



Virginia
Regulatory
Town Hall

Emergency Regulation Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Volunteer practice by out-of-state licensees
Date:	

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an “emergency situation” means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

Chapter 740 of the 2002 Acts of the Assembly mandates that the board promulgate regulations for an out-of-state practitioner to be licensed to volunteer his services to a non-profit organization that has no paid employees and offers health care to underprivileged populations throughout the world. Regulations set forth the information and documentation that must be provided prior to such service to ensure compliance with the statute.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief

statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

The legal authority to promulgate the emergency regulation is in second enactment clause of Chapter 740 and Chapter 549 of the 2002 Acts of the Assembly. Chapter 740 states: "That the Board of Opticians and the Boards of Dentistry, Medicine, Nursing, Optometry, Pharmacy and Veterinary Medicine shall promulgate regulations to implement the provisions of this act within 280 days of its enactment."

<http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0740>

The Office of the Attorney General has certified that the "emergency situation" which exists is specified in § 2.2-4011 of the Code of Virginia as one in which the agency is required by statutory law to have a regulation in effect within 280 days from the enactment of the law.

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-4011>

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

Chapter 740 of the 2002 Acts of the Assembly provides specific conditions under which a health care practitioner who is licensed in another state can provide free care in underserved areas of Virginia. Statutory requirements include: 1) that they do not regularly practice in Virginia; 2) that they hold a current valid license or certificate in another U. S. jurisdiction; 3) that they volunteer to provide free care; 4) that they file copies of their licenses or certificates in advance with the Board; 5) that they notify the Board of the dates and location of services; and 6) that they acknowledge in writing that they will only provide services within the parameters stated in the application. The statute also provides specific requirements for the non-profit organization sponsoring provision of health care and allows the Board to charge a fee for each practitioner.

As provided in the law, the emergency regulations will insert the following requirements for volunteer practice:

A practitioner who does not hold a license to practice in Virginia and who seeks registration to practice on a voluntary basis under the auspices of a publicly supported, all

volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world shall:

1. File a complete application for registration on a form provided by the board at least 15 days prior to engaging in such practice;
2. Provide a complete list of professional licensure in each state in which he has held a license and a copy of any current license;
3. Provide the name of the nonprofit organization, the dates and location of the voluntary provision of services;
4. Pay a registration fee of \$10; and
5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of the applicable section of the Code of Virginia.

As also provided by the statute, the Board has the right to deny practice to any person whose license or certificate has been previously revoked or suspended, who has been convicted of a felony, or who is otherwise found to be in violation of applicable laws or regulations. In order to protect the health, safety and welfare of the consuming public and to ensure that the care provided by out-of-state practitioners will be minimally competent, the Board will use the information garnered from the application and verification from other states to determine whether the practitioner meets the criteria set forth in the law.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

There were no alternatives to adoption of a regulation as it was mandated by Chapter 740 of the 2002 Acts of the Assembly. The most burdensome aspect of the regulation on volunteer practice by out-of-state practitioners is specifically mandated by the Code, and that is that the group sponsoring the practice of the health care provider must be a “publicly supported, all volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world.” Meeting such stringent criteria may be difficult for many nonprofits who would like to set up one-time or temporary clinics in underserved areas of Virginia and utilize the services of out-of-state practitioners who are willing to provide services at no charge. Since the qualifying language for the organization is taken from the provisions of law, the Board had no option about those criteria.

The law is also very specific in providing an exemption from the requirement for licensure in Virginia, so the regulations simply set forth the process for filing an application and submitting the documentation necessary to determine whether the applicant and the organization meet the statutory qualifications. The law provides that the applicant notify the Board at least 15 days

before provision of services, but the Board will not be able to process an application until it is complete and the qualifications and licensure have been verified. There is also a provision in the legislation for a fee to be paid prior to providing services in Virginia, so the Board has adopted a very minimal fee of \$10 to cover some of the costs of processing the application.

With the passage of House Bill 1318 (Chapter 740 of the 2002 Acts), the Board is mandated to promulgate regulations implementing provisions of the laws within 280 days. It has also adopted a Notice of Intended Regulatory Action to receive comment on its intent to replace the emergency regulations with permanent regulations.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the 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.

The proposed regulatory action would not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, strengthen or erode the marital commitment or increase or decrease disposable family income. The ability of out-of-state practitioners to provide health care services at no charge to persons in underserved areas may benefit a small number of families who have limited access to such services.