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Emergency Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Reporting immunizations to VIIS
Date this document prepared	9/10/20

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 the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.

A new section 271 is added to require any pharmacist who administers an immunization or directs a pharmacy intern to administer an immunization under his supervision to a person aged three through eighteen years during the COVID-19 public health emergency declared by the US HHS to report such immunization to and provide all information required by the Virginia Immunization Information System.

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.

VIIS = Virginia Immunization Information System

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change.

The authority for pharmacists to order and administer pediatric immunizations authorized by HHS preempts state law and is limited to the period of the national health emergency related to COVID-19 as declared by HHS. Most pediatric vaccines must be administered at specific ages. It is critical for pharmacists to report such administrations to the VIIS to mitigate potential patient harm from unnecessary or duplicative vaccine administrations. Because the HHS allowance for pharmacists to order and administer vaccines is currently in effect, it is essential to have a requirement for reporting of such immunizations in place immediately, so there is a record that can be utilized by patients and practitioners. Board counsel has advised that an emergency regulation mandating reporting is a legal option and this approach has been approved by the Secretary of Health and Human Resources and by the Governor's Office.

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 or 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.).

Authority for promulgation of an emergency regulation is found in:

§ 2.2-4011. Emergency regulations; publication; exceptions.
A. Regulations that an agency finds are necessitated by an emergency situation may be adopted by an agency upon consultation with the Attorney General, which approval shall be granted only after the agency has submitted a request stating in writing the nature of the emergency, and the necessity for such action shall be at the sole discretion of the Governor.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

Pharmacists are authorized under a declaration by the United States Health and Human Services under the Public Readiness and Emergency Preparedness Act (PREP Act) to order and administer immunizations to persons between three and 18 years of age. The declaration will only be applicable for the period of the COVID-19 public health emergency as declared by HHS and it is essential that a record of pediatric immunizations administered by a pharmacist be entered into a database, since they may not be captured in a pediatrician's medical record. An accessible record of immunizations by all providers will protect the health, safety and welfare of children and the communities in which they reside. The Commonwealth will not have the ability to track the pediatric vaccinations administered by pharmacists under the recent HHS authorization without such a mandate. This will present a significant gap in data and could lead to inappropriate vaccine administration and potential patient harm from duplicative vaccine administrations.

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.

A new section 271 is added to require any pharmacist who administers an immunization or directs a pharmacy intern to administer an immunization under his supervision to a person aged three through eighteen years during the COVID-19 public health emergency to report such immunization to and provide all information required by the Virginia Immunization Information System.

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 advantage to the public is maintenance of a record of immunizations in a central database so both patients and health care providers can be aware of which vaccines a patient has received and when they were administered; there are no disadvantages to the public.
2) There are no specific advantages or disadvantages to the agency. The Virginia Department of Health has confirmed that many pharmacies already report to the VIIS and that the system can accommodate increased reporting.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The proposed regulation promulgated by the Board does not represent any restraint on that competition. Regulations are a foreseeable result of the statute requiring the Board to protect the health and safety of patients in the Commonwealth. 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*" and has acted in accordance with its statutory mandate in § 54.1- 3307 to adopt regulations for the: *Maintenance of the quality, quantity, integrity, safety, and efficacy of drugs or devices distributed, dispensed, or administered*.

Alternatives to Regulation

Describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There is no alternative to regulation, other than a statutory requirement which would not meet the immediate need since the HHS allowance for pharmacist to order and administer pediatric vaccines is already in effect. In order for pharmacists to be mandated to report pediatric immunizations in a timely manner, it must be required by regulation.

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 emergency 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)

New chapter-section number, if applicable	Change, intent, rationale, and likely impact of new requirements
Chapter 20, Section 271	A new section 271 is added to require any pharmacist who administers an immunization or directs a pharmacy intern to administer an immunization under his supervision to a person aged three through eighteen years during the COVID-19 public health emergency to report such immunization to and provide all information required by the Virginia Immunization Information System. *The declaration, included in Public Readiness and Emergency Preparedness Act (PREP Act), is partly contrary to but supersedes state law, and will only be applicable to the period of the COVID-19 public health emergency as declared by the US HHS. Therefore, it is essential to have a regulation in effect as soon as possible so any such immunizations are recorded in a database that can prevent unnecessary and potentially harmful duplication. Without a record, medical practitioners may not have the information they need for a safe standard of care, and parents may not have the record they need for school attendance and other purposes.*