Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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 revisions
Date this document prepared	8/6/12

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

1) Please explain why this is an emergency situation as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

Chapter 213 of the 2012 Acts of the Assembly (HB346) requires the Boards of Nursing and Medicine to promulgate regulations to implement provisions of the act with 280 days of its enactment. Therefore, the Board is authorized to adopt emergency regulations establishing rules for practice of nurse practitioners in collaboration and consultation with a patient care team physician and revising the requirements for supervision and site visits.

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.

In addition, Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the emergency regulation is to revise requirements for prescriptive authority for nurse practitioners 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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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 detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

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	*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.*

		prescriptive authority for an NP who has allowed it to lapse.	
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	The only amendment changes the term "supervising" physician to "patient care team" physician.

		against a licensee.	

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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.

Public participation

The agency is seeking comments on the regulation that will permanently replace this emergency regulation, including but not limited to 1) ideas to be considered in the development of the permanent replacement regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) the potential impacts of the regulation.

The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax 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. Comments may also be submitted on the Regulatory Townhall at: **www.townhall.virginia.gov** In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website

(http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi). Both oral and written comments may be submitted at that time.

Family impact

Assess the potential 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.