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Final Regulation
Agency Background Document

Agency name	Boards of Nursing and Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC90-40-10 et seq.
Regulation title(s)	Regulations Governing Prescriptive Authority for Nurse Practitioners
Action title	Practice in patient care teams
Date this document prepared	2/19/15

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation.

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

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.

On January 27, 2015, the Board of Nursing adopted final amendments and on February 19, 2015, the Board of Medicine adopted final amendments to 18VACC90-40-10 et seq., Regulations Governing Prescriptive Authority for Nurse Practitioners.

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. Describe the rationale or justification of the proposed regulatory action. Describe 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.

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 the new substantive provisions, the substantive changes to existing sections, or both.

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 of 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 regularly 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 there are 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 requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There were no changes made to the text of the proposed regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

A public hearing was conducted on October 8, 2014; there was a 60-day comment period from September 22, 2014 to November 21, 2014. There were no comments received.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

There were no changes from the emergency regulation in effect from 5/8/13 to 11/6/14.

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 requirements for reinstatement of prescriptive authority for an NP who has allowed it to lapse.	*Since a practice agreement no longer has to be submitted 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 may take disciplinary action against a licensee.	The only amendment changes the term "supervising" physician to "patient care team" physician.