



Virginia  
Regulatory  
Town Hall

## Proposed Regulation Agency Background Document

<b>Agency Name:</b>	Board of Pharmacy/Department of Health Professions
<b>VAC Chapter Number:</b>	18 VAC 110-20-10 et seq.
<b>Regulation Title:</b>	Regulations Governing the Practice of Pharmacy
<b>Action Title:</b>	Voluntary practice
<b>Date:</b>	10/3/2002

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

### Summary

*Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

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.

## 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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board 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 (§ 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 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) 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 by letter that the Board has the statutory authority to promulgate the proposed 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 proposed 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 providing detail of the regulatory action's changes.*

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 proposed regulatory action. The term "issues" means: 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, 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.

## Fiscal Impact

*Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.*

### **Projected cost to the state to implement and enforce:**

(i) Fund source: 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 for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than \$1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

### **Projected cost on localities:**

There are no projected costs to localities.

### **Description of entities that are likely to be affected by regulation:**

The entities that are likely to be affected by these regulations would be licensed pharmacists in other states.

### **Estimate of number of entities to be affected:**

There is no way to predict the number who may be affected, but, given the limited scope of the law, the number is expected to be very small. To day, no out-of-state pharmacists have been authorized to practice under the emergency regulations.

### **Projected costs to the affected entities:**

The cost for compliance is \$10 to apply for authorization to practice at a specific location for a limited period of time.

## 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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed 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 proposed 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.

## Alternatives

*Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets 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 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 that 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 was mandated to promulgate regulations implementing provisions of the law within 280 days. It adopted emergency regulations and now proposes these amendments to replace them with permanent regulations prior to July 18, 2003.

### Public Comment

*Please summarize all public comment received during the NOIRA comment period and provide the agency response.*

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received August 12, 2002 until September 11, 2002. During the 30-day comment period, no comments were received from members of the public.

### Clarity of the Regulation

*Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.*

Members of the Board met in open session to work on the emergency regulations and the proposed regulations, which are identical. The public has been invited to comment during the course of those meetings. No comments have been received regarding the need for clarity in the proposed amendments. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

### Periodic Review

*Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.*

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. These regulations will be reviewed again during the 2004-05 fiscal year.

### Family Impact Statement

*Please provide an analysis of the proposed regulatory action that assesses the potential 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 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.