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PENNSYLVANIA ACADEMY
OF FAMILY PHYSICIANS

October 13, 2009

Arthur Coccodrilli, Chair
Pennsylvania Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101

Re: Regulation Number: 16A-5124

Dear Mr. Coccodrilli:

On behalf of the over 4,700 members of the Pennsylvania Academy of Family Physicians (PAFP), I write to provide our feedback and analysis of regulation number 16A-5124, which was recently submitted in its regulatory final form by the State Board of Nursing (Board) dealing with certified registered nurse practitioner (CRNP) regulatory revisions.

In the first draft regulation of 16A-5124 as proposed, the PAFP provided its careful thoughts and concerning comments to the Board. Our comments continue to be rooted in the necessity for patient safety but also with the real understanding that regulatory revisions are needed in order to bring them in line with the overriding statute in The Professional Nursing Law. As a result, we are pleased with some of the changes that are reflected in these final proposed regulations. However, we are equally disappointed in other sections of the final form regulations that lack revision from their proposed draft because of the potential negative impact in some medical settings in the Commonwealth.

In §21.251, the PAFP is pleased that the statutory definition of "collaboration" was carried over from The Professional Nursing Law and included in this final form regulation. We do remain skeptical as to why the Board chose to retain two definitions that are identical to one another as is the case with "collaborative agreement" and "prescriptive collaborative agreement." In our opinion there is little policy merit to this decision.

In §21.282a, the PAFP is pleased that the final form regulations follow the statute by including the physician collaboration requirement when the enumerated functions are being performed by a CRNP. We do question why the statute permits a CRNP to "perform" acts of medical diagnosis and the regulations state that the CRNP can "establish" acts of medical diagnosis. While this may seem on the surface to be benign, it may in fact cause confusion in practice. Or worse, be construed to have a meaning below, or beyond what was intended by the statute.

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In §21.284, the PAFP believes that the law with regards to the Drug Review Committee (DRC) has been circumvented by the Board. The policy intent of the DRC was to have clinicians – CRNPs, pharmacists and physicians - practicing in the field, provide the needed expertise to the Board when it was considering changing the prescribing and dispensing parameters of CRNPs. In its preamble to these final form regulations, the Board states that they "proposed to the Drug Review Committee to amend the regulations". We ask how this could happen when the DRC entity was never formed?

Unfortunately we are not convinced that a letter to the Department of Health by the Board, which in turn was apparently not acted upon, could somehow satisfy the law which requires that the "Drug Review Committee" act, or fail to act. Nowhere does it state that a unilateral decision by the Department of Health could substitute or fulfill the legal responsibilities of, and for, the DRC. While these points appear to be legally moot for the time being, it stands as evidence in our opinion that at a minimum, the firm public policy intent of the General Assembly in this case has been sidestepped, or otherwise ignored.

On page 4 of the October 21, 2008 preamble section of the proposed regulations, the Board stated with regards to its intent in §21.284(d): "The Board proposes to delete subsection (d), which regulates the collaborating physician and allows the State Board of Medicine to regulate physicians." This subsection deletes an accountability component that serves as a check and balance between the collaborating physician and CRNP. We are hopeful that the Board will not prove resistant in the event that the State Board of Medicine proposes future regulation of physicians in a similar path under its regulatory authority. Our same rational holds true for the deletion of §21.287. This is especially true since this existing subsection has a built-in exceptions process with regards to the collaboration ratio requirements that to our understanding has never been triggered and no exceptions have been requested.

In §21.284(e), the PAFP is pleased that the final regulation includes language that references the collaborative agreement with regards to prescribing Schedule II-IV prescription drugs. However, we remain concerned that the amended and elongated timeframes permitted by a CRNP to prescribe these powerful drugs is too long for many family physician practice settings throughout the state.

In sum, while the PAFP is somewhat pleased with a few of the changes in the regulations we would have liked to see more thoughtful draft revisions regarding our commentary and that of the House Professional Licensure Committee and the Independent Regulatory Review Commission. Notwithstanding our concerns contained herein, the PAFP neither supports nor opposes the regulations.

Sincerely,

Madalyn Schaefgen, MD
PAFP President

CC: The Honorable Robert M. Tomlinson, Republican Chair - Senate Consumer Protection and Professional Licensure Committee
The Honorable Lisa Boscola, Democratic Chair – Senate Consumer Protection and Professional Licensure Committee
The Honorable Michael Patrick McGeehan, Democratic Chair – House Professional Licensure Committee
The Honorable William F. Adolph, Jr., Republican Chair – House Professional Licensure Committee