Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
June 23, 2008

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to make many clarifying and substantive changes to its regulations as a part of the periodic review process. The Board proposes to:

1) Add several definitions to aid readers in understanding these regulations,
2) Require pharmacy technician training programs to apply for renewal every two years; to pay for staff time to process renewal and other forms, the Board has added fees for program renewal, late renewal and reinstatement; the Board also proposes that pharmacy continuing education programs expire after two years,
3) Remove a requirement for the Board to approve robotic pharmacy systems and also remove the fee that pharmacies were charged for this from the fee schedule,
4) Rewrite requirements and procedures for gaining pharmacy practical experience so these requirements apply to all individuals seeking practical experience and so pharmacists are not limited to supervising one intern at a time,
5) Require foreign trained pharmacy students to get their certification from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) before they apply to be interns,
6) Require a 30 day waiting period before an applicant who has taken and failed the jurisprudence exam can take it again,
7) Require pharmacy interns to report within 14 days (by email or regular mail) any change of address; the Board also proposes to extend to 14 days the time that Board licensees have to report a change of address, shorten the time registration certificate holders have

to report a change of address to 14 days and to require pharmacy technician training programs to report any substantive changes to the program within 14 days,

8) Require licensees to maintain proof of completion of continuing education for three (rather than two) years following license renewal; continuing education providers will be required to maintain records on all programs, program participants and continuing education hours earned for five (rather than three) years,

9) Specify that pharmacy technician trainees may only perform tasks restricted to pharmacy technicians for nine months and require pharmacies to maintain employment records that show a start and end date for employment of trainees,

10) Allow pharmacists with restricted licenses to serve as program directors for pharmacy technician training programs,

11) Require pharmacy technicians to maintain their certificates at their principal places of practice. Pharmacy technicians who work at more than one pharmacy will be able to keep their certificates either at the home addresses that they have reported to the Board or at one of their workplaces,

12) Restrict private residences from being licensed as pharmacies,

13) Require that pharmacies maintain a perpetual inventory with reconciliation of that inventory every thirty days,

14) Move guidance language for approving special use pharmacies within free clinics to these regulations,

15) Require pharmacies that are going out of business to transfer prescription files to another pharmacy so that customers can still access their records,

16) Specify that drugs may not be stocked by a new pharmacy more than two weeks before the pharmacy opens and require that a pharmacist be at the pharmacy on a daily basis while drugs are stocked but the pharmacy has yet to open so that security for all drug supplies is maintained,

17) Clarify that all pharmacies that have any hours that they are not open, whether daily or sporadically, must have an approved alarm system in place before they close,

18) Simplify rules for prescription department enclosures to allow greater flexibility to pharmacies,

19) Clarify standards for storage of drugs and require pharmacies to put medical devises that require a prescription where the pharmacist can supervise who accesses them,

20) Allow drugs to be destroyed by incineration or any other method that the Board approves,

21) Require that all records for schedule six drugs be maintained under the same rules as records for schedule II through V drugs; all records for these drugs will have to be kept for at least two years,

22) Eliminate restrictions on the number of pharmacy technician trainees that a pharmacist can supervise at one time and require pharmacies to retain forged prescriptions at least 30 days,

23) Require all contracts, agreements and policy and procedures manuals for alternate delivery sites be maintained both at the alternate site and the originating pharmacy,

24) Clarify that hospices that can fax chart orders to pharmacies include home hospices and that nurses may fax verbal orders. Additionally, the Board proposes to transfer language from guidance that would allow chart orders to serve as valid prescriptions that may be filled at a retail pharmacy,

25) Allow prescriptions refills to be dispensed early so long as the pharmacist documents a valid reason for doing so,

26) Move guidance language that outline packaging standards for dispensed prescriptions to these regulations,

27) Update special packaging rules to allow for electronic recordkeeping,

28) Limit the time that a bulk bin filling record must be maintained to one year and require a pharmacist's initials in this record as verification that he has checked the accuracy the bin,

29) Move guidance language for the re-dispensing of prescription drugs to these regulations,

30) Move guidance language that prohibits pharmacies from printing non-essential information on the front of prescription pads that they provide to prescribers to these regulations,

31) Allow licensed warehouses to sell Schedule II through VI drugs to pharmacies,

32) Allow nurses to access a "supply of drugs maintained by the pharmacy at a location outside of the pharmacy in order to obtain emergency medication during hours that the pharmacy is closed"; the location of any supply of medication in such cases must be kept secure,

33) Require pharmacists to check all Schedule II-VI drugs as floor stock before they are delivered to a hospital unit and to initial or sign that the record of distribution is accurate; all records will have to be maintained for two years,

34) Requires all records required for automated devises for dispensing and administration of drugs be retained for two years,

35) Allow intravenous solutions provided by a hospital pharmacy to an emergency services agency to be stored outside of a secured drug kit,

36) Allow pharmacies that serve long-term care facilities to repackage residents' medicines as unit doses to facilitate dispensing of medication in an institutional setting,

37) Move guidance language the governs how prescription drugs may be sent outside of a long-term care facility (when the resident is leaving for a short time or is being discharged from the facility altogether) to these regulations,

38) Clarify rules governing emergency drug kits by listing the licensed entities that are allowed to access these kits,

39) Allow drugs stocked in automated dispensing devises that would be appropriate for an emergency drug kit to be accessed prior to authorization from a pharmacist if not accessing the drugs would threaten the survival of a patient; these devises will have to be able to produce a hard-copy record of all distributions,

40) Require training records for animal shelter and humane society staff that are trained to euthanize animals be retained for two years,

41) Allow correctional facilities greater flexibility to return drugs to a provider pharmacy accompanied by one of a number of forms that would contain the same information,

42) Clarify rules that govern application for controlled substances registration and

43) Require any change in the responsible party for controlled substance registration to be reported to the Board within 14 days.

Result of Analysis

For many of these proposed changes, benefits likely outweigh the costs. For several other changes there is insufficient information to measure the magnitude of costs versus benefits. Costs and benefits for proposed changes are discussed below.

Estimated Economic Impact

About a quarter of the regulatory changes listed above (specifically, changes numbered 1, 9, 14, 16, 17, 19, 24, 26, 29, 30, 37, 38 and 42) are being made to bring greater clarity to these regulations. These changes are either standing Board policy being moved to regulation or other clarifications; for example, listing the specific licensed entities who are allowed to access emergency drug kits rather than stating that "only those persons licensed to administer drugs" are allowed access. These changes ought not represent a change in practice for regulated entities of the Board and, so, regulated entities will likely not incur any costs on account of these changes. Having these rules more clearly spelled out ought to, however, provide a benefit for individuals who are either affected by these regulations or are interested in knowing the rules under which Board licensees and certificate holders must operate.

Current regulations do not specify an expiration date for pharmacy continuing education or pharmacy technician training programs. Regulations for pharmacy continuing education classes state that continuing education programs must be approved by the Accreditation Council of Pharmacy Education (ACPE), be approved as a Category I continuing Medical Education (CME) course or be approved by the Board. While ACPE courses are not approved for more than two years before they have to be re-approved and CME courses already require periodic re-approval, there has been no such limitation on Board approved classes.

In order to make sure all types of continuing education classes are consistent and to insure that class materials and subjects are not outdated, the Board proposes to require that all

Board approved continuing education classes expire after two years. After that, old but still relevant, and new programs can be approved by meeting Board criteria for continuing educational programs and paying the $100 fee for program approval. Individuals and groups who teach continuing education programs approved by the Board will incur extra costs in time and resources for getting course materials re-approved, or for gathering and submitting new course material, and for the fee charged by the Board. Individuals who take continuing education classes that are Board approved will benefit from this regulatory change if continuing education classes do a better job of keeping course material current and relevant than they would absent Board action. Whether benefits for this change outweigh costs will depend on whether courses improve enough, on average, to outweigh the costs of going through the program approval process again.

The Board also proposes to amend regulations to require pharmacy technician training programs be re-approved every two years and to add fees to the fee schedule to cover re-approval of a training program, late (within two years of approval expiration) re-approval of a program and reinstatement of approval of a program when approval has expired more than two years ago. These fees are $75, $15 and $75, respectively. The Board proposes this change to address problems with programs that change instructors, programs that teach out-dated material and programs that just go out of business without informing the Board. Individuals and groups who teach training programs approved by the Board will incur extra costs in time and resources for getting course materials re-approved and for fees charged by the Board. Individuals who take continuing education classes that are Board approved will benefit from this regulatory change to the extent that it is easier to find correct information about available programs and to the extent that classes do a better job of keeping course material current and relevant. Whether benefits for this change outweigh costs will depend on whether the value of more accurate information on available courses plus the value of courses improvement, on average, outweighs the costs of re-approval.

Current regulations require that all robotic pharmacy systems be approved by the Board. The fee for this approval is $150. The Board proposes to eliminate both the requirement that all robotic systems be approved by the Board and the fee that paid for staff time for that approval. Instead of requiring all pharmacies go through the time and expense of gaining approval for each robotic system, the Board proposes to put the requirements that are currently part of each

approval order into the text of these regulations. These changes are likely to lower costs for pharmacies wanting to install these labor saving robotic systems while still protecting the public from any harm caused by prescription errors.

Current requirements that govern how and when pharmacy students can gain practical experience before they are licensed require licensure applicants who graduated from an approved school of pharmacy before January 1, 2003 to work at least 1,000 in a practical setting; at least 300 of those hours had to be worked outside of a school of pharmacy's practical experience program. Students graduating after January 1, 2003 are required to complete 1,500 hours of practical experience, 300 of these hours outside of any school practical experience program, before they could be licensed.

Because ACPE accredited schools now require at least 1,700 hours of practical experience before graduation, the Board proposes to eliminate the requirement that pharmacy graduates gain 300 hours of experience outside of their school setting. The Board also proposes to eliminate the language that allowed pre-2003 graduates to be licensed with only 1,000 hours of practical experience. The Board believes that any individuals who graduated that long ago and still have not been licensed likely would need the extra hours of practical experience should they choose to pursue licensure at this late date. Pharmacists who were licensed in other states that require fewer hours of pre-licensure practical experience, and who want to be licensed in Virginia, may count hours worked post-licensure toward practical experience requirements. Some individuals who graduated from pharmacy school before 2003 may incur extra costs for gaining practical experience if they choose to seek licensure after these amended regulations are promulgated. These costs are likely outweighed by the benefit to the public of ensuring individuals who have been out of school, and away from a pharmacy setting, for a number of years gain additional practical experience before they are licensed.

Current regulations only allow pharmacists to supervise one pharmacy intern and two pharmacy technician trainees at one time. Currently, pharmacists are allowed to supervise no more than four individuals performing technician functions (pharmacy technicians and pharmacy technician trainees) at one time. The Board proposes to eliminate these restrictions and allow pharmacists to determine how many interns, technician trainees and technicians he can safely and effectively supervise at one time. These proposed changes will give pharmacists greater

flexibility to staff their pharmacy in the way that works most efficiently for them. Pharmacists will still be accountable for the accuracy of prescriptions that are dispensed under their supervision so these changes should not adversely affect the public.

Currently, foreign-trained pharmacy students are required to go through several steps before they are eligible for licensure. They must 1) obtain verification from the FPGEC that they are a graduate of a foreign school of pharmacy, 2) pass the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), 3) pass the Test of English as a Foreign Language (TOEFL) or TOEFL iBT (internet based test), 4) pass the Test of Spoken English (TSE) and 5) complete practical experience requirements before they can sit for the other exams required for Virginia licensure. Regulations do not, however, list the order in which these steps must be accomplished. As a consequence, there has been some confusion as to whether foreign-trained pharmacy applicants need to prove proficiency in English before they become pharmacy interns.

The Board proposes to simplify rules for foreign-trained pharmacy graduates by removing requirements 1 through 4 in the preceding paragraph and, instead, only requiring that applicants obtain an FPGEC certificate. FPGEC verifies that applicants have graduated from a foreign school of pharmacy, that they have passed the FPGEE and that they are proficient in English. The Board also proposes to specify that an FPGEC certificate must be obtained before foreign students can register as pharmacy interns and complete their practical experience requirements.

Only requiring a FPGEC certificate will likely eliminate duplicative record keeping on the part of the Board and the FPGEC. This will also save foreign-trained applicants for licensure some amount of time, effort and expense that they previously would have spent gathering all their records and getting them to Board staff. Requiring that these applicants attain FPGEC certification before they can complete practical experience hours may cause some applicants to incur costs (foregone wages, time spent waiting for the certification process to be completed, etc) that they would not have under the current regulatory scheme. Foreign-trained student interns, and the public they will work with, may, however, benefit from these interns mastering the language that is in predominant use in Virginia before they are thrown into situations where such proficiency is necessary.

Currently, there is no practical limit on the frequency with which applicants for pharmacy licensure can take the required jurisprudence exam. As a consequence, problems have arisen with the integrity of the test question bank. The Board proposes to require applicants who have failed this exam to wait 30 days before they take it again. This change may slightly inconvenience applicants but will also help insure that current test bank questions are not available to applicants before they actually take the test.

Current regulations do not contain a requirement that pharmacy interns report any changes of address of record to the Board. Since the Board has an interest in having a way to communicate with these interns, the Board proposes to require interns to report any change of address, in writing, within 14 day. Interns will likely incur minimal cost for complying with this requirement because they have the option of notifying the Board electronically. The benefit to them of the Board having a valid address (so they can get notices from the Board in a timely fashion) very likely outweigh the costs.

To make all such reporting consistent, the Board also proposes to lengthen the time that licensees have to report a change of address from "immediately" to 14 days, shorten the time that certificate holders have to report address changes from 30 days to 14 days (both of these groups can electronically correct this information on the Board's website), require pharmacy technician training programs to report any substantive changes within 14 days and require that any change in the responsible party for a controlled substances registration be reported within 14 days. Again the costs of these changes are likely very minimal, even for certificate holders whose time limit is being shortened. The benefits of having a consistent, easily remembered, standard likely outweigh any costs.

Current regulations require licensees to maintain proof of continuing education completed for two years; continuing education providers are currently required to retain records for three years on all programs, program participants and continuing education hours earned through them. Because record auditing lags behind the renewal cycle, this can mean that some licensees will have gotten rid of half the records required for an audit before the audit can occur. The Board proposes to extend these record keeping requirements so that licensees will have to retain their records for three years and continuing education programs will have to retain their

records for five years. These changes will increase record keeping costs for affected entities but will also make auditing these records for regulatory compliance much easier.

The Board has also addressed other record keeping requirements in this regulatory action. Records for drug floor stocks delivered to hospital units, records for automated devises for dispensing and administration of drugs, records of inventories for schedule II through VI and records that document euthanasia training for humane society workers will all need to be retained for two years. Although these record keeping requirements are new to regulations, they are already Board policy and are consistent with the time inspectors would be auditing drug records. Any increased record keeping costs that may be incurred by affected entities will likely be outweighed by the benefit of more effective drug auditing.

Currently, regulations require that program directors for pharmacy technician training programs have current, unrestricted pharmacy licenses. The Board proposes to allow pharmacists with restricted licenses to serve as directors of such programs. The Board feels that license restrictions should not preclude an otherwise qualified candidate from serving as a program director. This regulatory change will likely increase the number of pharmacists who are willing to take on this job. This may encourage more programs to open and may increase the number of pharmacy technicians available for employment in Virginia.

Current regulations do not require pharmacy technicians to keep their certificates where they are readily available for inspection. The Board proposes to require technicians to maintain their certificates at their principal place of employment. Technicians who work at more than one location will be able to maintain their certificates either at their address of record with the Board or at one of their workplaces. Technicians are unlikely to incur anything but trivial costs on account of this regulatory change. Any costs that are incurred will likely be outweighed by the benefit of having these certificates readily available for inspectors and any other interested parties.

Currently, regulations for permitting of pharmacies have many requirements and restrictions but there is no restriction on opening a pharmacy in a private residence. Two years ago, an individual applied to operate a pharmacy in her garage. Since this space met all requirements for pharmacies, the Board issued a permit. The Board believes that a residential setting is not conducive to maintaining security and accountability of drug stocks, and is

proposing to prohibit any other residences from being permitted as pharmacies. A Board representative reports that there have been no security violations or instances of drugs going missing from this residential pharmacy thus far. Individuals who may have wanted to open pharmacies in their residences at some point in the future would lose that opportunity on account of this proposed regulatory change. Whether the benefits of this proposed change outweigh the costs will depend on whether any actual improvements in drug security outweigh the profits lost to future entrepreneurs who might have chosen to open such a pharmacy.

Current regulations require pharmacies to take an inventory of schedule I through VI drugs at least biennially. The Board reports that, in the past, there have been instances where "tens of thousands of dosage units of (schedule II) drugs were diverted without detection for a year or more in some cases". Because of this, the Board proposes to require that all pharmacies maintain a perpetual inventory of schedule II drugs and that this inventory be reconciled against actual drug stocks monthly. The Board reports that all hospital pharmacies and most chain drug stores already maintain a perpetual inventory but they may or may not review them for discrepancies on a monthly basis. This regulatory change may drive up costs for some pharmacies, particularly small pharmacies that don't already have some kind of electronic record of drug stores. Overall, pharmacies may actually save money from an inventory system that helps them quickly catch or even prevent drug losses.

Currently there is no regulatory provision for pharmacies that go out of business to make sure their customers can still access pertinent records. Although this lack of regulatory provision is apparently not usually a problem, the Board reports that these records are a salable asset, there have been instances where pharmacies have closed and just abandoned customer records. The Board proposes to require that customer records be transferred to another pharmacy where customers can access them when the originating pharmacy closes. Both customers and receiving pharmacies will likely benefit from this required records transfer.

Current regulations contain very specific, prescriptive requirements for prescription department enclosures. For example, entrances to enclosed areas must currently have doors with no more than a six inch gap from the floor. The Board proposes to remove some of the more prescriptive requirements for these enclosures and instead allow pharmacies more flexibility in securing the drugs they are responsible for. Instead of exactly describing how far from the floor

a door may be, for instance, the proposed regulations only stipulate that an enclosure must be capable of being securely locked when the pharmacist is not present. This proposed change will benefit pharmacies which will now have the flexibility to meet security requirements in the most cost effective manner available. Since drugs will still be required to be secured, there will likely be no offsetting costs.

Current regulations only allow drugs to be destroyed by incineration. The Board proposes to also allow drugs to be destroyed in other Board approved ways. Although there are no methods for disposal of drugs currently that are as safe and effective as incineration, the Board wants the freedom to approve other methods when they are developed. This change will give the Board benefit of flexibility.

Current regulations do not allow prescriptions to be refilled early to accommodate patients who are, for instance, going on vacation. The Board proposes to allow pharmacists to dispense refills early so long as they can document good cause for doing so. This change will likely benefit pharmacy customers who will have greater flexibility to coordinate drug refills so that they do not interfere with other plans.

Businesses and Entities Affected

These regulatory changes will affect 1,647 pharmacies that are permitted in Virginia, 513 non-resident pharmacies, 9,491 pharmacists, 1,415 pharmacist interns, 8,750 pharmacist technicians and all pharmacist technician trainees working in the Commonwealth. These regulatory changes will also affect 613 controlled substance registrations and 34 humane societies.

Localities Particularly Affected

No locality will be particularly affected by this proposed regulatory action.

Projected Impact on Employment

Requiring English proficiency before internship may lower in the short-term the number of foreign-trained pharmacy students that are available for employment as interns. This effect will likely be short lived as current and future students will adjust to the time-table of licensure requirements.

Effects on the Use and Value of Private Property

Putting an expiration date on continuing education programs and pharmacy technician training programs will increase costs for these programs. To the extent that these programs are a profit-making venture, these regulatory changes will likely decrease profits.

Small Businesses: Costs and Other Effects

The Department of Health Professions (DHP) reports that the number of pharmacies that qualify as small businesses is unknown but is likely a small minority of 1,647 pharmacies in Virginia. These businesses may incur some additional bookkeeping costs because of some of these regulatory changes. These costs will likely be outweighed by savings accrued on account of other regulatory changes in this action.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Absent proof that home pharmacies are inherently more likely to be unsafe and non-securable, the Board may wish to reconsider banning licensure for pharmacies in private residences.

Real Estate Development Costs

This regulatory action will likely have no effect on real estate development costs in the Commonwealth.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other

administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.