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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)	18 VAC 110-20 18 VAC 110-21 18 VAC 110-30 18 VAC 110-50 18 VAC 110-60
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy Regulations Governing the Licensure of Pharmacists Regulations for Practitioners of the Healing Arts to Sell Controlled Substances Regulations Governing Wholesale Distributors, Manufacturers and Warehousers Regulations Governing Pharmaceutical Processors
Action title	Handling fee
Date this document prepared	5/18/20

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, 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.

The Office of the Comptroller has advised the Department that the costs for handling a returned check or dishonored credit card or debit card payment is $50, as set forth in § 2.2-4805 of the Code of Virginia. Therefore, all board regulations are being amended to delete the returned check fee of $35 and replace it with a handling fee of $50.

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.

N/A

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 May 18, 2020, the Board of Pharmacy amended:

Regulations Governing the Practice of Pharmacy
Regulations Governing the Licensure of Pharmacists
Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Regulations Governing Pharmaceutical Processors

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 Office of the Comptroller has advised the Department that the costs for handling a returned check or dishonored credit card or debit card payment is $50, as set forth in § 2.2-4805 of the Code of Virginia. Therefore, all board regulations are being amended to delete the returned check fee of $35 and replace it with a handling fee of $50. The Office of the Attorney General concurs with amending regulations accordingly but advised that it is not an exempt action. The rulemaking is concurring with financial policy of the Commonwealth and is not expected to 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 (6), which provides the Board of Counseling 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:…

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.) 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 for collection of a handling fee is found in the Virginia Debt Collection Act:

§ 2.2-4805. Interest, administrative charges and penalty fees.

A. Each state agency and institution may charge interest on all past due accounts receivable in accordance with guidelines adopted by the Department of Accounts. Each past due accounts receivable may also be charged an additional amount that shall approximate the administrative costs arising under § 2.2-4806. Agencies and institutions may also assess late penalty fees, not in excess of ten percent of the past-due account on past-due accounts receivable. The Department of Accounts shall adopt regulations concerning the imposition of administrative charges and late penalty fees.

B. Failure to pay in full at the time goods, services, or treatment are rendered by the Commonwealth or when billed for a debt owed to any agency of the Commonwealth shall result in the imposition of interest at the judgment rate as provided in § 6.2-302 on the unpaid balance unless a higher interest rate is authorized by contract with the debtor or provided otherwise by statute. Interest shall begin to accrue on the 60th day after the date of the initial written demand for payment. A public institution of higher education in the Commonwealth may elect to impose a late fee in addition to, or in lieu of, interest for such time as the institution retains the claim pursuant to subsection D of § 2.2-4806. Returned checks or dishonored credit card or debit card payments shall incur a handling fee of $50 unless a higher amount is authorized by statute to be added to the principal account balance.

C. If the matter is referred for collection to the Division, the debtor shall be liable for reasonable attorney fees unless higher attorney fees are authorized by contract with the debtor.

D. A request for or acceptance of goods or services from the Commonwealth, including medical treatment, shall be deemed to be acceptance of the terms specified in this section.

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 amendments conform the regulation to the Virginia Debt Collection Act (§ 2.2-4800 et seq.) of the Code of Virginia in which the General Assembly has determined that the cost for handling returned checks or dishonored credit or debit cards is $50. The department and its regulatory boards license and discipline health care practitioners with the mission of protecting the health and safety of the public, which must be supported by its licensing and miscellaneous fees.

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.

All board regulations are being amended to delete the returned check fee of $35 and replace it with a handling fee of $50 for a returned check, dishonored credit card or dishonored debit card.

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.

There are no primary advantages or disadvantages to the public.
2) The primary advantage to the Department is compliance with auditors from the Office of the Comptroller.
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.*" Any restraint on competition that results from this regulation is in accord with the General Assembly's policy as articulated in § 54.1-100.

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

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, 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.	None
For all agencies: Benefits the regulatory change is designed to produce.	Consistency with debt collection policy of the Office of the Comptroller

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.	Persons or entities regulated by the Board or applying for licensure or registration by the Board.
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.	For the Board of pharmacy, there was a total of 6 dishonored checks in FY19.
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.	For those who pay renewal, application or other fees with insufficient funds (returned check, dishonored credit card, or dishonored debit card), the penalty fee with be $50, $15 more than the current fee of $35.
Benefits the regulatory change is designed to produce.	Consistency with state policy; greater incentive to have sufficient funds in account from which payment will be drawn.

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.

Board counsels from the Office of the Attorney General have advised the Department that the handling fee of $50 in Virginia Code 2.2-4805 governs. The Board had set the fee at $35 based on language in § 2.2-614.1, which states that a "penalty fee of $35 or the amount of any cost, whichever is greater," shall be imposed. By amending § 2.2-4805 in 2009, the General Assembly determined that the costs, in the form of a "handling fee" is $50, and thus greater than the $35 penalty imposed under § 2.2-614.1. Therefore, the Board must amend its regulations to reflect the higher fee.

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; the fee is set in regulation.

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 at 9960 Mayland Drive, Henrico, VA 23233, (804) 527-4434 or 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
Chapter 20, Section 20	Establishes fees for pharmacy facilities	The fee for returned check charge of $35 is deleted, and a handling fee of $50 for returned check or dishonored credit card or debit card is added.
Chapter 21, Section 20	Establishes fees for pharmacists and pharmacy technicians	The fee for returned check charge of $35 is deleted, and a handling fee of $50 for returned check or dishonored credit card or debit card is added.
Chapter 30, Section 15	Establishes fees for physicians selling drugs	The fee for returned check charge of $35 is deleted, and a handling fee of $50 for returned check or dishonored credit card or debit card is added.
Chapter 50, Section 20	Establishes fees for wholesale distributors, warehousers, manufacturers, and third-party logistics providers	The fee for returned check charge of $35 is deleted, and a handling fee of $50 for returned check or dishonored credit card or debit card is added.
Chapter 60, Section 20	Establishes fees for pharmaceutical processors, practitioners and patients	The fee for returned check charge of $35 is deleted, and a handling fee of $50 for returned check or dishonored credit card or debit card is added.