligently to support health care reform that would put our state on the map as being forward-thinking and progressive by mobilizing the entire healthcare workforce. Part of the mission of PCNP is to remove legislative and regulatory barriers that restrict our profession's ability to provide the high-quality care that focuses on health promotion and disease prevention for the citizens in our Commonwealth.

Nationally, there is a shortage of health professionals who provide primary care. As of September 30, 2008, there were 6,033 Primary Care HPSAs with 64 million people living in them. It would take 16,336 practitioners to meet their need for primary care providers (a

[1] Safriet BJ: Health care dollars and regulatory sense. The role of advanced practice nursing. Yale J Regul 1992; 9: 417-488

population to practitioner ratio of 2,000:1)[2] As of October 2008, there are approximately 876,000 persons living in Pennsylvania's 60 Primary Care Health Professional Shortage (geographic or population) areas. This is approximately seven percent of Pennsylvania's total population. The Pennsylvania Department of Health estimates that recruitment of 63 full-time equivalent primary care physicians would be needed to remove these designations. As of October 2008, approximately 1.8 million, or nearly 15 percent, of Pennsylvania's population resides in areas that are designated as Medically Underserved Areas or Populations[3]. Increasing the capacity of nurse practitioners to provide care to populations that reside in these areas of Pennsylvania will help to offset the need for primary care providers and improve access to care for our residents.

With a few minor suggestions related to 21.284a, which will be discussed later, we support the proposed rulemaking and appreciate the opportunity to review changes to address the comments submitted by our colleagues in medicine.

21. 285. PRESCRIPTIVE AUTHORITY COLLABORATIVE AGREEMENT

Our organization has read the comments submitted to the House Professional Licensure Committee by our physician colleagues regarding their concerns with the proposed rulemaking. Respectfully, we would like to clarify the concerns expressed pertaining to the nature of a collaborative agreement between a nurse practitioner and physician. Act 206 of 2002 speaks to the nature of the collaborative agreement. The collaborative agreement between a prescribing CRNP and a physician is defined in statute. Each unique agreement has enabled the parties involved to meet the needs of their unique clinical situation, documents the details of collaboration and provides a clear algorithm of how each party is responsible to the other based on patient needs. This agreement is between two skilled, highly educated professionals who make decisions based on the needs of the patients they care for. Additional restrictions do not fit into collaboration, but rather imply an outdated and unnecessary supervisory relationship. This basic principal of professional responsibility speaks to both disciplines being able to recognize their own knowledge and experience and seek consultation from an appropriate source when the clinical situation warrants.

CRNPs are required to have distinct 45 hours of advanced pharmacology as part of their Master's degree. Many other hours of course work covering care of special populations and distinct disease processes integrate additional pharmacology. Sixteen of the mandated 30

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[2] (U.S. Bureau of Health Professions, Health Resources and Services Administration. (Last visited November 18, 2008)

[3] Pennsylvania Department of Health, Bureau of Health Planning, Division of Health Professions Development. (2008)

hours of continuing education required for renewal of the CRNP certificate must be in pharmacology.

Nurse practitioners bring unique experiences and skills to the relationship that is developed within the collaborative agreement. Their knowledge is often complementary and both CRNP and physician should be able to use the full extent of that knowledge to serve the patient. Comments submitted by our physician colleagues suggest the collaborating physician must have familiarity with all medications that a CRNP is prescribing. Both parties who sign this agreement are licensed, highly educated, clinically competent professionals who have had adequate experience with the science and practice of pharmacotherapuetics. To require some form of further proof of competency of either party is redundant, and in some cases may limit the ability of the CRNP to prescribe medications well within their scope and clinical knowledge base.

CRNPs have held prescriptive authority in Pennsylvania since 2000, and there has been no data to support that the current agreement has rendered any negative patient outcomes. Additionally, the collaborative agreement that is mandated for the CRNP to hold prescriptive authority already poses great difficulty for our profession and hinders our goal to improve access to care. Not only are we required to find one physician collaborator in order to prescribe medications, we must also find a 'back-up' collaborating physician who would be willing to step in if our primary collaborating physician becomes unavailable for some reason. The CRNP must find TWO collaborating physicians for every collaborative agreement they file with the Board. For CRNPs who work part-time or have more than one clinical practice setting, they are required to find anywhere from two to four or six different physicians to sign the agreement. CRNPs are often denied reimbursement by insurers unless the collaborative physician is also in the insurers' network.

Additionally, we are required to have a different prescription pad that holds the name of the CRNP and the collaborating physician for each separate collaborative agreement we hold. With 15 other states across the nation who have plenary authority (are not legally required to have ties to a physician), and no data supporting poor outcomes within those states, it is objectionable that Pennsylvania still requires such outdated regulatory measures for our profession.

The suggestion that a written collaborative agreement be required when prescriptive authority is unnecessary is not required by statue. Many nurse practitioners are working in positions that do not require them to be prescribing, such as roles where they are contracting to perform only physical examinations, or in occupational health settings, school-based settings and nursing homes, to name a few. The SBON clearly appreciated this and the PCNP supports their decision and their sole regulatory authority. The written collaborative agreement template currently available from the SBON is easy to use, comprehensive and easily available for use from the SBON website.

These comments are not only the byproduct of intense review by the leaders of our coalition; they also have been reviewed by legal consultants and other advisors. We have asked that the statutory scheme be dissected to confirm that our interpretation of Act 206 of 2002 and Act 48 of 2007 support the current interpretation of the SBON and hence the interpretive rules which were proposed in the Pennsylvania Bulletin on November 8, 2008. The guidance we have received is that these regulations are wholly consistent with legislative intent and well-established principles of statutory construction. For example, and as noted above, our General Assembly took careful steps to distinguish between the form of collaborative agreements required generally as opposed to a collaborative agreement which entails "prescriptive authority". Specifically, under § 8.2, relating to the scope of practice for Certified Registered Nurse Practitioners, subsection (b) provides the following:

> A certified registered nurse practitioner may perform acts of medical diagnosis in collaboration with the physician and in accordance with regulations promulgated by the Board.

63 P.S. § 218.2(b).

In significant contrast, under subsection (3) of Act 206, our General Assembly, when discussing "prescriptive authority for Certified Registered Nurse Practitioners", directed the following:

> A certified registered nurse practitioner may prescribe medical therapeutic or corrective measures if the nurse...(2) is acting in collaboration with a physician as set forth in a written agreement which shall, at a minimum, identify [certain specifics such as area of practice and categories of drugs].

63 P.S. § 218.3.

As advised by our legal consultants, we must assume that the General Assembly understood both the law as it currently existed and further understood what amendments to the law would create. Here, with relation to the question of a collaborative agreement, the General Assembly expressly required that any "prescriptive authority" include a written collaborative agreement, whereas a general interrelationship for collaboration between the physician and the CRNP need not be a written agreement. Simply stated, the General Assembly desired that any collaboration involving the prescribing of drugs be in writing, whereas other collaborative agreements need not be in writing. The current proposal of the SBON makes that refined distinction and, in final rulemaking, that distinction should not be blurred. Although these two provisions are easily reconcilable, the Statutory Construction Act, at 1 Pa. C.S.A. § 1933 expressly provides that when there is a general provision in a statute, along with a special provision in that same statutory scheme, the special provision shall be construed "as an exception to the general provision..." – precisely what the proposed regulations do in this instance. Again, the Legislature is presumed to have known what it was doing when it inserted the word "written" before the word "agreement" when discussing collaboration for

"prescriptive authority", but chose not to insert the word "written" before the word "agreement" when discussing collaboration arrangements generally and not involving prescriptions on pharmacology. See May Corp. 427 A.2d 203, 205 Pa. Super, 241 (Pa. Super 1981) (reasoning that our legislature is presumed not to have intended its laws to contain surplusage.)

The State Board of Nursing has been charged with carrying out the provisions of the Professional Nursing Law and its interpretation of those statutory provisions must be accorded deference and great weight. See In Re Thompson, 896 A.2 659 (Pa. Commw. 2006), appeal denied, 916 A.2d 636 (2006) (holding that even if statutory language is not explicit, "courts should give great weight and deference to the interpretation of a statutory or regulatory provision by the administrative or adjudicatory body that is charged with the duty to execute and apply the provision at issue.")

The General Assembly's decision to distinguish between collaborative agreements generally and collaborative agreements relating to prescriptive authority is well founded.

21.287. Removal of the 4:1 Physician-to-NP Ratio

As noted previously, in the original version of the rules which were jointly promulgated by the two boards in 2002, a 2:1 ratio of CRNPs to physicians was included at the insistence of the SBOM, with a strong assist by "organized medicine". IRRC did not find favor with this arrangement and the subsequent version of the regulations dropped the ratio back to 4:1 and added language that said by way of example that a physician "may supervise four prescribing CRNPs who work in the morning and four other prescribing CRNPs who work in the afternoon, as long as the physician has a collaborative agreement with each CRNP." We do not believe "supervise" is the appropriate term here, but we have historically had great difficulty in convincing some of our physician colleagues that collaboration does not equate with supervision.

PCNP believes the ratio is unnecessary when the relationship is seen as defined and not as a supervisory relationship. Many of the comments offered by "organized medicine" are predicated on the belief that this is a supervisory relationship, not a collaborative relationship, as defined by Pennsylvania statute. Often necessary consultation is done with a variety of health care professionals -- specialist physicians, pharmacists, physical therapists, psychologists, or other nurses -- in addition to the collaborative agreement partner. The goal is to seek the best resource to care for the patient, whether the provider is the nurse practitioner or a physician.

The current regulatory provision that a physician can only collaborate with four prescribing CRNPs at any given time has created difficulties and unnecessary financial hardship for clinics that provide care to medically underserved populations. Federally qualified health clinics (FQHCs), nurse-managed centers, and family planning or free clinics become limited in the

number of NP providers they can hire because it is difficult to find collaborators. There is no research to date that supports maintaining this arbitrary number. With only 2-3 percent of new physicians choosing to enter family practice, this national trend has created a significant shortage of primary care providers, thus contributing further to the difficulties this restriction has on the CRNP's ability to practice. PCNP strongly believes that the proposed regulatory changes will help to increase access to care.

21.284 a. Prescribing and dispensing drugs

PCNP respectfully disagrees with the Board's recommendation to have all CRNP prescription pads bear the name of the collaborating physician. We find this information redundant and confusing to the public at large. This information is found both on the State Board of Nursing website and at the practice site on the written collaborative agreement that is required to be made available for anyone who requests to see it. The new Model Act of the National Council of State Boards of Nursing (NCSBN) which was approved in August 2008[4] also made recommendations that the CRNP prescription pad not hold the collaborating physician name on the prescription. The PA SBON voted in favor of the new Model Act for implementation in all states by 2015.

Having this additional provider name on the written prescription causes confusion to the patient, our healthcare colleagues and the institutions in which the prescriptions are referenced for purposes of ordering lab work, radiology or other diagnostic or therapeutic studies for patient care. When a patient leaves the office with a prescription and takes it to a pharmacy for the medication, there have been situations reported when the collaborating physician is contacted rather than the prescribing CRNP, causing confusion, delay in treatment and unnecessary disruption to a physician who did not examine or recommend treatment for this patient.

For many of our CRNPs around the state, the collaborating physician is not always in the same practice site as the CRNP. Another concern raised by many members of our organization about this issue was the CRNP not receiving lab reports or test results in a timely or efficient fashion because they are filed under the collaborating physician rather than the ordering CRNP. In addition to causing a delay in patient care, this current requirement creates a vicarious liability to both parties whose name is on the prescription blank.

Many nurse practitioners have an excellent working relationship with their collaborating physician; they exchange information and expertise and are mutually supportive. The care provided in these relationships utilizes the best of each other's discipline when respect of each other's profession prevails and the goal is to provide excellent patient care.

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[4] National Council of State Boards of Nursing, (August 2008). APRN Model Act/Rules and Regulations Approved August 2008. Article XIX APRN Scope of Nursing Pracitice. Chapter Nineteen. Printed from www.ncsbn.org

21.284b. Prescribing, administering and dispensing controlled substances

This present regulatory restriction of three day prescriptions for Schedule II controlled substances, and 30 days for Schedule III and IV controlled substances is not supported by logic or objective research. Research has shown that NPs are more cautious in their prescriptive interventions and provide more teaching for patients than their physician colleagues, in addition to more non-pharmacotherapeutic interventions for their patients, and a tendency to recommend more over-the-counter medications[5]. As of January 2005, in 13 states and the District of Columbia, nurse practitioners were described as prescribing independent of any required physician involvement[6]. We are acutely aware of the risks of inappropriate use, dependence and diversion in prescribing these medications and research supports our sound clinical judgment in their appropriate use.

The limitation to prescribe adequate Schedule II medications to the patients we care for presents daily inconvenience and at times lack of access to necessary medication to manage acute and chronic needs of thousands of patients. Many of the commentators, including physicians, have noted that this particular restriction is time consuming, inconvenient for not only patients but physicians, and confusing to patients who can receive all of their other prescriptions from a nurse practitioner, but must have a physician sign for more than a three day dose of a Schedule II drug. If a physician is not available to write a full prescription for a Schedule II drug, then the nurse practitioner is forced to prescribe what often times is an insufficient course of treatment for the patients' needs. Frequently this causes delays in hospital discharges, unnecessary emergency room utilization for pain control, and a disruption in continuity of care.

Providing adequate pain management, treatment of debilitating anxiety, augmentation of seizure control and treatment for attention deficit are health care needs that nurse practitioners address routinely. The current barriers have caused unwarranted difficulty in getting patients the care they require and deserve. Given the geographic make-up of our state, with its large rural population, the reality of practice often finds the nurse practitioner the only provider on site. The current regulatory limitations create a barrier to care and an inconvenience to our patients.

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[5] Running A, Kipp C, & Mercer, V: Prescriptive patterns of nurse practitioners and physicians. Journal of the American Academy of Nurse Practitioners 2006; 18: 228-233.

[6] Phillips SJ. A comprehensive look at the legislative issues affecting advanced nursing practice. Nurse Pract. 2005; Jan; 30 (1): 14-47.

The increase of Schedule III and IV medications to a 90-day supply will allow us to support our patients to fully utilize the prescription benefit plans offered by their insurance companies. It is unacceptable that we have not been able to accommodate patients with this cost-saving benefit.

Again, there is no data to support that the proposed changes would negatively impact patients' safety. In states where these restrictions do not exist there have been no reports of inappropriate prescribing of controlled substances by CRNPs.

21.286. Identification of the CRNP

Nurse practitioners are proud to identify themselves as such whether they have a masters or doctoral degree. Verbally, we introduce ourselves as a nurse practitioner; CRNP is identified on name tags, as well as the title 'doctor' if applicable. Many health care professionals care for patients who are not physicians but hold a doctorate in their profession. It is a routine part of an initial visit to identify the discipline they represent and service they plan to provide. If patients require more detail the information is gladly offered, whether the health care professional is the psychologist consulting, the nurse anesthetist completing a pre-operative visit, or a nurse practitioner meeting a new patient for the first time.

We do not believe it is necessary for a CRNP who has a doctorate to announce that he or she is not a medical doctor or osteopathic physician. We support the regulations relating to this section as proposed.

Conclusion

Historically, Pennsylvania has been very slow to adopt change, as evidenced by being one of the last states in the nation to implement the prescriptive authority of nurse practitioners. Given the number of inadequately insured and the high rural population in our state, it is illogical to continue to restrict access to care by continuing to underutilize and restrict a profession that has been proven to provide high quality, cost effective care. Given our current national financial crisis, the number of underserved and inadequately insured is growing daily.

The comments made by medical organizations are suggesting questions of patient safety and quality of care if sufficient physician oversight, direction or supervision is not provided. However, there is no data backing up what they are suggesting. There are data that support that care provided by a nurse practitioner is equal to, and in some cases better than that of our physician colleagues. We depend on an objective review where decisions are based on fact, supported by research, and data from states whose nurse practitioners practice to their full scope of practice. Other professions should not be attempting to restrict and limit our scope of practice and use scare tactics to deter the general public from utilizing us as competent, compassionate providers of care. In this day and age of a significant shortage of both primary

care physicians and nurses, we should all be working together as a healthcare community to mobilize all the resources we have to improve the health and wellness of our state and country.

PCNP appreciates the opportunity to provide comments to the State Board of Nursing on its proposed CRNP regulations. If you have any questions about PCNP comments, please feel free to contact our Executive Director, Susan Schrand, at (215) 512-0011 or by email at sschrand@pacnp.org .

Sincerely,

Patricia Schwabenbauer MSN CRNP

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President
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Copy: Sen. Robert M. Tomlinson, Chair
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