Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Boards of Nursing and Medicine; Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC90-40-10
Regulation title	Regulations Governing Prescriptive Authority for Nurse Practitioner
Action title	Clarification of requirements for supervision
Date this document prepared	7/13/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

As currently written, the requirements for supervision and site visits by physicians who oversee the practice of nurse practitioners with prescription authority in section 100 have led to some confusion and misinterpretation. Therefore, the purpose of the action is to clarify the language for consistency with the boards' rules and with the Code of Virginia. The provisions for practice of nurse practitioners within local health departments, federally funded clinics or nonprofit health clinics will be separated into subsection C to distinguish those requirements for supervision from those for nurse practitioners in other practice settings.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The Board of Nursing adopted the amendments to 18VAC90-40-10 et seq., Regulations Governing Prescriptive Authority for Nurse Practitioners on May 15, 2007, and the Board of Medicine adopted the amendments on June 21, 2007.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 and Chapter 25 of this title…

Chapter 29 of Title 54.1 establishes the requirements for supervision of physicians for nurse practitioners exercising prescriptive authority:

§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed nurse practitioners.
A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title, a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title as follows: (i) Schedules V and VI controlled substances on and after July 1, 2000; (ii) Schedules IV through VI on and after January 1, 2002; (iii) Schedules III through VI controlled substances on and after July 1, 2003; and (iv) Schedules II through VI on and after July 1, 2006. Nurse practitioners shall have such prescriptive authority upon the provision to the Board of Medicine and the Board of Nursing of such evidence as they may jointly require that the nurse practitioner has entered into and is, at the time of writing a prescription, a party to a written agreement with a licensed physician which provides for the direction and supervision by such physician of the prescriptive practices of the nurse practitioner. Such written agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the physician providing direction and supervision.
B. It shall be unlawful for a nurse practitioner to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written agreement between the licensed nurse practitioner and the licensed physician.
C. The Board of Nursing and the Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of nurse

practitioners as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.

The Board of Medicine and the Board of Nursing shall be assisted in this process by an advisory committee composed of two representatives of the Board of Nursing and one nurse practitioner appointed by the Board of Nursing, and four physicians, three of whom shall be members of the Board of Medicine appointed by the Board of Medicine. The fourth physician member shall be jointly appointed by the Boards of Medicine and Nursing. Regulations promulgated pursuant to this section shall include, at a minimum, (i) such requirements as may be necessary to ensure continued nurse practitioner competency which may include continuing education, testing, and/or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients, and (ii) requirements for periodic site visits by physicians who supervise and direct nurse practitioners who provide services at a location other than where the physician regularly practices.

D. This section shall not limit the functions and procedures of certified registered nurse anesthetists or of any nurse practitioners which are otherwise authorized by law or regulation.

E. The following restrictions shall apply to any nurse practitioner authorized to prescribe drugs and devices pursuant to this section:

1. The nurse practitioner shall disclose to his patients the name, address and telephone number of the supervising physician, and that he is a licensed nurse practitioner.

2. Physicians, other than physicians employed by, or under contract with, local health departments, federally funded comprehensive primary care clinics, or nonprofit health care clinics or programs to provide supervisory services, shall not supervise and direct at any one time more than four nurse practitioners. In the case of nurse practitioners, other than certified nurse midwives, the supervising physician shall regularly practice in any location in which the nurse practitioner exercises prescriptive authority pursuant to this section. A separate office for the nurse practitioner shall not be established. In the case of certified nurse midwives, the supervising physician either shall regularly practice in the location in which the certified nurse midwife practices, or in the event that the certified nurse midwife has established a separate office, the supervising physician shall be required to make periodic site visits as required by regulations promulgated pursuant to this section.

3. Physicians employed by, or under contract with, local health departments, federally funded comprehensive primary care clinics, or nonprofit health care clinics or programs to provide supervisory services, shall not supervise and direct at any one time more than four nurse practitioners who provide services on behalf of such entities. Such physicians either shall regularly practice in such settings or shall make periodic site visits to such settings as required by regulations promulgated pursuant to this section.

F. This section shall not prohibit a licensed nurse practitioner from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

G. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Nursing and Medicine in the category of certified nurse midwife and holding a license for prescriptive authority may prescribe Schedules II through VI controlled substances without the requirement for either medical direction or supervision or a written

agreement between the licensed nurse practitioner and a licensed physician while participating in a pilot program approved by the Board of Health pursuant to § 32.1-11.5.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the action is to clarify the requirements for physician supervision, site visits and chart reviews of nurse practitioners prescribing medications to patients. Currently, there is some confusion about the requirement of law and regulation in regard to the requirement for the physician to regularly practice in the same location where the nurse practitioner with prescriptive authority is practicing. The law allows physicians in public health, federally funded clinics or nonprofit health clinics to either practice in the same location or make site visits to that location; physicians who supervise nurse practitioners in private practices must regularly practice in that same location. With the expansion of practices into retail settings, that requirement of law and regulation needed to be further specified to prevent situations in which the practice of a nurse practitioner is not appropriately and legally supervised by a physician in accordance with a practice agreement. Such a clarification is necessary to protect the health and safety of patients who may be receiving care under such agreements.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The Boards have determined that a fast-track process is appropriate because there are no substantive changes proposed. The amendments are intended to restate current requirements in a re-organized format that should be less confusing and lead to clearer understanding and compliance.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

The supervision and site visit requirements are separated into two subsections for practices in public health or nonprofit clinics and for practices in private settings. The physician providing supervision in a private practice is required to regularly practice in the same location as the nurse practitioner; but in other settings, the physician is allowed to make regular site visits.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public is greater oversight and protection by clarifying that a physician supervising the prescriptive authority of a nurse practitioner must regularly practice in the same location. The supervision cannot be remote or electronic; the law and regulation requires the physician to regularly practice at the location where patients are being seen by the nurse practitioner to ensure appropriate prescribing and care are being given. There are no disadvantages to the public.
2) The primary advantage to the agency and the Commonwealth is greater clarity of the regulations and consistency with the Code to reduce the confusion and misinterpretation by some who have read the rules incorrectly.
3) This clarification has been given verbally to corporate entities who have inquired about setting up nurse practitioners in clinics set in retail locations. The law and regulation clearly provide that a separate practice setting may not be established for the nurse practitioner, but there may continue to be a lack of understanding about the requirement for physician oversight.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and	a) As a special fund agency, the Board must generate

enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There will be no on-going expenditures related to this action.
Projected cost of the regulation on localities	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals affected by this regulation would be nurse practitioners with prescriptive authority and the supervising physicians with whom they have practice agreements.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 2973 nurse practitioners with prescriptive authority. To the extent those persons are employed by physician practices, there may be some effect if the practice for the nurse practitioner does not currently comply.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There should be no costs associated with this action since it is a restatement and reorganization of current requirements.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The issue of regular practice by a physician supervising nurse practitioners with prescriptive authority came to the attention of the Board of Nursing when representatives of a corporate entity asked to speak to the board regarding its intent to establish clinics staffed by nurse practitioners in retail settings. During the presentation, it became apparent that there was some misunderstanding of current law and regulation regarding the necessity for the supervising physician to "regularly practice in the same location" with the nurse practitioner. While "regularly practice" is deliberately left undefined, the Board made it clear that its expectation

would be that patients could regularly be seen by the supervising physician in the location where care is routinely provided by nurse practitioners. There was confusion between requirements for private practices and public health or nonprofit clinics.

The boards referred the issue to the Committee of the Joint Boards, which recommended amending section 100 by a fast-track action to provide further clarity in the regulation. There was discussion of the use of a guidance document, but reorganization and restatement of the regulation was preferred so persons seeking compliance with law and regulation would have the rules more clearly stated without having to look for further guidance.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family or family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
100	n/a	Sets out the requirements for supervision and site visits for physicians overseeing the practice of nurse practitioners with prescriptive authority	In subsection A, there is a reference to the applicable Code section to direct the reader to the requirements of law. Subsection B is amended to eliminate language that only applies to the supervision of nurse practitioners in local health departments, etc. and to include those provisions that apply to all other types of practice. Those provisions include regular practice by the physician in the same location, no separate practice setting for the nurse practitioner, and monthly, random review of patient charts.

			Subsection C is created to set out the requirements for supervision in local health departments, federally funded clinics and nonprofit health clinics, in which the physician may either regularly practice in the same location or make regular site visits for consultation and direction. Site visits must be specified in the protocol between the practitioners but must be no less than quarterly. Those physicians are also required to conduct monthly, random reviews of patient charts.