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INDEPENDENT REGULATORY
REVIEW COMMISSION

Pennsylvania Medical Society

2729

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November 25, 2008

Ms. Ann Steffanic
Board Administrator
State Board of Nursing
P.O. Box 2649
Harrisburg, PA 17105-2649

Re: No. 16A-5124 CRNP General Revisions

Dear Ms. Steffanic:

I am writing as President of the Pennsylvania Medical Society to offer comments on the above-captioned proposed rulemaking relating to general revisions to the regulations for Certified Registered Nurse Practitioners (CRNPs). The Medical Society is pleased to have the opportunity to provide input on these important regulations.

I would first like to emphasize that Pennsylvania physicians recognize the contribution that Certified Registered Nurse Practitioners are making in their expanded roles in the delivery of health care services to the citizens of this Commonwealth. Our intent in providing these comments is threefold: to clarify the collaborative relationship intended by statute to be created and maintained between the nurse practitioner and the physician in the delivery of care, including the prescription of drugs; to delineate the responsibilities of the parties to the collaborative agreement; and to provide for patient safety and quality of care.

In reviewing the proposed rulemaking, we have identified a number of areas of concern which I will attempt to summarize below. I have also attached a more detailed set of comments which address specific sections of the proposed rulemaking.

777 East Park Drive
PO Box 8820
Harrisburg, PA 17105-8820

Tel: (717) 558-7750
Fax: (717) 558-7840
Email: stat@pamedsoc.org
www.pamedsoc.org

Areas of concern are:

Deletion of Collaborative Agreement Requirements

The proposed regulations delete critical requirements that not only shape the collaborative relationship/agreement, but also permit the nurse practitioner to practice in an expanded role in "collaboration" with physicians. Some of those requirements were included in the definition of "direction" which has been deleted and included level of availability of the collaborating physician, a predetermined plan for emergency services, establishing and updating of standard orders and protocols, and documenting accountability of both parties.

We believe that the definitions proposed for "collaborative agreement" and "prescriptive authority collaborative agreement" offer far less delineation of these requirements than the definition of "collaboration" contained in statute. Further, we strongly disagree that even the most basic of collaborative agreements should be permitted to be "oral" instead of written. Patient safety and accountability for care rendered requires that both parties clearly understand and acknowledge their individual and collective responsibilities and are held accountable for them.

Expanded Scope of Practice within the Collaborative Agreement

The listing of expanded practice in the medical examination and treatment of patients does not clarify that those expanded services are to be performed within the parameters of the collaborative agreement, as authorized by statute. Without statutory reference, it appears that these services may be performed independently.

Expansion of Drug Prescribing and Dispensing Parameters

The substantial expansion in the ability of nurse practitioners to prescribe Schedule II-IV controlled substances fails to provide adequate qualifications and safeguards to protect the patient from inappropriate care. Additionally, the proposed rulemaking makes changes to the prescribing parameters without the involvement of physicians knowledgeable in the drugs and their use and the statutorily mandated Drug Review Committee. The proposed rulemaking even deletes the current requirement that the collaborative agreement for nurse practitioners with prescriptive authority contain an attestation by the collaborating physician that the physician has knowledge and experience with any drug that the nurse practitioner will prescribe. The changes also remove the requirement for the collaborating physician to take corrective action on behalf of the patient if it is determined that the nurse practitioner is prescribing or dispensing a drug inappropriately.

Identification and Patient Notification

The lack of adequate patient notification and identification requirements limit the patient's ability to know that they are being treated by a nurse practitioner. Proposed language deletes the notification of patients at the time of appointment that they will be seen by a nurse practitioner, permits the nurse practitioner to wear a badge containing their name and the abbreviated title "CRNP," and deletes the requirement that the nurse practitioner notify the patient if he/she holds a Doctor *of Nursing* (emphasis added) degree.

Nurse Practitioner/Physician Ratio

Regulations propose deletion of the requirement to limit the ratio between nurse practitioners with prescriptive authority and the collaborating physician. This requirement, currently 4:1, insures that the physician has adequate time to interact with the nurse practitioner to provide safe, quality care, especially in the prescription of drugs. Current regulations permit physicians to collaborate with four nurse practitioners with prescriptive authority in the morning and four others in the afternoon. There is no ratio for nurse practitioners who aren't prescribing drugs. In the six years since the statute passed, there has been only one request for exception to the ratio.

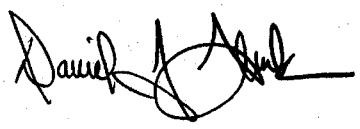
Finally, the Society notes that some of the provisions omitted in this proposed rulemaking are in the statute, and that nurse practitioners will still be required to collaborate with physicians whether the requirements are in the regulations or not. The regulations should serve, however, as a template for the construction of the agreement, informing all parties, not just nurse practitioners, of what is expected in the relationship. Nurse practitioners, like physicians, are health care professionals, not legal experts. They should not have to interpret between the statute and the regulations and should have a single understandable source for what their scope of practice is and how they are to function as nurse practitioners.

The following documents contain detailed comments and rationale on the proposed rulemaking:

- Pennsylvania Medical Society Comments on Proposed Amendments to the Certified Registered Nurse Practitioner (CRNP) Regulations
- Section-by Section Comments on Proposed Rule Making #16A-5124
- Pennsylvania Medical Society Recommended Changes (marked up regulations)

Representatives of the Medical Society would be pleased to discuss these comments with representatives of the Board of Nursing.

Sincerely,



Daniel J. Glunk, MD
President

Attachments
Section by Section Comments
Proposed Regulations Annotated
Issue Chart
Concerns re: Controlled Substance Dosage

cc: Robert M. Tomlinson, Chair,
Senate Consumer Protection and Professional Licensure Committee
P. Michael Sturla, Chair
House Professional Licensure Committee
Sabina Howell, Board Counsel
State Board of Medicine
Barbara Holland, Esq.
Office of Health Care Reform
Ollice Bates, MD, Chair
State Board of Medicine

Pennsylvania Medical Society
Section by Section Comments on the Proposed Certified Registered Nurse Practitioners Regulations – General Revisions

Please see enclosed chart and annotated regulations for proposed wording changes

§ 21.251. Definitions

Collaborative agreement. – Unlike the statutory definition of collaborative agreement, the proposed definition provides no guidance for the parties to develop an agreement that outlines their respective responsibilities and accountabilities. Collaboration should be defined as:

A process in which a CRNP 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 the following:

- *(i) Immediate availability of a licensed physician to the CRNP through direct communications or by radio, telephone or telecommunications.*
- *(ii) A predetermined plan for emergency services.*
- *(iii) A physician available to the CRNP 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 cosigning records when necessary to document accountability by both parties.*

The agreement should be written and signed so there is a clear delineation of duty, authority and liability. **The Pennsylvania Medical Society recommends that the proposed definition be deleted and replaced with the definition of "collaborative agreement" found in the statute. The Society further recommends that the definition be supplemented with elements found in the definition of "Direction" contained in the current regulations that is proposed for deletion.**

§ 21.282a. Medical examination, diagnosis and treatment – Entire section deals with expanded services a nurse practitioner may perform by statute within the terms of a collaborative agreement with a physician and the CRNP's specialty certification. The proposed language, however, makes no reference to the fact that the services must be performed under the agreement. There should also be language included that specifically prohibits surgery and other medical care outside the scope of the CRNP's scope of practice. For example: *A CRNP may perform acts of medical diagnosis, provided that the CRNP is acting within the scope of the CRNP's written collaborative agreement with a physician and the CRNP's specialty certification.* **The Pennsylvania Medical Society recommends that the section be amended to reflect the concerns regarding performing medical diagnosis provided that the CRNP is acting within the scope of the collaborative agreement and within their specialty certification.**

§ 21.283 Authority and qualifications for prescribing and dispensing drugs and other medical therapeutic or corrective measures – 21.283(a) needs to emphasize that the collaborative agreement must be in writing and that the CRNP is working within the scope of the CRNP's specialty certification. It is important to note that the prescriptive authority is not limited to drug prescriptions, it also applies to blood products, diets, and durable medical equipment referenced in 21.282. **The Pennsylvania Medical Society recommends that prescriptive authority for blood products, diets, and durable medical equipment be relocated from 21.282 to 21.283(a) and that language be added that the CRNP may prescribe if expressly written in the collaborative agreement and is within the CRNP's specialty certification.**

Subsection (b)(2)(iii) addresses the 45 hours of advanced pharmacology courses that a CRNP must complete prior to applying for prescriptive authority. The proposed language states that the required advanced pharmacology course work shall have been completed within five years immediately preceding the date the applicant applies for initial prescriptive authority approval. Given the rapid changes in pharmacology and the need to remain current in training and experience, this timeframe needs to be reduced to two years. **The Pennsylvania Medical Society recommends that the "five" year limit be changed to "two" years preceding the application for initial prescriptive authority.**

§ 21.284. Prescribing and dispensing parameters. [Note: Please see attached "Concerns with Schedule Drug Dosage Parameters" for additional details and rationale.] – The proposed rulemaking makes several changes to the prescribing parameters. The Medical Society recommends the addition of language stating that the collaborating physician is knowledgeable in the drugs the CRNP is prescribing and that several sections be revised to retain original language for patient safety. Also, we believe there a protocol for inappropriate prescribing by the CRNP should be added, and the statutorily mandated Drug Review Committee issue needs to be resolved.

§ 21.284(b) should include language regarding the collaborating physician's knowledge of any drugs the CRNP will be prescribing. It is only logical that the CRNP should be working with the same drugs as the collaborating physician. Those drugs or drug categories would be listed in the collaborative agreement. **The Pennsylvania Medical Society recommends that an attestation by the collaborating physician be contained in this section, certifying that the physician has knowledge and experience with any drug that the CRNP will prescribe.**

In § 21.284(b)(3), the original language should be retained to read: Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aides *if originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy.* We do not believe CRNPs have the training or experience to prescribe antineoplastic medications. They can be interpreted to cover a wide range of medication. For example, prednisone, an oral steroid, can be used as an antineoplastic agent, but it

can also be used in other anti-inflammatory clinical contexts. **The Pennsylvania Medical Society recommends that the proposed regulations retain the original language.**

§ 21.284(b)(7) should retain the original language to read: Central nervous system agents, *except that the following drugs are excluded from this category: (i) General anesthetics; and (ii) Monoamine oxidase inhibitors.* **The Pennsylvania Medical Society recommends that the proposed regulations retain the original language.**

The intent of § 21.284(d) should be retained, but amended to read: *If a CRNP identifies an inappropriate prescription by the CRNP, the CRNP shall immediately notify the collaborating physician. In that event or if a collaborating physician notifies a CRNP of an inappropriate prescription by the CRNP, the CRNP shall advise the patient to modify or discontinue use of the drug as medically appropriate and note this action in the patient's medical record, unless the CRNP verifies that the action has been or will be taken by the collaborating physician.* **The Pennsylvania Medical Society recommends that this subsection be retained as a patient safety protection.**

Subsection (d) (1) proposes to change the dosage limit from 72 hours for Schedule II controlled substances to 30 days and removes the requirement for the nurse practitioner to notify the collaborating physician as soon as possible but in no event longer than 24 hours. Expanding the dosage level and removing the requirement for notification of the collaborating physician creates the potential for serious patient safety and quality of care issues from extended treatment without physician involvement and intervention if required. **The Pennsylvania Medical Society recommends that the dosage level be raised from 72 hours to <u>seven</u> days, thus permitting the nurse practitioner increased latitude, and further recommends that the physician notification requirement be retained as a patient safety requirement.**

As recently as last summer when the legislature expanded the CRNP scope of practice in Act 48 of 2007, it did not adopt the CRNP's proposal to remove the requirement for the Drug Review Committee to approve any changes to the formulary. Contact with the Department of Health leads us to believe that the administration has never appointed a Drug Review Committee; therefore, the regulations cannot be "deemed approved" if the Committee has never been appointed.

The purpose of the Drug Review Committee is to provide input from physicians and pharmacists on proposed modifications to the categories of drugs that CRNPs can safely prescribe. The Society does not believe that the legislature intended to allow the administration to circumvent this important patient safety issue and permit *de facto* approval of the proposed modifications to the categories of drugs that CRNPs may prescribe by refusing to follow through with its statutory obligation to appoint the Drug Review Committee. **The Pennsylvania Medical Society recommends that all changes**

to the regulated formulary go through the statutorily mandated Drug Review Committee.

§ 21.285 Prescriptive authority collaborative agreement. – This section provides for specific requirements of the collaborative agreement for prescriptive authority. The proposed changes delete important current requirements. For example, an attestation by the collaborating physician of knowledge and experience with any of the drugs that the CRNP will prescribe, qualification for the types of circumstances and the frequency that the collaborating physician will personally see the patient, and for listing of conditions under which the nurse practitioner may prescribe Schedule II controlled substances.

The collaborative agreement is a written agreement between the nurse practitioner and the collaborating physician as to how they will work together and it is important that both parties clearly understand the terms of the relationship. It is intended to be a living document varying by type of practice, sites of service, type and condition of patient, etc. It should also reflect the level of the relationship and trust between the nurse practitioner and the physician. By example, an agreement between a nurse practitioner and physician who have never worked together will have to be more detailed than one between practitioners who have worked together for a long time. The requirements recommended for deletion are important in tailoring the agreement so that it clearly reflects the responsibilities and accountability of parties to the agreement. **The Pennsylvania Medical Society recommends that the current language in subsections (b) (4) – (6) be retained with the exception of change subsection (b) (6) to reflect a change in dosage level Schedule II controlled substances from 72 hours to seven days and Schedules III and IV for thirty days.**

§ 21.286. Identification of the CRNP. – Current regulations require patient notification at the time of appointment that the patient will be seeing a nurse practitioner, and when the nurse practitioner has a doctoral degree in nursing. These requirements are to insure that the patient is appropriately informed as to who is providing care and to permit the patient to make an informed choice as to the practitioner that will be providing their care.

The proposed changes delete these requirements and only require that the nurse practitioner to use the initials CRNP on their identification badges. The initials CRNP are a relatively new abbreviation compared to Medical Doctor (MD) or Doctor of Osteopathy (DO). At the time of care, things and events are often stressful, practitioners are often dressed alike and some are masked. The patient deserves clarification and needs to know which practitioner is caring for them.

In similar fashion, a nurse practitioner with a doctoral degree should be obligated to inform the patient that he or she is not a physician, which would be the more common reference in the medical care treatment setting. **The Pennsylvania Medical Society recommends that the proposed deleted language regarding patient notification and identification be retained.**

§ 21.287. Physician supervision. – This section needs to be retained, with regard to the CRNP/physician ratio, and amended to reflect the physician characteristics the CRNP should be looking for in a collaborating physician.

§ 21.287 should be amended to include language regarding the type of collaborating physician the CRNP should be looking for.

A CRNP may only collaborate with a physician who meets the following minimum qualifications:

(1) The physician has an unrestricted license to practice medicine or osteopathic medicine in the Commonwealth of Pennsylvania.

(2) The physician is in active clinical practice.

(3) The normal and customary practice of the physician includes the services provided by the CRNP.

(4) The physician is reasonably available to take referrals of the CRNP's patients and to perform other collaboration functions in a timely fashion as required by the definition of collaboration in section 21.251.

(5) In the case of a CRNP with prescriptive authority, the physician has knowledge and experience in the drugs or categories of drugs that the CRNP is authorized to prescribe under the CRNP's prescriptive authority collaborative agreement.

Current regulations require that a physician supervise no more than four nurse practitioners who prescribe and dispense drugs at any given time. A physician may supervise four nurse practitioners with prescriptive authority in the morning and four others in the afternoon. There is no ratio limitation on non prescribing nurse practitioners.

Since the statute authorized increased scope of practice for nurse practitioners in both drug prescribing and dispensing and other types of care, there is even more need to retain some limit in the numbers of collaborative relationships that can exist at any given time to insure that the physician has adequate time to perform his or her responsibilities as outlined in the collaborative agreement, including availability and involvement with the care of the patient.

In the six years since the statute was passed, there has been only one occasion where a physician has sought an exception to the limit. The Board of Nursing has stated that they are not able to regulate the actions of physicians and that the section should be deleted from these regulations. While this is true, the Board still needs to uphold the ratio so that their licensees are not placed in a situation where they are forced to be in a collaborative

relationship beyond the ratios established, unless their collaborating physician has successfully sought exception from either the Medical or Osteopathic Medical Board. **The Pennsylvania Medical Society recommends that the section be retained, with amendments to reflect the requirements the CRNP must look for in a collaborating physician, and with the current nurse practitioner/physician ratio for those CRNPs who have prescriptive authority.**

§ 21.311. Accountability of CRNP – The CRNP should be held accountable to the collaborating physician in the area of medical diagnosis and therapeutics. Accountability is an integral element of a meaningful collaborative arrangement, especially with regard to evaluating skills and demonstrating proficiency. **The Pennsylvania Medical Society recommends that § 21.311 be retained.**

§ 21.321. Performance of tasks without direction; performance of tasks without training; other – The current regulations provide that practicing outside a collaborative agreement with a physician is grounds for discipline of a CRNP. It is critical that the CRNP work within the intended and agreed upon scope of practice. Removal of this provision gives the appearance that the Board of Nursing does not intend to enforce the collaborative agreement. **The Pennsylvania Medical Society recommends that § 21.321 be retained.**

Pennsylvania Medical Society Recommended Changes

Underline recommends addition; strike-through recommends deletion; strike-through of brackets recommends bracketed language be retained

PROPOSED RULEMAKING

STATE BOARD OF NURSING

[49 PA. CODE CH. 21]

Certified Registered Nurse Practitioners; General Provisions

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 21. STATE BOARD OF NURSING

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

GENERAL PROVISIONS

§ 21.251. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

***Act*--The Professional Nursing Law (63 P. S. §§ 211--225.5).**

[*Boards*--The State Board of Nursing and the State Board of Medicine.]

***Board*--The State Board of Nursing of the Commonwealth.**

CRNP--*Certified Registered Nurse Practitioner* **[*(CRNP)*]**--A registered nurse licensed in this Commonwealth who is certified by the **[Boards] Board** in a particular clinical

specialty area and who, while functioning in the expanded role as a professional nurse, performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures in collaboration with **[and under the direction of]** a physician licensed to practice **[medicine]** in this Commonwealth **and in accordance with the act and this subchapter**. Nothing in this subchapter is to be deemed to limit or prohibit a nurse from engaging in those activities which normally constitute the practice of nursing as defined in section 2 of **[The Professional Nursing Law] the act** (63 P. S. § 212).

Collaboration – **A process in which a CRNP 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 the CRNP through direct communications or by radio, telephone or telecommunications.

(ii) A predetermined plan for emergency services.

(iii) A physician available to the CRNP 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 cosigning records when necessary to document accountability by both parties.

Collaborative agreement--**The ~~oral or~~ written and signed agreement between a CRNP and a collaborating physician in which they agree to the details of their collaboration.**

[*Direction*--**The incorporation of physician supervision to the certified registered nurse practitioner's performance of medical acts in the following ways:**

(i) Immediate availability of a licensed physician through direct communications or by radio, telephone or telecommunications.

(ii) A predetermined plan for emergency services which has been jointly developed by the supervising physician and the certified registered nurse practitioner.

(iii) A physician available on a regularly scheduled basis for:

(A) Referrals.

(B) Review of the standards of medical practice incorporating consultation and chart review.

(C) Establishing and updating standing orders, drug and other medical protocols within the practice setting.

(D) Periodic updating in medical diagnosis and therapeutics.

(E) Cosigning records when necessary to document accountability by both parties.]

***Prescriptive authority collaborative agreement*--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.**

§ 21.252. **[Purpose] (Reserved).**

[The Boards have established rules and regulations to govern acts of medical diagnosis or prescription of medical therapeutic or corrective measures as authorized by The Professional Nursing Law (63 P. S. §§ 211--225.5) and the Medical Practice Act of 1985 (63 P. S. §§ 422.1--422.51a).]

LEGAL RECOGNITION

§ 21.261. **[Designation of CRNP; authority to use CRNP] Use of title; authorization to practice.**

(a) A registered nurse who has satisfactorily met the requirements set forth in **the act and** this subchapter **[and in additional rules and regulations that may be jointly promulgated by the Boards shall be designated on his license "Certified Registered Nurse Practitioner (CRNP)," in the area for which qualified] and holds current certification issued by the Board as a CRNP or whose certification is maintained on inactive status may use the designation CRNP.**

(b) **The Board will identify the particular clinical specialty area in which a CRNP is certified by the Board on the certification issued to the CRNP.**

(c) [A nurse may not practice or offer to practice as a Certified Registered Nurse Practitioner in this Commonwealth or use the abbreviation CRNP unless authorized to do so by the State Board of Nursing] Only persons who hold current active certification from the Board as a CRNP may practice or offer to practice as a CRNP in this Commonwealth.

(d) A nurse may not practice or offer to practice as a CRNP in this Commonwealth during the time the nurse's certification is revoked, suspended, inactive, lapsed or expired.

CERTIFICATION REQUIREMENTS [FOR APPROVAL]

§ 21.271. **[Currently licensed; course of study and experience; continuing education] Licensure, educational and National certification requirements for applicants seeking certification as a CRNP.**

(a) **[The applicant for whom approval is requested shall be currently licensed as a registered nurse by the State Board of Nursing.**

(b) The applicant shall have successfully completed a course of study consisting of at least 1 academic year in a program administered by nursing in an institution of higher education as approved by the Boards.

(c) Nurses currently practicing in the role covered by this subchapter prior to the promulgation of this subchapter who have not completed an approved course of study, may individually petition the Boards for certification within 2 years following the final filing of this subchapter.

(d) Evidence of continuing competency in the area of medical diagnosis and therapeutics at the time of renewal of the applicant's certification renewal.]

Initial certification. **An applicant for initial certification as a CRNP by the Board shall meet the following requirements:**

(1) ***Professional nurse license.*** **An applicant for certification by the Board shall hold a current, unrestricted license as a professional nurse in this Commonwealth.**

(2) ***Education.*** **An applicant for certification by the Board shall have completed an accredited, Board-approved master's or postmaster's nurse practitioner program or other Board-approved program that awarded an advanced degree or a course of study considered by the Board to be equivalent to that required for certification in this Commonwealth at the time the course was completed.**

(3) ***National certification.*** **An individual applying for initial certification by the Board after February 7, 2005, shall hold certification as a CRNP from a Board-recognized National certification organization which required passing of a National certifying examination in the particular clinical specialty area in which the nurse is seeking certification by the Board.**

(b) ***Certification by endorsement.*** **An applicant for certification by the Board who holds a current, unrestricted license or certificate as a CRNP from another state, territory or possession of the United States or a foreign country, shall meet the certification requirements of the Board that were effective at the time the applicant was licensed or certified as a CRNP by the other jurisdiction. Applicants who were initially licensed by another state, territory or possession of the United States or a foreign country on or after February 7, 2005, shall hold certification as a CRNP from a Board-recognized National certification organization which required passing of a National certifying examination in the particular clinical specialty area in which the nurse is seeking certification by the Board.**

(c) ***Change of clinical specialty area.*** **A CRNP who is already certified by the Board may apply for certification in an additional specialty area. To be granted**

certification in an additional specialty area, the CRNP shall meet the educational and National certification requirements for the specialty area in which the CRNP is applying for certification.

§ 21.272. **[Certification by endorsement; currently licensed] (Reserved).**

[(a) A registered nurse who has been granted certification by another state board may be granted certification in this Commonwealth by endorsement of the original certifying board if the credentials are equivalent to those required by the Boards.

(b) The applicant for certification in this Commonwealth by endorsement shall meet the requirements as stated in the act for licensure as a registered nurse.]

§ 21.273. Application for certification as a CRNP.

(a) An applicant for certification as a CRNP shall submit an application form provided by the Board to the Board for its review and approval. The applicant shall verify compliance with section 8.7 of the act (63 P. S. § 218.7) regarding liability coverage.

(b) An applicant for initial certification shall include documentation satisfactory to the Board of the following:

(1) Proof of completion of a Board-approved master's or postmaster's nurse practitioner program or other Board-approved program that awarded an advanced degree as a nurse practitioner or proof of completion of a course of study and evidence demonstrating that the course of study is equivalent to that required in this Commonwealth at the time the course was completed.

(2) Proof of current certification as a nurse practitioner from a Board-recognized National certification organization that requires passing of a National certifying examination in the particular clinical specialty area in which the nurse is seeking certification by the Board.

(c) An applicant for certification by endorsement shall verify compliance with section 8.7 of the act and include documentation satisfactory to the Board of the following:

(1) Verification of current, unrestricted licensure or certification as a CRNP issued by the proper licensing authority of another state, territory or possession of the United States or a foreign country.

(2) Copy of the licensure or certification requirements at the time the applicant was first licensed or certified by another jurisdiction and a copy of the criteria under which the applicant was originally licensed or certified.

(3) Official transcript from the applicant's CRNP program, including degree awarded.

(4) Proof of current National certification as a nurse practitioner from a Board-recognized National certification organization that requires passing of a National certifying examination in the particular clinical specialty area in which the nurse is seeking certification by the Board, if the applicant was first licensed after February 7, 2005.

(d) An applicant who holds certification from the Board as a CRNP who is applying for certification in a different specialty than the applicant's current certification shall verify that the applicant is in compliance with section 8.7 of the act and submit documentation of the following:

(1) Official copy of the transcript from the applicant's CRNP program and any additional educational programs, including degree awarded, demonstrating a concentration in the specialty area in which the applicant is seeking certification.

(2) Proof of current certification as a nurse practitioner from a Board-recognized National certification organization that requires passing of a National certifying examination in the particular clinical specialty area in which the nurse is seeking certification by the Board.

(e) An applicant shall remit the certification fee set forth in § 21.253 (relating to fees).

(f) An applicant shall submit additional information as identified on the application or as requested by the Board. Applications will remain on file for 12 months.

[APPLICATION FOR APPROVAL]

§ 21.281. **[Application for approval] (Reserved).**

[The applicant shall submit an application form provided by the State Board of Nursing to the Board for its review and approval. The application shall include the following:

(1) An official document from the program.

(2) Additional information as identified on the application.]

§ 21.282. **[Approval by the State Board of Nursing] (Reserved).**

[Applicants approved by the State Board of Nursing may use the designation C.R.N.P., and the designation and area of specialty will be indicated on the current license of the nurse.]

CRNP PRACTICE

§ 21.282a. Medical examination, diagnosis and treatment.

A CRNP may perform acts of medical diagnosis, provided that the CRNP is acting within the scope of the CRNP's written collaborative agreement with a physician and the CRNP's specialty certification. These acts may include:

(~~a~~1) ~~A CRNP may perform c~~Comprehensive assessments of patients and establish medical diagnoses.

(~~b~~2) ~~A CRNP may o~~Order, perform and supervise diagnostic tests for patients and, to the extent that the performance and interpretation of diagnostic tests is within the CRNP's capabilities and consistent with other laws and regulations, ~~may~~ perform and interpret diagnostic tests.

(~~c~~3) ~~A CRNP may i~~Initiate referrals to and consultations with other licensed professional health care providers, and ~~may~~ consult with other licensed professional health care providers at their request.

(~~d~~4) ~~A CRNP may d~~Develop and implement treatment plans~~, including issuing orders to implement treatment plans~~ excluding surgery and other medical care outside the CRNP scope of practice; however, only a CRNP with current prescriptive authority approval from the Board may develop and implement treatment plans for ~~pharmaceutical treatments~~medical therapeutic or corrective measures.

(~~e~~5) A CRNP may complete admission and discharge summaries.

~~**(f) A CRNP may order blood and blood components for patients.**~~

~~**(g) A CRNP may order diets for patients.**~~

~~**(h) A CRNP may order durable medical equipment required to carry out a treatment plan developed by the CRNP or by a physician.**~~

(~~i~~6) A CRNP may perform other acts of medical diagnosis as authorized by section 8.2(c.1) of the act (63 P. S § 218.2(c.1)).

§ 21.283. **[Prescribing] Authority and qualifications for prescribing** and dispensing drugs **and other medical therapeutic or corrective measures**.

(a) A CRNP **with prescriptive authority approval from the Board** may, **when acting in collaboration with a physician as set forth in a written prescriptive authority collaborative agreement and within the scope of the CRNP's specialty certification,** prescribe and dispense drugs **[if the following requirements are met] and give written or oral orders for medical therapeutic or corrective measures. These ~~orders~~acts may include orders for**:

(1) ~~Orders for d~~Drugs, Total Parenteral Nutrition and lipids, in accordance with §§ 21.284 and 21.285 (relating to prescribing and dispensing parameters; and prescriptive authority collaborative agreement).

(2) Disposables and devices adjunctive to a treatment plan.

(3) Blood and blood components.

(4) Diets.

(5) Durable medical equipment required to carry out a treatment plan developed by the CRNP or by a physician.

(6) Other medical therapeutic or corrective measures which CRNPs are authorized to order by section 8.2(c.1) of the act.

(b) To obtain prescriptive authority approval, a CRNP shall:

(1) **[The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.**

(2) The CRNP has successfully completed] Successfully complete at least 45 hours of course work specific to advanced pharmacology in accordance with the following:

(i) The course work in advanced pharmacology may be either part of the CRNP education program or, if completed outside of the CRNP education program, an additional course or courses taken from an educational program or programs approved by the **[Boards] Board**.

* * * * *

(iii) The course work shall have been completed within ~~5~~2 years immediately preceding the date the applicant applies for initial prescriptive authority approval.

(2) Submit an application for prescriptive authority approval to the Board.

(3) **Pay the fee set forth in § 21.253 (relating to fees).**

(c) A CRNP who has prescriptive authority shall complete at least 16 hours of State Board of Nursing approved continuing education in pharmacology in the 2 years prior to

the biennial renewal date of the CRNP certification. The CRNP shall show proof that the CRNP completed the continuing education when submitting a biennial renewal. **The forms for the application, collaborative agreement and verification of completion of pharmacology are available on the Board's website or by contacting the Board.**

[(4) In prescribing and dispensing drugs, a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92--16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §§ 25.51--25.58, 25.61--25.81 and 25.91--25.95.]

§ 21.284. Prescribing and dispensing parameters.

* * * * *

(b) A CRNP **with current prescriptive authority approval from the Board** may prescribe **[and dispense a drug], dispense and administer drugs and therapeutic or corrective measures consistent with the prescriptive authority collaborative agreement and** relevant to the **CRNP's** area of practice **[of the CRNP]** from the following categories ~~{~~**if that authorization is documented by drug or drug category in the collaborative agreement (unless the drug is limited or excluded under this or another subsection)**~~}~~:

* * * * *

(3) Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aids ~~{~~**if originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy**~~}~~.

* * * * *

(7) Central nervous system agents~~{~~**, except that the following drugs are excluded from this category:**

(i) General anesthetics.

(ii) Monoamine oxidase inhibitors~~}~~.

* * * * *

(c) A CRNP ~~may~~**shall** not prescribe or dispense a drug from the following categories:

* * * * *

(5) Schedule I controlled substances as defined section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-104).

(d) **If a CRNP identifies an inappropriate prescription by the CRNP, the CRNP shall immediately notify the collaborating physician. In that event or if a collaborating physician notifies a CRNP of an inappropriate prescription by the CRNP, the CRNP shall advise the patient to modify or discontinue use of the drug as medically appropriate and note this action in the patient's medical record, unless the CRNP verifies that the action has been or will be taken by the collaborating physician.** **[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.]**

(e)~~]~~ Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for **initial therapy** up to a **[72 hour]** ~~30~~**7-day** dose. ~~[~~**The CRNP shall notify the collaborating physician as soon as possible but in no event longer than 24 hours.**~~]~~ **A CRNP may write a prescription for a Schedule II controlled substance for up to a 30-day supply if it was approved by the collaborating physician for ongoing therapy. The prescription must clearly state on its face that it is for initial or ongoing therapy.**

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to **[30] 90** days. **[The prescription is not subject to refills unless the collaborating physician authorizes refills for that prescription.]**

(3) A CRNP shall not use post-dated prescriptions to exceed the dosage limits imposed in paragraphs (1) and (2).

(f)~~]~~ ~~(e)~~ A CRNP ~~may~~**shall** not **[:**

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-14).

(2) Prescribe or dispense a drug for a use not approved by the United States Food and Drug Administration without approval of the collaborating physician.

(3) Delegate] delegate prescriptive authority **[specifically assigned to the CRNP by the collaborating physician]** to another health care provider.

[(g) A prescription blank shall bear the certification number of the CRNP, name of the CRNP in printed format at the top of the blank and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

(h) The CRNP shall document in the patient's medical record the name, amount and dose of the drug prescribed, the number of refills, the date of the prescription and the CRNP's name.]

§ 21.284a. Prescribing and dispensing drugs.

(a) *Professional samples.* **A CRNP who holds current prescriptive authority approval may request, receive and sign for professional samples and may distribute professional samples to patients, provided that the CRNP is acting in accordance other applicable regulations in this Subchapter pertaining to prescribing drugs, including but not limited to this section and sections 21.283, 21.284, 21.284b, and 21.285.**

(b) *Prescription blanks.* **The requirements for prescription blanks are as follows:**

(1) Prescription blanks ~~must~~shall bear the name, title and identification number of the CRNP in printed format. The collaborating physician must be identified on the prescription blank.

(2) When appropriate, the CRNP's National Provider Identifier (NPI) number must appear on the prescription. When prescribing controlled substances, the CRNP's DEA registration number must appear on the prescription.

(3) Prescription blanks may not be presigned.

(4) The CRNP may use a prescription blank generated by a hospital, provided the information in paragraph (1) appears on the blank.

(c) *Recordkeeping requirements.* **Recordkeeping requirements are as follows:**

(1) When prescribing a drug, the CRNP shall document in the patient's medical record the name, amount and dosage of the drug prescribed, the number of refills, the date of the prescription and the CRNP's name.

(2) When dispensing a drug, the CRNP shall record in the patient's medical records the CRNP's name, the name, amount and dosage of the medication dispensed and the date the medication was dispensed.

(3) The CRNP shall provide immediate access to the prescriptive authority collaborative agreement to anyone seeking to confirm the CRNP's authority to prescribe or dispense a drug. The agreement must list the categories of drugs that the CRNP is permitted to prescribe.

(d) *Packaging.* **Prescription drugs shall be dispensed in accordance with Federal regulations pertaining to packaging. (See 16 CFR Part 1700 (relating to poison prevention packaging).)**

(e) *Labeling of dispensed drugs.*

(1) The label on a dispensed drug container ~~must~~shall include the name of the drug, using abbreviations if necessary; the quantity; and the name of the manufacturer if the drug is a generic drug. If a CRNP specifically indicates that the name of the drug may not appear on the label, the recognized National drug code number shall be placed on the label if the number is available for the product. The label ~~must~~shall also bear the name and address of the CRNP, the date dispensed, the name of the patient and the directions for use of the drug by the patient.

(2) Drugs that, at the time of their dispensing, have full potency for less than 1 year, as determined by the expiration date placed on the original label by the manufacturer, ~~may~~shall only be dispensed with a label that indicates the expiration date. The label ~~must~~shall include the statement, "Do not use after manufacturer's expiration date," or similar wording.

(f) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A CRNP shall comply with this section, § 21.284b (relating to prescribing, administering and dispensing controlled substances) and regulations of the Department of Health in 28 Pa. Code §§ 25.51--25.58, 25.61--25.63, 25.72, 25.81 and 25.91--25.95.

§ 21.284b. Prescribing, administering and dispensing controlled substances.

(a) A CRNP authorized to prescribe or dispense, or both, controlled substances shall register with the Drug Enforcement Administration.

(b) A CRNP shall carry out the following minimum standards when prescribing, administering or dispensing controlled substances:

(1) *Initial medical history and physical examination.* In a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government, an initial medical history shall be taken and an initial physical examination shall be conducted to the extent required by the Department of Health in 28 Pa. Code (relating to health and safety) or Department of Public Welfare in 55 Pa. Code (relating to public welfare) or the Federal government in appropriate Federal regulations, whichever is applicable, and bylaws of the health care facility and its medical staff. In other practice settings, before commencing treatment that involves prescribing, administering or dispensing a controlled substance, an initial medical history shall be taken and an initial physical examination shall be conducted unless emergency circumstances justify otherwise. Alternatively, medical history and physical examination information recorded by another health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding 30 days. The physical examination must include an evaluation of the heart, lungs, blood pressure, pain level, and body functions that relate to the patient's specific complaint.

(2) *Reevaluations.* Among the factors to be considered in determining the number and frequency of follow-up evaluations that should be recommended to the patient are the condition diagnosed, the controlled substance involved, expected results and possible side effects. For chronic conditions, periodic follow-up evaluations shall be recommended to monitor the effectiveness of the controlled substance in achieving the intended results.

(3) *Patient counseling.* Appropriate counseling shall be given to the patient regarding the condition diagnosed and the controlled substance prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) *Medical records.* In a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government, information pertaining to the prescription, administration or dispensation of a controlled substance shall be entered in the medical records of the patient and the health care facility under 28 Pa. Code or 55 Pa. Code or appropriate Federal regulations, whichever is applicable, and bylaws of the health care facility and its medical staff. In other practice settings, certain information shall be recorded in the patient's medical record on each occasion when a controlled substance is prescribed, administered or dispensed. This information must include the name of the controlled substance, its strength, the quantity and the date it was prescribed, administered or dispensed. On the initial occasion when a controlled substance is prescribed, administered or dispensed to a patient, the medical record must also include a specification of the symptoms observed and reported, the diagnosis of the condition for which the controlled substance is being given and the directions given to the patient for the use of the controlled substance. If the same controlled substance continues to be prescribed, administered or dispensed, the medical record must reflect changes in the symptoms observed and reported, in the diagnosis of the condition for which the controlled substance is being given and in the directions given to the patient.

(5) *Emergency prescriptions.* In the case of an emergency phone call by a known patient, a prudent, short-term prescription for a controlled substance may be issued. Neither a refill nor a consecutive issuance of this emergency prescription may be given unless a physical examination and evaluation of the patient are first conducted. The results of this examination and evaluation shall be set forth in the patient's medical record together with the diagnosis of the condition for which the controlled substance is being prescribed. An emergency oral prescription for a Schedule II controlled substance shall be covered by a written prescription delivered to the pharmacist within 72 hours. In certain health care facilities regulated by the Department of Health, the Department of Public Welfare and the Federal government, an order for the immediate, direct administration of a Schedule II controlled substance to a patient is not considered a prescription and is, therefore, not subject to the requirements in this paragraph. Further information

regarding this exclusion can be found in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101--780-144) and 28 Pa. Code Chapter 25 (relating to controlled substances, drugs, devices and cosmetics).

(c) This section establishes minimum standards for the prescription, administration and dispensation of controlled substances by a CRNP. This section does not restrict or limit the application of The Controlled Substance, Drug, Device and Cosmetic Act or of another statute or regulation, and does not relieve a CRNP from complying with more stringent standards that may be imposed by another statute or regulation, or policy of the CRNP's employer or facility in which the CRNP is employed.

(d) Compliance with this section will not be treated as compliance with the standards of acceptable and prevailing practice as a CRNP when medical circumstances require that the CRNP exceed the requirements of this section.

§ 21.285. **[Collaborative] Prescriptive authority collaborative** agreement.

(a) **[A collaborative agreement is the signed written agreement between a CRNP and a collaborating physician in which they agree to the details of the collaborative arrangement between them with respect to the care of CRNP patients.**

(b)] The **prescriptive authority** collaborative agreement between a physician and a CRNP who will prescribe drugs **[shall] and other medical therapeutic or corrective measures, as set forth in § 21.283(a) (relating to authority and qualifications for prescribing and dispensing drugs and other medical therapeutic or corrective measures), must** satisfy the following requirements. The agreement **[shall] must**:

(1) Identify the parties, including the collaborating physician, the CRNP, and **[a] at least one** substitute physician who will provide collaboration **[and direction for up to 30 days]** if the collaborating physician is unavailable.

(2) Identify the **[area of practice] clinical specialty** in which the CRNP is certified **by the Board**.

(3) Identify the categories of drugs from which the CRNP may prescribe or dispense in accordance with **{§ 21.284 (relating to prescribing and dispensing parameters)}** **and section 8.3(a)(2)(ii) of the act (63 P. S. § 218.3(a)(2)(ii))**.

(4) **{Contain attestation by the collaborating physician that the physician has knowledge and experience with ~~any~~the drugs or the categories of drugs that the CRNP will prescribe.**

(5)} Specify the circumstances and how often the collaborating physician will personally see the patient**{, based on the type of practice, sites of service and condition**

of the patient, whether the treatment is for an ongoing or new condition, and whether the patient is new or continuing.

(6) Specify the conditions under which the CRNP may prescribe a Schedule II controlled substance ~~for up to 72 hours~~].

~~[~~(7)~~]~~ **~~(5)~~** Be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupational Affairs.

~~[~~(8)~~]~~ **~~(6)~~** Be made available for inspection **[to anyone seeking to confirm the scope of practice of the CRNP] and be provided, without charge, to any licensed pharmacist or pharmacy**.

~~[~~(9)~~]~~ **~~(7)~~** Be **reviewed and** updated by the **primary** collaborating physician and the CRNP **at least once every 2 years or** whenever **[it] the agreement** is changed **[substantively]**.

~~[~~(10)~~]~~ **~~(8)~~** Specify the amount of professional liability insurance **[carried by] that covers** the CRNP.

[(c)] (b) The CRNP shall notify the Bureau whenever a **prescriptive authority** collaborative agreement **[of a CRNP who prescribes and dispenses drugs]** is updated or terminated.

§ 21.286. Identification of the CRNP.

~~[~~(a) A patient shall be informed at the time of making an appointment that the patient will be seen by a CRNP.

(b)~~]~~ A CRNP shall wear a name tag **[that clearly identifies the]** **~~using the title CRNP [with the title "certified registered nurse practitioner."]~~** **or "nurse practitioner"** **and comply with State, Federal and facility regulations regarding identification of personnel**.

~~[~~(c) A CRNP who holds a doctorate should take appropriate steps to inform patients that the CRNP is not a doctor of medicine or doctor of osteopathic medicine.]

§ 21.287. **[Physician supervision]** **~~(Reserved)~~**Collaborating Physician.

A CRNP may only collaborate with a physician who meets the following minimum qualifications:

(1) The physician has an unrestricted license to practice medicine or osteopathic medicine in the Commonwealth of Pennsylvania.

(2) The physician is in active clinical practice.

(3) The normal and customary practice of the physician includes the services provided by the CRNP.

(4) The physician is reasonably available to take referrals of the CRNP's patients and to perform other collaboration functions in a timely fashion as required by the definition of collaboration in section 21.251.

(5) In the case of a CRNP with prescriptive authority, the physician has knowledge and experience in the drugs or categories of drugs that the CRNP is authorized to prescribe under the CRNP's prescriptive authority collaborative agreement.

[(~~a~~6) Except as consistent with a waiver granted to the physician by his licensing board, ~~A~~at any time ~~a~~the physician ~~may~~does not ~~supervise~~collaborate with more than four CRNPs who prescribe and dispense drugs. This section, however, does not limit the number of collaborative agreements that a physician may have with prescribing CRNPs. By way of example, a physician may ~~supervise~~collaborate with four prescribing CRNPs who work in the morning and four other prescribing CRNPs who work in the afternoon as long as the physician has a collaborative agreement with each CRNP.

[(b) A physician may apply for a waiver of the supervision requirements expressed in subsection (a) for good cause, as determined by the Boards.

(c)] The limit of the general rule of not more than four prescribing CRNPs to one physician does not apply to CRNPs who do not prescribe or dispense drugs. By way of example, a physician may ~~supervise~~collaborate with at the same time four CRNPs who prescribe and dispense drugs and one or more CRNPs who do not prescribe and dispense drugs.]

§ 21.288. CRNP standards of conduct.

A CRNP shall undertake a specific practice or procedure only if the CRNP has the necessary knowledge, preparation, experience and competency to properly execute the practice or procedure and the practice is within the scope of the CRNP's written collaborative agreement with a physician and the CRNP's particular clinical specialty. A CRNP shall comply with § 21.18 (relating to standards of nursing conduct).

[HEALTH CARE FACILITY POLICIES]

§ 21.291. [Institutional health care facility committee; committee determination of standard policies and procedures] ~~(Reserved)~~.

[(a) In those health care facilities providing health services in which the practice of certified registered nurse practitioners involves the acts of medical diagnosis or prescription of medical therapeutic or corrective measures, there shall be a committee in each area of practice whose function is to establish standard policies and procedures, in writing, pertaining to the scope and circumstances of the practice of the nurses in the medical management of the patient.

(b) The committee may serve not only as a policy making body for the special area but also as an advisory and interpretative body to the various staff of the health facility. The committee shall include equal representation from the medical staff, the nursing staff, including a nurse practitioner and nursing administration.]

§ 21.292. **[Free-standing health care facility committee] ~~(Reserved)~~.**

[If a certified registered nurse practitioner is associated with a physician or group of physicians, the committee may consist of, but need not be limited to, the nurse practitioners and the physicians.]

§ 21.293. **[Review and acceptance of standard policies and procedures by the committee] ~~(Reserved)~~.**

[The standard policies and procedures shall be reviewed and accepted by the committee at least annually and at such other times as necessary.]

§ 21.294. **[Review of the medical functions of the C.R.N.P. by the committee] ~~(Reserved)~~.**

[The committee shall review annually the effectiveness of the medical functions of the C.R.N.P. through an evaluation of the care rendered to patients using the data sources as patient records, statistics and patient follow-up.]

[ACCOUNTABILITY]

§ 21.311. **[Accountability of CRNP] ~~(Reserved)~~.**

[The CRNP is responsible for his own professional judgments and is accountable to the individual consumer. He is also accountable to the physician and the employing agency in the area of medical diagnosis and therapeutics.]

[TERMINATION OF APPROVAL]

§ 21.321. **[Performance of tasks without direction; performance of tasks without training; other] (Reserved).**

[(a) The approval as provided in this subchapter for a certified registered nurse practitioner may be terminated by the State Board of Nursing when, after notice and hearing, the Board finds the following:

(1) That the registrant has engaged in the performance of medical functions and tasks other than at the direction of a physician licensed by the State Board of Medicine, except in the situations as provided for in section 1 of the act of August 8, 1963 (P. L. 582, No. 301) (Reserved).

(2) That the registrant has performed a medical task or function which the registrant is not qualified by education to perform.]

MAINTENANCE OF CERTIFICATION

§ 21.331. Biennial renewal of certification.

(a) **[Effective October 31, 1985, the certifications of Certified Registered Nurse Practitioners shall be renewed at the same time as their registered nurse licenses. See § 21.29 (relating to expiration and renewal of license).**

(b) The certification renewal fee for certifications that expire on April 30, 1986 will be 25% of the renewal fee for the usual 2-year renewal period. The renewal fee for certifications that expire on a biennial anniversary of April 30, 1986 will be the renewal fee for the usual 2-year renewal period.

(c) The certification renewal fee for certifications that expire on October 31, 1986 will be 50% of the renewal fee for the usual 2-year renewal period. The renewal fee for certifications that expire on a biennial anniversary of October 31, 1986 will be the renewal fee for the usual 2-year renewal period.

(d) The certification renewal fee for certifications that expire on April 30, 1987 will be 75% of the renewal fee for the usual 2-year renewal period. The renewal fee for certifications that expire on a biennial anniversary of April 30, 1987 will be the renewal fee for the usual 2-year renewal period.

(e) The certification renewal fee for certifications that expire on October 31, 1987 will be the renewal fee for the usual 2-year renewal period. The renewal fee for certifications that expire on a biennial anniversary of October 31, 1987 will be the renewal fee for the usual 2-year renewal period.

(f) The certification renewal fees for certifications that expire on April 30, 1986, October 31, 1986, April 30, 1987 or October 31, 1987 shall be paid to the Board by October 30, 1985. The certification renewal fees for certifications that expire on a biennial anniversary of April 30, 1986, October 31, 1986, April 30, 1987 or October 31, 1987 shall be paid to the State Board of Nursing by that anniversary date] The certification, and prescriptive authority approval, if applicable, of a CRNP will

expire at the same time as the CRNP's registered nurse license as provided in § 21.29 (relating to expiration and renewal of license).

(b) Notice of application for renewal will be forwarded biennially to each active CRNP at the CRNP's address of record with the Board prior to the expiration date of the current biennial period.

(c) As a condition of biennial renewal, a CRNP shall:

(1) Simultaneously renew the CRNP's registered nurse license.

(2) Complete a minimum of 30 hours of Board-approved continuing education in the 2 years prior to renewal. As a condition of biennial renewal of prescriptive authority approval, a CRNP shall complete a minimum of 16 of the 30 hours of Board-approved continuing education in pharmacology in the 2 years prior to renewal.

(3) For a CRNP certified by the Board after February 7, 2005, also maintain current certification as a nurse practitioner from a Board-recognized National certification organization which requires passing of a National certifying examination in each particular clinical specialty area in which the nurse is certified by the Board.

(d) Renewal application forms shall be accompanied by the required renewal fee in § 21.253 (relating to fees) and verification that the CRNP is in compliance with section 8.7 of the act (63 P. S. § 218.7) regarding liability coverage. Upon approval of the renewal application, the CRNP will receive a certification for the current renewal period.

(e) Any written communication with the Board shall be typed or printed and include the CRNP's full name, including former names, the current address and certification number.

§ 21.332. Requirement of continuing education.

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(b) Continuing education requirements shall be completed each biennial cycle.

(1) **[An applicant for biennial renewal of certification is required to complete, during the 2 years preceding renewal, a minimum of 30 hours of Board-approved continuing education, as set forth in section 8.1(c) of the act (63 P. S. § 218.1(c)). Completion of a course described in § 21.283(2) (relating to prescribing and dispensing drugs) satisfies the continuing education requirement for the biennial renewal period in which it is completed.**

(2) An applicant for biennial renewal of prescriptive authority approval is required to complete, during the 2 years preceding renewal, a minimum of 16 of the 30 hours of continuing education in pharmacology. Completion of a course described in § 21.283(2) shall satisfy the continuing education requirement for the biennial renewal period in which it is completed.

(3) A person] An individual failing to meet the continuing education requirements for a biennial renewal period will be subject to formal disciplinary action under section 14(a)(3) of the act (63 P. S. 244(a)(3)).

[(4)] (2) The Board may waive the requirements of continuing education in cases of illness or undue hardship. It is the duty of each licensee who seeks a waiver to notify the Board in writing and request the waiver prior to the end of the renewal period. The Board will grant, deny or grant in part the request for waiver.

(3) An individual who requests a waiver may not prescribe or dispense drugs after the expiration of his current prescriptive authority **[and]** until the Board grants the waiver request **or the prescriptive authority approval has been renewed**.

§ 21.332a. Inactive status and reactivation.

(a) A CRNP who places his certification on inactive status is not required to meet the continuing education requirements in **[§ 21.332(b)(1) (relating to requirement of continuing education)] section 8.1(c) of the act (63 P. S. § 218.1(c))** during the period the certification is on inactive status. Upon application for reactivation of certification, the CRNP shall show proof of meeting the continuing education requirements for the biennial period immediately preceding the request for reactivation**[(.)], and, if the certification has been lapsed or on inactive status for 5 years or longer, the CRNP shall have a current, active professional nurse license, reactivated in accordance with the continued competency requirements in § 21.30a (relating to continued competency), and at least one of the following:**

(1) Proof of current certification as a nurse practitioner from a Board-recognized National certification organization that requires the passing of a National certifying examination in the particular clinical specialty area in which the nurse is seeking reactivation of certification by the Board, if the CRNP was initially certified after February 7, 2005.

(2) Evidence that the applicant has practiced as a registered nurse practitioner in another jurisdiction at some period of time within the last 5 years under a current license or certification during that time.

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(c) A CRNP who places his prescriptive authority approval on inactive status for 3 years or longer **or whose prescriptive authority approval is lapsed for 3 years or**

longer, may reactivate the prescriptive authority approval by meeting one of the following conditions:

(1) Complete the requirement in **[§ 21.283(2) (relating to prescribing and dispensing drugs)] § 21.283(b)(1) (relating to authority and qualifications for prescribing and dispensing drugs and other medical therapeutic or corrective measures)** by taking at least 45 hours of course work in advanced pharmacology.

(2) Provide evidence to the Board that:

* * * * *

(iii) The CRNP was required, as a condition for continued practice in the other jurisdiction, to complete continuing education that is substantially equivalent to the requirements **[of] in § [21.283(3)] 21.283(b)(1)**.

* * * * *

(d) A CRNP whose certification has been suspended for 5 years or longer shall meet the requirements in subsection (a), and other requirements set forth by Board order. A CRNP whose prescriptive authority approval has been suspended for 3 years or longer shall, in addition to meeting the requirements to renew the CRNP certification, meet the requirements in subsection (c), and other requirements by Board order.

(e) A CRNP whose certification has been revoked shall meet all of the requirements for original licensure as a CRNP, the requirements in subsection (a), and other requirements set forth by Board order. A CRNP whose prescriptive authority approval has been revoked shall, in addition to meeting the requirements to reinstate the CRNP certification, meet the requirements in subsection (c), and other requirements by Board order.

§ 21.333. Continuing education subject matter.

(a) Continuing education courses **[shall] must** address the CRNP's area of **[practice and meet the requirements of § 21.332(b)(1) (relating to continuing education)] specialty certification**.

(b) Pharmacology continuing education courses **[shall meet the requirements of section 8.1(c) of the act (62 P. S. § 218.1(c)) and § 21.332(b)(2) and]** must provide the knowledge and skills to understand the pharmacokinetics and pharmacodynamics of broad categories of drugs **or drugs used in the CRNP's particular specialty** and to analyze the relationship between pharmacologic agents and physiologic/pathologic responses.

§ 21.334. Sources of continuing education.

(a) The following providers of continuing education and credentialing organizations have currently met the standards for course approval for continuing education. **Therefore, all courses offered by these providers are approved for continuing education credits required for biennial license renewal.**

(1) **[Accordingly, provided that these providers agree to abide by § 21.336(a) (relating to continuing education course approval), the courses offered or approved by the following providers or credentialing organizations are approved:**

(i) Board-approved CRNP programs.

(ii) The American Nurses Credentialing Center's Commission on Accreditation (ANCC).

(iii) The American Academy of Nurse Practitioners (AANP).

(iv) The National Association of Pediatric Nurse Practitioners (NAPNP).

(v) The American Medical Association (AMA).

(2) The approval given to the providers and credentialing organizations in paragraph (1) is subject to reevaluation. A rescission of provider or credentialing organization approval will be made only in accordance with 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure) or by amendment of this section.] Board-approved CRNP educational programs and CRNP educational programs approved by other state boards of nursing or that hold current accreditation issued by a National nursing accreditation organization.

(2) National and international nursing organizations and their state and local affiliates.

(3) National and international medical and osteopathic organizations and their state and local affiliates.

(4) National pharmaceutical organizations and their state and local affiliates.

(5) National nursing specialty organizations.

(6) Continuing education programs approved by other state boards of nursing.

(b) CRNPs may obtain credit for courses offered by providers not indicated in subsection (a)(1)**--(6)** if the provider receives approval of the course under § 21.336 **(relating to continuing education course approval)** prior to its implementation.

* * * * *

PENALTIES FOR VIOLATION

§ 21.351. Penalties for violation.

Certification as a CRNP may be suspended **[or]**, revoked or **[the violator may be placed on probation as the Boards, or a joint committee thereof, determine after a formal hearing has been held, and a violation of The Medical Practice Act of 1974 (63 P. S. §§ 421.1--421.18) and of The Professional Nursing Law (63 P. S. §§ 211--225), of this subchapter, or of regulations pertaining to the aforementioned has been adjudicated.] otherwise restricted when, after notice and opportunity to be heard, the Board finds that:**

(1) The CRNP has engaged in the performance of medical functions and tasks beyond the scope of practice permitted for a CRNP or beyond the scope of the CRNP's clinical specialty area as provided in the act and this subchapter.

(2) The CRNP has engaged in the performance of medical functions and tasks without the collaboration of a physician as required by this subchapter.

(~~2~~3) The CRNP has performed a medical task or function which the CRNP does not have the necessary knowledge, preparation, experience and competency to perform properly or is not qualified under the act and this subchapter to perform.

(~~3~~4) The CRNP has violated the act or this subchapter, or engaged in any conduct prohibited for professional nurses.

PENNSYLVANIA MEDICAL SOCIETY
CONCERNS WITH SCHEDULE DRUG DOSAGE PARAMETERS

The current regulations (§21.284(e)) limit CRNP prescriptions of Schedule II drugs to 72 hours and Schedule III and IV drugs to 30 days and prohibit refills except with the collaborating physician's permission. The current regulations also require prompt notification of the collaborating physician after the prescription of Schedule II drugs. While some modifications of these restrictions may be appropriate, the expansions permitted by the revised regulations allow CRNPs to practice well beyond their training and expertise. Under the revised regulations, CRNPs may prescribe Schedule II drugs for up to 30 days and Schedule III and IV drugs for up to 90 days and place no restriction on refills. These expansions potentially will jeopardize patient care and increase drug diversion problems[1] in the Commonwealth.

Schedule II drugs

The proposed modification to the duration limit on Schedule II prescriptions is especially troubling. Schedule II drugs include dangerous narcotics (opiates), stimulants, and depressants. Examples include morphine, hydrocodone (Vicodan), oxycodone (Percocet and OxyContin), meperidine (Demerol), methylphenidate (Ritalin), and dextroamphetamine (Dexedrine). Their use in treatment regimens must be judicious, as they 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.[2]

CRNPs certainly can play a positive role in managing the treatment of patients with Schedule II drugs. However, they must be required to collaborate in a meaningful way with a qualified physician and specific additional protections and restrictions are warranted. CRNPs have critical voids in the education, training, and experience that are necessary to diagnose conditions that are appropriately treated with Schedule II drugs; to make initial and subsequent assessments of how to integrate Schedule II drugs into treatment plans for these conditions, if at all; and to identify and address potential problems that may result.

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[1] The number of pills CRNPs will be able to prescribe is essentially ten times greater for Schedule II drugs and three times greater for Schedule III-IV.

[2] Narcotic analgesics are used to treat pain. These drugs block pain messages and cause drowsiness. A large single dose can cause severe respiratory depression and death. Long-term use commonly leads to physical dependence and, in some cases, addiction. Opioids are the most commonly abused prescription drugs.

Central nervous system depressants are used to treat anxiety, panic attacks, and sleep disorders. They slow down normal brain function and can cause a sleepy, uncoordinated feeling in the beginning of treatment. Long-term use can lead to physical dependence and addiction.

Central nervous system stimulants are used to treat the sleeping disorder narcolepsy and attention-deficit/hyperactivity disorder. These drugs, which can be addictive, enhance brain activity and increase alertness and energy. They elevate blood pressure, heart rate, and respiration. Very high doses can lead to irregular heartbeat and high body temperature.

The deficiencies in education, training, and experience of CRNPs will be accentuated by the proposed expansion of CRNPs authority to prescribe Schedule II drugs. The current 72-hour restriction essentially limits CRNPs to prescribing Schedule II drugs for acute pain. The increase to 30 days allows CRNPs to venture into diagnosis and treatment of a wider range of medical conditions, such as chronic pain, narcolepsy, and attention deficit disorder. A physician should be actively involved in the diagnosis of these conditions and in any decision to utilize a Schedule II drug in the treatment regimen.

Another important concern is that the regulation is not clear as to whether the CRNP may provide only a single 30 day prescription of a Schedule II drug or can treat a patient with a Schedule II drug for a longer period by writing multiple prescriptions—with the additional prescriptions written either at a subsequent visit or at the same visit and post dated. (The federal Drug Enforcement Administration recently amended its regulations to allow practitioners to issue multiple prescriptions during a single visit, to be filled sequentially, allowing the patient to receive a 90-day supply of that controlled substance via this method.[3])

In the State Society's view, the following restrictions should apply when CRNPs prescribe Schedule II drugs (in addition to the collaboration requirements previously discussed): Prescriptions for initial therapy must be limited to a seven-day supply. Prescriptions for ongoing therapy past the initial prescription must be approved by the collaborating physician and limited to a 30-day supply (with no automatic refills as required by federal law.) The prescription must clearly state on its face that it is for initial or ongoing therapy. The CRNP must notify the collaborating physician of the prescription as soon as possible but in no event longer than 24 hours.[4]

A number of individuals making comments have argued that the changes to the Schedule II dosage parameters are needed to improve pain management care for cancer patients. Our recommendations will allow CRNPs to play an appropriate role in prescribing Schedule II drugs to alleviate the pain of cancer and other patients without jeopardizing patient safety. Once a physician diagnoses the patient as having cancer or another condition that warrants long term use of Schedule II drugs for the treatment of the patient's pain, a CRNP may prescribe Schedule II drugs in 30 day dosages for the patient's ongoing pain management therapy.

At the same time, our recommended dosage parameters will help assure that patients with chronic pain are not treated with Schedule II drugs on a long term basis when a different treatment regiment was appropriate for the patient's condition. A patient who needs a Schedule II drug for longer than seven days should be evaluated by a physician to determine the cause of the pain and whether continued use of a Schedule II drug to treat the patient's pain is medically appropriate. However, as written, the proposed amendments would allow a CRNP to treat a patient for pain on a long term basis without the patient ever being evaluated by a physician.

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[3] See 72 Fed. Reg. 64921 (Nov. 19, 2007)(amending 21 C.F.R. §1306.12).

[4] These restrictions are consistent with those applicable to physician assistants (PAs) with the exception that PAs currently are limited to a 72-hour dose for initial therapy.

The Pennsylvania Society of Anesthesiologists (a specialty which includes pain management) is submitting comments which describe in more detail why our recommended dosage parameters allow CRNPs to play an appropriate role in prescribing Schedule II drugs to alleviate the pain of cancer and other patients without jeopardizing patient safety.

Schedule III and IV drugs

But for the proposed watering down of the collaboration protections, the State Society would support extending the duration limit to 90 days and removing the refill prohibition for CRNP prescriptions of Schedule III and IV drugs. However, the State Society opposes these revisions in the absence of meaningful collaboration protections. Schedules III and IV include anabolic steroids as well as narcotic, stimulant, and depressant drugs, such as hydrocodone with acetaminophen (Vicodin), alprazolam (Xanax), chlordiazepoxide (Librium), diazepam (Valium), and temazepam (Restoril). While drugs on these schedules are somewhat less dangerous than Schedule II drugs, their use in treatment regimens likewise must be judicious for similar reasons, and CRNPs are not qualified to prescribe them virtually independently.

PENNSYLVANIA MEDICAL SOCIETY COMMENTS ON
PROPOSED AMENDMENTS TO THE CERTIFIED REGISTERED NURSE PRACTITIONER (CRNP) REGULATIONS

(Unless otherwise indicated, page references are to document labeled Pennsylvania Medical Society Recommended Changes.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
COLLABORATION			
Collaboration requirement The amended regulations fail to articulate, and require CRNPs to comply with, the essential elements of "collaboration" as defined by Act 206. Indeed, the amended regulations describe a relationship between CRNPs and physicians that is almost akin to that between two physicians. At most, the amended regulations describe a relationship in which the physician, *when asked* by the CRNP, assists in managing a patient.	The law mandates that CRNPs collaborate with a physician when performing acts of medical diagnosis, or prescribing medical therapeutic or corrective measures. "Collaboration", as that term is defined and used in Act 206 and the Professional Nursing law, has three essential elements: *Delineation of CRNP's areas of practice*—The Professional Nursing Law defines the potential universe of what CRNPs *may* do in collaboration with a physician. The collaborative agreement defines what they *can* do within that universe, based upon the mutual agreement of the CRNP and the physician who are parties to the agreement. *Availability of physician for back-up*—The physician must be immediately available should he or she be needed to provide a consultation to the CRNP. The physician further must be available on a regularly scheduled basis for referrals of CRNP patients whose care is beyond the CRNP's capabilities. *Provision of oversight by physician*—The	The importance of the collaboration requirement to quality patient care cannot be overstated. A physician completes pre-med in college, four years of medical school, then at least two and usually four to seven (or more) years of residency. In contrast, a CRNP needs to complete only two years of post-college education. Because of their more extensive education, training, and experience, physicians have a greater depth of knowledge in the basic building blocks of medicine such as anatomy, physiology, and body systems, as well as in disease processes, diagnosis, and treatment. In one sense, the oversight requirement appropriately limits CRNP independence. It is common that persons with some, but not extensive, knowledge in a field "do not realize what they do not know." Accordingly, the collaboration definition requires the physician to review with the CRNP "the standards of medical practice"	See pages 2 to 7 of this document.

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
	physician must be available on a regularly scheduled basis to oversee the care provided by the CRNP, as appropriate to the circumstances, via for example, standing orders and protocols, chart review, and co-signing. The written agreement between a prescribing CRNP and the collaborating physician must identify the circumstances and how often the collaborating physician will personally see the patient. The regulations must, under fundamental principles of administrative law, be consistent with the statutes. They cannot violate or undercut the "collaboration requirement," including the essential elements in the statutory definition of "collaboration".	through "consultation and chart review, drug and other medical protocols within the practice setting, periodic updating in medical diagnosis and therapeutics and cosigning records when necessary to document accountability by both parties." At the same time, the oversight requirement also provides important opportunities for CRNPs to expand their clinical judgment through additional training and specifically to expand what they *can* do over time as their expertise grows through mentoring.	
Definition of collaboration The statute defines "collaboration" almost identically to the definition of "direction" in the current regulations. The amendments delete the definition of "direction" and do not substitute the definition of "collaboration." [§21.251]	The regulations should include the statutory definition of "collaboration" as follows: "Collaboration" means 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 predetermined plan for emergency services.	We recognize that CRNPs are still bound to collaborate with physicians as per the statutory definition, regardless of whether the definition is in the regulations. However, CRNPs and physicians know where to find the regulations; they are much less likely to know where to find the pertinent statutory provisions, let alone how to interpret the statute and regulations together in the proper relationship. Also, the exclusion of the statutory definition, combined with other changes, signals that the Board of Nursing will tolerate CRNPs acting independently.	Add statutory definition of "collaboration" to §21.251. (See page 2.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
	(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 cosigning records when necessary to document accountability by both parties.		
Need for written agreement The amendments only require a written agreement for those aspects of the collaboration involving the CRNP prescribing drugs. [See definition of "collaborative agreement" in §21.251; see also §21.282a & §21.283]	Collaborative agreements should be in writing.	This is important so that both parties clearly understand the terms of the relationship, in particular how the aspects of collaboration will be handled. In any event, the law requires that the agreement be written if the CRNP is prescribing medical therapeutic or corrective measures. The statutory requirement for a written agreement is not limited to collaboration on drug prescriptions. It would include, for example, collaboration regarding a treatment regimen that includes an order for physical therapy.	Modify the definition of "collaborative agreement" in §21.25 to require it to be written and signed in all cases. (See page 2.) Modify §21.282a & §21.283 to reference the CRNP's written collaborative agreement. (See pages 7 to 8.)
Qualifications of collaborating physician			Modify §21.287 to specify the qualification requirements for collaborating physicians. (See pages 15 to 16.)
PA license	The physician must have an unrestricted PA	Restrictions on the physician's license will	Add unrestricted PA license requirement in

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
The definition of CRNP requires that the collaborating physician be licensed in Pennsylvania, but does not expressly state that the license must be unrestricted.	license. A CRNP should not be permitted to collaborate with a physician who, for example, is on active-retired status or a physician who only has a graduate education license.	impede effective collaboration.	new §21.287(1). (See page 15.)
Active clinical practice The amended regulations are silent on whether the collaborating physician must be in active clinical practice.	The physician must be in active clinical practice.	This is required by the statutory definition of collaboration. How can the physician be available for referrals if the physician is not in active clinical practice?	Add active clinical practice requirement in new §21.287(2). (See page 15.)
Relevant practice area The amended regulations are silent on whether the collaborating physician must practice in the areas of the CRNP's practice .	The services provided by the CRNP should not exceed the physician's normal and customary practice.	A physician who collaborates with a CRNP must, *a fortiori*, have relevant knowledge and experience and be actively practicing in the CRNP's specific area of practice. Otherwise, how can the physician adequately perform his or her back-up and oversight responsibilities?	Add requirement that normal and customary practice of collaborating physician must encompass the CRNPs intended practice in new §21.287(3). (See page 15.)
Knowledge and experience with drugs The current regulations require that the physician have knowledge and experience in the drugs that the CRNP is authorized to prescribe. [§21.285(b)(4)] The amendments delete this	In the case of a CRNP with prescriptive authority, the physician should have knowledge and experience in the drugs or categories of drugs that the CRNP is authorized to prescribe.	The above rationale applies here as well. Deletion of this requirement is especially troubling given that the revised regulations also give CRNPs broader authority to prescribe scheduled drugs. Concerns about delay in the authority of CRNPs to prescribe new drugs can be addressed by adding "or categories of drugs".	Retain the current knowledge and experience requirement in §21.285(b)(4). (See page 14.) Add knowledge and experience requirement in new §21.287(5). (See page 16.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
requirement.			
Location The amended regulations are silent on issues relating to the location(s) of the CRNP and collaborating physician practice sites.	The physician does not need to be on site. However, the physician should practice close enough to make referrals of the CRNP's patients to the physician convenient and practical and to perform other collaborative functions.	This is consistent with the statutory definition of collaboration. We are not advocating for a specific distance radius in either miles or travel time. What is acceptable will vary depending upon the circumstances, such as the type of practice, rural versus urban, etc. However, a physician practicing in Chicago clearly cannot perform the required responsibilities of a collaborating physician.	Add reasonable availability requirement in new §21.287(4). (See page 16.)
Contents of collaborating agreement			
Scope of covered services The amended regulations are silent on this issue except as described below.	The agreement should define the scope of the covered services, i.e. the general range of care for which the physician is providing collaboration.	This is consistent with the statutory definition of collaboration, and is an explicit requirement in the expansions of CRNP practice enacted last year. CRNPs are permitted to perform a service only if it is "within the scope of the CRNPs collaborative or written agreement with a physician." In essence, the law defines what a CRNP *may* do in collaboration with a physician; the collaborative agreement defines what a CRNP *can* do in his or her particular practice setting and relationship.	Add requirement for CRNP to be acting within the scope of the CRNP's collaborative agreement to §21.282a and §21.283(a). (See page 7.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
List of drugs or categories of drugs The current regulations require that the collaborative agreement list the drugs that the CRNP may prescribe. [§21.285(b)(3)] The amended regulations seem to delete this requirement. [§21.284(b) & §21.285(b)(3)]	The agreement should list the drugs or categories of drugs that the CRNP may prescribe. (This is referred to as a "positive formulary".)	This is mandated by law and is an essential patient safety requirement.	Retain the current positive formulary requirement in §21.284(b). (See page 9.) Retain the current positive formulary requirement in §21.285(b)(3). (See page 14.)
Collaboration terms The current regulations state that the agreement must delineate when and how often the patient is to be seen personally by the physician based upon "the type of practice, sites of service and condition of the patient, whether the treatment is for an ongoing or new condition, and whether the patient is new or continuing." [§21.285(b)(5)] The amendments delete the language in quotes.	The collaborative agreement should describe when and how the physician and the CRNP will collaborate. The regulations should recognize that the nature of the collaboration will vary depending upon the circumstances such as the care provided, the site of service, the condition of the patient, whether the patient is new or continuing, whether the treatment is for a new of continuing condition, and the training and experience of the CRNP.	This is consistent with the statutory definition of collaboration and good medical practice. Often, the amount of direction or collaboration necessary is dependent on the familiarity developed between the CRNP and the physician and the resulting level of "trust". The collaborative agreement should be dynamic and reflect the documented training, experience, and current skill sets of the CRNP; it requires periodic updating as the CRNP gains experience and skill sets and develops a trusting, professional relationship with the collaborating physician. A "newly graduated" or "newly hired" CRNP may require more restrictions and oversight than warranted for an experienced CRNP who has a long-time professional relationship with the collaborating physician. An experienced CRNP may also be more	Retain the current language in §21.285(b)(5) giving examples of factors that influence how often the patient is to be seen by a physician. (See page 14.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
		reliable in knowing when additional expertise is needed.	
Accountability The revised regulations delete the requirement that the CRNP is accountable to the collaborating physician in the area of medical diagnosis and therapeutics. [§21.311]	The CRNP should be accountable to the collaborating physician in the area of medical diagnosis and therapeutics.	Accountability is an integral element of a meaningful collaborative arrangement. How is a collaborating physician to evaluate whether to continue or expand the CRNP's areas of practice if the CRNP is not required to demonstrate proficiency to the physician?	Retain current §21.311. (See page 17.)
Discipline The current regulations provide that practicing outside a collaborative agreement with a physician is grounds for discipline of a CRNP. [§21.321(a)(1)] The amendments delete this provision. [See also §21.351.]	Practicing outside a collaborative agreement with a physician should be grounds for discipline of a CRNP.	We are at a loss as to why this provision is being removed in the amendments. It is critically important that CRNPs practice within the intended and agreed-upon scope. Removal of this provision again signals that the Board of Nursing does not intend to enforce the collaboration requirement.	Add to §21.351 language providing that practicing outside the scope of a collaborative agreement with a physician is grounds for discipline. (See page 23.)
PHYSICIAN/CRNP RATIO			
The current regulations provide that physicians may not collaborate with more than four CRNPs with prescriptive authority at any given time, absent the approval of their licensing board. [§21.287]	Physicians should not collaborate with more than four CRNPs with prescriptive authority at any given time, absent the approval of their licensing board.	For collaboration to be done correctly, the physician must devote a meaningful amount of time to the required tasks, including monitoring the CRNP's performance. This is especially true when the CRNP prescribes or dispenses drugs. A four-to-one ratio clearly does not pose an	Retain ratio requirement in §21.287. Modify to impose duty on CRNP to collaborate only with a physician who is not exceeding the ratio. (See page 16.)

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The amendments delete this provision entirely.		undue burden on CRNP practice in Pennsylvania; to date, there has been only a single request for an exception in a situation where the limit would otherwise apply. (The exception request involved CRNPs practicing at family planning clinics.) While there may be some situations where it would be appropriate to allow a physician to collaborate with more than four CRNPs, these isolated situations can be adequately addressed by an exception process. The Board of Nursing may have viewed it as unnecessary, as similar language in the Medical Board regulations at 49 Pa. Code §18.57 remains in effect. However, the Board of Nursing should have, at the minimum, substituted new language that requires CRNPs to collaborate only with physicians who are in compliance with regulations issued by their respective licensing boards for collaboration with CRNPs.	
AREAS OF PRACTICE			
Parameters of collaborative agreement and specialty certification The revised regulations add a lengthy listing of what tasks a CRNP is authorized to do,	Regulation listings of care that CRNPs *can* provide should state that CRNPs *may* provide service if it is within the scope of their collaborative agreement and specialty certification.	These restrictions are mandated by law and are essential patient safety requirements.	Add to §21.282a & §21.283(a) a requirement that the CRNP *may* provide listed service only if it is within the scope of the CRNP's collaborative agreement and specialty certification. (See page7.) Add to §21.288 the requirement that the

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
without indicating in any way that these tasks can be done only if within the scope of the CRNP's collaborative agreement and specialty certification. [§21.282a & §21.283]			CRNP must be acting within the scope of the CRNP's collaborative agreement. (See page 16.)
Treatment plans One of the listed categories is "develop and implement treatment plans." [§21.282a]	Regulation listings of care that a CRNP can provide should not include overbroad categories that include services beyond the CRNP scope of practice. Authorization to "develop and implement treatment plans" should be limited to care within a CRNP's scope of practice.	"Develop and implement treatment plans" is so broad that it potentially would include surgery and other matters outside CRNP training and scope of practice.	Add restriction to §21.282a to exclude implementation of treatment plans involving surgery or other services outside the CRNP scope of practice. (See page7.)
PRESCRIPTIVE AUTHORITY			
Prescriptive authority requirements The revised regulations do not make the prescriptive authority requirements applicable to orders for blood products, diets, and durable medical equipment.	The prescriptive authority requirements should be applicable to orders for blood products, diets, and durable medical equipment.	This is mandated by law. The statute sets forth requirements that must be satisfied for a CRNP to prescribe medical therapeutic or corrective measures. These statutory requirements are not limited to drug prescriptions.	Limit §21.282a to acts of medical diagnosis. (See page 7.) Move authority to issue orders for blood products, diets, and durable medical equipment from §21.282a to §21.283 (which sets forth the requirements applicable when CRNP is prescribing medical therapeutic or corrective measures). (See pages 7 to 8)
Drug review committee approval for changes to regulatory formulary	Any changes to the current formulary must be approved by the Department of Health Drug Review Committee.	This is mandated by the law. Importantly, as recently as last summer when the legislature expanded the CRNP scope of	Retain current formulary restrictions in §21.284(b)(3)&(7). (See page 9.)

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The current regulations have a positive formulary, i.e., list the categories of drugs that CRNPs can prescribe (provided that they are authorized to do so in their collaborative agreement) and delineate certain restrictions. [§21.284(b)] The amendments modify the formulary.	Section 8.4 of the Professional Nursing Law creates a Drug Review Committee, and mandates that this Committee approve any modification to the formulary categories. The Drug Review Committee is to consist of seven members, including the Secretary of Health and six practitioners in active clinical practice who are to be appointed by the Secretary of Health – two physicians (one of whom must be a collaborating physician for a CRNP), two pharmacists, and two CRNPs. The Committee is required to act on a submitted request within 60 days of the request. If the Committee fails to approve or disapprove a submitted request within the required time-frame, the request may be deemed approved.	practice in Act 48 of 2007, it did not adopt the CRNP's proposal to remove the requirement for the Drug Review Committee to approve modifications to the formulary. To the best of our knowledge, the administration has never appointed a Drug Review Committee at any time since given the mandate to appoint the committee six years ago. Accordingly, the regulations could not have been "submitted to" the Committee, and the Nursing Board cannot rely on a so-called "deemed approval" of a non-existent committee. The purpose of the Committee was to provide otherwise missing input from physicians and pharmacists on proposed modifications to the categories of drugs that CRNPs can prescribe. We do not believe that the statute permits the administration to circumvent this important safety net and *de facto* approve proposed modifications to the categories of drugs that CRNPs may prescribe, by refusing to follow through with its statutory obligation to appoint the Committee.	
Completion of advanced pharmacology course work The revised regulations allow the required pharmacology coursework to be completed	The required coursework should be completed within *two* years of the application.	Due to the nature of pharmacological evolution and the need for a current knowledge base, a *two* year period between the advanced pharmacology training and the application is more appropriate.	Modify 21.283(b)(iii) to change the time period from five to two years. (See page 8.)

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within *five* years of the application for prescriptive authority. [§21.283(b)(iii)]			
Notice of problems The revised regulations delete language requiring the collaborating physician to notify the patient when he or she learns that the CRNP prescribed a drug inappropriately, but fail to substitute any requirement that the CRNP assure that the patient and the collaborating physician are notified or otherwise aware of an identified inappropriate prescription by the CRNP. [§21.284(d)]	Provision should be made to assure that both the patient and the collaborating physician are notified or otherwise aware of an identified inappropriate prescription by the CRNP.	This is a basic requirement for patient safety. If there is a mis-prescription of a Schedule II drug, it should be rectified promptly.	Modify current language in §21.284(d) to impose obligation on CRNP to assure that the patient and the collaborating physician are notified or otherwise aware an identified inappropriate prescription by the CRNP. (See pages 9-10.)
SCHEDULED DRUGS			
Schedule II			
Dosage limit The current regulations allow CRNPs to prescribe Schedule II drugs for up to a 72 hour dosage. [§21.284(e)(1)] The amendments increase the dosage limit to 30 days.	The dosage limit should be increased to seven days for initial therapy and 30 days only for ongoing therapy approved by collaborating physician. Post-dated prescriptions allowing dosages beyond those restrictions should be prohibited.	We agree that the current dosage limit (72 hours) is inadequate to address certain episodes of acute pain. Our recommended increase to seven days addresses this concern. We also agree that CRNPs should be permitted to prescribe Schedule II drugs for *ongoing* therapy approved by their collaborating	Modify §21.284(e)(1) to allow 7-day dosage for initial therapy, but limit 30-day dosage to ongoing therapy approved by collaborating physician. (See page 9.) Add restriction to §21.284(e) prohibiting use of post-dated prescription to allow dosages beyond those restrictions.

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		physician. However, we disagree that CRNPs should be permitted to prescribe Schedule II drugs for up to 30 days for *initial* therapy. This would allow CRNPs to venture into diagnosis and treatment of a wider range of medical conditions, such as chronic pain, narcolepsy, and attention deficit disorder and other complex medical diagnoses. A physician should be actively involved in the diagnosis of these conditions and any decision to utilize a Schedule II drug in the treatment regimen. Our recommended expansions are consistent with those applicable to physician assistants (PAs) with the exception that PAs currently are limited to a 72-hour dose for initial therapy. For additional explanation, see document entitled Concerns with Scheduled Drug Dosage Parameters.	
Authorization in agreement The current regulations require that the collaborative agreement delineate the conditions for which the CRNP may prescribe Schedule II drugs. [§21.285(b)(6)] The amendments delete this	The collaborative agreement should delineate the conditions for which the CRNP may prescribe Schedule II drugs.	This is consistent with the definition of collaboration and good medical practice.	Retain current requirement in §21.285(b)(6) that the collaborative agreement delineate the conditions for which the CRNP may prescribe Schedule II drugs. (See page 14.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
requirement.			
Notice to physician The current regulations require the CRNP to notify the physician of a Schedule II prescription as soon as possible, and no later than 24 hours. [§21.284(e)(1)] The amendments delete this requirement.	The CRNP should notify the collaborating physician ASAP and no later than 24 hours.	This is an important patient safety protection.	Retain current requirement in §21.284(e)(1) that the CRNP notify the collaborating physician of an Schedule II prescription. (See page 10.)
Schedules III-IV *Dosage limit/refills* The current regulations allow CRNPs to prescribe Schedule III-IV drugs for up to 30 days and prohibit refills of those drugs. [§21.284(e)(2)] The amendments extend the time limit to 90 days and allow refills.	Assuming the collaboration issues are addressed, the dosage limit for Schedule III and IV drugs should be increased to 90 days and refills should be permitted. However, absent the changes that we have recommended, the dosage limit for Schedule II drugs should remain at 30 days and no refills should be permitted.	See document entitled Concerns with Scheduled Drug Dosage Parameters.	
NOTICE AND IDENTIFICATION REQUIREMENTS			
Name tag The current regulations require a	CRNPs should wear a name tag identifying themselves as a "certified registered nurse	While the "CRNP" identification may be sufficient for some patients who are	Retain current §21.286(b) and modify to allow use of title "nurse practitioner". (See

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
CRNP to wear a name tag with the identification "certified registered nurse practitioner." [§21.286(b)] The regulations change the identification to "CRNP".	practitioner" or "nurse practitioner".	knowledgeable in health system acronyms, it will be uninformative at best, and will most likely confusing or misleading, for most patients.	page 15.)
Appointment notification The current regulations require that patients who seek an appointment be provided with prior notice that they will be seen by a CRNP before they are scheduled with a CRNP. [§21.286(a)]	Patients calling a practice, which includes physicians and CRNPs, should be made aware when their appointment is with a CRNP.	Notice is essential for informed patient choices. In many cases, such as a request for a routine physical, the patient may be satisfied with being seen by a CRNP in lieu of a physician member of the practice. In other cases, the patient may prefer to be seen by a physician due to the serious nature of the problem or individual preference.	Retain current §21.286(a). (See page 15.)
Use of "doctor" title The current regulations require a CRNP who holds a doctorate to take appropriate steps to inform a patient that the CRNP is not a doctor of medicine or osteopathic medicine. [§21.286(c)] The amendments delete this requirement.	CRNPs with a doctorate should clarify that they are not a physician if they are initially introduced to a patient by the title "Doctor".	This provision is essential to assure informed patient choices, as most patients associate the title "doctor" with a physician, particularly in a hospital setting. Optometrists, podiatrists, and physician assistants all have similar identification requirements. Deletion of this requirement for CRNPs inevitably will result in patient confusion at best and may cause patients to make health care decisions that they would not have otherwise made based upon the incorrect assumption that they were following the	Retain current §21.286(c). (See page 15.)

ISSUE	MEDICAL SOCIETY POSITION	RATIONALE	RECOMMENDED CHANGES
		advice of a physician.	
HEALTH CARE FACILITY POLICY COMMITTEES			
The revised regulations eliminate sections that require health care facilities to have a committee in each area of practice whose function is to establish written standard policies and procedures pertaining to the scope and circumstances of the practice of the CRNPs in the medical management of the patient. [§§21.291-21.294]	Hospitals should continue to have CRNP policy committees.	These committees provide valuable processes for defining the scope of practice of CRNPs and evaluating the quality of care provided by CRNPs within the facility.	Retain current [§§21.291-21.294. (See pages 16 to 17.)
MISCELLANEOUS			
"May" vs. "shall" Throughout the regulations use "may" or "must" to describe the CRNPs responsibilities.	The term "shall" should be used when describing the CRNPs responsibilities.	This terminology is clearer that the requirement is absolute.	Substitute "shall" for "may" or "must" in §21.284(c), §21.284(f), 21.284a(b)(1), 21.284(e)(1), 21.284(e)(2) (See pages 9 to 12.)
Lack of coordination with physician licensing boards The revised regulations apparently were developed without any consultation or discussions with the physician	The State Board of Nursing should have developed the regulations in consultation with the physician licensing boards to assure coordination with their regulations defining standards for physician behavior in collaborative relationships.	The physician licensing boards still are authorized to discipline a physician who serves as a CRNPs collaborating physician, but fails to perform that responsibility in accordance with appropriate standards. Moreover, the physician licensing boards are	

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licensing boards, i.e., the State Board of Medicine and the State Board of Osteopathic Medicine.		authorized to define standards for how physicians collaborate. For example, the physician licensing boards may choose to preclude physicians from collaborating with more than four CRNPs at one time. Such a requirement is valid as it defines a standard of care for physician behavior and does not restrict a CRNP's scope of practice. Yet, the regulations read as if the physician licensing boards play no role whatsoever in defining an appropriate collaborative relationship. As discussed above, any language referencing a collaborating CRNP/physician ratio has been removed entirely. At the minimum, this should have been discussed with the physician licensing boards. Ideally, the three boards should discuss and attempt to come to agreement as to what, if any, ratio requirements they should apply. Of even greater concern, the Board of Nursing ignored an opportunity to work with the physician licensing boards to develop templates for collaborative agreements, which physicians and CRNPs could use as a starting point to adapt to their unique circumstances. Such templates would protect patient safety by providing further guidance as to the respective responsibilities of physicians and CRNPs in	

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		collaborative relationships. In addition, template agreements would facilitate more collaborative relationships by providing guidance to physicians who would be willing to collaborate with a CRNP but for the current need to develop an agreement from a blank slate.	