

Economic Impact Analysis Virginia Department of Planning and Budget

18 VAC 110-20 – Virginia Board of Pharmacy Regulation Department of Health Professional February 8, 2006

Summary of the Proposed Regulation

The Board of Pharmacy (board) proposes to amend The Board of Pharmacy Regulations to exempt certain controlled substances registrants from having to store filled prescriptions in alarmed spaces. Specifically, the board proposes to add humane societies and alternate delivery sites to the list of other registrants, researchers and animal control officers, who are allowed to store small amounts of Schedule II-V drugs in unalarmed buildings so long as other security protocols are followed.

Result of Analysis

The benefits likely exceed the costs for this proposed regulatory change.

Estimated Economic Impact

Current Board of Pharmacy Regulations require that controlled substances registrants whose facilities are not staffed 24 hours a day store prescription drugs "... in a fixed and secured room, cabinet or area which has a security devise for the detection of breaking". The only controlled substances registrants who are currently exempt from this alarm requirement are researchers and animal control officers. The board proposes to extend this exemption to cover humane societies, which store small quantities of drugs for animals, and alternate delivery sites such as campus health centers and after-care pharmacies at local Community Service Boards, where prescriptions that are filled at offsite pharmacies may be held for patient pick-up.

Humane societies have traditionally been allowed to store drugs in their unalarmed facilities but were inadvertently left off of the list of registrants who are exempted from code alarm requirements when this regulation was written. The proposed regulatory change adds them to this list so that they may continue to operate without having to install expensive alarm

systems. This change will benefit Virginia's citizens as it will allow humane societies to use their funds to take care of unwanted animals that might otherwise constitute a public nuisance.

The board also seeks to extend the exemption from alarm requirements to alternate delivery sites that receive filled prescriptions and hold them for patient pick-up. This exemption would allow student health centers to receive students' prescriptions and hold them in unalarmed buildings so long as these prescriptions are kept in a locked room or cabinet where only authorized personnel can access them. Although this exemption covers storage of Schedule II-V drugs, one would expect most prescriptions held for students would be things like antibiotics and birth control pills that are Schedule V drugs, non-addictive and unlikely to be abused. Universities and colleges will certainly benefit from being allowed to have their student health centers in unalarmed buildings. This not only saves the price of an alarm system, but also allows greater flexibility to relocate these centers as necessary or convenient. Since most held prescriptions are likely to have a low risk of abuse, there is likely to be little risk of increased theft of prescriptions from unalarmed student health centers.

The alarm exemption for alternative delivery sites will allow local Community Service Boards (CSB) to serve as after-care pharmacies for clients of the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS). Like student health centers, CSBs will benefit from the proposed regulation in that they will not have to pay for alarm systems and will have greater flexibility to move their facilities as they see fit. Given the population that DMHMRSAS serves, however, CSBs will likely receive more filled prescriptions of Schedule II-IV drugs that are more addictive and more likely to be abused. Because of this and because part of DMHMRSAS's, and the CSBs', target clientele is comprised of substance abusers, CSBs are likely more at risk for increasing drug theft than are student health centers. As drugs will be held in a locked and secure room or cabinet, the risk of theft, though increased, will still be minimal. In any case, the benefits to both the Community Service Boards and their clients, who will be able to choose when and where to pick up their prescriptions, likely outweigh the costs that may arise from drug theft.

Businesses and Entities Affected

This proposed regulatory change will affect the 44 humane societies that are located in the Commonwealth as well as all alternative delivery sites such as student health centers and Community Service Boards.

Localities Particularly Affected

The proposed regulation will affect all localities in the Commonwealth.

Projected Impact on Employment

The proposed regulation is unlikely to affect employment.

Effects on the Use and Value of Private Property

The proposed regulation will allow affected entities greater flexibility in how they use their property and will increase the value of that property by an amount equal to the cost of the now unnecessary alarm system.

Small Businesses: Costs and Other Effects

To the extent that affected entities are small colleges that are for-profit and have student health centers, the proposed regulation will lower costs for affected small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact

The proposed regulation will decrease the compliance burden on the regulated community.

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 21 (02). 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.