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INDEPENDENT REGULATORY REVIEW COMMISSION

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

January 7, 2009

Mary E. Bowen, R.N., C.R.N.P., Chairperson
State Board of Nursing
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5124 (IRRC #2729)
State Board of Nursing
Certified Registered Nurse Practitioners; General Provisions

Dear Chairperson Bowen:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. We will send a copy to the new Standing Committees when they are designated.

If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director

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Enclosure

cc: Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission



State Board of Nursing Regulation #16A-5124 (IRRC #2729)

Certified Registered Nurse Practitioners; General Provisions

January 7, 2009

We submit for your consideration the following comments on the proposed rulemaking published in the November 8, 2008 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Nursing (Board) to respond to all comments received from us or any other source.

1. Protection of the public health, safety and welfare.

This proposed regulation has generated interest from various members of the medical community and the general public. Those that support the proposal believe the amendments will increase access to health care for citizens of the Commonwealth and will allow certified registered nurse practitioners (CRNPs) to practice to the full extent of their education and training. Those that oppose the proposal believe certain amendments could jeopardize patient safety and quality of care.

We acknowledge that those who support and oppose the regulation raise many valid points to support their positions. While increased access to quality, affordable health care is a necessity, we believe it must be balanced with adequate protection of the public health, safety and welfare. The Preamble submitted with the proposed regulation describes many of the changes being made, but in some instances, does not adequately explain the rationale for all of the changes. Without this information, the Commission is unable to determine if the proposed regulation is in the public interest.

The remainder of our comments provides a more detailed analysis of the proposed regulation. However, as a preliminary matter, we ask the Board to further explain how the amendments adequately protect the public health, safety and welfare of the citizens of the Commonwealth. As noted by many of the commentators, including the House Professional Licensure Committee, the

following sections are of particular concern: § 21.251; § 21.282a; § 21.284; § 21.285; § 21.286 and § 21.287.

2. Section 21.251. Definitions. - Protection of the public health, safety and welfare; Implementation procedures; Reasonableness; Clarity.

“Collaborative agreement”

This new term is defined as, “The oral or written agreement between a CRNP and a collaborating physician in which they agree to the details of their collaboration.” We note the existing requirements for a collaborative agreement, found at § 21.285(a), require the collaborative agreement to be a signed, written agreement. While we are not questioning the Board’s authority to allow oral collaborative agreements, we do question the reasonableness of it. How could the Board ensure that a CRNP is acting within the specifications of a collaborative agreement if that agreement is not in writing?

“Direction”

This term closely mirrors the statutory definition of “collaboration” found in Section 2(12) the Professional Nursing Law (Law) (63 P.S. § 212(12)). However, it is being deleted from the Board’s regulations. This could give the regulated community the false impression that the specific provisions being deleted are no longer applicable. Beyond the Board’s contention that the definition is being deleted to “reflect changes made by Act 206,” why is this definition being deleted and how does this adequately protect the public health, safety and welfare?

If the Board concludes that the definition of “direction” is no longer needed, we ask that a cross-reference to the statutory definition of “collaboration” be added to the final-form regulation.

“Prescriptive authority collaborative agreement”

This term is defined as: “The written and signed agreement between a CRNP with prescriptive authority and a collaborating physician in which they agree to the details of their collaboration.” Section 8.3 of the Law (63 P.S. § 218.3) addresses prescriptive authority for CRNPs and provides greater detail of what must be in the written agreement. To improve clarity and assist the regulated community in complying with requirements of what must be in a “prescriptive authority collaborative agreement,” we recommend that the details found in Section 8.3(a)(2)(i)-(iii) of the Law be included in the regulation.

3. Section 21.273. Application for certification as a CRNP. - Clarity.

Subsections (a), (c) and (d) require an applicant to verify compliance with Section 8.7 of the Law (63 P.S. § 218.7), regarding professional liability coverage. However, the subsections do not specify the type of documentation that would be acceptable to verify compliance. We recommend that the types

of documents that could be supplied to the Board to verify compliance be included in the final-form regulation.

4. Section 21.282a. Medical examination, diagnosis and treatment. - Protection of the public health, safety and welfare; Implementation procedures; Clarity.

This section is being added to implement Section 8.2 of the Law (63 P.S. § 218.2), pertaining to scope of practice for CRNPs. A comparison of the Law to the regulation reveals several problems.

First, while the regulation may not directly conflict with the Law, it paints an incomplete picture of the statutory scope of practice requirements. Of particular concern is the fact that the Law requires a CRNP to practice within the scope of practice of his or her particular clinical specialty and may only perform acts of medical diagnosis in collaboration with a physician, but these provisions are not reflected in the regulation. We believe the regulated community would benefit from a regulation that more closely tracks the Law. If the Board decides to omit these two important provisions from the final-form regulation, we request a detailed explanation of why the provisions are being omitted and how the regulated community benefits from the omissions.

Second, the Law lists eight activities that a CRNP has the authority to perform. Some, but not all, of the activities are contained in the regulation. Similar to our concern above, the regulation paints an incomplete picture of the statute. While Subsection (i) does reference the authorized activities in the statute, we believe clarity would be improved if all eight activities contained in the Law were enumerated in the regulation.

In addition, we have identified concerns related to clarity. The phrase "other laws and regulations" found in Subsection (b) and the term "pharmaceutical treatments" found in Subsection (d) are vague. We recommend that the "laws and regulations" be identified and "pharmaceutical treatments" be defined in the final-form rulemaking.

5. Section 21.283. Authority and qualifications for prescribing and dispensing drugs and other medical and therapeutic or corrective measures. - Clarity.

Under Subsection (a), what is meant by the term "oral orders"? We recommend that this term be defined in the final form regulation.

6. Section 21.284. Prescribing and dispensing parameters. - Statutory authority; Protection of the public health, safety and welfare; Reasonableness; Clarity.

Categories of drugs

Section 8.4 of the Law (63 P.S. § 218.4) requires any proposed addition or deletion to the categories of drugs that CRNPs are authorized to prescribe,

pursuant to Board regulations, to be approved by the Drug Review Committee. Commentators contend that the changes being proposed by the Board would require approval by the Drug Review Committee and that approval was never obtained. However, the Board contends that it is not adding or deleting categories of drugs from which CRNPs may prescribe. In the Preamble to the final-form regulation, the Board should further explain why the changes it has proposed are not additions or deletions to the categories of drugs and why approval of the Drug Review Committee is not needed. We also recommend that the Board add a definition for the term “categories of drugs.” This would avoid further confusion if this section of the regulation is amended in the future.

Existing Subsection (d)

The Board proposes to delete the following language from the regulation:

If a collaborating physician determines that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately take corrective action on behalf of the patient and notify the patient of the reason for the action and advise the CRNP as soon as possible. This action shall be noted by the CRNP or the collaborating physician, or both, in the patient’s medical record.

Commentators representing the physician community believe this provision is needed to protect patient safety. We agree that the provision is important and recommend that it either be retained or a similar provision be mandated for any prescriptive authority collaborative agreements.

Revised Subsection (d)

Under Subsection (d)(1), the Board proposes to allow a CRNP to write a prescription for Schedule II controlled substances for up to a 30-day dose, instead of a 72-hour dose. The requirement that a CRNP notify the collaborating physician of the prescription is also being eliminated. Under Subsection (d)(2), the Board proposes to allow a CRNP to write a prescription for Schedule III or IV drug for 90 days, instead of 30 days. The requirement that the collaborating physician authorize any refills for Schedule III and IV drugs is also being eliminated. The Board contends that the amendments will allow consumers to utilize common insurance discounts for these categories of drugs, that the deletion of the notification requirement to the collaborating physician for Schedule II drugs eliminates unnecessary paperwork requirements, and the deletion of the provision related to authorization of refills eliminates duplicative health care efforts. As noted in our first comment pertaining to the protection of the public health, safety and welfare, we ask the Board to further explain why these amendments will not put the health of patients at risk. In particular, the Board should explain why it believes CRNPs have the appropriate education and training to administer these provisions, especially without oversight of a physician.

In addition, we ask the Board to consider the alternative language offered by some of the commentators pertaining to this subsection. For example, the Board should consider amending Subsection (d)(1) to allow for a seven-day dosage, with proper notification to the physician. This subsection could also include a provision that would allow for a 30-day dosage for on-going therapy as approved by a collaborating physician.

7. Section 21.284a. Prescribing and dispensing drugs. - Protection of the public health, safety and welfare; Clarity.

Subsection (b)(1) requires prescription blanks of CRNPs to identify the collaborating physician. The Preamble states that proposed regulation would allow a CRNPs prescription blank to omit the collaborating physician as long as the physician is identified on the prescription as finally written. The requirements, as described in the Preamble, are not reflected in the regulation. What is the Board's intention for this subsection? At minimum, we believe the name of the collaborating physician should be on the prescription as finally written. This would provide patients and other health care providers, such as pharmacists and emergency medical personnel, additional information if questions about a patient's care arose.

8. Section 21.285. - Prescriptive authority collaborative agreement. - Protection of the public health, safety and welfare; Reasonableness; Implementation procedures; Clarity.

According to the Board, this section is being amended to reflect requirements of Section 8.3(a)(2) of the Law (63 P.S. § 218.3(a)(2)). We are concerned with language that is being deleted from §§ 21.285 (a)(4) and (a)(6). Subsection (a)(4) deletes the requirement that the prescriptive authority collaborative agreement contain attestation by the collaborating physician that the physician has knowledge and experience with any drug the CRNP will prescribe. Subsection (a)(6) deletes the requirement that the prescriptive authority collaborative agreement specify the conditions under which the CRNP may prescribe a Schedule II controlled substance. Given the expanded prescriptive authority for CRNPs this rulemaking proposes, we believe §§ 21.285 (a)(4) and (a)(6) provide additional protection of the public health, safety and welfare and should be retained. If the Board persists in deleting these provisions, we ask the Board to further explain why it is in the public interest to delete these two sections.

In addition, we note that Subsection (a)(6) is being amended to limit access to a prescriptive authority collaborative agreement to any licensed pharmacist or pharmacy. What is the reason for this amendment? We believe the existing language that allows "anyone seeking to confirm the scope of practice of the CRNP" is more appropriate and would allow patients access to information they may need.

9. Section 21.286. Identification of the CRNP. - Protection of the public health, safety and welfare; Reasonableness.

This section currently requires: a patient to be informed at the time of making an appointment that the patient will be seen by a CNRP; a CRNP to wear a name tag that clearly identifies the CNRP with the title “certified registered nurse practitioner”; and a CRNP who holds a doctorate to take appropriate steps to inform patients that the CRNP is not a doctor of medicine or osteopathic medicine. The Board proposes to modify this section by only requiring a CRNP to wear a name tag using the title “CRNP” and to comply with state and federal facility regulations regarding identification of personnel. The Board contends that Pennsylvania Department of Health regulations provide appropriate identification requirements for licensed health care providers working at licensed facilities. We believe the current regulations of the Board provide more protection to the public and recommend that they be retained. Of particular concern are Subsection (a), which currently requires patients to be notified of the fact that they will be seen by a CRNP and Subsection (c), which requires CRNPs with a doctorate degree to inform patients that they are not medical doctors.

10. Section 21.287. Physician supervision. - Protection of the public health, safety and welfare; Reasonableness.

This section is being deleted from the Board’s regulations. It currently limits a physician to supervising no more than four CRNPS with prescriptive authority at a given time. While we understand the Board’s contention that the State Board of Medicine is the proper regulatory body to adopt regulations relating to the parameters of a physician’s practice, we are not certain that the deletion of this section serves the public. As noted several times above, given the expanded scope of practice for CRNPS that this proposal would provide, how can the Board ensure that the public health safety and welfare of patients is adequately protected if this section is deleted?

11. Section 21.288. CRNP standards of conduct. - Protection of the public health, safety and welfare; Reasonableness.

The House Professional Licensure Committee has suggested that in addition to the requirements of this section, CRNPs should be required to practice within the specifications set forth in the collaborative agreement. A similar concern is raised pertaining to § 21.351, pertaining to penalties for violation. We agree with the Committee and recommend that references to compliance with the collaborative agreement be added to the final-form regulation.

