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Notice of Intended Regulatory Action 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 practitioners
Date:	

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

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 provided prior to such service to ensure compliance with the statute. The enactment clause required the board to adopt emergency regulations, and it is the board's intent to replace those regulations with permanent regulations.

Basis

Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

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:

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§ 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

Substance

Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. 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 citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

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 proposed regulations will insert the following requirements:

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;

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- 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, to the extent known, the specific alternatives to the proposal that have been considered or will be considered 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 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.

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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. In accordance, it has adopted emergency regulations and a Notice of Intended Regulatory Action to receive comment on its intent to replace those regulations with permanent regulations.

Family Impact Statement

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