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Fast-Track Regulation Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	CE credit for volunteer hours
Date this document prepared	12/12/16

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Chapter 82 of the 2016 General Assembly requires health regulatory boards to promulgate regulations to allow some volunteer service time to count towards meeting some of a licensee's continuing education requirements.

The Board has adopted proposed regulations to allow pharmacists to count up to two hours of the 15 hours required for annual renewal to be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those

services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic. Pharmacy technicians will be allowed to count up to one hour of the five required for annual renewal by volunteering.

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

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 December 12, 2016, the Board of Pharmacy adopted amendments to 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

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 Board of Pharmacy the authority to promulgate regulations to administer the regulatory system and a specific mandate of Chapter 82 of the 2016 General Assembly:

§ 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.
2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

- 3. To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.
- 4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.
- 5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.
- 6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) *that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services.* 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.).

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 purpose of the amended regulation is compliance with the mandate of the General Assembly and to provide an incentive for licensees to volunteer professional services to free clinics or public health centers. While a licensee can satisfy up to two hours of continuing education with six hours of volunteer service, he or she is still required to have 13 hours of approved continuing education necessary to acquire new knowledge and skills. (For pharmacy technicians, one hour could be credited for volunteering with four hours of continuing education.) Therefore, public health is served by a potential increase in badly-needed volunteer service for pharmacy services; but public safety is not sacrificed by eliminating most or all of the continuing education hours required for renewal.

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 allowance of hours for volunteer service to be counted towards the continuing education requirement is a mandate of the General Assembly. A licensee is not required to provide

volunteer service but may be credited with continuing education hours for doing so. The provisions are permissive and neither is controversial.

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.

To comply with the mandate of Chapter 82 of the 2016 General Assembly, the Board has adopted a proposed regulation to allow pharmacist to count up to two hours of the 15 hours required for annual renewal to be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic. Pharmacy technicians will be allowed to count up to one hour for three hours of volunteer service.

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 advantage to the public is the incentive given for pharmacists and pharmacy technicians to volunteer their services in exchange for credit towards meeting continuing education requirements. There are no disadvantages.

2) There are no advantages or disadvantages to the agency or the Commonwealth.

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.) *that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services.* 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.) There is no restraint on trade as a result of compliance with this statutory mandate.

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 is no alternative to the adoption of regulations for continuing education credit for volunteer hours; it is a mandate of the General Assembly.

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>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. There are no on-going expenditures.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>None</p>
<p>Description of the individuals, businesses, or</p>	<p>Pharmacists and pharmacy technicians are</p>

<p>other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>potentially affected, but the regulation is permissive.</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 14,210 pharmacists and 14, 373 pharmacy technicians with current licenses. A minority of pharmacy practices would be considered small businesses.</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 costs.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The beneficial impact may be an increase in volunteer hours for free clinics and health centers that provide pharmacy services to the poor or uninsured.</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.

Given that the Board has a statutory mandate to promulgate a regulation for CE credit for volunteer hours, it selected the alternative that would achieve the essential purpose of encouraging volunteering while not substantially reducing the amount of continuing education necessary to improve and maintain competency.

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 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; 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
18VAC110-20-90 18VAC110-20-106	Set out the requirements for continuing education	Subsection D is added in section 90 as follows: Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic. Subsection D is added in section 106 as follows: Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the

		<p>health department or free clinic.</p> <p><i>The intent of the Board was to comply with a statutory mandate to allow credit for volunteer hours. The criteria and settings for such volunteer services are specified in § 54.1-2400 (6). The ratio of one hour for three hours of service was adopted to encourage licensees to donate a block of time to the clinics or health department. If a pharmacist volunteers with one of the clinics that operate a pharmacy, he or she would be able to satisfy two of the 15 hours of continuing education required for renewal. If a pharmacy technician volunteers with one of the clinics that operate a pharmacy, he or she would be able to satisfy one of the 5 hours of continuing education required for renewal.</i></p>
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