Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
January 2, 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 to: 1) allow chart orders for hospice or home infusion patients, 2) allow pharmacists to record dispensing records by a combination of electronic and manual means, 3) allow for delivery of prescription drugs to intermediate sites, 4) allow nursing homes to donate unused pharmaceuticals to a pharmacy that will re-dispense those drugs to the indigent free of charge, and 5) allow physicians who do not possess a license to sell controlled substances to provide controlled substances to patients in a free clinic if they or the clinic obtain a controlled substances registration.

Estimated Economic Impact

The current regulations limit the use of chart orders, which contain multiple prescription orders on one sheet, to hospital and nursing home patients. Pharmacies that serve hospice patients and home infusion patients have a need for the use of chart orders for prescriptions because of the nature of the illnesses involved and the complexity of the drug therapy. Hospice

patients usually receive a “kit” in addition to regularly administered drugs for use in end stages of their disease or for emergencies. The kit contains one to two doses of several drugs. The drugs for the kit are standardized and on a list with standard instructions for use. Additionally, many of these orders are either originally written upon discharge from a hospital on a chart order or are written as standing orders on a multiple prescription format. Under the current regulations, pharmacies must receive a separate prescription on a separate form for each individual drug to be placed in the kit. In order for these pharmacies to receive a separate prescription on a separate form for each drug order, someone must transcribe each ordered drug from the chart order to onto separate prescription blanks for the prescriber’s signature. This process is costly because: 1) the probability for prescription errors increases due to the chance that transcription mistakes are made, 2) the possibility of accidental deletion of one or more of the drugs from the multiple order, and 3) the extra labor time required for the person doing the transcribing and the physician who must divert his activities to read and sign the separate sheets. According to the Department of Health Professions (department), it is not uncommon for pharmacies to receive chart orders for drugs prescribed to hospice patients and home infusion patients. When this happens, pharmacists and their staff must spend time finding the prescriber and informing him that he must reissue the chart order as separate prescription. In these circumstances, there can be a significant delay in when the hospice patients and home infusion patients receive their medications.

The board proposes to permit pharmacies to accept chart orders for hospice patients and home infusion patients. Permitting pharmacies to accept chart orders will save the costs of labor time for physicians, transcribers, and pharmacy staff; remove the chance of transcription errors; and eliminate the occasional delays in patients receiving their medications due to pharmacies’ inability to accept chart orders as under the current regulations. There are no apparent new costs associated with permitting pharmacies to accept chart orders for hospice patients and home infusion patients. Thus, this proposed amendment will create a net benefit.

The current regulations allow pharmacists to record dispensing information either manually on the prescription itself or in "an automated data processing system,” but not a combination of both systems. According to the department, pharmacists have found inadequacies with their data processing software in that it fails to allow for accurate recording of partially filled prescriptions, etc. Thus, several licensees have indicated that in order to maintain

accurate records and not be forced to switch to an entirely handwritten record keeping system, they need to be permitted to use a combination of the electronic system and handwritten supplemental records for the data that the software cannot handle. The board proposes to permit pharmacists to record dispensing records by a combination of electronic and manual means. Since the department is satisfied that the combination system can be accurate and will meet their review needs, the proposed amendment will create a net benefit.

The term "dispense" has been defined to mean the delivery of the drug to the ultimate user. Based on this definition, the board has prevented the use of intermediate delivery locations or "drop stations" where a pharmacy delivers a group of prescriptions to a central location for subsequent pick-up by patients. Pursuant to Chapter 411 of the 2002 Acts of the Assembly, the board proposes to permit the delivery of prescriptions to intermediate locations under circumstances designed to: 1) ensure that the security and proper storage of the drugs are maintained until patient pickup, 2) protect patient confidentiality, 3) minimize the risk of mistakes in handing out the drugs, and 4) ensure accountability by requiring accurate records be kept. Specifically, the proposed regulations permit that

> in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver prescriptions to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with … applicable state or federal law.

Permitting delivery of prescription drugs through an intermediate location, rather than directly to the patient, may increase the chance that the drugs do not reach their intended patient due to the possibility that individuals intermediately involved may either mistakenly lose the drugs, deliver them to the wrong individual, or theft could occur. On the other hand, permitting the delivery of prescriptions to intermediate locations may allow for significant timesavings for patients in receiving the drugs. Some patients may have schedules that do not permit them to pickup or receive prescription drugs from a pharmacy in a timely fashion. Also, in some circumstances, using a well-run intermediate location will reduce the probability that drugs are stolen or rendered unsafe. According to the department, it is not uncommon for delivered drugs to be left

inside a screen door, which may be ajar, when the recipient does not answer the door. The outdoor temperature or precipitation may render the drugs unsafe or ineffective in these circumstances. Also, the drugs are subject to a nontrivial probability of theft. Permitting that the drugs be delivered to a nearby well-run intermediate location would likely reduce the number of occurrences where drugs are left in these circumstances.

Under the current regulations, nursing homes may only return unused pharmaceuticals to the pharmacy from which it was originally dispensed. Pursuant to Chapter 632 of the 2002 Acts of the Assembly, the board proposes to permit nursing homes to donate unused drugs to other pharmacies if those pharmacies dispense the donated drugs to the indigent, free of charge. The drugs must be in the manufacturers' original sealed containers or sealed individual dose or unit dose packaging and the return must comply with federal law. This proposed amendment will create a net benefit. Drugs that otherwise would likely been thrown away will be used by the indigent who may not otherwise have had access to the beneficial properties of the prescription drugs.

Pursuant to Chapters 666 and 707 of the 2002 Acts of the Assembly, the board proposes to amend these regulations so that practitioners of medicine or osteopathy who do not possess a license to sell controlled substances may provide controlled substances to patients in a free clinic[1] if the drugs were donated, and they or the clinic obtain a controlled substances registration.[2] Controlled substances registration differs from licensure to sell controlled substances in several ways that reduce costs for volunteering physicians and free clinics. Unlike licensure, registration does not require that there be a separate room for dispensing. This, coupled with less stringent record keeping requirements, make registration less costly than licensure. Further, the annual registration fee is $90 while the annual licensure fee is $270. Since licenses apply to individuals while registration may be obtained for an entity whereby all practitioners of medicine or osteopathy within the entity are considered registered, the difference in fee costs can be substantially larger than $180; for example, if a free clinic has four physicians that at various times volunteer in the clinic, the registration fee is only $90 as compared to $1,080 for the four licenses. These significant reductions in cost may make it more likely that

[1] The controlled substances must be provided without charge.
[2] If the controlled substances are donated by a pharmaceutical manufacturer as described in subdivision 10 of Chapters 666 and 707 of the 2002 Acts of the Assembly, then registration is not required.

free clinics will be able to be fully staffed with individuals who are legally qualified to provide donated drugs to patients. Using and dispensing donated drugs rather than purchasing drugs for their patients reduces operating costs for free clinics and allows them to serve more patients and stay open longer. On the other hand, not requiring a separate dispensing room and reduced record keeping requirements may increase the probability that drugs are lost or stolen.

Businesses and Entities Affected

The proposed amendments affect the 1,497 pharmacies and 7,807 pharmacists licensed in the Commonwealth, as well as their staff and customers. Physicians, their staff, and free clinics and their patients are affected as well.

Localities Particularly Affected

The proposed regulations affect localities throughout the Commonwealth, but areas with larger populations of elderly and the indigent will be particularly affected.

Projected Impact on Employment

The proposed amendments will not significantly affect employment levels.

Effects on the Use and Value of Private Property

Permitting pharmacies to accept chart orders will save the costs of labor time for physicians, transcribers, and pharmacy staff. This will marginally increase the value of pharmacies physicians' practices. Nursing homes will be able to donate more unused drugs to the indigent.