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Fast-Track Regulation Agency Background Document

Agency name	Board of Nursing, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC90-40-10 et seq.
Regulation title(s)	Regulations for Prescriptive Authority for Nurse Practitioners
Action title	Correction of cite on practice agreements
Date this document prepared	8/11/17

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 (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation.

When the Code was amended in 2016 relating to practice agreements between nurse practitioners and physicians, the requirement for agreements to be submitted to the Board of Nursing was eliminated. Other sections of regulation were amended accordingly, but section 120 in Chapter 40 was overlooked. The change eliminates reference to an agreement being on file with the board and included the allowance for an agreement to be electronic rather than written.

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 July 18, 2017, the Board of Nursing adopted an amendment to 18VAC90-40-10 et seq., Regulations for Prescriptive Authority for Nurse Practitioners; on August 4, 2017, the Board of Medicine adopted the same amendment.

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.

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 (§2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system...

Section 54.1-2957.01 sets out the requirements for a practice agreement for nurse practitioners who have prescriptive authority, including the provision for an electronic practice agreement.

§ 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.

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.

The goal of the proposal is to eliminate a potential conflict between Code and regulation. Public health and safety continues to be protected with practice agreements that are maintained in written or electronic form and must be available to the Board if there are questions about practice.

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?

The proposed amendment is less burdensome for all parties and conforming to the Code, and therefore, the Board is confident that the rulemaking is noncontroversial and should be promulgated as a fast-track action.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The change eliminates reference to an agreement being on file with the board and included the allowance for an agreement to be electronic rather than written.

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 of the amendment is elimination of confusing and conflicting language in regulation. There are no disadvantages.
- 2) There are no advantages or disadvantages to the Commonwealth.

3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to “*promulgate regulations in accordance with the Administrative Process Act (§2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system.*” There is no restraint on competition as a result of promulgating this regulation. The language is less burdensome and has no effect on competition.

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.

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.

There are no alternative methods consistent with health and safety of the public.

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.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>There are no cost for implementation and enforcement, since the proposed regulation conforms to Code amended in 2016.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There are no costs to localities</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	
<p>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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 6,748 nurse practitioners with prescriptive authority. None are affected since the regulation is conforming to language in the Code, which prevails over regulation.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>There are no projected costs.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>No potential confusion for regulants and consistency with the Code.</p>

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 viable alternatives to the proposed regulatory action that would achieve the intent of conforming to the Code as amended in 2016.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-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: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

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 family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. 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 follow the instructions in the text following the three chart templates below.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
120	Sets out the requirements for dispensing of manufacturers’ samples	The current regulation specifies that the nurse practitioner may only dispense samples of drugs that are included in the written practice agreement on file with the Board. As amended in 2016, the Code allows a practice agreement to be electronic rather than written and no longer requires submission of the agreement to the Board. The amendment to section 120 conforms the rule to the Code.