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Final 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	Requirement for e-profile ID number
Date this document prepared	12/18/18

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.

The Board has adopted a regulation to require an applicant as a pharmacist, a pharmacy intern, or a pharmacy technician to obtain an e-profile ID number that may be utilized by the applicant and the Board to track discipline, exam scores, and continuing education. The e-profile number will also be required to renew a license or registration. There is no cost to applicants to obtain the number, and there is no cost to the Board for using an e-profile ID number to get information from the National Association of Boards of Pharmacy (NABP).

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.

NABP = National Association of Boards of Pharmacy

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 18, 2018, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no changes to previously reported information.

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 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:

- 1. To establish the qualifications for registration, certification, licensure, permit, 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, licensure, or registration. 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, permit, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification, permitting, 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 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 proposed regulatory action is to streamline the licensure process and expedite NABP reporting of demographic information, examination scores, licensure status in all states, disciplinary history, and continuing education. By having real time information, the Board will have greater assurance that there are no grounds for denial of an initial or reinstatement application for a pharmacist, a pharmacy intern, or a pharmacy technician. The e-profile information available to the Board will enhance its ability to protect the public health and safety.

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.

Sections relating to initial application for licensure or registration as a pharmacist, pharmacy intern, or pharmacy technician or for renewal of any of such license or registration are amended to include a requirement for each such person to report an e-profile ID number obtained from NABP.

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;
- 2) The advantage to the agency is the ability to expedite applications by accessing data in a centralized location with NABP; there are no disadvantages to the agency; and
- 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 which are reasonable and necessary to administer effectively the regulatory system.*” The proposed regulations do not represent any restraint on competition.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – None

Localities Particularly Affected – None

Other Entities Particularly Affected – None

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.

There was a public comment period from 9/17/18 to 11/16/18 and a public hearing on 9/25/18. No comment was received.

Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

There are no changes to the proposed text that was published.

Detail of All Changes Proposed in this Regulatory Action

*Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

Current section number	New section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
N/A	22		<p>Adds a requirement that each application for licensure as a pharmacist or for registration as a pharmacy technician or pharmacy intern include an e-profile number issued by NABP.</p> <p><i>NABP reports that most pharmacists, technicians, and interns already possess an e-profile ID since it is assigned anytime someone uses an NABP service, e.g., examination CE monitoring, licensure endorsement, etc. By communicating with NABP on possible disciplinary history, the Board can use the e-profile number to identify the applicant rather than using a social security number.</i></p>
80 and 105	N/A	Sets out the requirements for renewal of a pharmacist license or a pharmacy technician registration	<p>Adds a requirement that the renewal application, which is provided electronically, must include an e-profile ID number.</p> <p><i>A pharmacist or pharmacy technician can use the e-profile system to track his continuing education. If audited, the licensee or registrant can verify CE compliance through NABP rather than having to submit individual documentation.</i></p>