



**11 Virginia
Regulatory
Town Hall**

Final 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:	Voluntary practice
Date:	

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The Board of Pharmacy is recommending that 18 VAC 110-20-10 et seq. be amended to comply with Chapter 740 of the 2002 Acts of the Assembly, which 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. The enactment clause required the board to adopt emergency regulations, and the proposed regulations are identical to and must replace those regulations prior to their expiration on July 18, 2003.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

There were no changes made in the text since proposed regulations were published.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On April 29, 2003, the Board of Pharmacy adopted final amendments to 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy to implement requirements of Chapter 740 of the 2002 Acts of the Assembly.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy was promulgated under the general authority of Title 54.1 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 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 or licensure 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 or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
- 4. To establish schedules for renewals of registration, certification and licensure.*

5. To levy and collect fees for application processing, examination, registration, certification or licensure 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 (§ 9-6.14:1 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 and Chapter 25 of this title.

The specific legal mandate to promulgate the regulation for the provision of voluntary health care services by out-of-state practitioners in clinics in underserved areas sponsored by nonprofit organizations is found in Chapter 740 of the 2002 Acts of the Assembly.

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

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the amended regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amended regulation is to ensure that out-of-state practitioners who are registered and authorized to provide treatment to patients have provided sufficient information to determine their eligibility and their standing with the licensing board of their state. While the treatment is being provided free of charge to underserved populations in the state, the Board needs to carry out its statutory mandate to protect the public health, safety and welfare. Therefore, basic information on licensure must be verified by the board of the licensing state to ensure that a practitioner whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations does not come into Virginia to practice, even on a voluntary basis.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

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 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.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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, please include a sentence to that effect.

The primary advantages to the public of implementing the amended regulations are as follows: a) additional practitioners may be available to staff voluntary clinics, especially in the Southwestern part of the state with proximity to several other states; b) a requirement for licensure in another state to be verified will ensure that the practitioner holds a current, unrestricted license; and c) the requirement for a notarized statement from a representative of the nonprofit organization will ensure compliance with provisions of law for voluntary practice.

There are no disadvantages to the public as all amendments are intended to provide better access to qualified practitioners who are duly licensed in another state.

There are no advantages or disadvantages to the agency; the amended regulation does not impose a new responsibility on the Board. Since the number of practitioners seeking registration is expected to remain very small, it does not involve additional cost or staff time.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Proposed regulations were published in the Virginia Register of Regulations on December 30, 2002. Public comment was requested for a 60-day period ending February 28, 2003.

A Public Hearing before the Board of Pharmacy was held on February 10, 2003 at which no public comment was received.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

A new section (**18 VAC 110-20-75**) is added to specify the requirements for registration of out-of-state licensees to register for voluntary practice in Virginia.

The amended regulations provide that 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.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory 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 regulatory action will 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.