Department of Planning and Budget
2004 Fiscal Impact Statement

1. Bill Number HB 359

House of Origin ☒ Introduced ☐ Substitute ☐ Engrossed

Second House ☐ In Committee ☐ Substitute ☐ Enrolled

2. Patron BaCote

3. Committee Health, Welfare and Institutions

4. Title: Pharmaceutical services for certain low-income patients, preventive; established.

5. Summary/Purpose:

HB 359 would require the Commissioner of Health to establish, by January 1, 2005, a mechanism whereby any public health clinic operated by a local or district health department that maintains pharmacy services would continue to provide free or low-cost prescription drugs (on a sliding fee scale) to any low-income patients who do not have any prescription drug benefit and whose primary and specialty health care services have been transferred to a community health clinic delivering free or reduced price services to such patients at the recommendation of the public health clinic. However, any such patients would be required to obtain prescription drugs from pharmaceutical companies' free or reduced price programs in so far as possible.

6. Fiscal Impact Estimates are preliminary (See Item 8)

6a. Expenditure Impact:

	Dollars		
Fiscal Year	***GF***	***NGF***	***Positions***
2003-04	$ 0	$ 0	0.0
2004-05	$5,412,253	$21,218,605	0.0
2005-06	$5,953,478	$23,340,465	0.0
2006-07	$6,548,826	$25,674,512	0.0
2007-08	$7,203,708	$28,241,963	0.0
2008-09	$7,924,079	$31,066,159	0.0
2009-10	$8,716,487	$34,172,775	0.0

7. **Budget amendment necessary:** Yes. Item 310, Communicable and Chronic Disease Prevention and Control (40500) and Item 314, Community Health Services (44000)

8. **Fiscal implications:**

Because HB 359 extends drug discounts to patients of a different health care provider than the prescribing physician, it appears to violate the "own use" provisions established under federal "restraint of trade" law, dating back to 1936, and a series of court cases, dating back to 1976. Thus, the bill is expected to jeopardize the Commonwealth's savings under all discount programs in which the Virginia Department of Health participates, and it may jeopardize savings under other discount programs utilized by other state agencies.

Current State Pharmaceutical Purchases under Large-Volume Discount Programs:

Most drugs purchased by the Virginia Department of Health (VDH), and many purchases by the Aftercare Pharmacy program of the Department of Mental Health, Mental Retardation and Substance Abuse Services (MHMRSAS) are made through special programs that allow substantial cost savings due to large-volume price negotiations. Primary among these are:

- The Minnesota Multi- State Contracting Alliance for Pharmaceuticals (MMCAP) and
- Purchases under Section 340B of the Veterans' Health Care Act of 1992

According to a 2002 JLARC study, prices of pharmaceuticals obtained through the 340B program are 51 percent lower than average wholesale prices. According to the VDH Director of Pharmacy Services, MMCAP discounts are about 20 or 25 percent. Most VDH pharmaceuticals – on the order of 70 percent - are purchased through the 340B program, with the remaining 30 percent purchased through MMCAP. Using this distribution, the overall average discount is estimated to be 43 percent.

JLARC Study Supports Use of Discount Purchasing Programs

The 2002 JLARC study of state spending on pharmaceuticals commended VDH's performance in obtaining discount prices and recommended that all state agencies pursue these and other discount programs to reduce the cost of providing health care.

Legal Background to Purchasing Based on Large-Volume Discounts:

Generally, MMCAP prohibits dispensing drugs to people who are not patients of the dispensing public entity. Community health centers and free clinics, as 501(c)(3) organizations, do not qualify as public entities for purposes of the current MMCAP definitions.

With regard to the Section 340B purchases, the federal Robinson-Patman Act of 1936 (15 U.S.C. 13(a)) was designed to prevent the government from competing unfairly with private sector entities through use of its purchasing power.

The courts have applied the principle of "own use" incorporated in this legislation to Section 340B purchases and are likely to extend that principle to purchasing agreements like MMCAP. The two controlling cases are Abbott Labs v. Portland Retail Druggists (425 U.S. 1 (1976)) and Jefferson County Pharmaceutical Association, Inc. v. Abbott Labs (460 U.S. 150 (1983)).

HB 359, by implicitly requiring that VDH abandon the principle of "own use," would jeopardize the Commonwealth's participation in both programs and could well result in both legal costs (not estimated here) and higher drug costs for all VDH and other state agency purchases under these programs. MMCAP would recognize the Commonwealth's designation of 501(c)(3) corporations as legitimate buyers under the program, but that would not prevent a potential legal challenge to that participation from parties who objected to extending eligibility for reduced price purchasing.

Cost Estimates, Lost Discounts, Department of Health (VDH)

If the Commonwealth were found to be in violation of the requirements of the "own use" principle, the impact for the VDH budget would be as listed in Item 6 above, and explained below. This estimate does not include court costs and legal fees.

Loss of access to the federal 340B program and the MMCAP contract would sharply increase pharmaceutical expenditures by VDH, which totaled $29,174,685 in FY 2003. If the estimated average discount of 43 percent had not been available, the agency's pharmaceutical costs would have been $51,183,658 or $22,008,973 higher than they were:

$29,174,685 / 57% = $51,183,658
$51,183,658, less $29,174,685 = $22,008,973

The distribution of funds expended for pharmaceuticals in 2003 was as follows (percentages are rounded):

General fund	20.3 %
Federal funds	54.0 %
Local government, etc.	25.7 %

Accordingly, the FY 2003 fund impact of the lost discount would have been as follows:

General fund	$4,472,936
Local government, etc.	$5,656,306

VDH pharmaceutical purchases grew from $23 million in 2002 to $29 million in FY 2003 (due primarily to continued growth in ADAP/Ryan White HIV/AIDS drug purchases), an increase of 26 percent, and pharmaceutical costs are widely predicted to continue to increase at rapid rates over the next decade. The estimated expenditure (lost savings) impacts through FY 2010 conservatively allow a 10 percent annual growth rate to include future growth in programs and general pharmaceutical inflation.

Rates of increase could well be higher than that if pharmaceutical inflation and rates of

uninsured patients do not moderate. Thus, potential costs from HB 359 could well be higher than those included here

Estimating Lost Discounts for Other State Agencies

The Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS) also accesses savings through purchasing under the MMCAP program. While HB 359 does not clearly mandate any changes to current DMHMRSAS practices about distribution of discount pharmaceuticals, if VDH is found in violation of program requirements in this regard, the discount for DMHMRSAS may also be jeopardized. The amount of loss is not estimated here, however, because data on the amount of drugs purchased under the MMCAP program is not readily available.

However, DMHMRSAS reports that its FY 2004 Aftercare Pharmacy budget is $20.7 million. There is no data readily available to determine what proportion of that spending is made under the MMCAP program. The Aftercare Pharmacy is currently not eligible for Section 340B discounted prices.

To the degree that the Department of Corrections and/or other state agencies participate in similar drug discount purchasing, any "own-use" ruling might affect their cost savings, as well. Again, such costs are not reflected in Item 6, above.

9. Specific agency or political subdivisions affected:

- Virginia Department of Health (VDH)
- Localities that operate state-locally funded health department pharmacies and share in the current savings (Alexandria, Chesterfield, Petersburg, Fairfax, Hampton, Lynchburg, Newport News, Norfolk, and Roanoke)
- Virginia Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS)
- Virginia Department of General Services (DGS), which manages the discount purchasing contracts
- Virginia Department of Corrections (DOC)

10. Technical amendment necessary: Yes

If the bill were amended to give the Commissioner of Health discretion in attempting to identify viable options that achieve the bill's purpose within the limitations of the eligibility requirements of the discount programs and prior court rulings regarding "own use," then the risk to the Commonwealth's current savings and current services may be reduced.

11. Other comments: None

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c: Secretary of Health and Human Resources