Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Boards of Nursing and Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC90-40-10 et seq.
Regulation title	Regulations Governing Prescriptive Authority for Nurse Practitioners
Action title	Practice in patient care teams
Date this document prepared	8/6/13

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The revised requirements for prescriptive authority for nurse practitioners are consistent with a model of collaboration and consultation with a patient care team physician working under a mutually agreed-upon practice agreement within a patient care team. The goal of the amended regulation is to revise terminology and criteria for practice for consistency with changes to the Code in Chapter 213 of the Acts of the Assembly.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

NP = nurse practitioner

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Boards of Nursing and Medicine the authority to promulgate regulations to administer the regulatory system:

§ 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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The specific mandate to promulgate regulations for the prescriptive authority for nurse practitioners is found in § 54.1-2957.01 of the Code of Virginia:

§ 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.), a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.). 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 or electronic practice agreement with a patient care team physician that clearly states the prescriptive practices of the nurse practitioner. Such written or electronic practice agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as described in the practice agreement. Evidence of a practice agreement shall be maintained by a nurse practitioner pursuant to § 54.1-2957. Practice agreements authorizing a nurse practitioner to prescribe controlled substances or devices pursuant to this section shall either be signed by the patient care team physician who is practicing as part of a patient care team with the nurse practitioner or shall clearly state the name of the patient care team physician who has entered into the practice agreement with the nurse practitioner.

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 or electronic practice agreement.

C. The Board of Nursing and the Board of Medicine 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.

Regulations promulgated pursuant to this section shall include, at a minimum, such requirements as may be necessary to ensure continued nurse practitioner competency, which may include continuing education, testing, 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.

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 the patient at the initial encounter that he is a licensed nurse practitioner. Any member of a patient care team shall disclose, upon request of a patient or his legal representative, the name of the patient care team physician and information regarding how to contact the patient care team physician.

2. Physicians shall not serve as a patient care team physician on a patient care team at any one time to more than six nurse practitioners.

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 collaboration and consultation with a patient care team physician as part of a patient care team pursuant to § 54.1-2957 or a written or electronic practice 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 by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Following the paradigm of the law, the regulations achieve the goal of increasing access chiefly by elimination of identified obstacles such as the current requirement for the physician to

regularly practice or make site visits to the setting where nurse practitioners prescribe. Through appropriate collaboration and consultation, patient health and safety are protected by having an agreement between parties that includes the prescriptive authority for the nurse practitioner.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The following changes are proposed:

- Definitions are revised for consistency with definitions in the Code (see §§ 54.1-2900 and 54.1-3000)
- The provision relating to a practice agreement is amended to delete the requirement for it to be submitted to the boards and approved prior to issuance an authorization or following a revision of an agreement. The practice agreement must be either signed or clearly state the name of the physician who has entered into the practice agreement.
- The previous ratio of four NP's with prescriptive authority for each supervising physician has been replaced in the Code by six NP's per patient care team physician.
- Section 100 is being repealed because it is now inconsistent with the model of collaboration and consultation of a patient care team. A requirement for the physician to regulatory practice in the same location was eliminated in the law.
- Requirements for prescriber information on prescriptions are amended for consistency with requirements for other types of prescribers.
- Requirements on disclosure to patients are amended for consistency with subsection E 1 of § 54.1-2957.01.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

1) The most significant benefit is to the patients/clients in Virginia who may benefit from an expansion of care by nurse practitioners since they are not required to practice in the same location as the patient care team physician and are able to deliver care in a collaborative approach in which each member of the team practices to the extent of his training. There are no disadvantages to the public.
2) There are no specific advantages to the agency or the Commonwealth except possibly better utilization of nurse practitioners throughout underserved parts of the state. There are no disadvantages.

3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434**.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The individuals affected are nurse practitioners and the physicians with whom they practice.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	There are 4641 nurse practitioners (out of a total of 7408) who hold a current authorization to prescribe controlled substances. (Certified registered nurse anesthetists, who are included in the total number of NP's, do not have prescriptive authority). Each of the NP's would have *at least* one patient care team physician with whom he has a practice agreement. The number of persons who would constitute a small business is unknown. Some NP's establish their own practice; some practice within a physician practice; others practice in large medical centers.
Benefits expected as a result of this regulatory proposal.	The benefit of the regulatory proposal is consistency with the Code, which was amended in 2012 to eliminate the requirement for NP's to practice in the same location as their supervising physicians.
Projected cost to the state to implement and enforce this regulatory proposal.	There are no projected costs to implement and enforce the proposal. Notification of statutory and regulatory changes has been done electronically through the website or email. The promulgation of regulations and conducting a public hearing are accomplished during regularly scheduled meetings of the Boards of Nursing and Medicine
Projected cost to localities to implement and enforce this regulatory proposal.	There are no costs to localities.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	There are no costs to affected entities.

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.

There are no alternatives that will achieve the essential purpose of the action.

After working together for two years, the leadership at the Medical Society of Virginia (MSV) and the Virginia Council of Nurse Practitioners (VCNP) reached an agreement that outlined a team-based care model designed to help improve access to MD and NP care and reduce paperwork. In response to recommendations emerging out of the Virginia Health Reform Initiative (VHRI) to explore solutions that address systemic challenges to access to care in the Commonwealth, the legislation passed by the General Assembly emphasizes a consultative and collaborative approach between physician and NPs with the physician providing leadership and management of the care team.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Since the promulgation of regulations for collaboration and consultation by a nurse practitioner with a patient care team physician under a written or electronic practice agreement is specified by the Code of Virginia, there are no alternative methods that will accomplish the objectives of applicable law.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

The NOIRA and emergency regulation were published in Vol. 29, Issue 30 of the Register of Regulations on June 3, 2013; comment was requested until July 3, 2013. There were no comments on the Virginia Regulatory Townhall. Comments sent to the Boards are summarized as follows:

Commenter	Comment	Agency response
Russell C. Libby, M.D., President of the Medical Society of Virginia	MSV supports the nurse practitioner regulations as drafted.	The agency acknowledges the support of MSV.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

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

There are no changes from the emergency regulation currently in effect.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
10		Establishes definitions for words and terms used in the regulations	The definition for the term "nurse practitioner" is revised for consistency with definitions in the Code (see §§ 54.1-2900 and 54.1-3000) The definition of "practice agreement" is revised for consistency with changes in Code. The definition of "supervision" is deleted because it is no longer applicable to prescriptive authority for nurse practitioners. *The likely impact of the proposed changes in definitions is minimal since terms are also used and defined in the Code.*
40		Sets out the qualifications for initial approval of prescriptive authority	The provision relating to a practice agreement is amended to delete the requirement for it to be submitted to the boards and approved prior to issuance of a prescriptive authority license. *The Code does require that a nurse practitioner have a practice agreement prior to writing a prescription, but it does not require the practice agreement to be submitted and approved.*
60		Sets out the	*Since a practice agreement no longer has to be submitted*

		requirements for reinstatement of prescriptive authority for an NP who has allowed it to lapse.	*and approved, the requirement for a new practice agreement to be filed with the boards is deleted.*
90		Sets out the requirements for a practice agreement	Changes are made in section 90 to reflect changes in the law: 1) the practice agreement may be "signed" and maintained electronically; 2) the physician is now referred to as the "patient care team physician" rather than the supervising physician; and 3) the agreement must be maintained by the NP but not submitted to the boards. The practice agreement must be either signed or clearly state the name of the physician who has entered into the practice agreement. (see subsection A of § 54.1-2957.01) Subsection D is added to replace the language in subsection A of section 100 (which is being deleted). The previous ratio of four NP's with prescriptive authority for each supervising physician has been replaced in the Code by six NP's per patient care team physician. (see subsection E 2 of § 54.1-2957.01)
100		Sets out the requirement for site visits and supervision of a nurse practitioner by a physician, include a requirement for the physician to regularly practice in the same location with the NP.	*Section 100 is being repealed because it is now inconsistent with the model of collaboration and consultation of a patient care team. A requirement for the physician to regulatory practice in the same location was eliminated in the law (see § 54.1-2957.01, subsection E in the HB346)*
110		Sets out the requirements for disclosures.	Subsection A is amended for consistency with information on prescriptions by other prescribers. If a nurse practitioner has a number issued by the Drug Enforcement Administration (DEA), that is the only identifier, a pharmacist would need to validate the prescriber. The addition of a prescriptive authority number issued by the boards is unnecessary and confusing. If a nurse practitioner is only authorized to write Schedule VI drugs, he is not legally required to have a DEA number because the DEA does not consider those drugs to be "controlled substances." In that situation, the pharmacist would need the prescriptive authority number as an identifier and authorization for the prescriber. Subsection B is amended and subsection C is added for consistency with requirements on disclosure to patients in subsection E 1 of § 54.1-2957.01.
130		Sets out the grounds by which the boards	The only amendment changes the term "supervising" physician to "patient care team" physician.

		may take disciplinary action against a licensee.	