Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-30 – Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Department of Health Professions
March 31, 2005

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

Following a periodic review of these regulations, the Board of Pharmacy (board) proposes to make several amendments to these regulations, including: 1) amending fees for consistency with similar fees for similar activities by a pharmacist or a pharmacy, 2) amending renewal and reinstatement requirements for consistency with pharmacist and pharmacy requirements, 3) adding a required re-inspection of storage and selling area for reinstated licensees, 4) adding a fee to cover the approximate cost of conducting a re-inspection, if required, 5) eliminating a restriction on limited-use licenses, 6) eliminating the inactive license, 7) specifying qualifications of non-licensee permitted in storage and selling area, 8) allowing compounding to be performed by registered pharmacy technicians under the licensee's supervision, 9) requiring that the licensee conduct a prospective drug review and offer counsel prior to dispensing, 10) amending the list of required minimum equipment and resources, 11) requiring that a conspicuous sign be posted in every examination room notifying patients of their

right to choose where to have their prescription filled, 12) permitting electronic storage of records, and 13) clarifying language.

Estimated Economic Impact

License renewal, late fees, and reinstatement

Currently, a practitioner who fails to renew her license on or before its expiration date may renew the license if she 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, 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 expiration 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 and pay a $210 reinstatement fee, but is not required to pay all back renewal fees. An individual who seeks to reinstate two years after expiration will also be $40 better off under the proposed regulations.[1] (See table below.) 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] An individual who seeks to reinstate five years after expiration will be $310 better off under the proposed regulations.[4] Thus, the fee savings under the proposed regulations versus the current regulations increase the longer the license was expired.

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[1] Fees for reinstatement after two years under the current regulations: ($180 in back fees) + ($70 delinquent fee) = $250. Fees for reinstatement after two years under the proposed regulations: $210. $250 - $210 = $40.

[2] Fees for reinstatement after three years under the current regulations: ($270 in back fees) + ($70 delinquent fee) = $340. Fees for reinstatement after three years under the proposed regulations: $210. $340 - $210 = $130.

[3] Fees for reinstatement after four years under the current regulations: ($360 in back fees) + ($70 delinquent fee) = $430. Fees for reinstatement after four years under the proposed regulations: $210. $430 - $210 = $220.

[4] Fees for reinstatement after five years under the current regulations: ($450 in back fees) + ($70 delinquent fee) = $520. Fees for reinstatement after four years under the proposed regulations: $210. $520 - $210 = $310.

	Current	Proposed
On-time	$90	$90
Within 60 days after expiration date	$120	$120
61 days to one year after expiration date	$160	$120
Up to two years after expiration date	$250	$210
Up to three years after expiration date	$340	$210
Up to four years after expiration date	$430	$210
Up to five years after expiration date	$520	$210

Re-inspection

Under the current regulations if an 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 applicant 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 applicant and the Department of Health Professions (department). In addition to saving $120 in fees, the facility 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.

The current regulations do not specify a requirement that applicants for reinstatement have their storage and selling area re-inspected. Under the proposed regulations, a licensee

applying for reinstatement must have their storage and selling area re-inspected and pay the $150 re-inspection fee unless another practitioner at the same location has held an active license to sell controlled substances during that period. For those licensees applying for reinstatement that do not have another practitioner at the same location who has held an active license during the period that the applicant's license was expired, the total fees for reinstatement will be $360.[5] The table below compares the required fees for renewal and reinstatement under the current regulations, with the required fees for renewal and reinstatement under the proposed regulations when the applicant has a continually licensed colleague at the same location, and with the required fees for renewal and reinstatement under the proposed regulations when the applicant does not have a continually licensed colleague at the same location.

	Current	Proposed with a licensed colleague	Proposed without a licensed colleague
On-time	$90	$90	$90
Within 60 days after expiration date	$120	$120	$120
61 days to one year after expiration date	$160	$120	$120
Up to two years after expiration date	$250	$210	$360
Up to three years after expiration date	$340	$210	$360
Up to four years after expiration date	$430	$210	$360
Up to five years after expiration date	$520	$210	$360

In terms of fees, an individual without a continually licensed colleague at the same location who seeks to reinstate two years after expiration will be $110 worse off under the proposed

[5] $360 = $210 reinstatement fee + $150 re-inspection fee

regulations.[6] An individual who seeks to reinstate three years after expiration will be $20 worse off under the proposed regulations.[7] An individual who seeks to reinstate four years after expiration will be $70 better off under the proposed regulations.[8] An individual who seeks to reinstate five years after expiration will be $160 better off under the proposed regulations.[9] Thus, for individuals without a continually licensed colleague at the same location who seek to renew or reinstate their license between one year and one day after expiration and three years after expiration, the required fees are higher under the proposed regulations. Individuals without a continually licensed colleague at the same location who seek to renew or reinstate their license either 61 days to one year after expiration, or more than three years after expiration, will encounter lower fees under the proposed regulations.

Limited-use license

Both the current and proposed regulations permit the board to issue a limited-use license when the scope, degree, or type of services provided to the patient is of a limited nature. The issued license is based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. Under the current regulations possessors of limited-use licenses can only sell controlled substances which have been received prepackaged in ready to dispense quantities and containers needing only the addition of required labeling. The board proposes to eliminate this limitation.

Limited-use licenses can vary in detail and are approved by the board on a case-by-case basis. Repealing the language that restricts limited-use licensees to only selling controlled substances that are received prepackaged in ready to dispense quantities and containers provides the board with the flexibility to permit other type of sales for some limited-use licensees where

[6] Fees for reinstatement after two years under the current regulations: ($180 in back fees) + ($70 delinquent fee) = $250. Fees for reinstatement after two years under the proposed regulations: ($210 reinstatement fee) + ($150 re-inspection fee) = $360. $250 - $360 = -$110.

[7] Fees for reinstatement after three years under the current regulations: ($270 in back fees) + ($70 delinquent fee) = $340. Fees for reinstatement after three years under the proposed regulations: ($210 reinstatement fee) + ($150 re-inspection fee) = $360. $340 - $360 = -$20.

[8] Fees for reinstatement after four years under the current regulations: ($360 in back fees) + ($70 delinquent fee) = $430. Fees for reinstatement after four years under the proposed regulations: ($210 reinstatement fee) + ($150 re-inspection fee) = $360. $430 - $360 = $70.

qualifications and conditions indicate no undue safety risk. The removal of this restriction can potentially reduce costs for affected limited-use licensees. The board retains the right to create and approve limited-use licenses where the licensee is not permitted to sell non-prepackaged controlled substances. This proposed amendment should provide a net benefit since costs can be lowered without significant addition to health risks, assuming that the board can accurately judge when the introduced risks are minimal.

Inactive license

Licensees who intend to cease selling controlled substances are required to notify the board 10 days prior to cessation. Under the current regulations, the individual chooses to either place her license on inactive status, or to surrender the license. An individual with an inactive license is not permitted to engage in the sale of controlled substances. The inactive license may be reactivated through application to the board. There is no reactivation fee beyond the standard licensing fee.

The board proposes to eliminate inactive status. In its stead, the board proposes to state that "a licensee who has surrendered his license pursuant to (cessation) may request that it be made current again at anytime within the same renewal year without having to pay an additional fee, …" In practice, the proposed change will not change behavior beyond that the designation "inactive license" will not be used.

Compounding and assistance

The current regulations permit one non-licensee in the storage and selling area at any given time for the purpose of assisting the licensee in the preparation, packaging, and labeling of a controlled substance. The board proposes to specify that the non-licensee be a registered pharmacy technician, or a licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians. The department is not aware of any practitioner seller of controlled substances who uses anyone other than a nurse to assist in the storage and selling area for preparation, packaging and labeling of a controlled

[9] Fees for reinstatement after four years under the current regulations: ($450 in back fees) + ($70 delinquent fee) = $520. Fees for reinstatement after four years under the proposed regulations: ($210 reinstatement fee) + ($150 re-inspection fee) = $360. $520 - $360 = $160.

substance. Thus, in practice, the proposal to specify that the assistant be either a registered pharmacy technician, or a licensed nurse or physician assistant will likely have little impact.

The current regulations state, "Any compounding of a controlled substance shall be personally performed by the licensee." The board proposes to permit a registered pharmacy technician under the supervision of the licensee to compound controlled substances. Registered pharmacy technicians are deemed competent to assist in this field. Permitting registered pharmacy technicians to compound can result in the faster processing of prescriptions. The time that the licensee would have spent compounding can be productively used on other activities. Given the profession's relative wage rates, spending a pharmacy technician's time on compounding rather than a physician's time can be considered a cost saving.[10] Since, as stated above, the department is not aware of any practitioner seller of controlled substances who uses anyone other than a nurse to assist in the storage and selling area for preparation, packaging and labeling of a controlled substance, this proposed will initially not have a significant impact. Since compounding will become less expensive to conduct under the proposed regulations, it may occur more often going forward.

Prospective drug review and counseling

Pharmacists are required to conduct a prospective drug review before each new prescription is dispensed. Such reviews "include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse."[11] The pharmacist is also required to offer counsel to counsel any person who presents a new prescription for filling.

The current regulations do not address prospective drug review and counseling for doctors licensed to sell controlled substances. The board proposes to explicitly state that licensees must conduct a prospective drug review and offer counsel. It is hoped that licensees

[10] November 2003 U.S. Bureau of Labor Statistics National Occupational Employment and Wage Estimates (mean annual salary): Family and General Practitioners ($139,860), Internists ($159,820), Podiatrists ($107,390), Pharmacy Technicians ($24,540).

are already doing this. Failure to check for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, drug-allergy interactions, etc., can lead to seriously adverse health outcomes. Despite the high wages earned by licensees (see footnote 10), it seems likely that the cost of the time spent conducting prospective drug reviews is outweighed by the benefit of reduced adverse health outcomes. Thus, to the extent that explicitly stating this requirement increases the frequency that licensees conduct prospective drug reviews and offer counsel, this proposed new language will create a net benefit.

Required minimum equipment or resources

The board proposes changes to the list of required equipment. The current regulations require that licensees keep current copies of the Virginia Drug Control Act, board regulations, and the Virginia Voluntary Formulary. Since these documents are readily retrievable through the Internet at no cost, the board proposes to eliminate the requirement that copies are kept in the dispensing area. Eliminating this requirement saves the expenses incurred by the Department of Health Professions (department) for copying and mailing the documents to the licensees. Lower expenses will in the long run result in lower fees than otherwise would be charged.

The current regulations specify that a laminar flow hood be present if sterile products are prepared. The board proposes to allow more flexibility in the type of equipment used for sterile product preparation. Potentially this could result in cost savings for affected licenses. The current regulations also require that prescription balances, sensitive to 15 milligrams, and weights or an electronic scale be present, if the licensee is engaged in extemporaneous compounding. The board proposes to only require this weighing equipment if the licensee is engaged in "dispensing activities that require the weighing of components." Some extemporaneous compounding can occur where weighing is not necessary. Thus, this proposed change could save licensees the cost of purchasing, maintaining, and providing space for weight-measuring equipment. The department estimates that balances and weights or an electronic scale used for pharmacy sell for between $700 to $1200. Since department staff are not aware of any physicians preparing sterile products for dispensing or engaged in extemporaneous compounding, the proposed amendment is not likely to have a significant impact.

[11] Source: § 54.1-3319 of the Code of Virginia.

Notification of dispensing choice

The current regulations require that licensees conspicuously display a sign in the public area of the office that advises patients of their right to choose where they have their prescriptions filled. The board proposes to further require that such signs be also conspicuously posted in every patient examination room. The reasoning is that patients may be more likely to notice the signs in the exam rooms. It will cost licensees a small amount to produce and post the additional signs. Some patients may prefer to purchase their prescriptions outside the licensee's office due to lower prices or other reasons. These patients in particular will value knowing that they may purchase the drugs elsewhere. To the extent that more patients learn about their right of purchase location, this proposal will likely produce a net benefit.

Electronic storage of records

The board proposes to allow electronic storage of Schedule II through VI drugs sold, rather than hard copies. This proposal has the potential to produce significant savings that result from not having to file and store thousands of hard copy prescription records. Valuable physical space could be used for productive purposes other than paper storage. Worker filing time will also be saved. As long as the electronic data is adequately backed-up, so that the risk of loss of that data is minimal, this proposed amendment produces a net benefit.

Businesses and Entities Affected

The proposed amendments affect the 227 doctors of medicine, osteopathic medicine or podiatry with active licenses to sell controlled substances, the 4 individuals with inactive licenses, as well as their employers and potential employers, their patients and potential patients, and future doctors that may become interested in becoming licensed to sell controlled substances.

Localities Particularly Affected

The proposed regulations affect all Virginia localities.

Projected Impact on Employment

Currently, the department is not aware of any practitioner seller of controlled substances who uses anyone other than a nurse to assist in the storage and selling area for preparation,

packaging, and labeling of a controlled substance. There is a small probability that the proposal to permit a registered pharmacy technician under the supervision of the licensee to compound controlled substances will encourage the hiring of pharmacy technicians.

Effects on the Use and Value of Private Property

The proposed amendments to the timing and amounts of late fees and reinstatements will in most instances lower costs for affected licensees. The proposal to allow an applicant to schedule a re-inspection without resubmitting a full permit application will save her $120 in fees, and will likely enable her facility to be re-inspected sooner, potentially permitting it to begin operations and earning revenue sooner. Repealing the language that restricts limited-use licensees to only selling controlled substances that are received prepackaged in ready to dispense quantities and containers can potentially reduce costs for affected limited-use licenses. Permitting registered pharmacy technicians to compound can result in the faster processing of prescriptions, allowing the licensee to use her time more productively. Allowing electronic storage of records in lieu of hard copies can produce significant savings for licensees. These licensees will have their net worth correspondingly affected.