PENNSYLVANIA
society of
ANESTHESIOLOGISTS

Physicians Protecting Patients.

2729

December 3, 2008

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

Re: *State Board of Nursing, Regulation 16A-5124*
Certified Registered Nurse Practitioners

Dear Ms. Steffanic:

As a practicing anesthesiologist and as the President of the 1300 member Pennsylvania Society of Anesthesiologists ("PSA"), I offer the following comments on proposed regulations from the Board of Nursing concerning Certified Registered Nurse Practitioners ("CRNPs").

As background, anesthesiologists interact with CRNPs in two distinct settings. First, CRNPs work in preoperative evaluation clinics, in which anesthesiologists see surgical patients in preparation for surgery. In this context, CRNPs commonly take a preoperative surgical history from the patient and perform physical examinations, at and under the direction of anesthesiologists. Anesthesiologists perform the preoperative anesthesia evaluation, discuss the contemplated anesthetic plan, and obtain patient consent to care. Second, some anesthesiologists practice in the specialty of pain medicine, typically in an out-patient office setting. Increasingly, CRNPs work as member of the patient care team in that setting. In this patient care setting, patients often are prescribed Schedule II drugs.

Separately, anesthesiologists have a long history of working with non-physician health care providers, in particular CRNAs, as part of an anesthesia care team. In hospitals and ASFs, licensing regulations require CRNAs to work under physician (and usually anesthesiologist) supervision. The structure of the typical anesthesia care team – one anesthesiologist supervising CRNAs or medical residents in 2-3 operating rooms – has worked exceedingly well in insuring that physician expertise is immediately available when needed so that patients receive high-quality, safe care. When the Legislature considered a bill to expand a CRNA's scope of practice from working under an anesthesiologist's "supervision" to "collaboration" with non-anesthesiologist physicians, a concept that was akin to independent practice for CRNAs, we strongly and successfully expressed our opposition. We believed and believe that patient safety was at issue in that proposed expansion. We believe that physician involvement must be maintained at critical junctures in care. We carry those views to this context.

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These experiences lead to PSA's central position: CRNPs should practice only under established relationships with physicians who know the area in which the CRNP is practicing and in ways that permit and facilitate active supervision at important points. We believe that the regulations weaken the present rules in many areas pertinent to that concern. We detail our primary concerns below:

Collaboration Issues

1. In many places throughout, the amendments support what appears to be independent or near-independent practice by CRNPs. But the statute requires physicians and CRNPs to interact in multiple ways, ranging from "immediate availability ... through direct communications or by radio, telephone or telecommunications" to "chart review." Beyond being required, these interactions are appropriate to make sure that CRNPs do not get beyond their depth, do not make repeated errors, and are up-to-date on changes in practice. These various forms of supervision/review should be added into the proposed regulations, or, more accurately, that language under the definition of "direction" in the present regulations should be maintained. More specifically, either the statutory definition of "collaboration" should be added to § 21.251, or § 21.285, which used to address "collaborative agreements" and has now been essentially gutted, should be restored.

2. It is critically important that a collaborating physician actively practice in the CRNP's specific area of practice and have experience with the medications the CRNP is authorized to prescribe. Absent that, the various forms of supervision and review become meaningless. That "knowledge and experience requirement" is in the existing regulations and its deletion in new § 21.287(5) should be reversed.

Prescription Issues re Schedule II Drugs

Pain management in general, and the use of opioid medications for pain relief in particular, require more training and knowledge than CRNPs typically have or can be expected to have. Pain management is rarely an established subject area for CRNP specialized training. CRNPs have a constructive role to play as physician extenders in pain management, but doing so successfully requires physician involvement of a kind the regulations do not now require.

We believe that the expansion of a CRNP's authority to prescribe Schedule II medications should be more gradual than is currently proposed; that it should be limited to maintenance prescribing rather than the initiation of treatment; and that physician involvement throughout the patient's treatment with these medications is necessary. The proposed expansion in Schedule II prescriptive authority – from 72 hours to 30 days – is substantial, particularly so for a new prescription, and particularly when the requirement to provide notice to the collaborating physician is being deleted and physician oversight substantially reduced. We support a more modest increase in prescriptive authority and reinstatement of the requirement that the CRNP notify the collaborating physician in a timely manner.

Schedule II drugs used in pain medication are primarily opioids, such as hydrocodone (Vicodan®), morphine, oxycodone (Percocet® and OxyContin®), and meperidine (Demerol®).

All have a high potential for addiction or dependence, are highly susceptible to patient abuse and illegal diversion, and can result in severe adverse reactions and other complications affecting major body systems, even when prescribed appropriately.

In pain medicine, opioids are used to treat chronic pain, which comes in two main varieties: (1) chronic cancer pain, and (2) chronic non-cancer pain, usually caused by some skeletal, muscular, or nerve problem. In the latter category, many patients come on referral with established diagnoses, but others do not. In that event, pain treatment seeks to determine the underlying causes for the pain complaints.

For cancer patients, pain management typically implies end-of-life care with an advanced cancer. Dosage escalations for pain relief in that context are expected and predictable based upon disease progression; a patient's complaint of breakthrough pain and a request for additional medication are relatively easy to assess as legitimate, not a sign of addiction.

Treatment of non-cancer patients is quite different. The condition causing the pain is typically not life-threatening, and the disease's progression is neither inevitable nor easy to determine. Distinguishing between genuine requests of breakthrough pain, whether from progression of the disease or from patient tolerance to the medication, from requests that are indicative of an addiction, can be difficult. Management of dosing schedules is both more difficult and has more implications in this group than in non-cancer patients.

Patients with chronic pain are often medically complex. As the population ages, pain patients more commonly have multiple health care problems that complicate medication management. Opioids, separate from their addictive qualities, present a risk of side effects, including itching, nausea, increased appetite with weight gain, constipation, and respiratory depression. They also present subtler effects, such as weight gain leading to complications with existing co-morbidities (*e.g.*, sleep apnea, arthritis, degenerative spine conditions, muscular strains). There is emerging evidence of neuroendocrine effects, with disruptions in testosterone and estrogen levels, thyroid function, and loss of muscle mass. There are also the issues of dependence, addiction, and diversion. These issues require insight, judgment, and experience. The most challenging aspect of prescribing opioids for non-malignant conditions is the threshold decision as to which patients are good candidates for that course of treatment and which are not.

Opioid therapy should be part of an integrated course of care that includes non-opioid medication management, interventional therapy, activating physical therapy, and cognitive-behavioral therapy. Integrated interdisciplinary pain care requires active participation by a qualified physician, and should only be done by health care team in which the members work in close collaboration. The physician's involvement must be patient-specific, and not merely documentation of a cooperative agreement.

As this discussion suggests, pain medicine requires use of very powerful drugs that pose substantial risks of harm, both in terms of side effects but more so in terms of addiction and its sequella. Prescribing opioids successfully for other than a short-term basis for an acute episode of pain (*e.g.*, post surgery) must be done carefully and with a sophisticated understanding of the risks, benefits, and alternatives. This is particularly true in treating chronic non-cancer pain.

With that extensive background, we offer the following specific recommendations:

- The expanded 30 day prescription period is acceptable for drug maintenance but not for initial diagnosis and prescription. The initial prescription of a Schedule II medication is, in many instances, an important medical event, with potentially serious consequences. It should be made by a physician.

- For these same reasons, any meaningful increases in dosing should be made only by a physician or by a CRNP in consultation with a physician. This is particularly so for treatment of chronic non-cancer pain patients. We realize that defining a "meaningful increase" can be difficult. PSA is willing to work with the Board to flesh out that concept.

- CRNPs should be required to advise their collaborating physicians promptly of all prescription refills.

- CRNPs should not be permitted to issue "do not fill before" prescriptions for Schedule II drugs. These allow CRNPs to write prescriptions for longer periods of time that the sensible limitations discussed in this letter.

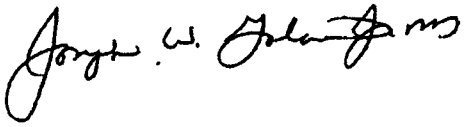
Miscellaneous Issues

1. Increasingly, CRNPs, as well as CRNAs, are receiving doctorate level degrees. While they thereby have the right to refer to themselves as "Dr.", they are not medical doctors. It is important that patients understand the difference in the credentials of the person who is treating them. Thus, it is important that a CRNP who is introduced or held out as "Dr." take appropriate steps to inform a patient that s/he is not a doctor of medicine or osteopathic medicine. The current regulations, § 21.286(c), require that and the requirement should be reinstated.

2. We believe that the collaborating agreement between the physician and CRNP should be in writing in all cases.

Thank you for your consideration of our concerns and comments.

Sincerely,



Joseph W. Galassi, Jr., M.D.

cc: Arthur Coccodrilli
Hon. P. Michael Sturla
Hon. Robert M. Tomlinson