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INDEPENDENT REGULATORY

SAINT VINCENT

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Arthur Coccodrilli
Chairman Independent Regulatory Review Commission
333 Market Street
Harrisburg, PA 17101
December 3, 2008

Dear Mr. Coccodrilli,

I am writing to express my concerns with the proposed changes in the Regulations regarding Certified Registered Nurse Practitioners (CRNPs) scope of practice as introduced by the Pennsylvania Board of Nursing on November 8, 2008.

There are seven specific issues with which I have concern. Below I will address each issue in kind.

First: The new recommendations do not have a sufficient definition of "Collaborative Agreement", Previously the General Assembly provided legal meaning for physicians and CRNPs to refer to when entering into such an agreement. It is as follows:
"a process in which a certified registered nurse practitioner works with one or more physicians to deliver health care services within the scope of the certified registered nurse practitioner's expertise. The process includes all of the following: (i) immediate availability of a licensed physician to a certified registered nurse practitioner through direct communications or by radio, telephone or telecommunications; (ii) a pre - determined plan for emergency services; and (iii) a physician available to a certified registered nurse practitioner on a regularly scheduled basis for referrals, review of the standards of medical practice incorporating consultation and chart review, drug and other medical protocols within the practice setting, periodic updating in medical diagnosis and therapeutics and co - signing records when necessary to document accountability by both parties."

The proposed regulations virtually ignore the enacted definition. This does not meet the original intent of the General Assembly, nor the spirit of the law, specifically Act 206. Also, the recommendations, by eliminating the need for a written collaborative agreement blurs the lines and can be misleading—it does not ensure the safety of the patient.

The definition of collaboration should be maintained and not eliminated, and all collaborative agreements should be in writing.

Second: The new recommended regulations allow for an overly expansive scope of practice for CRNPs,

Current law allows a CRNP to make medical diagnosis only in collaboration with a physician and in Act 48 of 2007 the General Assembly modified the CRNP scope of practice by enumerating 8 functions specifically that they may perform in collaboration with a physician.

The proposed regulations under §21.282a attempt to add another extremely broad 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.

This broad and all-inclusive list of medical functions allowed without a defined collaboration is clearly not in the best interest of the public health, safety and welfare. CRNPs need to practice within their education and training and the collaborative oversight of a physician is imperative to ensure the safety and quality of care. CRNP responsibilities should be agreed upon by the CRNP and the collaborating physician and put into their agreement, not written into law becoming practice rights. Finally, the regulation is not reasonable or clear in informing CRNPs, or anyone else reading the regulations, the limitation of a CRNP's authority.

The broad and all-inclusive list of medical functions needs to be eliminated, and the language from act 48 of 2007 should be reinstated ensuring physician collaboration.

Third: The recommendations for changes in Prescribing and Dispensing parameters eliminate current oversight as written into law. Current law requires that the Board of Nursing "shall not change by addition, or deletion, the categories of authorized drugs without prior approval of the Drug Review Committee." The Drug Review Committee (DRC) was to prevent the Board of Nursing from making decisions outside of their scope of practice. To date, I am unaware whether the Drug Review Committee has even been formed.

The proposed regulatory changes—some of which may have merit—ignore the DRC, and the safeguard provided by such oversight. No categories of medication that a CRNP may prescribe or dispense should be changed without approval of the DRC, and thus the proposed changes in the regulations should be deleted.

Fourth: The proposed limits on prescribing controlled substances have insufficient limitations.

Subject to the terms of the collaborative agreement, the current regulatory law permits a CRNP to write a Schedule II controlled substance for up to a 72 hour dose and notify the physician within 24 hours. The CRNP can also write a prescription for a Schedule III or IV controlled substance for up to 30 days and any refills must be approved by the collaborating physician.

As above, the DRC should have oversight and approval of any prescribing regulations. The proposed changes recommended by the board of nursing—without any input from a DRC—would delete the 72 hour current requirement for Schedule II controlled substances and physician notification requirement and replace it with a flat 30 - day authorization. The Board of Nursing also intends to eliminate the 30 day requirement and any physician oversight when a CRNP is prescribing a schedule III or IV controlled substance and replace is with a 90 day authorization which may be followed with refills without physician consultation. This has problems on several levels.

The current regulations mirror those of the Physician Assistants and there is no reason why CRNPs should have a looser restriction. The 72 hour dose allows for weekend coverage and

emergency prescribing where the collaborative physician will have the ability to ensure that the prescribed medications are appropriate and safe. As far as Schedule III or Schedule IV controlled substances, there are rare circumstances where physicians would write a prescription for more than thirty days and to say that there would be a situation where a CRNP would need to write a Schedule III or Schedule IV medication for more than 30 days is taking things to an extreme.

The regulations should not change the existing patient safety measures as are currently in place.

Fifth: The proposed changes eliminate the mandatory physician notification and review of CRNP actions.

Current regulatory law requires a physician who is collaborating with a CRNP to take corrective action on behalf of the patient if the CRNP is prescribing or dispensing inappropriately. In §21.284, the draft regulations propose to eliminate these protections in their entirety. Also, current language mirrors the language in Physician Assistant regulations.

It is obvious that it is not in the best interest of patient safety to eliminate these requirements. The regulations should not be changed.

Sixth: The proposed changes eliminate the requirement that a CRNP properly identify themself as a CRNP when they are seeing patients protecting the patient. Transparency is a very important initiative—right now there is an issue with transparency within health care and we are looking to ensure for proper identification of all healthcare providers whether they be Medical Doctors, Doctors of Osteopathy, Chiropractors , Doctors of Pharmacy, CRNPs, Physician Assistants and all others who take part in caring for patients—and while we are looking to the legislature to enact regulations requiring identification badges to ensure patient safety, these proposals are looking to move in the other direction.

The proposed deletion should not be enacted and current regulations should stay in place.

Seventh: There currently is a 1:4 ratio between Physicians and CRNPs. The proposed changes would eliminate this in its entirety. This is clearly not in the best interest of patient safety. As physicians, it can be taxing to appropriately supervise 4 CRNPs. To eliminate the 1:4 ratio could put a physician in a position to attempt to supervise more CRNPs than would be safe. This limit was carefully thought out when first enacted and should be left intact.

I would be happy to discuss these issues with you personally at any time. You can contact me at the above phone number, by e-mail at bfox@svhs.org, or by cell phone at 814-746-6313. Thank you for your time.

Respectfully,

Bradley P. Fox, M.D.