Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
August 1, 2003

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G 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. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

The Board of Pharmacy (board) proposes numerous amendments to these regulations, including: 1) lengthening the period after pharmacist licensure renewal due dates by which a licensee may pay a late fee in lieu of reinstatement, 2) changing the required fees for licensure reinstatement, 3) introducing the re-inspection process and a re-inspection fee for pharmacy permits, 4) eliminating the requirement that applicants for examination file affidavits or certificates of experience with the board no less than 30 days prior to the date of the examination, 5) for those seeking reinstatement, capping the number of required hours continuing education at 60 hours, 6) for those whose licenses have been suspended, lapsed or inactive for more than five years, requiring passage of the board-approved law examination and documentation of either active practice in another state or practical experience of at least 160 hours within the past six months as a pharmacy intern, 7) eliminating the requirement that pharmacists maintain continuing education documentation at their principal place of practice, 8) allowing a pharmacist to serve as pharmacist-in-charge (PIC) at two pharmacies rather than just one, 9) specifying that

a PIC who is absent from practice for more than 30 consecutive days is deemed to no longer be the PIC, 10) allowing extensions to the 14-day deadline to obtain a replacement PIC, 11) eliminating requirements that certain equipment and resources be kept if unnecessary for pharmacy's practice, 12) permitting pharmacy technicians to enter the prescription department in the absence of a licensed pharmacist under certain conditions, 13) allowing off-site storage of certain required records, 14) allowing an electronic image of a prescription to be maintained in an electronic database in lieu of a hard copy file for Schedule VI prescriptions, 15) allowing an electronic image of a prescription to be maintained in an electronic database in lieu of a hard copy file for Schedule II-V prescriptions if permitted by federal law, 16) allowing prescriptions to be faxed from a long term care facility or a hospice, 17) eliminating certain pharmaceutical labeling requirements for drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer, 18) eliminating the requirement that a signed release be obtained when non-special (non-child resistance) packaging is requested, 19) allowing transfer between two pharmacies of a prescription whether it has been filled or not, 20) when authorized by the PIC, permitting nurses other than the supervisory nurse to have access to the pharmacy in the absence of the pharmacist in order to obtain emergency medication, 21) allow receipts of floor stock drugs and the records that are used to document administration of Schedule II through V drugs to be maintained by the hospital pharmacy in offsite storage, 22) permitting audits of the distribution and administration of drugs from automated dispensers to cover a sample of records, rather than all records, 23) expanding the permitted use of automated dispensing devices in nursing homes, 24) permitting certain cost-saving measures by correctional institutions, and 25) allowing medical equipment suppliers to keep original orders on file at a centralized office.

Estimated Economic Impact

License renewal, late fees, and reinstatement

Currently, a pharmacist who fails to renew his license on or before it's expiration date, may renew the license if he pays a $30 late fee and the $90 annual renewal fee within 60 days after the expiration date. After the 60 days, the licensee must apply for reinstatement, pay a $70 delinquent fee, demonstrates compliance with continuing education (CE) requirements, and pay all back renewal fees.

The proposed regulations allow licensees one year from the expiration date to renew a late license. During that year the license may simply pay the $30 late fee in addition to the $90 renewal fee. Thus, those individuals who seek to renew their license from 31 days after its experience to one year after its expiration save $40 in fees and the time and effort it takes to apply for reinstatement.

After the one year, the licensee must apply for reinstatement, pay a $210 reinstatement fee, pay the current $90 renewal fee, demonstrate compliance with continuing education requirements, and pay the current $90 renewal fee, but is not required to pay all back renewal fees. An individual who seeks to reinstate two years after expiration will be $40 better off under the proposed regulations.[1] An individual who seeks to reinstate three years after expiration will be $130 better off under the proposed regulations.[2] An individual who seeks to reinstate four years after expiration will be $220 better off under the proposed regulations.[3] Thus, for individuals who seek to renew or reinstate their license four or fewer years after its expiration, the proposed regulations offer lower costs than the current regulations.

The current regulations have been interpreted as meaning that individuals must document having taken 15 hours of CE for each year that the license has not been active or current. The proposed regulations cap the number of required hours at 60. For individuals whose license has been inactive or non-current four years or less, this change will have no impact. For those whose license has been inactive or non-current for more than four years, the cap will reduce cost.[4] For example, someone who seeks to reactivate or reinstate their license after five or six years will only need to complete 60 hours of continuing education versus 75 or 90 hours[5] under the current regulations. There is no evidence concerning the marginal effectiveness of 75 or 90 hours of

[1] Fees for reinstatement after two years under the current regulations: ($90 current fee) + ($180 in back fees) + ($70 delinquent fee) = $340. Fees for reinstatement after two years under the proposed regulations: ($90 current fee) + ($210 reinstatement fee) = $300.

[2] Fees for reinstatement after three years under the current regulations: ($90 current fee) + ($270 in back fees) + ($70 delinquent fee) = $430. Fees for reinstatement after three years under the proposed regulations: ($90 current fee) + ($210 reinstatement fee) = $300.

[3] Fees for reinstatement after four years under the current regulations: ($90 current fee) + ($360 in back fees) + ($70 delinquent fee) = $520. Fees for reinstatement after four years under the proposed regulations: ($90 current fee) + ($210 reinstatement fee) = $300.

[4] According to the Department of Health Professions, costs for continuing education courses can range from $10 for an on-line course to several hundred dollars for a live seminar. Applicants' time also has value. Since applicants in this situation are not currently able to practice, the value of their time is likely best judged at a figure somewhat less than hourly rate earned by licensed pharmacists ($40 an hour).

[5] Calculation: (15 CE hours per year) x 6 = 90 CE hours

continuing education relative to 60 hours of continuing education. Due to this uncertainty, not reliable conclusion may be drawn concerning the net economic impact of the change although we do know that, for those few seeking reinstatement of a long-lapsed license, the proposed change will certainly reduce compliance costs. An individual who seeks to reinstate five years after expiration will be more than $310 better off under the proposed regulations.[6]

Though the board proposes to reduce the CE burden for applicants whose license has been inactive or non-current for more than four years, the board also proposes to introduce new requirements for those whose license has been inactive or non-current for more than five years. A pharmacist who has allowed his Virginia license to lapse for more than five years and is unable to document active practice in another jurisdiction will be required to serve a 160-hour internship under the supervision of a pharmacist with current licensure. Since staff pharmacists earn approximately $40/hour, while pharmacy technicians and interns earn approximately $12/hour,[7] this proposed requirement may cost affected pharmacists as much as $4,480.[8] According to the department, changes in pharmacy practice and pharmaceuticals occur frequently, and five or more years away from pharmacy work leaves pharmacists unable to practice safely without supervision.

One month's work (160 hours) under the supervision of an active pharmacist will likely enable a pharmacist to become significantly more current in his knowledge of changes to pharmacy practice over his time away from active work. Information is not available, though, to determine the amount by which the risk of potential mistakes is diminished by requiring the internship. Since this information is not available, it cannot be determined whether the cost imposed on the applicant exceeds the benefit of a potential reduced risk of mistakes by the pharmacist returning to practice.

The board also proposes to require those pharmacists whose license has been inactive or non-current for more than five years to pass a board-approved law examination at a cost of $200. Though federal and state laws concerning drugs and pharmacy practice can change significantly over five or more years, it is not clear that the benefits of requiring applicants to pass a legal examination exceed or equal $200 per individual. Given the required 160-hour internship for

[6] Fees for reinstatement after five years under the current regulations: ($90 current fee) + ($450 in back fees) + ($70 delinquent fee) = $610. Fees for reinstatement after five years under the proposed regulations: ($90 current fee) + ($210 reinstatement fee) = $300. In addition, the proposed regulations require 15 fewer hours of CE.
[7] Source: Department of Health Professions

such individuals, it is likely that they will learn about the important changes in law in recent years through their 160-hour internship. Plus, the PIC will have the incentive to ensure that a returning pharmacist is caught up as well due to their responsibility concerning pharmacy operations. An individual who seeks to reinstate six years after expiration will be financially worse off under the under the proposed regulations.[9]

Practical experience

Some states do not require as many hours of practical experience in an internship as Virginia does for licensure, or do not maintain complete records; so an applicant for licensure by endorsement in Virginia who may have already been practicing in another state may be required to first work in an internship in the Commonwealth in order to practice. Practically, this potentially discourages some highly skilled and experienced out-of-state pharmacists from seeking to practice in Virginia. Interns earn much lower pay than independent pharmacists ($12 per hour versus $40 per hour);[10] and even if the pay was comparable, it is unlikely that many pharmacists would be tempted to leave an out-of-state position as an independent pharmacist to work as someone else's intern in Virginia. Discouraging out-of-state pharmacists from seeking licensure in Virginia this way reduces the potential number of working pharmacists in the Commonwealth. This reduces the amount of pharmacy services that can be made available to Virginians.

The board proposes to accept verification of practical experience hours worked as a pharmacist in other states in lieu of intern hours in order to meet Virginia's practical experience requirement for licensure. This will effectively remove the above-mentioned disincentive for out-of-state pharmacists to seek licensure by endorsement. Potentially, more pharmacies may open or existing pharmacies may be open for longer hours due to greater availability of licensed pharmacists in Virginia. An increased supply of pharmacists may lower the market wage for pharmacists in the Commonwealth. If there are more available to choose from, pharmacy owners may not have to offer as high a wage in order to find pharmacists to accept job offers.

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[8] [($40 per hour) – ($12 per hour)] x 160 hours = $4,480

[9] Fees for reinstatement after six years under the current regulations: ($90 current fee) + ($540 in back fees) + ($70 delinquent fee) + (the cost of 90 hours of CE) = $700 + (the cost of 90 hours of CE). Fees for reinstatement after six years under the proposed regulations: ($90 current fee) + ($210 reinstatement fee) + ($4,480 for 160 hours as intern rather than pharmacist) + ($200 for the legal exam) + (the cost of 60 hours of CE) = $4,980 + (the cost of 60 hours of CE). As long as the value of 30 hours of CE is less than $4,280 ($4,980 - $700), then the individual is financially worse off under the proposed regulations.

A requirement for an applicant for examination to file affidavits or certificates of experience with the board no less than 30 days prior to the date of the examination was deleted as unnecessary. When the regulation was first enacted, the examination was only given three times a year. This requirement ensured that the board would have time to verify the documents in time for the candidate to sit for the examination. Now examinations are given via computer and can be scheduled immediately once the application is approved. This proposal eliminates an unnecessary cost for applicants.

Record keeping

The board has proposed several amendments that will reduce record-keeping costs by allowing off-site storage. Pharmacists will no longer be required to maintain CE documentation at their "principal place of practice," since CE is no longer audited as part of the pharmacy inspection. Random audits are conducted by the agency, and licensees are required to send in documentation upon a request from the board.

In addition, another proposed amendment will allow off-site storage of certain required records, such as invoices, if allowed by the U.S. Drug Enforcement Administration (DEA), provided the records are readily retrievable for inspection when requested. This change has been frequently requested by Virginia pharmacies.[11] DEA does not allow for off-site storage of certain records, but will, upon request, allow others to be stored at an off-site location.[12]

Further proposed amendments will allow receipts of floor stock drugs and the records that are used to document administration of Schedule II through V drugs to be maintained by hospital pharmacies in offsite storage provided they are retrievable and can be made available for inspection or audit within 48 hours of a request by the board or an authorized agent. This provision will alleviate the need to retain the receipts at the hospital, where storage is often a problem.

The ability to store certain records in off-site storage will likely provide a significant benefit to pharmacies that are now required to utilize valuable in-house space for such use. This proposed amendment allows pharmacies and medical equipment suppliers to utilize on-site storage space for other purposes, and in some cases potentially expand their operations.

[10] Source: Department of Health Professions
[11] Ibid
[12] Ibid

Pharmacist-in-charge

The Code of Virginia requires the pharmacist-in-charge (PIC) to be “fully engaged” in the practice of pharmacy at that location. Under the current regulations a pharmacist may only be PIC of one pharmacy. The board proposes to allow a pharmacist to serve as PIC at two pharmacies. The board determined that a pharmacist, for example, working full time for a chain pharmacy, could work an average of 20 hours one week at one pharmacy, and 20 hours the same week at a second pharmacy and still be "fully engaged" at both locations, have full knowledge of pharmacy practice at that site, and be able to control the practice (including inventory issues) at both locations. Allowing individuals to be PIC at a second pharmacy allows pharmacy owners additional flexibility in hiring and management decisions. In particular, it may allow additional pharmacy locations to be established, since, according to the department, there is a shortage in the Commonwealth of individuals with the skills and desire to work as a PIC. Also, for example, an owner of two pharmacies may judge that one of his PICs is significantly more talented than the other, and the two pharmacies would be better managed with the better PIC as PIC of both.

Re-inspection

Under the current regulations if a pharmacy applicant fails their site inspection, but successfully completes all other aspects of their permit application, the applicant must still submit a new permit application with a $270 fee and wait 14 days to reschedule an inspection. The board proposes to amend the regulations to allow the pharmacy to schedule a re-inspection without resubmitting a full permit application. The re-inspection fee is set at $150. This will save the time and cost of redoing the initial part of the application process for both the pharmacy and the department. In addition to saving $120 in fees, the pharmacy will likely be able to be re-inspected sooner, potentially permitting it to begin operations and earning revenue sooner. This amendment produces a net benefit since there is no downside to the change in procedure.

Required minimum equipment or resources

The current regulations require that all pharmacies maintain a set of prescription balances and weights or an electronic scale, a general dispensing information reference that may contain the entire scope of pharmaceuticals, and a copy of the current Virginia Drug Control Act and board regulations. Under the proposed regulations, a set of prescription balances and weights or an electronic scale will only be required if the pharmacy engages in dispensing activities that

require the weighing of components; and pharmacies only have to keep present a reference consistent with the scope of pharmacy practice at the location of the permitted pharmacy. Also, pharmacies will no longer required to possess a copy of the current Virginia Drug Control Act and board regulations. Pharmacies that have no business need for a set of prescription balances and weights or an electronic scale will save on purchasing those items, or may sell them if they are already present. The department estimates that balances and weights or an electronic scale used for pharmacy sell for between $700 to $1200. Amending the requirements for the pharmacy to maintain a copy of pharmacy laws and regulations will result in a cost saving to the board and hence to licensees. The most recent estimate for copying and mailing to all pharmacies was approximately $10,000. Those and other pharmacy resources are readily available and retrievable through the Internet at no cost.

Access to prescription department

Current regulations do not allow anyone to enter the prescription department in the absence of a licensed pharmacist. Pharmacies have occasionally had problems with a patient needing to pick up a prescription that has already been filled, reviewed and certified for accuracy by a pharmacist. This problem occurs when a pharmacist is unexpectedly not available during regular business hours, for example, if the pharmacist had to leave unexpectedly due to an emergency, or if the pharmacist scheduled to open the prescription department in the morning is ill and cannot make it to open. There are likely prescriptions that have already been filled and checked but not yet picked up by the patient. For example, a patient calls in a refill request on a given day and it is filled that day, but when he comes to pick it up the next morning during regular pharmacy hours, there is no pharmacist there due to an unexpected event.

To alleviate the problem, the board has established conditions under which a pharmacy technician, with permission of a pharmacist employed at that pharmacy, could disable the alarm and enter the pharmacy accompanied by management to retrieve the already filled prescriptions. That entry would have to be fully documented, and the access code changed by the PIC after such an event. This proposed change produces a net benefit. Patients may experience serious negative health outcomes if there is a delay in their receipt and use of their prescribed pharmaceuticals. Permitting pharmacy technicians to retrieve previously reviewed and certified prescriptions when the pharmacist is unexpectedly not available, reduces the likelihood that

patients will experience negative health outcomes due to delay in treatment. The conditions under which the drugs can be retrieved do not significantly increase the chance that mistaken prescriptions are distributed.

Under the current regulations, only a supervisory nurse may have access to a hospital pharmacy in the absence of the pharmacist in order to obtain emergency medication. The board proposes to permit nurses other than the supervisory nurse to have access to the pharmacy in the absence of the pharmacist in order to obtain emergency medication, if previously authorized by the PIC. This will also reduce the likelihood that patients will experience negative health outcomes due to a delay in treatment.

Electronic data in lieu of hard copy

The board proposes to allow an electronic image of a prescription to be maintained in an electronic database in lieu of a hard copy file for Schedule VI prescriptions, provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours. DEA does not currently allow electronic data to be maintained in lieu of hard copies for Schedule II – V prescriptions, but proposed language would allow this if the federal rules are amended. This proposal has the potential to produce significant savings for pharmacies since the cost of scanning equipment can be offset and exceeded by the savings that result from not having to file and store thousands of hard copy prescriptions. Valuable physical space would be replaced by electronic storage at a cost saving to the pharmacy.

Labeling and packaging

Current labeling requirements provide that if a generic drug is dispensed when a prescription is written for a brand name drug, the label must contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed. The purpose for this requirement is to ensure that patients do not mistakenly self-administer double doses, by taking one dose from the name brand bottle and another dose from the generic name bottle.[13] A proposed amendment will eliminate this requirement for drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer. This will result in some savings in the time and cost of producing the extra information on the prescription. Persons licensed to administer are less likely to not recognize that a generic

[13] Ibid

prescription is actually the same medication as a brand name, but they are not immune from this mistake. It is unclear whether the cost savings of not adding the extra information exceeds the increased risk of accidental double doses.

If non-special packaging is requested (non-child resistance), federal law only requires a notation on a record that such a request was made by the patient or the patient's agent. State statute only requires that a request be made in order to dispense in non-child-resistant packaging. Current regulations require a signed release. The board proposes an amendment that will allow a notation on a patient's electronic record of a request for non-special packaging in lieu of a signed release. This will relieve pharmacies of the cost of securing and maintaining hard copies of a signed release from the patient.

Prescription transfer between pharmacies

Proposed amendments will permit the transfer of prescriptions from pharmacy to pharmacy prior to the filling of the prescription. For an example of where this is relevant, there are firms that have long-term contracts to deliver drugs to institutions by mail order. On occasion, mail order firms may know that they will not be able to make certain deliveries on time. In these circumstances, the unfilled prescription could be transferred to a local pharmacy. Thus, this proposed amendment will allow for the timely delivery of prescriptions that otherwise would not occur. This may prevent significant negative health outcomes due to the delay in receipt and use of drugs by patients.

Automated dispensing devices

The board proposes to permit audits of the distribution and administration of drugs from automated dispensers to cover a sample of records, rather than all records as currently required. Audits of all records is considered redundant due to other requirements such as complete reviews of the discrepancy report, full checks that all drugs removed from the pharmacy were actually loaded into the device, random checks to ensure that valid orders exist, and checks of at least one day's administration records from each device for each month. These checks are judged to be at least as effective at detecting errors and intentionally diverted drugs as the required procedures for manual floor stock systems. Using audits covering samples rather than all records will same time and labor costs for pharmacies.

Correctional institutions

The board proposes to permit: 1) correctional facilities to return unused or discontinued drugs to the provider pharmacy or to a secondary pharmacy within 30 days, 2) a pharmacist from the correctional facility to forward drugs to a returns company, and 3) drugs to be stocked at a medical clinic or surgery center that is part of the correctional facility and is staffed by one or more physicians, providing the clinic applies for and receives a controlled substance registration. All of these proposed amendments will allow correctional facilities to reduce the cost of their pharmacy operations.

Businesses and Entities Affected

The proposed amendments affect the 7,655 actively licensed pharmacists, 888 pharmacists with inactive licenses, the 1,597 permitted pharmacies, their clients, health care facilities, medical equipment suppliers, and correctional institutions in the Commonwealth.

Localities Particularly Affected

The proposed regulations affect all Virginia localities. Amendments permitting pharmacists to serve as PIC at two locations and that lower the cost for out-of-state or recently inactive pharmacists to begin or resume practicing in Virginia may particularly affect rural parts of the Commonwealth by providing making additional pharmacist labor services available there.

Projected Impact on Employment

Amendments that lower the cost for out-of-state or recently inactive pharmacists to begin or resume practicing in Virginia may increase the number of individuals who seek to actively practice in Virginia.

Effects on the Use and Value of Private Property

Amendments permitting pharmacists to serve as PIC at two locations and that lower the cost for out-of-state or recently inactive pharmacists to begin or resume practicing in Virginia may result in additional pharmacy services being offered in Virginia. The introduction of the re-inspection fee and process may allow new or moved pharmacies to open or re-open earlier. Several proposals will permit pharmacies to store paperwork and data offsite or electronically, allowing space at the pharmacy to be used for other purposes. Pharmacies that do not need balances and weights or an electronic scale will no longer be required purchase or maintain them.