PENNSYLVANIA ACADEMY
OF FAMILY PHYSICIANS

2729

RECEIVED
2008 DEC 11 PM 2:22
INDEPENDENT REGULATORY
REVIEW COMMISSION

December 5, 2008

Ms. Ann Steffanic, Board Administrator
State Board of Nursing
PO Box 2649
Harrisburg, PA 17105-2649

Re: Proposed Regulations #16A-5124 (CRNP General Revisions)

Dear Ms. Steffanic:

On behalf of the Pennsylvania Academy of Family Physicians (PAFP), I write to share some of our specific concerns and objections to the proposed regulations of the State Board of Nursing which intend to revise the scope of practice of certified registered nurse practitioners (CRNPs).

The PAFP represents over 4,700 members and over 75% of the practicing family physicians in the Commonwealth. Our members employ and work in collaboration with physician assistants (PAs), CRNPs and other allied health professionals in hospital settings and family physician offices throughout the Commonwealth. Together, these clinician teams strive to provide strong patient centered medical homes and serve as a continual source of care. Our family physician members report having very strong relationships with these clinicians under the current regulatory paradigm and continue to utilize their services in the primary care setting.

The PAFP has analyzed the proposed CRNP regulations against the criteria established by the Regulatory Review Act. This requires that the regulations must be consistent with the legislative intent; that they protect the public health, safety and welfare; and, that they are clear, feasible and reasonable. The PAFP believes that the proposed CRNP regulations, contrary to these required standards, deviate substantially from the legislative intent; would not protect the public health, safety and welfare; are not clear, feasible and reasonable; and require multiple revisions to adequately protect patients through the delivery of quality medical care.

Insufficient Definition of Collaboration

In §21.251 of the proposed regulations, the statutory definition of "collaboration" is not carried over to the regulations. Rather, the regulations have made a distinction between a written collaboration agreement required for prescriptive authority and simply an oral agreement which could govern all other aspects of the collaboration between a CRNP and

2704 Commerce Drive ■ Suite A ■ Harrisburg, PA 17110-9365

VOICE 717.564.5365 TOLL FREE 800.648.5623 FAX 717.564.4235 mail@pafp.com www.pafp.com

a physician. Accordingly, the act of diagnosing and treating a condition in any manner other than through prescription drugs could be done by a CRNP with nothing more than an oral understanding with a physician. In our opinion, this presents danger both to CRNPs and to physicians, and more importantly to patients, who cannot be fully apprised of the collaborative arrangement between the two if the agreement is not in written form.

Adding two new meanings to define "collaboration" and in effect ignoring the enacted definition, does not in our opinion meet the intent of the General Assembly, nor the spirit of Act 206 of 2002. The distinction drawn by the regulations is misleading at best and dangerous at worst. The definition for collaboration found in the statute should be reinserted in the definition section of the regulations; and, all collaborative agreements should be required to be in writing. All references throughout the regulatory draft should likewise be conformed to the statutory definition consistent with the legislative intent and for the protection of the public health, safety and welfare.

Overly Expansive Scope of Practice

§21.282a would be added to provide a list of medical examination, diagnosis and treatment tasks and functions that a CRNP may perform, many of which may exceed the education and training of CRNPs, and *without indicating that the tasks may only be performed in collaboration with a physician actively licensed to practice medicine in Pennsylvania.*

For example, in the first enumerated task, the regulations intend to permit the CRNP to "establish medical diagnoses." However, the law is clear that a CRNP can only make acts of medical diagnoses in collaboration with a physician.

The PAFP believes that this broad and all-inclusive list of medical functions is not in the best interest of the public health, safety and welfare nor is the regulation reasonable or clear in informing CRNPs, or anyone else reading the regulations, the limitation of their authority. The PAFP believes that the list should be deleted and left to the physician and nurse collaborative team and the written agreement between the two parties. At a minimum, the entire section needs to begin with the same language the General Assembly used in its enactment of Act 48 of 2007 that provides for specific physician collaboration. This referenced language is found in The Professional Nursing Law, § 8.2(c.1).

Prescribing and Dispensing Parameters

The PAFP does not believe that any changes in the prescribing and dispensing parameters in §21.284, are legally permissible unless and until the Board of Nursing

obtains prior approval from the statutorily created Drug Review Committee (DRC). The intent of the DRC was to prevent the Board of Nursing - with potentially a majority of board members that were not able to prescribe - from making decisions that were outside of their scope of practice. Modeled after the Ohio statute, the DRC was an attempt to have clinicians practicing in the field, provide the needed expertise to the Board of Nursing when it was considering changing the prescribing and dispensing parameters of CRNPs. To our knowledge, the DRC was never formed and never considered the proposed changes. Therefore, we do not believe that any changes to the existing prescribing regulations are permitted and the proposed changes should be reversed. Further, while some of the modifications may contain elements the PAFP can support, the fact that they defy the law make their policy merits moot. This is a clear matter of public health, safety and welfare.

Insufficient Limitations on Controlled Substance Prescribing

The proposed regulations would also eliminate most of the restrictions on CRNP scheduled drug prescribing found at §21.284 of the current regulations. Specifically, CRNPs would be able to issue a prescription for a Schedule II controlled substance for up to a 30-day dose and would not be required to notify the collaborating physician that the prescription was issued. Moreover, the CRNP could prescribe a Schedule III or IV controlled substance for up to 90 days with no limitations on refills and no notification to the collaborating physician.

Current regulations provide a defined timeline for notification of the collaborating physician as well as physician involvement in the diagnosis and treatment involving scheduled drugs. Indeed, language in the current regulations which provides for that involvement has been specifically deleted in the proposed regulations.

This is a dangerous departure from the intent of the General Assembly and from the protection of the public health, safety and welfare. The regulatory changes are inconsistent with regulations governing other mid-level practitioners including identical language found in the physician assistant regulations. The regulatory limitations applicable to mid-level practitioners should be applied to CRNP prescribing to assure public health and safety and reasonably clarify appropriate and necessary limitations based on the CRNP's level of medical training.

Elimination of Physician Notification and Review Requirements

Protections inherent in the collaborative arrangement between a physician and CRNP, including necessary physician involvement, have been eliminated in the proposed

regulations. By example, the requirements in current §21.284 for corrective actions by a physician necessitated by inappropriate prescribing by a CRNP have been eliminated and nowhere in the proposed regulations is there a requirement that a physician review the patient's chart within a reasonable period of time and co-sign the record when necessary to assure medical accountability to the patient as well as accurate diagnosis and treatment. This language is again identical to the regulations that govern the practice of physician assistants and should not be altered. The public health, safety and welfare require it.

Misleading Identification

The proposed regulation would delete most of §21.286 of the current regulations which provides that a patient be informed at the time of making an appointment that the patient will be seen by a CRNP; that the CRNP must wear a name tag clearly identifying the person as a certified registered nurse practitioner; and requiring a CRNP who holds a doctoral degree to assure that patients are informed the degree is not that of a doctor of medicine or doctor of osteopathic medicine.

The obvious purpose of the current regulation is to assure that the public is not misled into believing the health care provider who will be rendering care to him or her holds credentials of a medical doctor or osteopathic physician when in fact he or she does not. The removal of these provisions from the regulation will mislead the public and should be reinserted as a reasonable measure to assure the legislative intent that CRNPs may not in fact independently practice medicine and should not be misleading the public into believing that they may. All other mid-level practitioners, including psychologists, optometrists and chiropractors who by definition and training hold doctoral degrees, must clearly identify the degree so as not to mislead patients that they are medical doctors or doctors of osteopathic medicine. CRNPs must be held to the same standards. The current identification provisions are clear, reasonable and necessary to protect the public health, safety and welfare and must be retained.

Physician-CRNP Ratio Eliminated

Finally, the collaboration ratio whereby a physician may not collaborate with more than four CRNPs who prescribe and dispense drugs currently found at §21.287 of the regulations would be deleted in the proposed package. The removal of the ratio is clearly a public protection concern. While most physicians would not collaborate with more prescribing CRNPs than they would be comfortable, regulations must address those situations where bad practitioners would seek to exploit the collaboration relationship and ignore their responsibilities within its parameters.

Additionally, the current regulations provide for an exceptions process for good cause if there is a compelling reason why a medical practice would need additional leeway from the current ratio requirement. While there are proponents of the draft regulations that would eliminate the ratio requirement, we question whether any of those proponents' medical practices have requested an exception to the process? If they have applied and then were denied, what was the reasoning for the denial? If they have not applied for an exception, then how can they claim there is a problem in meeting the current regulatory requirements?

Further, the PAFP has analyzed the database of nurse practitioners which it purchased from the State Board of Nursing's database. This database did not differentiate between CRNPs who have prescribing rights and those who do not. However, it did reveal that in some counties in the state, for example - Bedford, Cameron, Clinton, Elk, Forest, Fulton, Huntington, Jefferson, Juniata, Mifflin, Perry, Pike, Potter, Snyder and Sullivan – there were between zero and 11 CRNPs in each county, regardless of their prescriptive authority. While again, there may be practices that can make a case for an exception to the current regulatory rule; based on the data we have analyzed, this is not the case in many rural areas of the state which have family physicians that are equal to in numbers, or more than the amount of CRNPs in many of those counties.

Thank you for your time and consideration of these comments. If you have any questions or concerns regarding these comments, please do not hesitate to contact Andy Sandusky at 800-648-5623 or asandusky@pafp.com.

Sincerely,

Bradley P. Fox, MD

PAFP President

Cc: Mr. Arthur Coccodrilli, Chairman, Independent Regulatory Review Commission
The Honorable Robert M. Tomlinson, Chair, Senate Consumer Protection and Professional Licensure Committee
The Honorable P. Michael Sturla, Chair, House Professional Licensure Committee