VIRGINIA ACTS OF ASSEMBLY -- 2000 SESSION

CHAPTER 876

An Act to amend the Code of Virginia by adding a section numbered 54.1-3307.2, relating to approval of innovative pharmacy programs.

[H 1198]

Approved April 9, 2000

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-3307.2 as follows: § 54.1-3307.2. Approval of innovative programs.

A. Any person who proposes to use a process or procedure related to the dispensing of drugs or devices or to the practice of pharmacy not specifically authorized by Chapter 33 (§ 54.1-3300 et seq.) of this title or by a regulation of the Board of Pharmacy may apply to the Board for approval to use such process or procedure. The application under this section may only include new processes or procedures, within the current scope of the practice of pharmacy, that relate to the form or format of prescriptions, the manner of transmitting prescriptions or prescription information, the manner of required recordkeeping, the use of unlicensed ancillary personnel in the dispensing process, and the use of new technologies in the dispensing process. The authority granted the Board under this section shall not authorize expansion of the current scope of practice for pharmacists and shall not interfere with the requirement that pharmacists only dispense drugs in accordance with instructions from a prescriber, as defined in § 54.1-3401.

B. The application to the Board shall address safety to the public regarding the new process or procedure, any potential benefit to the public, promotion of scientific or technical advances in the practice of pharmacy, compliance with prescriber's instructions for any drug dispensed, any impact the new process may have on the potential for diversion of drugs, maintenance in the integrity of and public confidence in the profession of pharmacy and of the drugs dispensed, impact on cost to the public and within the health care industry, means of monitoring the new process or procedure for any negative outcomes or other problems, and the reporting of such outcomes to the Board.

C. An informal conference committee, composed of not less than two members of the Board and in accordance with § 9-6.14:11, shall receive and review the application and any investigative report requested by the committee. The committee shall have the authority to grant or deny approval of the request. The committee may grant approval of the request unconditionally or may impose conditions on the approval as follows:

1. The committee may grant approval for a finite period of time, after which time the applicant must provide additional information as requested by the committee in order to continue the approval;

2. The committee may require that ongoing reports concerning performance and problems be submitted; or

3. The committee may impose such other conditions as it deems necessary to provide assurance of public health and safety and accountability for controlled substances.

D. If an applicant does not agree with the decision of the committee, the applicant may request a hearing before the Board or a panel of the Board, in accordance with § 9-6.14:12.

E. Application under this section shall be on a form provided by the Board and shall be accompanied by a fee determined by the Board.

2. That the Board shall promulgate regulations, in consultation with the Board of Medicine, to implement the provisions of this act to be effective within 280 days of its enactment.