Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 76-20 – Rules Governing the Prescription Monitoring Program
Department of Health Professions
November 7, 2005

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. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

The Department of Health Professions (DHP) proposes to amend the Regulations Governing the Prescription Monitoring Program (PMP) to:

- Include reporting of dispensed Schedule III and IV drugs.
- Expand the PMP to include reporting from all dispensers statewide as well as some dispensers located outside the Commonwealth.
- Allow reporting to drug prescribers who are licensed in jurisdictions other than the Commonwealth.
- Allow reporting of dispensed schedule II, III and IV drugs to set non-prescribing entities.
- Facilitate electronic requests and disclosures.
- Allow drug dispensers to submit queries to the PMP and establish notification of disclosure requirements to which drug dispensers must adhere.

Estimated Economic Impact

Under the most recent non-emergency PMP regulation, drug dispensers in Southwestern Virginia reported the dispensing of Schedule II drugs only. To reflect changes made to Code of Virginia §54.1-2519 et seq. during the 2005 legislative session, current emergency, and this proposed, regulation expand both the geographic scope of the PMP and the number of drugs monitored. Drug dispensers statewide will be required to report dispensing of Schedule II, III and IV drugs[1].

Dispensers who were not part of the pilot PMP program will incur the same, very minimal, reporting costs as have the pilot program dispensers. The data system that they will use for prescription monitoring is the same system pharmacies now use for third party payments so dispensers will not have to put much effort at all into reporting to the PMP. In addition, dispensers who intend to request information from the PMP will be required to disclose this intention to their customers. The least expensive way that dispensers can meet this notification requirement is by posting a sign next to the counter where customers drop off their prescription. DHP estimates that this will cost dispensers less than five dollars. DPB estimates that, since dispensers may print a sign on their in-store computer, cost associated with meeting disclosure requirements will likely be much less than one dollar per dispenser.

DHP estimates that they will incur one time costs for expanding the PMP of approximately $225,000. This expenditure will pay for new software that can accommodate the vastly increased number of reports that are likely to arise because the number of dispensers covered by the proposed regulation is so much greater than the number that were part of the pilot program and because three classes of dispensed drugs, rather than one, will be reported by dispensers and queried by prescribers. Approximately 300 dispensers were part of the pilot program; DHP expects that approximately 2000 dispensers will be submitting reports once the expanded PMP is fully implemented. Dispensers currently report 20,000 instances of dispensed

[1] Schedule II drugs are drugs that have a high abuse risk, but that also have safe and accepted medical uses in the United States. These drugs can cause severe psychological or physical dependence. Schedule II drugs include certain narcotic, stimulant, and depressant drugs. Some examples are morphine, cocaine, oxycodone, methylphenidate and dextroamphetamine. Schedule III and IV drugs have an abuse risk that is high but less severe than Schedule II drugs. Schedule III drugs include Buprenorphine, anabolic steroids and combination drugs like hydrocodone plus acetaminophen and codeine plus acetaminophen. Schedule IV drugs include mood altering drugs like Valium, Xanax, Librium, Rohypnol and Klonopin.

Schedule II drugs every two weeks. DHP expects to get two million reports per year once the expanded PMP is fully implemented. Prescribers currently submit 150 queries per month to the PMP. DHP expects to receive 500 queries per day once the expanded PMP is fully implemented.

In addition to the fixed costs associated with software purchase and installation, DHP expects to incur ongoing costs associated with processing increasing numbers of reports from dispensers and answering increasing numbers of queries from prescribers; these costs will be approximately $125,000 per year. Software maintenance will cost DHP about 18% of their original software investment, about $40,500, per year. All of the fixed and ongoing expenses associated with the PMP are expected to be covered by federal grant money at least through 2010. The General Assembly has authorized DHP to fund the PMP with user fees if expected grants do not materialize and when grant money runs out.

Current regulation requires that prescribers who are querying the PMP submit their DHP issued license number with the query. Because the pilot PMP program has almost certainly pushed drug abusers to seek prescriptions outside of the borders of the program in neighboring states, and prescribers who are licensed in neighboring states rather than by DHP have expressed interest in being able to submit queries to the Commonwealth's PMP, DHP proposes that a prescriber be allowed to submit his United States Drug Enforcement Administration (DEA) registration number with his PMP query. This regulatory change will make drug abusing citizens of Virginia less able to thwart the intent of the PMP by obtaining prescriptions just over the state's border.

Pursuant to changes made to §54-1.2523 during the 2005 legislative session, the proposed regulation will allow designated agents of the Virginia Department of Medical Assistance Services (DMAS) to query the PMP for "information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services". Designated agents of the Health Practitioners Intervention Program (HPIP) will be able to query "Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary

proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board". The Chief Medical Examiner will also be able to query the system. This will allow DMAS to better recognize and stop Medicaid fraud, HPIP to better monitor health care professionals who have abused drugs in the past and will allow the Medical Examiner's office to better determine a drug recipient's cause of death.

The proposed regulation will eliminate the need for prescribers to submit, with any PMP query, a signed form attesting that they have obtained signed consent from the potential drug recipient; this signed consent then would be kept in the drug recipient's patient file. Instead, amendments will allow for electronic attestation by prescribers that they have signed consent on file from the recipient whose information is being queried. In addition, the consent signed by potential drug recipients will no longer have to be on a separate, distinct form; the proposed regulation will allow the recipient's signed consent to be part of a more general privacy notice. This change will reduce the paperwork burden borne by providers in parts of the Commonwealth that were part of the pilot PMP program.

Authorized government employees of the State Police, the Medical Examiners Office, DMAS, HPIP and other agencies that are allowed to access PMP information will also no longer have to submit queries in writing. The proposed regulation allows DHP to more easily accept electronic queries from these agencies and from other authorized information recipients. Taken together, these changes will allow DHP to make the PMP more efficient and less costly.

The proposed regulation allows dispensers to query the PMP if they make customers aware that this query is possible in a way that is acceptable to DHP. Dispensers may post a sign prominently at the prescription intake counter, hand out written disclosures to individual pharmacy customers or obtain written consent. This will allow drug dispensers to check if a customer has a suspicious and potentially abusive pattern of dispensed prescriptions (for instance, a customer might have had many prescriptions for the same drug from different doctors). This will allow dispensers to judge whether they should fill prescriptions that are presented to them. Dispensers will then be part of a system that will hopefully reduce the abuse of prescription drugs within the Commonwealth.

Businesses and Entities Affected

The proposed regulation will affect drug dispensers who intend to query the PMP and who must comply with parts of the regulation that require notice to patients who are the subjects of those intended queries. This regulated community comprises 1576 pharmacies, 492 non-resident pharmacies and 198 physicians who dispense drugs.

Localities Particularly Affected

The proposed regulation will affect all localities in the Commonwealth.

Projected Impact on Employment

The proposed regulation may likely have a positive effect on the employment opportunities of health care professionals who are subject to monitoring by the Health Practitioners Intervention Program (HPIP). Because this regulatory change will allow HPIP to reduce the possibility of program participants secretly obtaining and using drugs, employers are likely to be more confident that a formerly drug abusing health professional will stay sober, or will be unable to hide future drug abuse, and may be more likely to hire them.

Effects on the Use and Value of Private Property

Drug dispensers will have to pay the very small costs associated with notifying their patients of intended queries to the PMP. Dispensers may notify patients by posting a sign where prescriptions are accepted for dispensing, providing individual written material to patients or obtaining written consent from the patient.

Small Businesses: Costs and Other Effects

Drug dispensers that qualify as small businesses will have to pay the very small costs associated with notifying their patients of intended queries to the PMP. Dispensers may notify patients by posting a sign where prescriptions are accepted for dispensing, providing individual written material to patients or obtaining written consent from the patient.

Small Businesses: Alternative Method that Minimizes Adverse Impact

There are likely no alternative methods to accomplish DHP’s goals that would be less costly than the methods mandated by the proposed regulation.