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EMBARGOED MATERIAL

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REPLY TO: ☐ DISTRICT ☑ HARRISBURG

Majority Caucus Secretary

Senate of Pennsylvania

COMMITTEES

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July 12, 2000

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

Dear Mr. McGinley:

I am concerned about a regulation that will be considered by your committee at tomorrow's public hearing. It is regulations promulgated jointly at 16A-499 by the Nursing and Medical Boards regarding Certified Registered Nurse Practitioners ("CRNPs").

Initially I wrote to the Secretary of State on behalf of my constituent, Maureen Glendon. Ms. Glendon who resides in my senatorial district is a pediatric Nurse Practitioner at a local Catholic high school. I believe her letter outlines her overall concerns about these regulations. I have enclosed copies of her letter and the Secretary's response for your review.

Even after the Secretary's response I remain concerned about whether they satisfy the requirements of the Independent Regulatory Act -- are they clear in their intent and reasonable? Most importantly is there law that permits these regulations to be promulgated?

The Secretary agrees that the purpose of the regulations is to give CRNPs the authority to prescribe drugs within specified parameters. Why then does the regulation provide a requirement about non-prescribing CRNPs, such as an agreement and disclosure requirements? This appears to go farther than the intended scope.

In addition, the boards created a continuing education requirement for prescribing CRNPs. I couldn't find a law that permitted this to be required. The issue of continuing education is hotly debated in any licensing bill, normally negotiated in any reform measure to improve the standards of a profession. It is my view that it is something that should continue to be decided in the General Assembly and not through the regulatory process.

Thank you for your consideration of my concerns.

Warm regards,

Frank A. Salvatore

FAS/maw
Enclosures

COPY

3417 Rhawn Street
Phila., PA 19136
June 13, 2000

Senator Hank Salvatore
3330 Grant Avenue
Phila., PA

Dear Senator Salvatore,

I am a Pediatric Nurse Practitioner living in your district. I work for the Philadelphia School District at Archbishop Ryan High School, and I provide patient care for 1400 students. As you may know, the Certified Registered Nurse Practitioner (CRNP) regulations were recently voted upon by the Board of Nursing. I urge you to contact the Independent Regulatory Review Commission to ask them to disapprove the amendment to the CRNP regulations. I am aware of the vast amount of attention and effort on the Board's part that went into the negotiation of the amendment. However, I have grave concerns about the effects that these regulations may have on access to essential health care for citizens of Pennsylvania. I strongly urge the IRRC to disapprove the regulations based on the following four issues that are critical to the health, safety, and welfare of the citizens of the Commonwealth:

1. Ensure access to care by eliminating the 2 CRNP: 1 physician ratio.

The ratio limitation is a substantive change that was added after the close of the October 1999 public comment period on the proposed regulations. Stakeholders and the public have had no opportunity to comment on this most limiting and arbitrary aspect of the regulations. When objections to the ratio were raised on 3/15/00 by members of the Board of Nursing and the Board of Medicine, comments by the Chair of the Board of Medicine and the Physician General that supported the ratio focused on hypothetical and undocumented abuses of CRNPs by physicians. There are only two other states known to have ratios--New York and Colorado. The ratio in both is 5 NPs: 1 physician.

2. Allow summation of advanced pharmacology hours to credit a total of 45 hours. A 45-hour course was not specified in the proposed regulations

Practice Nurse] as a competent provider, it is odd indeed to condition practice upon the agreement or permission of a private individual...Any state that adopts such a mechanism has in effect yielded its governmental power to one private individual, the physician...At worst, [such schemes] constitute a wholesale privatization of a core governmental function: assessing competence for licensed practice." (p. 452) [Safreit, B.J. (1992). Health care dollars and regulatory sense: The role of advanced practice nursing. Yale Journal on Regulation, 9, 417-490.]

Thank you for your attention to these concerns. Please ask IRRC to disapprove the regulations as they are written and return them to the Boards for further negotiation and collaboration with the regulated community. It is essential for the Board of Nursing to represent the interests of our profession in its role to protect the health, safety, and welfare of Pennsylvania citizens. Please contact me if you would like further information.

Sincerely,

Maureen P. Glendon

Maureen P. Glendon MSN, RNCS, CRNP
Pediatric Nurse Practitioner
215-333-7115
Email Mo6973@aol.com

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
HARRISBURG, PENNSYLVANIA
17120

SECRETARY OF THE COMMONWEALTH

COPY

July 6, 2000

The Honorable Frank A. Salvatore
Senate Box 203005
Harrisburg, PA 17120-3005

RE: Response to Maureen P. Glendon's Letter Concerning Prescriptive Authority for Certified Registered Nurse Practitioners - Expanding the Scope of Practice Without Impacting Current Practice

Dear Senator Salvatore:

Thank you for your letter dated June 20, 2000, which you wrote on behalf of your constituent, Maureen P. Glendon, a pediatric nurse practitioner. Ms. Glendon expressed concern about the effect of the Certified Registered Nurse Practitioner (CRNP) prescriptive authority regulations on access to essential health care for citizens in the Commonwealth. Ms. Glendon strongly urged that the regulations be disapproved. Ms. Glendon specifically did not approve of the two CRNPs to one physician ratio; the 45 hour course requirement; and the restrictions on some of the drugs from American Hospital Formulary. Ms. Glendon also expressed the belief that the statutory Board authority over CRNP acts of medical prescription was shifted to collaborating physicians.

Ms. Glendon's concerns appear to rely on two premises: (1) that the revisions made to the proposed regulations require further public comment, and (2) that the regulations will restrict the practice of CRNPs and thus, result in reduced access health care for the citizens in the Commonwealth. These premises are incorrect.

1. The revisions to the regulations do not enlarge the purpose of the proposed regulations and thus, conform to the Commonwealth Documents Law.

The purpose of the CRNP prescriptive authority regulations is to give CRNPs the authority to prescribe drugs within specified parameters. Currently, CRNPs are advanced practice registered nurses who work in collaboration with and under the direction of a physician to perform acts of medical diagnosis and prescribe medical, therapeutic, or corrective measures. Pre-draft copies of the regulations were sent to stakeholders, and over 300 comments were received. Revisions were made based upon these comments, and then proposed rulemaking was published. Following publication of proposed rulemaking, the State Board of Nursing (SBON) and the State Board of Medicine (SBOM) received over 600 comments from the Senate Committee on Consumer Protection

and Professional Licensure (Senate), the House Committee on Professional Licensure (House), the Independent Regulatory Review Commission (IRRC), and numerous groups, associations, consumers, and individuals. The SBON and SBOM carefully considered all the comments and made well-reasoned revisions which did not enlarge the original purpose of proposed rulemaking. The revisions refined and clarified the parameters within which CRNPs will be authorized to prescribe drugs. This means that the revisions were made in accordance with Section 202 of the Commonwealth Documents Law, Act of July 31, 1968, P.L. 769, No. 240, as amended, 45 P.S. §1202, and additional public comment is not required before the regulations are published as final rulemaking.

2. The regulations broaden the practice of CRNPs, do not restrict current practice, and increase access to health care.

The regulations broaden the practice of CRNPs by giving them prescriptive authority in accordance with the regulations and thus, increase access to health care for the citizens of the Commonwealth. The revised regulations do not restrict the current practice of CRNPs. CRNPs who do not want to prescribe drugs may continue to practice the same way they have always practiced after these regulations are published as final. CRNPs who want to broaden their practice by prescribing drugs will not have the unlimited authority of physicians to prescribe but will have authority to prescribe drugs within the parameters specified for this new practice area.

a. The ratio of two CRNPs to one physician, which pertains only to prescriptive authority, and the opportunity for a physician to request a waiver of the ratio are appropriate safeguards.

Ms. Gendon's letter urged eliminating the two CRNPs to one physician (2:1) ratio because she believed that the 2:1 ration was limiting and arbitrary. The SBOM clarified at its April 25, 2000, meeting that the 2:1 ratio pertains only to CRNPs with prescriptive authority. The 2:1 ratio does not impact current practice. For example, a physician who supervises and collaborates with five CRNPs who do not have prescriptive authority may continue to supervise and collaborate with them. If two of the five supervised nurse practitioners obtain prescriptive authority, that would also be allowed under the regulations. Thus, access to healthcare is increased under the regulations.

The 2:1 ratio has a waiver provision whereby a physician may request a waiver in order to supervise more than two CRNPs with prescriptive authority. For example, if a physician supervises five CRNPs, and all five CRNPs want to prescribe drugs, then the physician must apply for a waiver. The physician applies for the waiver because the physician is in the best position to know how many CRNPs he or she can appropriately supervise. The physician is also in the best position to objectively evaluate the skill, training and ability of the collaborating CRNPs and determine how much supervision they require. Further, as noted above, giving CRNPs prescriptive authority, even with restrictions, increases access to health care because there is no impact on current practice.

The 2:1 ratio is not arbitrary. Prescribing drugs is a new practice area for CRNPs, and the 2:1 ratio is a proven start point that has been used successfully with respect to physician assistants

with prescriptive authority and doctors. It is important to note that CRNPs, in general, have a much broader scope of practice than physician assistants and therefore, would be more difficult to supervise in their new practice area. The 2:1 ratio for prescriptive authority is an appropriate ratio which has been proven effective in protecting the health, safety and welfare of the citizens of the Commonwealth. Additionally, states without ratios have other safeguards built into their regulatory framework. For example, Delaware does not allow CRNPs to prescribe refills (the Pennsylvania regulations do allow refills); Ohio and West Virginia forbid CRNPs to prescribe Schedule II drugs (the Pennsylvania regulations allow Schedule II drugs to be prescribed for 72 hours); Ohio allows CRNPs to prescribe Schedule III, IV, and V drugs for 72 hours with no refills (the Pennsylvania regulations allows Schedule III and IV drugs to be prescribed for 30 days and refills may be authorized in the collaborative agreement). The 2:1 ratio is an appropriate safeguard within Pennsylvania's regulatory framework.

The purpose of the CRNP prescriptive authority regulations is to give CRNPs the authority to prescribe drugs within specified parameters. The 2:1 ratio is a prudent safeguard which allows prescribing CRNPs even greater prescriptive authority than in some surrounding states. Please note that access to health care without a method to insure that quality care is being delivered would be detrimental to the health safety and welfare to the citizens of the Commonwealth. The 2:1 ratio and the waiver provision insures that quality health care is being delivered in this new practice area for CRNPs.

b. The separate 45-hour course is appropriate and reasonable.

Ms. Glendon's letter expressed concern about a separate 45-hour, or three credit course, in advanced pharmacology. She stated that the 45-hour requirement "was not specified in the proposed regulations published for public comment, nor in the comments from the Independent Regulatory Review Commission, nor in the written comments of the Pennsylvania Medical Society," and that the 45-hour requirement was arbitrary. It is important to note that both Boards received over 600 comments. Many commentators, including IRRC, requested that the course requirements be specified. The Pennsylvania Academy of Family Physicians recommended a 50-hour course.

Currently, at least 21 states require a separate and distinct course in pharmacology. Separate and distinct courses are recommended by both the National Council of State Boards of Nursing (NCSBN) and the National Organization of Nurse Practitioner Faculties (NONPF) in their *1998 Summary Report, Curriculum Guidelines & Regulatory Criteria for Family Nurse Practitioners Seeking Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care* (Summary Report). The Summary Report specifically recommends 45 contact hours, or three credit hours, over the course of a semester. Since at least 1992, all CRNP programs approved by the SBON have included a separate 45-hour, or three credit, course. Clearly the 45-hour requirement was not arbitrary.

There are approximately 4,667 CRNPs in Pennsylvania. The SBON estimates that approximately 1, 888 CRNPs would be required to take a 45-hour course, if they wanted to prescribe drugs. If they do not want to prescribe drugs, they would not be required to take the course. For

the CRNPs who want to prescribe drugs, Ms. Geldon has estimated that the cost of a 45 hour pharmacology course would be $5,000.00, including time away from work, however, she did not give support for this estimate. The SBON has estimated that the cost of a 45-hour course is between $630.00 and $1,875 for tuition depending upon the educational institution.

Ms. Geldon's letter accurately stated that CRNPs have been safely practicing for years. However, it is important to note that no matter how safe their practice has been, they have not been prescribing drugs. Prescriptive authority is a new practice area for CRNPs. Therefore, based upon the current SBON practice for CRNP program approval, the current practice of 21 states, and the recommendation of the NCSBN, in addition to numerous commentators, the SBON and the SBOM believe that a separate 45-hour, or three credit, course is appropriate and reasonable.

c. The language in the American Hospital Formulary is used for each drug category.

Ms. Geldon's letter suggested that the language in the American Hospital Formulary should be used for each drug category. The language in the American Hospital Forumulary has been used for each drug category. She also noted that the SBON voted on March 30, 2000, to approve the final regulations if some missing categories of drugs were added to the regulations. The Boards have approved the following revisions in final rulemaking: eye, ear, nose and throat preparations and hormones and synthetic substitutes were added to the list of drugs that may be prescribed as long as they are specified in the collaborative agreement. Unclassified therapeutic agents and devices and pharmaceutical aides were added to the list of drugs that may be prescribed as long as they are specified in the collaborative and if they are originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy. Oxytocics were not added. Please note that the addition of these categories of drugs further opens up this new practice area for CRNPs.

d. CRNPs are jointly regulated by the SBON and the SBOM, and the regulations do not partition liability.

Ms. Geldon's letter stated that the Board should maintain the "statutory board authority over CRNP acts of medical prescription instead of shifting to an individual collaborating physician the authorization to identify drug categories that the CRNP may prescribe and dispense." In support of her statement, Ms. Geldon quoted an article written by Barbara Safreit which pertains to the regulation of advanced practice nursing, and postulates that advanced practice nurses should not have physician oversight. The article is inapplicable. The article is about the economics of the healthcare system and the utilization of advanced practice nurses. It is not about protecting the heath, safety and welfare of the citizens of Pennsylvania while giving CRNPs the authority to prescribe drugs. Additionally, the article presents an argument and advocates a position. It does not present a balanced perspective.

It is important to note that CRNPs are jointly regulated by the SBON and SBOM. No statutory authority is abrogated by either Board. Indeed, abrogation of either Board's statutory authority would require an act of the Legislature. It appears that Ms. Geldon is concerned about responsibility and liability for physicians. Regulations and liability are two separate and distinct

issues. These regulations do not and cannot assign civil liability. Having a particular regulation does not make someone automatically civilly liable for something that happens. Liability is heavily fact specific and depends upon what happened in a particular situation.

Finally, Ms. Geldon's letter states, "It is essential for the State Board of Nursing to represent the interest of our profession as they protect the health, safety and welfare of Pennsylvania citizens." The SBON regulates the nursing profession to protect the health, safety and welfare of Pennsylvania citizens. The Board does not represent the interests of professional associations, special interests or groups. The SBON uses its knowledge and expertise to protect the health, safety and welfare of Pennsylvania citizens.

In conclusion, these regulations broaden the practice of CRNPs in Pennsylvania and thus, increase access to health care for citizens in the Commonwealth. The revisions to these regulations do not enlarge the original purpose of the proposed regulations. These regulations represent a successful collaboration of the SBON and SBOM to establish prescriptive authority for CRNPs. These regulations will increase access to health care without placing the health, safety and welfare of the citizens of the Commonwealth in jeopardy.

If you have any additional questions regarding these regulations, please do not hesitate to contact Jeff Cox, Legislative Liaison or myself.

Sincerely,

Kim Pizzingrilli
Secretary of the Commonwealth

KP/CMW/rc/bls

cc: Jeff Cox, Legislative Liaison
Robert C. Nyce, IRRC Executive Director
C. Michael Weaver, Deputy Secretary for Regulatory Programs
Dorothy Childress, Commissioner