Office of Budget and Management

John R. Kasich
Governor

Timothy S. Keen
Director

October 10, 2017

The Honorable Jon Husted
Ohio Secretary of State
180 East Broad St., 16th Floor
Columbus, Ohio 43215

Dear Secretary Husted,

Pursuant to Ohio Revised Code Section 3519.04, this letter contains the Office of Budget and Management's (OBM) fiscal analysis of the proposed addition to the Ohio Revised Code, State Issue 2, which would prohibit the State of Ohio from purchasing a prescription drug unless the net cost is equal to or less than the lowest price paid by the United States Department of Veterans Affairs (VA). This issue will appear before voters during the general election to be held on November 7, 2017.

Section 3519.04 specifically requires OBM to estimate the annual expenditure of public funds associated with an initiated statute or constitutional amendment. For reasons explained in detail in the attached analysis, OBM does not believe it is possible to estimate the change in public funds expenditures that would result from Issue 2 within an acceptable degree of accuracy and, thus, does not produce a specific net savings estimate. The fiscal analysis takes the approach of identifying and analyzing in detail those specific factors that must be considered to understand the potential fiscal and related impacts of Issue 2.

I trust that this letter and the attached analysis fulfills the statutory requirements of Ohio Revised Code Section 3519.04. Please contact me if you have any questions about the content of either.

Sincerely,

Timothy S. Keen
Director

Attachment

State Issue 2

Description of Proposal

Drug Price Limitation: Issue 2, an initiated statute referred to as the Drug Price Relief Act, would prohibit state entities from purchasing a prescription drug unless the net cost after all rebates and other discounts is equal to or less than the lowest price paid by the United States Department of Veterans Affairs (VA) for the same drug. This restriction would apply whether the state directly or indirectly pays for the drug.[1]

Court Challenge: Issue 2 also specifies that if the act is challenged in court following voter approval, the proponents' committee responsible for circulating the ballot petition may be a party to the case, and the state shall pay its reasonable attorney fees and expenses. After exhausting appeals, if any part of Issue 2 is ruled unenforceable due to a conflict with statutory or constitutional law, the proponents are liable to the state for a civil fine of $10,000.[2]

Effective Date: Issue 2 specifies an implementation date of July 1, 2017.[3] Pursuant to Article II, Section 1b of the Ohio Constitution, initiated statutes have a default effective date of 30 days after voter approval. Since the specified implementation date in Issue 2 has passed, this analysis assumes that, if successful, Issue 2 would become effective 30 days after passage (December 7, 2017).

Analytical Approach and Report Presentation

In theory, the fiscal impact of Issue 2's imposition of a price limitation on state drug purchases could be a straightforward analysis that would compare the price of each drug purchased by the state to the price at which the VA could purchase that drug, calculate the difference in cases where the VA price is lower, and multiply that price differential by the volume of state purchases to estimate potential savings. However, the exercise in practice is not straightforward, but complex and compromised by a lack of critical information and subject to dynamic and unpredictable supply- and demand-driven pricing impacts that would be brought about by Issue 2. For these reasons, which are explained in further detail in this report, OBM does not believe that it is possible to estimate potential state expenditures and savings for Issue 2 with an acceptable degree of accuracy and, thus, does not produce a specific net savings estimate as part of this report. Instead, this report identifies and discusses the specific factors that must be considered to understand the potential fiscal and related impacts of Issue 2. To that end, this report: i) provides an overview of the VA's prescription drug program and pricing; ii) identifies state entities affected by Issue 2, the populations served by those state programs, and their annual spending on prescription drugs; iii) discusses the implementation obstacles and market

[1] See division (D) of proposed R.C. §194.01.
[2] See division (G) of proposed R.C. §194.01.
[3] See division (D)(3) of proposed R.C. §194.01.

forces that preclude estimating net state savings within an acceptable degree of accuracy; and iv) summarizes fiscal impact considerations.

U.S. Department of Veterans Affairs—Prescription Drug Program

VA Drug Prices: The VA negotiates a schedule of drug prices available to federal agencies that is part of the Federal Supply Schedule (FSS) of goods and services purchased by the federal government. These prices must be based on the lowest price drug manufacturers charge their private sector customers under comparable terms and conditions. The FSS is published and publicly available.[4]

In addition, there is a federal ceiling price (FCP) that applies to the VA, Department of Defense, Public Health Service, and the Coast Guard (known as the "Big 4" based on the volume of drugs they purchase).[5] This annual calculation for each brand-name drug starts at 76% of the average price wholesalers and direct purchasers (excluding the federal government) pay to drug manufacturers for each specific drug, after all discounting. This ceiling is adjusted to add additional discounting if the average price increases more than inflation. If this calculated price for a drug is lower than the FSS, then the VA pays this price instead of the FSS price. The FSS includes these FCP prices available to the Big 4.

The VA also competitively bids national contracts with drug manufacturers for some equivalent drugs within certain drug classes to get a lower price than the FSS or FCP in exchange for committing to purchase a large volume and using the selected drugs throughout the VA system. These contract prices are also publicly available.[6] Finally, as a large drug purchaser serving millions of veterans across the country, the VA also negotiates supplemental discounts from drug manufacturers, but those supplemental discounts are confidential and, as a result, the final price paid by the VA for those prescription drugs is not publicly available.

While these limits focus on brand-name drugs, more than 80% of VA prescriptions are filled with generics.[7] They do not generally have discounted prices available only to the Big 4, but they do have favorable pricing on the FSS. While most VA prescriptions are generic though, three-quarters of VA prescription drug spending is for brand-name medications because of their significantly higher prices. VA drug spending is now approximately $7 billion per year.[8]

VA Program: The VA provides medical services to honorably discharged veterans through a priority enrollment system based on criteria such as minimum length of service, disability, service

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[4] U.S. Department of Veterans Affairs Office of Acquisition and Logistics, *Pharmaceutical Prices*. https://www.va.gov/oal/business/fss/pharmprices.asp

[5] Congressional Research Service, *Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies*. (Washington, D.C.: January 19, 2007).

[6] https://www.va.gov/oal/business/fss/pharmprices.asp

[7] Government Accountability Office, *Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices*, GAO-13-358 (Washington, D.C.: April 2013).

[8] Department of Veterans Affairs, *FY 2018 Funding and FY 2019 Advance Appropriations, Volume II Medical Programs and Information Technology Programs, Congressional Submission*.

in specified military operations, and income. Almost five million veterans used the VA pharmacy system in 2016. Significant VA drug purchases include those to combat cardiovascular disease, hepatitis C, diabetes, as well as central nervous system drugs and chemotherapy drugs to fight cancer.[9]

Unlike most state programs, the VA has its own in-house pharmacy system, including a large mail-order pharmacy, so it purchases drugs directly from manufacturers instead of through pharmacy benefits managers (PBMs) or insurers. It is important to note that the VA's cost of filling and dispensing drugs through the VA system is separate from the price it pays for drugs. This is not true, however, for most state programs, which fill and distribute drugs to their recipients through retail pharmacies that recoup those costs in the amounts charged to the state and individuals for the prescriptions.

Affected State Entities and Programs

Included and Excluded State Entities: Issue 2 applies its prescription drug purchasing limitation to the State of Ohio, state departments, agencies, and other state entities.[10] There are different definitions in statute for these terms, and Issue 2 does not specify which definitions apply. As a result, when determining what entities would be subject to Issue 2, this analysis included entities that perform or administer state programs or fulfill what has traditionally been considered a state function.[11] This predominantly includes state agencies, state community colleges, and universities, to which appropriations are made in the biennial operating budget. Based on this approach, this analysis excludes the following entities from the definition of state entities, as detailed below:

- Among the higher education institutions, the eight technical colleges[12] and six local community colleges[13] fulfill more of a local than state function as they have the authority to levy local property taxes[14] to raise their own revenues, most are governed by boards that consist of a majority of local rather than gubernatorial appointees,[15] and they are not

[9] U.S. Department of Health and Human Services, *Prescription Drugs: Innovation, Spending, and Patient Access*. (Washington, D.C.: December 7, 2016).

[10] See division (D)(1) of proposed R.C. §194.01.

[11] Ultimately, decisions with respect to applicable state entitles would likely be addressed in further implementing legislation passed by the General Assembly or resolved via legal challenges.

[12] Organized under R.C. Chapter 3357.

[13] Organized under R.C. Chapter 3354.

[14] See R.C. §§3354.12 and 3357.11 authorizing the board of trustees of these institutions of higher education to approve by resolution a levy for certain expenses to be placed on the ballot and voted on by local electors. All local community colleges have exercised this authority but currently, no technical college does. However, this option is not afforded to other types of higher education institutions. In order for a state community college to issue a levy, the institution would be required to become a local community college pursuant to R.C. §3358.02.

[15] Eastern Gateway Community College was formerly Jefferson County Community College. The district has since been expanded to four counties, with Jefferson County continuing its local levy for the sole benefit of residents of Jefferson County for educational activities occurring in Jefferson County. All trustees are appointed by the Governor

included in the state's reporting entity[16] for purposes of financial reporting and, as a result, this analysis excludes them. This analysis assumes Issue 2 applies to the nine state community colleges[17] and all state universities.

- Ohio has four multi-employer public retirement systems for teachers, school employees, local government police and fire personnel, and all other public sector employees not in the highway patrol; the Highway Patrol Retirement System; and the City of Cincinnati retirement system for its non-public safety employees. The retirement systems do not administer programs for the state but rather serve individuals who worked at the state and local government levels. All public employers, including the state, pay their required employer contributions to the respective retirement systems for their employees, but employers have no role in the retirement systems' operations. As a result, they are not considered to serve a state function, and this analysis assumes Issue 2 does not apply to them.
- Local governments including local school districts are not state entities in law and, thus, would not be subject to Issue 2.

Excluded Drug Programs of Otherwise Included Entities: This analysis includes all state agencies that purchase prescription drugs and all higher education institutions outside of the local community and technical colleges that were excluded for reasons described above.

Some state agencies, however, have drug programs where the agency does not directly or indirectly purchase prescription drugs. This analysis assumes Issue 2 does not apply to these programs, which include the following:

- The Bureau of Workers' Compensation (BWC) operates a self-insured program for some employers where the employers set aside funds to pay their claims. All claims costs, including prescription drugs, are paid from these employer funds and not BWC funds. (BWC's primary program, which the agency operates with state insurance fund premiums paid by participating employers, is included in this analysis.)
- The Department of Health (ODH) sponsors two programs that involve drug purchases, but the department exercises no decision making in these purchases. As a result, this analysis excludes them. For childhood vaccines and immunizations, ODH administers a federal allocation as a virtual inventory through which local entities may request vaccine, which is then distributed through the federal government or a third party. ODH does not fund the procurement or the distribution of the vaccine. For reproductive health, ODH gives grants to local organizations, which decide without any ODH involvement what to buy with these funds, including drugs.

(see R.C. § 3354.24). Sinclair Community College also consists of more than one county, but it is governed by local appointees, with only one county currently authorizing a levy (see R.C. §3354.25).

[16] See Ohio Comprehensive Financial Report for fiscal year 2016 here: http://obm.ohio.gov/StateAccounting/financialreporting/doc/cafr/2016/cafr_2016.pdf. Local community and technical colleges are considered "joint ventures" for purposes of the state financial statements.

[17] Organized under R.C. Chapter 3358.

- The Department of Rehabilitation and Correction (DRC) and the Department of Youth Services (DYS) pay for the operation of certain community facilities that are managed locally, not by the agencies. Thus, local entities make decisions with respect to the procurement of prescription drugs.
- The Department of Aging (ODA) sponsors the Best Rx program,[18] which contracts with a PBM to provide discounted drug prices for Golden Buckeye recipients as well as low-income Ohioans. Although Issue 2 specifically includes this program, individuals who use the program card to get pharmacy discounts on prescription drugs pay the entire cost. ODA does not purchase the drugs, pay a share, or pay PBM contract costs. The PBM is compensated from the prices participants pay to pharmacies for their prescriptions. Thus, the individual purchaser, not the state, bears the drug purchasing costs under this program.
- Universities and state community colleges purchase prescription drugs for their employees through insurer or PBM relationships. However, universities are not uniform in the way they acquire prescription drugs for their student health centers. Some purchase the drugs that are prescribed to students. Others do not, and instead contract out pharmacy services or provide access to student health plans fully paid for by students. We took these differences in our university sample into account when estimating prescription drug costs for university student health centers. In addition, community colleges do not offer student health plans or have student health centers.

[18] Division (D)(2) of proposed R.C. §194.04 specifically requires that the "drug price ceiling" set out in Issue 2 apply to the "Ohio Best Rx Program." However, the drug price ceiling is only applicable to the state, state departments, agencies, and entities. The Best Rx Program does not involve state purchasing and thus, this analysis cannot determine how the drug price ceiling would be applied to that program.

State Drug Spending

The state entities and programs included in this analysis spend approximately $2.8 billion per year for prescription drugs after all rebates and post-purchase adjustments.

Annual Prescription Drug Spending by the State, Fiscal Year 2016 or Later
All Funds (In Millions)

State Entity/Program	Gross Cost[a]	Federal Rebates	Supplemental Rebates	Net Cost
Medicaid[b]	$ 3,726	$ 1,635	$ 8	$ 2,083
OSU medical center	$ 285	$ -	$ 5	$ 280
Higher education institutions[c]	$ 181	$ -	$ 24	$ 157
State employee health benefits	$ 154	$ -	$ 8	$ 146
Workers' compensation	$ 83	$ -	$ 4	$ 79
Institutional facilities[d]	$ 49	$ -	$ 3	$ 46
Department of Health programs[e]	$ 17	$ -	$ -	$ 17
Total	**$ 4,495**	**$ 1,635**	**$ 52**	**$ 2,808**

a After upfront discounts, pricing agreement reductions, or other contractually negotiated terms.

[a] Excludes supplemental rebates retained by managed care organizations.

[b] Estimates based on a sample of universities and state community colleges.

[c] Includes the Departments of Mental Health and Addiction Services, Rehabilitation and Correction, Youth Services, Veterans Services, and Developmental Disabilities.

[d] Excludes Department of Health drug purchases through the Department of Mental Health and Addiction Services, which is represented in institutional facilities spending.

Medicaid

The Medicaid program administered by the Department of Medicaid (ODM) is the largest program to which Issue 2 would apply, serving more than three million Ohioans annually. Medicaid's beneficiaries represent a vast demographic, including low-income individuals, pregnant women, infants, children, older adults, and individuals with disabilities, all with unique medical needs. Commonly prescribed drugs treat narcotics addiction, diabetes, asthma, cardiopulmonary disease, and attention deficit disorder.

Medicaid reimburses retail pharmacies for drugs dispensed to its beneficiaries through both its fee-for-service (FFS) and managed care programs. To ensure that Medicaid receives a net price that is consistent with the lowest or best price for which manufacturers sold the drug, federal law requires drug manufacturers to pay rebates to state Medicaid agencies that participate in the Medicaid Drug Rebate Program. In exchange, state programs must generally cover a participating manufacturer's drugs, except for those excluded by federal law. The Affordable Care Act (ACA) increased the minimum rebate for brand-name drugs from 15.1% to 23.1% of an average price

paid to manufacturers, and from a flat 11% to 13% for generic drugs.[19] However, the ACA requires that state Medicaid agencies remit the amount (both federal and state share) attributable to this ACA rebate increase to the federal government.[20] The remaining federal rebates are subject to the federal medical assistance percentage (FMAP) and ODM retains the state share.

Additionally, both Medicaid FFS and managed care programs can negotiate supplemental rebates to further decrease drug costs. While the managed care organizations retain their supplemental rebates, the state benefits through lower per member per month (PMPM) rates that reflect these rebates. The state also receives its share of the FFS supplemental rebates, as determined by the FMAP rate. Nationwide, all state Medicaid programs participate in the federal rebate program and 46 states and the District of Columbia participate in supplemental rebate arrangements.

After the offset and the rebates have been accounted for, ODM then receives matching funds from the federal government for its net price paid to the pharmacy. In calendar year 2016, ODM spent $3.7 billion on drugs before receiving $1.6 billion in total rebates for Medicaid drug purchases. The federal government provided reimbursement for the remaining $2.1 billion at a blended FMAP rate of approximately 77%.

State Employee Health Benefits

The state provides health benefits to most of its employees and their dependents, totaling 115,000 covered lives, and pays a majority of the cost through biweekly state and employee contributions. For this population, the most commonly used drugs treat high cholesterol, high blood pressure, thyroid issues, acid reflux, and infections. The Department of Administrative Services (DAS) manages the state employee health benefits program and has a separate PBM contract for prescription drug coverage. After upfront price reductions, DAS spent $154 million on prescription drugs in fiscal year 2017. Rebates received back from the PBM exceed $8 million annually for a total net cost of $146 million.

Bureau of Workers' Compensation

The Bureau of Workers' Compensation (BWC) pays medical and prescription drug costs for approximately 40,000 injured workers annually. The most commonly prescribed drugs treat pain issues. BWC contracts with a PBM to administer its prescription drug claims through the PBM's pharmacy network. The agency also has a separate contract for its share of rebates negotiated with manufacturers by the contractor for specific drugs. After upfront price reductions, BWC paid $83 million in prescription drug costs in calendar year 2016. Rebates received afterwards totaled about $4 million for a total net cost of $79 million.

[19] Patient Protection and Affordable Care Act (ACA), §2501(a), (b), (d)
[20] Patient Protection and Affordable Care Act (ACA), §2501(a)(2)

Institutional Facilities

The Department of Mental Health and Addiction Services (MHA) operates the Ohio Pharmacy Service Center (OPSC), which purchases drugs for approximately 100,000 Ohioans in institutional settings in state facilities, plus purchases for individuals served by other state programs. This chiefly covers patients in MHA's six hospitals, prisoners in DRC facilities, and wards of the state in DYS facilities. Some common purchases include antipsychotics, methadone and other pharmaceuticals used to treat drug dependence, hepatitis C drugs, asthma inhalers, and insulin. Unlike most state agencies, MHA OPSC has a direct contract with a drug wholesaler because it has its own in-house pharmacy operations to package and distribute the drugs as needed.

Separately, the Department of Veterans Services (DVS) serves more than 700 veterans who reside at its homes in Georgetown and Sandusky. The most common drugs the agency buys treat diabetes, congestive heart failure, high blood pressure, and psychiatric issues from post-traumatic stress disorder. Because it serves veterans, DVS has access to FSS prices, directly purchasing drugs through a wholesaler. The agency has an in-house pharmacy at its Sandusky facility but not at Georgetown, where DVS contracts with a nearby pharmacy for drug storage and delivery.

The Department of Developmental Disabilities (DDD) serves more than 650 individuals who reside in its eight developmental centers across Ohio. The most common drugs the agency buys are central nervous system drugs that treat mental illnesses and psychiatric disorders, as well as anti-epileptic drugs. DDD contracts with two PBMs to fill and deliver prescriptions for the residents. After billing Medicare and private insurance for residents with those resources, agency spending on prescription drugs is small. In addition, the majority of its prescription drug expenses is later reimbursed by federal Medicaid dollars.

Collectively, the MHA OPSC, DVS, and DDD annually spend about $49 million on prescription drugs. For fiscal year 2017, discounts off drug prices and rebates totaled $3 million for a total net cost of approximately $46 million.

Department of Health

The Department of Health (ODH) operates or sponsors several programs that require the acquisition and distribution of drugs.

- Children with medical handicaps (CMH): ODH primarily serves children under the age of 21 that have an eligible medical handicap and whose family satisfies income eligibility criteria as a payer of last resort. ODH reimburses participating CMH pharmacies for eligible claims, which are validated by a contracted PBM. CMH pharmacy reimbursements are determined per a fee schedule developed by ODM that best estimates the actual acquisition cost (AAC) of a drug, or the amount a provider would pay to purchase the drug. ODM estimates the AAC based on a combination of national surveys of retail pharmacy providers, states' surveys of retail pharmacy providers, and published compendia prices.[21]

[21]Defined under Section 5160-9-05 of the Ohio Administrative Code.

It is important to note that this amount does not include Medicaid rebates and therefore does not reflect the Medicaid program pricing. For fiscal year 2017, annual costs of pharmacy reimbursement totaled $9.1 million for approximately 43,000 covered lives.

- Ohio HIV drug assistance program (OHDAP): The Ryan White Part B-funded OHDAP program provides access to medications for HIV-positive Ohioans with incomes up to 300% of the federal poverty level. ODH purchases the drugs in bulk through the federal 340B price schedule and distributes them to program participants through a mail order pharmacy to ensure confidentiality and easy access to the service.

  As part of the federal Medicaid drug rebate agreement, participating drug manufacturers are required to offer substantial discounts to covered entities such as AIDS Drug Assistance Programs (ADAP) under Section 340B of the Public Health Service Act. This price schedule creates a ceiling on the maximum price that manufacturers can charge for a drug, calculated by subtracting Medicaid federal unit rebate amount from the average manufacturer's selling price. Furthermore, OHDAP may negotiate additional discounts and rebates as an eligible ADAP.[22] Currently, ODH spends approximately $8.2 million per year to acquire the drugs to serve approximately 6,000 program participants.

- Drug overdose and emergency preparedness: ODH purchases naloxone from MHA OPSC for distribution primarily to local health departments that partner with community-based overdose education and naloxone distribution programs. Naloxone reverses the effects of an opiate overdose. Since Naloxone is originally purchased by MHA OPSC, this analysis does not count it again here.

As described above, this analysis considers the CMH and the HIV drug assistance programs to be the two areas impacted by Issue 2 within ODH. Within these programs, drug expenditures total approximately $17.3 million dollars annually.

OSU Medical Center

The OSU medical center is the only state public hospital in Ohio,[23] and this analysis assumes it would be subject to Issue 2 given its higher education setting. The medical center has inpatient, outpatient, and retail pharmacy operations that provide a wide range of health care services from childbirth to treatment for cancer and rare diseases. The medical center acquires most of its prescription drugs through a national purchasing consortium of other such centers and hospitals that contract with a drug wholesaler. A small portion of drugs purchased by the medical center to treat rare diseases are purchased directly from a drug manufacturer. In fiscal year 2017, after upfront price reductions, the medical center spent approximately $285 million for prescription

[22] National Alliance of State and Territorial AIDS Directors, *Ryan White Part B and AIDS Drug Assistance Program (ADAP) Technical Assistance and Frequently Asked Questions (FAQ).* (Washington, D.C.: March 2016).
[23] Ohio Department of Health.

drugs and received about $5 million in rebates, for a total net cost of $280 million. The cancer program alone represents more than 60% of this spending.

Higher Education

Public universities and state community colleges provide health insurance to their employees and their dependents as the state does. In addition, some of the universities OBM contacted acquire prescription drugs for their student health centers. (As discussed above, others have PBM contracts and no university spending to acquire drugs for their student health plans or student health centers. In addition, state community colleges do not provide student health services.) Extrapolating to all the higher education institutions included in this analysis, after upfront price reductions, spending on prescription drugs is estimated to be $181 million per year, predominantly for employees and their dependents. Estimated rebates total $24 million for a net estimated cost of $157 million for current drug purchases.

Implementation Considerations and Estimation Challenges

In order to assess the fiscal impact or net state savings from the implementation of Issue 2, one must compare drug prices and spending for state programs against VA drug prices and spending to determine the cost differential. However, there are many unknown issues that would impact such a calculation, including limited available drug pricing information, differences between the VA population and those served by the state, differences in the organization and administration of the VA program and state programs, and potential market reactions to state price limitations.

Final VA Pricing Is Not Always Known: As discussed above, the final VA price for drugs after all discounting is not always publicly available. This is because supplemental drug discounts negotiated by the VA are considered confidential per the terms of the agreements with drug manufacturers.[24] If voters were to approve Issue 2, it is not known to what extent the VA is willing or able to regularly provide this information or whether there is a mechanism for the State of Ohio to force the VA to disclose what it pays for drugs. Timely and complete access to this key information is critical to Ohio's ability to comply with Issue 2's price limit on a drug-by-drug basis.

Attempting to adhere as closely as possible to the intent of Issue 2 could require using only VA drug price data that is available or estimating VA savings beyond available data. Either approach could result in assuming higher drug prices than the VA actually pays, which would limit savings from Issue 2. In addition, it is not possible to predict whether such an effort to implement Issue 2 with available cost data, which in some cases does not reflect the lowest VA price, would be challenged in court.

State Serves a Different Clientele, Needs Different Mix of Drugs Than the VA: The state's many programs that provide prescription drugs serve a wider variety of populations than the VA—most notably an average of 1.3 million children (41.6%) and 1.1 million women (34.6%) covered

[24] Health Policy Brief: Veterans Health Administration," *Health Affairs*, August 10, 2017. DOI: 10.1377/hpb2017.9.

by Medicaid out of a total average enrollment of 3.1 million individuals in fiscal year 2017. In contrast, according to the 2015 survey of enrollees in the VA health care system, women comprise just 8% of the population. Additionally, 80% of enrollees are age 45 or older.[25]

The population differences between state programs and the VA mean that the mix of drugs purchased by the state can be quite different than what the VA purchases, as indicated by the common drug purchase examples noted above in the VA and state program descriptions. This weighting based on the drugs that are purchased would impact any state expenditures and savings from Issue 2, along with the price difference between the state and the VA for each drug. As a result, it is difficult to estimate potential Issue 2 net savings across total drug spending by state programs.

VA Drug Prices Do Not Include Pharmacy Costs: The VA has its own in-house pharmacy operations and therefore does not contract with a PBM or insurer for access to pharmacies to fill and distribute its prescriptions. This is not the case for most state programs. As a result, most state programs pay a dispensing fee that adds to the cost of prescription drugs, in addition to whatever portion of the drug price itself retail pharmacies retain to cover their costs. In OBM's review, agencies were often able to separate the dispensing fee from actual drug expenses because it is a separate fee component in PBM contracts. But to the extent the cost of a drug to a state program also includes pharmacy costs, Issue 2 ignores this key operational difference in its comparison to VA drug prices. In such cases, any calculation of state savings based solely on VA pricing would overstate potential savings.

Drug Manufacturer Responses to Issue 2: It is not realistic to assume that static estimates of Issue 2 savings would actually be realized because drug manufacturers are likely to respond in various ways that would limit the savings the state could realize if Issue 2 should become law.

The VA drug purchasing program as it exists today is the result of a reaction by drug manufacturers to a discount program that predated the VA program. Specifically, in 1990 the Medicaid Prescription Drug Rebate Program was enacted into law as part of the five-year Omnibus Budget Reconciliation Act (OBRA 1990). The Medicaid rebate provisions of OBRA 1990 granted the Medicaid program "most favored customer" status, requiring drug manufacturers to sell their drugs to Medicaid at the "best price" available to any other purchaser.[26] In return for accepting the pricing provisions, drug companies were assured that their products would be covered under each state's Medicaid prescription drug program.

Drug manufacturers were not passive in the face of this new federal "best price" requirement. Once the Medicaid rebate law took effect, some manufacturers canceled discounts to other

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[25]Joseph Gasper et al., *2015 Survey of Veteran Enrollees' Health and Use of Health Care.* (Rockville, MD: Westat, December 2015).
https://www.va.gov/HEALTHPOLICYPLANNING/SoE2015/2015_VHA_SoE_Full_Findings_Report.pdf

[26] For a discussion of the main features of Medicaid "best price" impacts, including exemptions, see "Health Policy Brief: Medicaid Best Price," *Health Affairs*, August 10, 2017. DOI: 10.1377/hpb2017.8.

purchasers (including the VA) to avoid setting a best price that would also have to be offered to Medicaid.[27]

Congress then responded to the manufacturers' cancellation of discounts by passing another law that would apply to the VA. The 1992 Veterans Health Care Act granted the VA minimum discounts on drugs. Specifically, the 1992 law set a ceiling on prices that manufacturers can charge the VA and the other three members of the Big 4, as discussed earlier.

Thus, the idea that drug manufacturers might react to legislative restrictions on prices by changing what they charge other purchasers is not theoretical; it has been observed in the past. In fact, it was just such a reaction that gave rise to the federal law that requires VA drug discounts today.

As stated earlier in this analysis, slightly less than five million veterans used the VA pharmacy system in 2016. If Issue 2 required manufacturers to offer lower prices than currently charged to Ohio Medicaid, then the VA drug price population would expand by three million, or 60% of the current five million receiving VA pricing. Thus, the Ohio market is large enough to cause drug manufacturers that are selling drugs in national markets to react. Even without Medicaid, the population affected by Issue 2 is at least 300,000, not counting higher education and OSU medical center clients. This would seem to be a large enough expansion in the VA discount population for manufacturers to notice and respond to recoup any losses where possible. In addition, if Issue 2 passes, other states might approve similar laws, making manufacturers more likely to respond to Issue 2.

There are several possibilities for how drug manufacturers might respond to Issue 2 if it passes; these are not mutually exclusive. This analysis does not attempt to identify an exhaustive list of potential market responses, but instead focuses on three types of responses that could offset savings that the state might realize and/or adversely affect those who receive prescription drugs through state programs or private insurance.

- Manufacturers could offer the lowest VA prices to the state for those drugs purchased by both the VA and the state, but raise prices to the state for those drugs not purchased by the VA and new drugs as they come out. As noted earlier in this analysis, the populations served by the VA are quite different—specifically older and more male—than those served by state prescription drug programs, and the maladies for which the drugs are prescribed are also very different. The state could end up saving costs on VA-purchased drugs but paying more for everything else.

- Manufacturers could refuse to offer the lowest VA prices to the state on some or all drug purchases. Issue 2 places a legal requirement on state purchasers, but no requirement on manufacturers. If manufacturers refuse to offer the lowest VA prices, then the state would have to decide how to respond. State purchasers might have to change which drugs they purchase. For example, they could change to buying a mix of drugs that includes those drugs that the VA does not purchase and drugs that manufacturers are willing to sell (if any) at the lowest VA price. They could also reduce the number of different drugs

[27] See the discussion of Medicaid best price and VA discount history in "Health Policy Brief: Veterans Health Administration," *Health Affairs*, August 10, 2017. DOI: 10.1377/hpb2017.9.

they purchase for their formularies—particularly of the same type or for treating the same condition—in order to increase the volume of the remaining drugs they do buy so that they can get lower prices for them.

With regard to Medicaid specifically, Issue 2 could set up a conflict between state and federal law. State Medicaid agencies are generally required by federal Medicaid law to offer Food and Drug Administration (FDA)-approved prescription drugs to Medicaid beneficiaries.[28] If ODM could not obtain the lowest VA price for an FDA-approved drug, Issue 2 would require ODM not to purchase that drug. However, not purchasing that drug would likely violate federal Medicaid law and could result in the federal government not paying the federal share of Ohio Medicaid pharmacy expenditures. Since Ohio Medicaid drug spending after rebates is $2.1 billion, this would put at risk approximately $1.6 billion in federal reimbursement. ODM might be forced as a result to disregard Issue 2's requirements in order to comply with federal Medicaid law.

- Manufacturers could increase VA drug prices. While federal law puts a ceiling on VA drug prices, such that prices cannot exceed the lower of the FSS price or the FCP, as mentioned earlier in this analysis, the VA sometimes negotiates lower prices than either the FSS price or the FCP. Manufacturers could refuse to offer these additional discounts on new contracts because they do not want these lower prices to serve as a benchmark price for hundreds of thousands or millions of additional clients. In fact, manufacturers could also raise the FSS and FCP prices themselves by charging more to private sector purchasers, since those federal prices are based on the lowest prices charged to private sector customers or the amount paid by wholesalers to manufacturers for non-federal purchases, respectively. A United States General Accounting Office (GAO) report published in 2000 concluded that offering VA prices to the much larger Medicare population would likely result in manufacturers raising private sector and then federal prices wherever possible in order to avoid having to give current VA discounted prices to Medicare recipients.[29]

In response to such manufacturer reactions, state entities may also restructure programs to comply with Issue 2—by expanding group drug purchases or changing from pharmacy fulfillment to direct drug purchases and internal dispensing, for example. Such measures would require significant program delivery and administrative changes. It is also possible that some programs would have to be curtailed or could not continue if they were unable to get VA prices for some or all of their drugs.

Indirect Local Government Impacts Possible: This analysis is geared, as required by law, to examine the impact of the proposed law on expenditures of public money in Ohio, and so increases in prices and spending for the federal government and private sector entities is not directly relevant. Because Issue 2 is specific to state expenditures, this analysis does not directly

[28] 42 U.S.C. § 1396r-8(k)(2)

[29] U.S. General Accounting Office. "PRESCRIPTION DRUGS: Expanding Access to Federal Prices Could Cause Other Price Changes." GAO/HEHS-00-118. http://www.gao.gov/archive/2000/he00118. August 2000.

address local governments. However, indirectly, these manufacturer developments could increase required spending by local government entities in Ohio, for example by increasing prescription drug spending by local governments (including school districts) for their employees.

Fiscal Summary

Insufficient Information to Estimate Savings: In theory, estimating potential net savings from imposing a ceiling on state drug prices might seem straightforward, if tedious. One would find the VA prices for drugs that are purchased by affected state entities, compare them to the current purchase prices, calculate the difference in the cases where the VA prices are lower, and multiply those price differences by volumes purchased in order to estimate state savings. However, the exercise is in practice not straightforward, but complex and compromised by a lack of critical information and subject to dynamic and unpredictable market responses. In fact, OBM does not believe that it can calculate net state savings with an acceptable degree of accuracy. There are a number of reasons for this, as discussed at greater length above and summarized briefly below.

The first and most fundamental issue is that VA final prices are often not known. FSS, Big 4, and VA national contract prices are available on the VA website with nearly 18,000 entries. (Some of these entries are for the same drug but at different dosage levels and in different forms.) However, for the drugs the VA buys from this list, these prices are not necessarily the final prices that the VA pays. Supplemental drug discounts negotiated by the VA are considered confidential according to the terms of the agreements with the drug manufacturers.[30]

Another practical impediment to estimating state savings is that the state serves a very different clientele that requires a different mix of drugs than VA enrollees need. VA pharmacy clients are almost exclusively male and largely over 45 years old, while state programs (especially Medicaid) serve a very large population of women and children. As a result, in many cases there will be no VA equivalent purchase price for drugs that are purchased by the state. In those cases, there would be no potential savings.

Finally, there is the issue of what calculated savings might be on a static basis versus a more realistic, dynamic basis. A dynamic analysis of the potential impacts of Issue 2 would account for the fact that, even if the state were to initially benefit from some drug expenditure savings by receiving VA prices, drug manufacturers could and likely would seek to recover lost revenues. Since, as stated above, many drugs that the state purchases are not bought by the VA, manufacturers could raise prices on these non-VA drugs. The VA price ceiling would not apply so these price increases could drive up state drug spending. Also, manufacturers could take actions that would increase what the VA itself pays (which is determined in part by the best price offered

[30] The California Legislative Analyst's Office encountered the same issue when trying to estimate the impact of Proposition 61 in 2016. See "State Prescription Drug Purchases. Pricing Standards. Initiative Statute." California Legislative Analyst's Office, May 10, 2016. "The measure prohibits the state from paying more for prescription drugs than the lowest VA price. While the VA publishes prices of the prescription drugs it purchases, it is unknown to what extent these listed prices are the lowest prices the VA pays. The VA has not confirmed whether the published drug prices accurately identify the lowest prices the VA pays. It is also uncertain whether public disclosure of the lowest prices paid would be required or exempt under FOIA [Freedom of Information Act]."

to non-federal purchasers), or increase new drug prices. Thus, this also would tend to offset any static savings that the state might realize.

Ultimately, there is insufficient information to reliably estimate potential savings from Issue 2.

Nonetheless Some Conclusions Emerged: However, theoretically, if all the issues identified in this analysis were worked through to successfully implement Issue 2, it is likely there would be some state savings. While it is not possible to estimate the level of such savings, some conclusions did become apparent in the course of this analysis. These are discussed below.

Medicaid Savings Unlikely: Despite these complexities in determining and comparing lowest price paid, there is evidence from several federal studies that Medicaid net drug prices are also the closest to VA drug prices and, in fact, may be equivalent or better. Based solely on Medicaid's level of mandatory rebates (excluding supplemental rebates), GAO concluded that the Medicaid program as a whole pays a lower average net unit price than both Medicare Part D and the Department of Defense (DOD) for both generic and brand-name drugs.[31] The comparison with DOD is particularly significant because DOD is part of the group of "Big 4" federal agencies—including the VA—that receive very favorable drug pricing (see VA purchasing discussion above). It follows that the VA and DOD prices should be similar, and a 2005 Congressional Budget Office (CBO) study found that, at that time, they were extremely close. Thus, Medicaid programs across the country are paying prices for prescription drugs that may already be as low or lower on average than what the VA pays. Even in those cases where Medicaid drug prices are not equivalent or lower, if savings for select drugs common to both formularies could be achieved via negotiation on post-price adjustments, approximately 77% of the rebates would accrue to the federal government via the FMAP rate, thereby minimizing the state's savings.

HIV Drug Assistance Program Savings Unlikely: Similarly, the same 2005 CBO report found 340B drug prices in general to be at the same level as Medicaid,[32] which is logical given the 340B ceiling price calculation of subtracting Medicaid federal unit rebate amount from the average manufacturer's selling price. Furthermore, OHDAP may negotiate further discounts and rebates. Additionally, the 340B ceiling price may be less than the net Medicaid price if a state generally pays a retail pharmacy more than the average manufacturer's selling price for the ingredient cost of a drug.[33] Therefore, ODH's HIV drug assistance program which purchases drugs according to the 340B schedule would generate little, if any, savings from Issue 2 compared to other state programs.

Some Savings Plausible, But Uncertain, for Other State Programs: The other state entities and programs with prescription drug spending—OSU medical center, higher education institutions, state employee health benefits, workers' compensation, institutional facilities, and CMH—are similar to one another in the amount of discounts and rebates they receive, which is far less than Medicaid. Thus, they generally appear to pay more than the VA pays for prescription

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[31]Government Accountability Office, *Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices,* GAO-14-578. (Washington, D.C.: June 2014).

[32]Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (Washington, D.C.: June 2005).

[33]Medicaid and CHIP Payment and Access Commission, *Medicaid Payment for Outpatient Prescription Drugs* (Washington, D.C.: March 2017).

drugs. So theoretically, if suppliers agreed to provide drugs currently purchased by the state and the VA at the lower VA prices, without any manufacturer response or implementation impediments, there could be savings in the millions of dollars. However, as this analysis makes clear, those three conditions are unlikely to be met. As a result, this analysis is not able to estimate a probable savings amount within an acceptable degree of accuracy.

In addition, because they appear to pay more than the VA, these state programs may face significant program changes trying to comply with Issue 2. Additional agency administrative costs could offset any savings. This would include hiring pharmacists and auditors to ensure ongoing compliance with Issue 2. It is also possible that state programs would move from PBM arrangements to direct drug purchasing and state dispensing models in order to reduce their drug costs. Such additional administrative costs could total as much as several million dollars.

Litigation Expenses: Court costs from a challenge to Issue 2 itself or its implementation would also be a one-time offset to any savings achieved. If Issue 2 itself were challenged, the state would have its own legal representation costs to pay and those of Issue 2 proponents, pursuant to Issue 2's court challenge provision.[34] However, if some aspect of its implementation were challenged, unrelated to the provisions of Issue 2, the state may only have its own legal costs to pay. This is because Issue 2's provision directing state payment of proponents' costs would only apply when defending the provisions of Issue 2. While there could be such court challenges, it is difficult to estimate how much this could cost the state as it depends substantially on how long and involved the litigation would be.

Implementation and Timing: As noted above, Issue 2 would become effective 30 days after voter approval. However, based on constitutional and statutory contract protections and principles of statutory construction, this analysis assumes that, if successful, Issue 2 would apply prospectively and not alter, supersede, or impair state contracts that took effect prior to the effective date of Issue 2. Therefore, this analysis assumes that currently effective state contracts for programs that acquire prescriptions drugs would continue under their negotiated terms, which vary in length, but contracts taking effect after Issue 2's effective date would have to comply with Issue 2 and any subsequent implementing legislation enacted by the General Assembly. In addition, as noted immediately above, any litigation against Issue 2 or its implementation could also delay when it becomes effective.

Finally, it is clear that implementing Issue 2 would be a substantial undertaking to set up the staffing, mechanisms, and potential program changes to comply with the drug price limitation. Affected state entities and programs simply could not be ready to comply with Issue 2 in that timeframe. It would take a significantly longer period of time for agencies to prepare to implement Issue 2.

The potential for savings depends on all of these circumstances. As a result, any potential savings would not begin to be realized immediately. Nor would savings begin to be realized all at once because of the differing lengths of existing prescription drug contracts. Because of these variables in the potential timeframe of implementation, the amount of delay, and therefore the timing of net savings, is not possible to predict.

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[34] See Division (G) of proposed R.C. §194.01.