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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(s)	18VAC90-40
Regulation title(s)	Regulations for Prescriptive Authority for Nurse Practitioners
Action title	Revision of prescriptive authority
Date this document prepared	10/31/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

This regulatory change will eliminate the requirement for renewal of prescriptive authority for a nurse practitioner. It will reduce the fee for an application for prescriptive from $75 to $35. Requirements for continuing competency and disclosure to patients remain in effect, as mandated by the Code of Virginia.

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.

N/A

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

This regulatory action was initiated and recommended by the Committee of the Joint Boards of Medicine and Nursing. It is consistent with Governor Northam's Executive Order 14 (2018), which states that: "All regulatory activity should be undertaken with the least possible intrusion into the lives of the citizens of the Commonwealth and be necessary to protect the public health, safety, and welfare."

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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 statutory provisions for prescriptive authority are found in:

§ 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 (i) Schedules II through V controlled substances in accordance with any prescriptive authority included in a practice agreement with a licensed physician pursuant to subsection H of § 54.1-2957 and (ii) Schedule VI controlled substances without the requirement for inclusion of such prescriptive authority in a practice agreement.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose is elimination of unnecessary regulation and cost for nurse practitioners. The Code of Virginia specifies certain requirements for prescriptive authority but does not require maintenance of a separate license, which is a creation of regulation. Therefore, the Boards will retain the requirements to be issued prescriptive authority and for continuing education, but they will eliminate the requirement to renew the license. "*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" (subsection* C of § 54.1-2957.01).

Requirements for continuing competency and disclosure to patients remain in effect, as mandated by the Code of Virginia, and as necessary to protect the health and safety of patients.

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.

This regulatory change will eliminate the requirement for renewal of prescriptive authority for a nurse practitioner. It will reduce the fee for an application for prescriptive from $75 to $35. Requirements for continuing competency and disclosure to patients remain in effect, as mandated by the Code of Virginia.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) There are no advantages or disadvantages to the public; the amendments will benefit nurse practitioners and make their practice less costly.
2) There are no advantages or disadvantages to the agency or the Commonwealth. The loss of revenue can be absorbed in the budget of the Board of Nursing without necessitating any increase in fees.
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 "*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. 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." There is no restraint on competition as a result of promulgating this regulation, which is less costly and less restrictive for licensees.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There is no applicable federal requirement.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. The proposed change will result in a reduction in revenue for the Board of Nursing, the board that

	administers the nurse practitioner program and incurs all expenditures related to licensing and discipline. For FY18 – the revenue related to prescriptive authority was: Application fee Count of payments: 967 Total amount: $72,585.00 Renewal Fee (includes late fees) Count of payments: 3269 Total amount: $90,383.00 Total amount of payments received FY2018: $162,968.00 Once the regulation is effective, there will be an application fee of $35 (versus the current fee of $75), and there will no renewal fee. In the future, if there is an equal number of applicants in a fiscal year, the revenue would be $33,845 – resulting in a total of $129,123 less revenue. The balance in the Board's budget at the end of the third quarter of FY18 was $10,401,356, so the agency concluded that the board can absorb the costs with existing resources.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	If there are agencies that pay the licensure fees of nurse practitioners they employ, there would be a reduction in costs for renewal of prescriptive authority on an on-going basis.
For all agencies: Benefits the regulatory change is designed to produce.	Potentially less costs for nurse practitioners with prescriptive authority employed by state agencies

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Nurse practitioners with prescriptive authority
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;	There are 7,417 prescriptive authorities issued to nurse practitioners. All will be affected by the reduction in costs and regulation. It is unknown how many would be small businesses; some work in large health systems, and others work in physician practices or are self-employed.

b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	An applicant for prescriptive authority will benefit from a reduction in the application fee for $75 to $35. Nurse practitioners who hold prescriptive authority will benefit from the elimination of a renewal fee of $35 each biennium.
Benefits the regulatory change is designed to produce.	Less cost associated with acquisition and maintenance of prescriptive authority by nurse practitioners

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The Boards of Nursing and Medicine noticed an intent to eliminate the requirement for a separate license for a nurse practitioner to have prescriptive authority. However, there are two emergency actions amending Chapter 40, the prescriptive authority regulations, so it was not advisable to repeal that chapter and incorporate provisions into Chapter 30 at this time. The goal was to reduce the financial and logistical burden on nurse practitioners who must now maintain a separate license in order to prescribe. That goal will be accomplished by a reduced application fee and elimination of the requirement to renew the prescriptive authority once issued.

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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There is no alternative to adoption of a less stringent and less burdensome requirement for prescriptive authority other than the promulgation of amended regulations.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

The Notice of Intended Regulatory Action was published on July 23, 2018 with a 30-day comment period until August 22, 2018. There were no comments.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Boards of Medicine and Nursing are 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 for the public comment file may do so by mail, email or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage 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 (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Detail of Changes

Current section number	Current requirement	Change, intent, rationale, and likely impact of new requirements
20	Sets out the authority and administration of regulations	Subsection B is amended to delete authority for biennial renewal of prescriptive authority as renewal is being eliminated.

50	Sets out provisions for the renewal of prescriptive authority	This section is being repealed.
55	Sets out requirements for continuing competency	A reference to renewal of prescriptive authority is deleted in subsection A. The Code of Virginia requires the Boards: *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.* Accordingly, the requirement for continuing education is not eliminated.
60	Sets out the requirements for reinstatement	This section is being repealed. *If the boards take a disciplinary action to restrict the license of a nurse practitioner by taking away his/her authority to prescribe drugs, that would be included in an order. Reinstatement of such authority would depend on the terms of the order.*
70	Sets out the fees relating to prescriptive authority	All fees are deleted except for the fee for initial issuance of prescriptive authority, which is reduced from $75 to $35, and the charge for a returned check, which is minimally set in Code at $35.
110	Sets out requirements for disclosure to patients	In subsection A, the word “issued’ is substituted for the word “written” since many prescriptions are now issued electronically rather than written on a prescription pad.