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Fast-Track Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-21
VAC Chapter title(s)	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	CE credit for volunteer hours
Date this document prepared	6/17/20

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 (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendm18ents to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The amendment to 18VAC110-21-120 will allow a pharmacist to satisfy two hours of the requirement for three hours of live or real-time interactive CE by volunteering pharmacy services for three hours.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

CE = continuing education

Statement of Final Agency Action

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 June 16, 2020, the Board of Pharmacy amended 18VAC110-21-10 et seq., Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians.

Mandate and Impetus

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, or board decision). 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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The impetus for the regulatory change was a response to requests from pharmacists to be able to count their volunteer time in providing pharmacy services as live CE hours; such a provision is intended to encourage pharmacists to volunteer. The amended rule will benefit pharmacists and free clinics or local health departments and will not be controversial.

Legal Basis

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

§ 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.) 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.).

The specific statutory mandate for continuing education is found in:

§ 54.1-3314.1. Continuing education requirements; exemptions; extensions; procedures; out-of-state licensees; nonpractice licenses.

A. Each pharmacist shall have obtained a minimum of 15 continuing education hours of pharmaceutical education through an approved continuing pharmaceutical education program during the year immediately preceding his license renewal date.

B. An approved continuing pharmaceutical education program shall be any program approved by the Board.

C. Pharmacists who have been initially licensed by the Board during the one year preceding the license renewal date shall not be required to comply with the requirement on the first license renewal date that would immediately follow.

D. The Board may grant an exemption from the continuing education requirement if the pharmacist presents evidence that failure to comply was due to circumstances beyond the control of the pharmacist.

E. Upon the written request of a pharmacist, the Board may grant an extension of one year in order for a pharmacist to fulfill the continuing education requirements for the period of time in question. Such *extension shall not relieve the pharmacist of complying with the continuing education requirement for the current period.*

F. The pharmacist shall attest to the fact that he has completed the continuing education requirements as specified by the Board.

G. The following shall apply to the requirements for continuing pharmaceutical education:

1. The provider of an approved continuing education program shall issue to each pharmacist who has successfully completed a program certification that the pharmacist has completed a specified number of hours.

2. The certificates so issued to the pharmacist shall be maintained by the pharmacist for a period of two years following the renewal of his license.

3. The pharmacist shall provide the Board, upon request, with certification of completion of continuing education programs in a manner to be determined by the Board.

H. Pharmacists who are also licensed in other states and who have obtained a minimum of fifteen hours of approved continuing education requirements of such other states need not obtain additional hours.

I. The Board shall provide for an inactive status for those pharmacists who do not wish to practice in Virginia. The Board shall require upon request for change from inactive to active status proof of continuing education hours as specified in regulations. No person shall practice in Virginia unless he holds a current active license.

J. As part of the annual 15-hour requirement, the Board may require up to two hours of continuing education in a specific subject area. If the Board designates a subject area for continuing education, it shall publish such requirement no later than January 1 of the calendar year for which the specific continuing education is required.

Purpose

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 of the regulatory change is to allow pharmacists to receive credit toward fulfilling the requirement of three hours of live CE by volunteering. To the extent such an allowance is an incentive for a pharmacist to work without compensation in a free clinic or local health department, the proposed rule will improve the health, safety and welfare of low income citizens who receive pharmacy services from one of those entities.

Substance

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.

Subsection C of 18VAC110-21-120 is amended to allow two hours of live CE credit for the delivery of volunteer pharmacy services in accordance with subsection D of that section.

Issues

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) The possible advantage to the public would be an increase in the amount of volunteer pharmacy services available to low-income individuals receiving health services through a local health department of a free clinic. There would also be an advantage to a pharmacist who is able to fulfill some of the three hours of live CE with such service. There are no disadvantages to the public.
2) There are no advantages or disadvantages to this agency or 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.) that 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.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

Requirements More Restrictive than Federal

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 are no applicable federal requirements.

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 – Local health departments that operate pharmacies through VDH may benefit from volunteer hours provided by pharmacists.

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, 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. 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. There are no on-going expenditures.
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.	No costs

For all agencies: Benefits the regulatory change is designed to produce.	Local health departments could potentially benefit if the amended rule encourages volunteering by pharmacists.

Impact on Localities

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

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.	Licensed pharmacists
Agency's best estimate of the number of such entities that will be affected. 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.	At the end of the 3rd quarter of FY20, there were 15,360 licensed pharmacists. There is no estimate of the number of small businesses, but the majority of pharmacists are employees of retail pharmacy corporations or large health systems.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. 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.	No costs.
Benefits the regulatory change is designed to produce.	It is a permissive rule that may encourage pharmacists to volunteer their services.

Alternatives to Regulation

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.

There are no viable alternatives that will achieve the purpose of this regulatory action.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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 regulatory flexibility; in order to make the allowance available, the regulatory requirement must be amended.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, 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.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; phone number (804) 3674688; fax number (804) 527-4434; email: Elaine.yeatts@dhp.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
120	Subsection C provides that: Of the 15 hours of CE required for renewal, five hours must be live or interactive.	Subdivision 3 is added to credit a maximum of two hours of live CE for the delivery of volunteer pharmacy services in accordance with subsection D. Subsection D states: *Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, 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.* Currently, pharmacists can receive up to two hours of CE credit for volunteering, but some have requested that they be able to count those hours toward the new requirement for five hours of live CE (effective 12/19). The Board decided to grant that request to add an allowance for counting hours for live CE for volunteer service. In accordance with subsection D, a pharmacist must volunteer for three hours per one hour of CE credit.