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## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation</b>	18VAC110-20-10 et seq.
<b>Regulation title</b>	Regulations Governing the Practice of Pharmacy
<b>Action title</b>	Adds an alternative test for English proficiency
<b>Document preparation date</b>	9/22/05

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The proposed amendment to Section 70 will provide an alternative to the current requirement for tests of English as a written and spoken language. In cooperation with the National Association of Boards of Pharmacy (NABP), the Educational Testing Service (ETS) has revised and combined the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE) into a four-part internet-based examination, called TOEFL iBT. While ETS will continue to offer TOEFL and TSE upon request until June of 2006, on and after September 24, 2005, the TOEFL iBT is the examination that will routinely be given to graduates of foreign schools of pharmacy. To pass the TOEFL iBT, a graduate will need to achieve a passing score on each of the four parts that test - writing, speaking, listening and reading. A failure on one part will necessitate retaking that part, but not the entire examination.

In the future, the Virginia Board will continue to receive applications from persons who have been practicing in some states who previously passed the TOEFL and TSE examinations, so it must retain those examinations in regulation. However, it must add the TOEFL iBT alternative, as that examination will be the only one available in the coming months.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

On September 16, 2005, the Virginia Board of Pharmacy voted to amend 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy, under a fast-track action to add the TOEFL iBT examination to those accepted for applicants who are graduates of foreign schools of pharmacy to provide evidence of written and oral communication in the English language.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

Regulations Governing the Practice of Pharmacy, 18VAC110-20-10 et seq., are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6), 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 (§ 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 statutory authority for the Board of Pharmacy to establish qualifications for applicants for licensure, including tests of written and oral communication in English is found in § 54.1-3312 of the Code of Virginia.

***§ 54.1-3312. Qualifications of pharmacist; approved school of pharmacy defined.***

*A. In order to be licensed as a pharmacist within the meaning of this chapter, an applicant shall present to the Board satisfactory evidence that he:*

- 1. Is at least eighteen years of age;*
- 2. Is of good moral character;*

3. *Is a graduate of a school of pharmacy approved by the Board, or a foreign college of pharmacy, if the graduate has satisfactorily completed (i) a college of pharmacy equivalency examination program approved by the Board and (ii) **written and oral communication ability tests of the English language approved by the Board;***

4. *Has had a period of practical experience in the United States in accordance with the Board's regulations; however, such requirement shall not exceed twelve months; and*

5. *Has passed the examination prescribed by the Board.*

*B. As used in this article, an approved school of pharmacy shall be an institution which meets the minimum standards of the American Council on Pharmaceutical Education and appears on the Council's list of schools of pharmacy as published annually.*

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

The proposed regulatory action is necessary to avoid confusion and problems for applicants who will be testing for English proficiency through the Educational Testing Service. Since TOEFL and TSE are being phased out and replaced by TOEFL iBT, the Board's regulation must be amended to accept the combined test. Without an amendment accepting the new TOEFL iBT, the Board may not be able to license graduates of foreign schools of pharmacy after June of 2006 when the current tests will no longer be available. To exclude that group of applicants could reduce the supply of pharmacists in Virginia, thereby reducing the availability of pharmacy services and negatively impacting the health and safety of citizens seeking to have drug histories reviewed, prescription filled and drug counseling provided.

### Rationale for using fast track process

*Please explain the rationale for using the fast track process in promulgating this regulation. Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

The law requires the Board to test graduates of foreign schools of pharmacy in "written and oral communication ability tests of the English language." Since the tests approved by the NABP and the Virginia Board, currently TOEFL and TSE, are being replaced, it is necessary to update the regulations in keeping with the changes being made. Over the next few months, the testing

service is phasing in the Internet Based TOEFL to replace TOEFL and TSE, so the action to recognize the new combined test is a technical but necessary amendment.

**Substance**

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)*

The proposed amendment to Section 70 will provide as an alternative to the current requirement for tests of English as a written and spoken language the four-part internet-based Test of English as a Foreign Language or TOEFL iBT.

**Issues**

*Please identify the issues associated with the proposed regulatory action, 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, please indicate.*

- 1) There are no disadvantages to the public. The advantage of the tests of written and spoken English is to ensure that licensed pharmacists can adequately communicate with the public and with prescribers. Otherwise, there are significant risks for drug interactions, errors in filling and mistakes in dosing and instructions to patients. Similar drug names can contribute to medical errors, so pharmacists need to be able to clearly understand the orders of a prescriber – whether in writing or given orally.
- 2) The primary advantage to the agency is to have a clearly stated regulation that is consistent with the tests currently being offered for graduates of foreign schools of pharmacy. There are no disadvantages.
- 3) There are no other pertinent matters of interest.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>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 or entities for necessary functions of regulation. There is a one-time expense of approximately</p>
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	\$1,000 for promulgation of the amended rule. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the costs. There would be no on-going expenditures
<b>Projected cost of the regulation on localities</b>	None
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	The individuals affected by the regulation would be graduates of foreign schools of pharmacy who are seeking licensure in Virginia.
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There is no estimate of the number of foreign graduates who may choose to apply for licensure in Virginia. There are no small businesses affected.
<b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b>	Administration fees for tests are as follows: TOEFL iBT - \$140 TOEFL - \$140 TSE - \$125 If a graduate of a foreign school of pharmacy takes the TOEFL iBT, as provided in the proposed regulation, there will be a savings of \$125 since both TOEFL and TSE are currently required at a total cost of \$265.

**Alternatives**

*Please describe any viable 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.*

In order to allow the Board to accept the TOEFL iBT, which is the examination graduates will be taking after September 24, 2005, it has amended Guidance Document 110-7, which gives instructions to graduates of foreign schools of pharmacy. The Guidance Document currently lists the regulatory requirement for TOEFL and TSE and gives the scores acceptable to the Board for passage of the tests. In the amended Guidance Document, the Board has deemed the TOEFL iBT as acceptable in lieu of the TOEFL and TSE and has given the scores acceptable for passage on each of the four tests within TOEFL iBT. The passing scores are identical to those recommended by NABP and ETS for these tests.

While the Guidance Document is instructive to applicants, it does not have the enforceability of regulation. Therefore, regulations need to be amended at the earliest possible date for consistency with the English-proficiency tests that will be available in the near future.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

There is no impact on the institution of the family and family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
70	n/a	Subdivision 3 and 4 of Subsection A require passage of the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE) as given by the Educational Testing Service with a score acceptable to the board.	The amended language adds the TOEFL iBT, the Internet Based tests of listening, reading, speaking and writing.