Analysis of Proposed Ohio Initiated Statute to Regulate State Prescription Drug Purchasing

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1. Introduction

The "Ohio Drug Price Relief Act" (the Proposed Statute) is a proposed initiated statute offered by the California-based AIDS Healthcare Foundation (AHF). Generally, the Proposed Statute would prohibit the state from agreeing to pay, directly or indirectly, for the purchase of a prescribed drug unless the net cost of the drug, inclusive of rebates, discounts, and other price concessions, is the same as or less than the lowest price paid for the same drug by the U.S. Department of Veterans Affairs (VA).[1]

The proposal is expected to appear on the Ohio ballot in November 2017.

If adopted, the Proposed Statute will impact roughly 4 million Ohioans, including:

- more than 3.7 million individuals currently receiving drugs and vaccines for their health care through state pharmacy programs;
- an additional 134,000 individuals who could receive affected health care services and drugs through several state pharmacy programs, though they do not currently participate in this coverage (for example, some employees of state universities and community colleges);
- approximately 41,000 individuals admitted for inpatient hospital services annually at OSU Wexner Medical Center;
- a significant number of children and other individuals who have received or could receive approximately 67,000 doses of vaccines; and
- more than 225,000 employers who rely upon the Ohio Bureau of Workers' Compensation state insurance fund program to provide essential health services to injured workers.[2]

Those impacted directly will include newborn babies and other children needing vaccines for hepatitis, diphtheria, tetanus and the flu; people with HIV/AIDS; college students; individuals with intellectual and other developmental disabilities; people receiving inpatient psychiatric hospital care or other inpatient hospital care for cancer and every other kind of medical condition; incarcerated youth and adults; state employees and their families; state retirees and their spouses; injured workers; and employees of colleges and universities. In addition, others could be impacted indirectly, including employees of some city and county governments and a variety of other Ohioans.

The authors of this report were hired by the Pharmaceutical Research and Manufacturers of America (PhRMA) to conduct an independent, objective analysis of the likely impact of the Proposed Statute on the state and the people of Ohio. This analysis was generated following reviews of existing policy, comparative analysis, and a series of interviews with Ohio state agency officials. Research was designed to determine how impacted state programs currently operate, to consider key questions and possible responses from the affected entities, and to make some conclusions about the impact of the Proposed Statute.

[1] http://www.sos.state.oh.us/sos/upload/ballotboard/2015/2015-07-21-petition.pdf
[2] See Figure 3 for details and references.

2. The Issue: Ohio Drug Price Relief Act (the Proposed Statute)

The Proposed Statute would create a new Chapter 194 in Title 1 of the Ohio Revised Code (O.R.C.). Ohio's new chapter would apply to any program or entity throughout Ohio law, as applicable. Further, as written, the Proposed Statute contains *no definitions of the key terms*, such as "drug," "state," "ultimate payer," "net cost of the drug" and other important terms. Further, the Proposed Statute specifies a liberal interpretation, meaning that we assumed the intent is to include the greatest number of drugs and to apply the Veterans Affairs (VA) lowest-price-paid benchmark as broadly as possible.

For purposes of the analysis, the report assumes the same definition of state agencies as that included in the Ohio statute defining state liability.[3] This definition of "state" includes cabinet agencies, state universities and colleges, state retirement systems, and state-owned or operated medical facilities or pharmacies that directly or indirectly purchase prescription drugs; it excludes county governments, municipalities, and other political subdivisions. Programs covering prescribed drugs paid for wholly or partially with state funds or federally funded if appropriated through a state budget act are included.

The Ohio Best Rx program and the Ohio HIV Drug Assistance Program are included because they are specifically named in the Proposed Statute, even though, in the case of the Ohio Best Rx program, the state does not pay directly or indirectly for drugs under the program.

The Proposed Statute does not specify how state pharmacy programs should handle the purchase of drugs that are not purchased by the VA. For example, some drugs are primarily used in the pediatric population and may not be purchased at all by the VA. The plain language of the proposed statute establishes the benchmark as "the lowest price ***paid***" for a drug by the VA, not the "lowest price ***available***." Thus, only drugs actually ***purchased and paid for*** by the VA establish the benchmark that impacts entities subject to the Proposed Statute. This report's interpretation is that drugs not purchased by the VA can be purchased by state entities without the consideration of the Proposed Statute. This could be a point of legal dispute that could further complicate implementation.

3. The Lowest Price Paid by the Department of Veterans Affairs (VA)

The Proposed Statute establishes a net cost benchmark that state drug programs must not exceed. This benchmark is the lowest price paid for the same drug by the U.S. Department of Veterans Affairs (VA). The Veterans Health Care Act[4] (VHCA) created a federal ceiling price (FCP) for the Big Four federal purchasers,[5] including the Veterans Administration, equal to 76% of the VHCA-defined average manufacturer price. The VA also receives additional discounts, which can further reduce its costs.

[3] O.R.C. § 2743.01 State Liability Definition. The definition of state liability provides a useful framework for this purpose as it reflects how the legislature and courts have classified various state entities, though not specifically in this context.
[4] Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943
[5] The Big Four federal agencies include the Department of Veterans Affairs, Department of Defense, the Public Health Service and the Coast Guard.

As described more fully in the report, the FCP is not, however, necessarily the lowest price paid by the VA for any particular drug. For example, the VA receives additional discounts through national contracts, prime vendor arrangements, and time-bound discounts that are offered to the VA and/or other federal agencies. Notably, the VA acquires drugs in bulk or otherwise from wholesalers and then dispenses drugs at VA-operated medical facilities or through the VA's own mail order system. In 2013, only 1% of VA drugs were dispensed using community retail pharmacies, which is dramatically different from the use of community retail pharmacies by the state programs impacted by the Proposed Statute. Finally, the VA uses a formulary of preferred drugs that reflect the needs of the veterans served, but it will also purchase drugs off-formulary when medically necessary. This is relevant because it is not always possible to determine *whether* the VA has purchased a drug. Section 4 of the report offers more detail on the VA's system of drug pricing, purchasing, and dispensing for VA beneficiaries.

4. Ohio's State Pharmacy Programs Impacted by the Proposed Statute

The state departments, agencies and other entities involved with the direct or indirect purchase of prescribed drugs employ a variety of approaches and strategies in the operation of their programs. Unlike the VA, most of these state programs do not purchase drugs and then dispense through their own medical facilities or mail order pharmacies. While the details of arrangements for each program are different, as are the state or federal statutes and regulations under which the programs operate, the report generally groups the programs reviewed into one of four basic models:

- State entity contracts with third-party insurer
- State entity contracts with pharmacy benefit manager (PBM)
- State entity contracts with wholesaler and/or manufacturer, including direct purchase of drugs
- State entity contracts for pharmacy discount card (Best Rx)

In section 5(B) of the report, these four models are addressed in detail, including which state agencies fall under what model, and descriptions are provided of the purchasing process and pharmaceutical supply chain involved with each model. These models illustrate the complexity of the purchasing arrangements impacted by the Proposed Statute and the portions of the pharmacy supply chain not included in the VA's lowest price paid.

5. Analysis of Key Questions Raised by the Proposed Statute

The report answers several important questions that must be considered in order to assess whether the Proposed Statute could achieve its stated purpose and be implemented as presented and to determine the impact to the state in the event of implementation. The conclusions presented here should not be considered as reflecting official positions or policies of any state entity, nor is this report attempting to predict what any state entity would do under the Proposed Statute.

A. Is it possible to identify the lowest price the VA pays for a drug?

No. The full set of information required to make the comparison is not publicly available. While the Federal Supply Schedule (FSS) contract prices are published within the VA's public contracts database, the publicly published prices for the Big Four federal entities are not inclusive of all discounts and may not be the lowest price paid by the VA for drugs. Section 6(A) of the report offers detail on the availability of VA drug pricing.

B. Is it possible to know what drugs the VA purchases?

No. While the VA uses a formulary that includes many products that are of importance to the VA population, the VA also routinely purchases "non-formulary" drugs on a case-specific basis when medically necessary. The actual purchasing behavior and patterns of VA might be discoverable after the fact but are not publicly available in an operationally feasible timeframe.

C. If we could identify the lowest price paid for all drugs purchased by the VA, is this a reasonable net cost target for the state drug programs?

No. The lowest price paid by the VA in acquiring drugs from wholesalers does not reflect all legitimate costs that state programs may incur in acquiring and dispensing drugs through the retail pharmacy system. In 2013 over 99% of VA covered drugs were dispensed to veterans through VA operated pharmacies (in medical facilities or by mail order); these distribution costs are *not included* in the required VA benchmark price but *are included* in the net cost incurred by most state programs. It is not an "apples to apples" comparison. Section 6(C) of the report offers detail on the differences between the costs included in the VA's lowest price paid compared to the costs included in a state entity's net cost for a drug.

D. Will manufacturers voluntarily negotiate discounts/rebates with Ohio's state entities to achieve the benchmark net cost?

It is not reasonable to assume that large numbers of manufacturers would be willing to negotiate voluntarily the significant additional discounts with Ohio state entities. Manufacturers could be reluctant to cooperate given the potential national precedent that could be set regarding state pharmacy programs. Also, extending deep discounts to state pharmacy programs could potentially limit established discount programs for the VA and other federal buyers. Further, without the additional discounts needed to achieve the benchmark, Ohio Medicaid would be unable to enter into direct rebate agreements and could lose existing supplemental rebates.

E. What additional strategies might state pharmacy programs employ to achieve compliance with the Proposed Statute?

If state entities cannot achieve the benchmark price through voluntary negotiation or discounts, then they will be forced to implement other restrictions in these programs in an attempt to reach the net cost benchmark established in the Proposed Statute.

Medicaid, with roughly three million people and about $1.5 billion in pharmacy purchases through both managed care and fee-for-service arrangement, is the largest state program targeted by the Pro-

posed Statute. The analysis indicates that the federal rebate program already provides Medicaid with a discount off average manufacturer price on par with the VA's discount. However, Medicaid might still need to obtain additional reductions because it must include its distribution expenses in "net cost," (as noted in section 3 above). The program could lower distribution expenses by limiting the number of pharmacies Medicaid beneficiaries can use or by cutting reimbursement to pharmacies. The Medicaid program may be unable to reach the benchmark net cost for some drugs after retail pharmacy costs are included. Medicaid would still be required to purchase medically necessary, covered outpatient drugs under federal regulations, but the program could lose valuable supplemental rebate agreements currently in place with manufacturers. There could also be significant administrative costs associated with achieving compliance.

Ohio's HIV Drug Assistance Program is also mentioned prominently by proponents as a program that will benefit with reduced drug costs. The analysis found that Ohio's HIV Drug Assistance Program already has achieved discounts on par with or below the VA's fee schedule price. Therefore, there appears little to be gained in terms of additional discounts from manufacturers, though again, the program could incur administrative costs associated with achieving compliance on a drug-specific basis. Potential implications for Medicaid and Ohio's HIV program are detailed in section 7 of the report.

Other state pharmacy programs, which are significantly smaller than Medicaid, would struggle to comply with the net cost benchmark, facing the need for voluntary participation by manufacturers. As discussed in section seven 7(C) of the report, these programs could be forced to adopt strategies that reduce access to prescription drugs for consumers. For example, state programs may have to use more restricted formularies, drop coverage of drugs for which the benchmark net cost is not achieved (where allowed under federal laws), restrict network pharmacy availability, lower pharmacy reimbursement rates, or raise co-payments for consumers. These responses would have a significant negative impact on consumers, increasing their costs or otherwise reducing access to necessary medications.

F. What is the potential impact on entities with pharmacy programs that are not the intended targets of the Proposed Statute?

In addition to those state entities that are intended targets of the Proposed Statute, there are other pharmacy programs that could also be impacted, specifically "non-targeted entities" including third-party payers such as private insurers. If the state must seek deep price concessions from manufacturers, wholesalers, and pharmacies, it is conceivable that manufacturers might compensate by raising prices for non-targeted entities and equally conceivable that those increases could be passed along to consumers in the form of higher co-pays.

There are also significant concerns about the potential impact that the Proposed Statute could have on future VA drug prices, e.g. increasing the cost of prescription drugs for veterans.[6] If states attempt to use the VA price concessions as a benchmark, manufacturers may be less willing to negotiate more generous discounts beyond those required by VHCA for active military, military retirees, and other veterans. In fact, an internal memo prepared by the Veteran's Administration identifies the threat of

[6] National Military and Veterans Alliance. Letter to Secretary McDonald, U.S. Department of Veterans Affairs. Dated April 26, 2016, stating "We write to express serious concerns about pending ballot measures in California and Ohio that would, we believe, increase the cost of prescription drugs for veterans, active duty military, their dependents and military retirees.

a loss to the VA in the amount of $3.8 billion dollars. The memo cites both the California ballot measure and the Ohio initiative and suggests that the passage of California ballot measure would result in the elimination of *all* non-statutorily required and *all* non-contractually required discounts, that is, $3.8 billion dollars.[7] Increased costs to an already stressed VA system would be a significant consequence and, if these increased costs are passed on to veterans who rely on the VA for pharmacy coverage, could impact veterans' access to drugs.

Finally, individuals currently relying on collaborative negotiations through the Rx Ohio Collaborative (RxOC), including some Ohio cities, counties, school districts, health consortiums, and others, could experience higher drug prices if significant numbers of state programs leave the collaborative and thereby reduce the purchasing power of the remaining programs and negatively impact access.

6. Final Conclusions

This analysis, informed by program reviews, interviews with state officials, and prior experience with state pharmacy program administration, leads us to several conclusions regarding the Proposed Statute.[8]

A. It is highly unlikely the Proposed Statute could be implemented.

First, complete information regarding what drugs the VA purchases and the lowest price the VA pays is not generally available. Second, even if all necessary information could be obtained, the VA's lowest price paid is not a reasonable net cost target for the state drug programs. Third, it is not reasonable to assume that a large number of manufacturers would be willing to voluntarily negotiate the deeper discounts/rebates needed to achieve the benchmark net cost for all impacted programs.

B. It is highly likely the Proposed Act would fail to achieve its purpose.

While state entities would incur significant administrative costs in attempting to comply, the largest state pharmacy program, Medicaid, already realizes manufacturers' discounts similar to those available to the VA system. Other programs, which might not currently enjoy similar discounts, would most likely fail to receive sufficient additional manufacturers' discounts to achieve the net cost benchmark because of the voluntary nature of manufacturer participation and the potential impact for manufacturers at a national level. As a result, state programs would be forced to adopt additional program changes that could in fact restrict access to drugs for Ohio consumers, and Medicaid could see *higher net drug costs* through loss of current supplemental rebate agreements.

C. It is highly likely that pharmacy programs of non-targeted entities would be negatively impacted.

Pharmacy programs of entities that are not the intended target of the Proposed Statute would likely be impacted as a result of potential cost-shifting across the supply chain as manufacturers, wholesalers,

[7] VHA Issue Brief, Department of Veterans Affairs, *Threat to Department of Veterans Affairs' Pharmaceutical Discounts* (http://www.noprop61.com/pdfs/VA-Memo-re-Impact-of-Prop-61-Given-to-LAO.PDF)

[8] Brief biographies for the authors are provided as an attachment to the report.

and pharmacies attempt to respond to the state seeking deeper price concessions. Increased costs to an already stressed VA system would be a significant consequence and, if these increased costs are passed on to veterans who rely on the VA for pharmacy coverage, could impact veterans' access to drugs. Finally, if state programs cannot continue their participation in collaborative purchasing, higher drug prices could be likely for those organizations currently relying on collaborative purchasing through the RxOC, including some Ohio cities, counties, school districts, health consortiums, and others.

1. INTRODUCTION

The Ohio Drug Price Relief Act ("Proposed Statute") is an initiative proposed by the California-based AIDS Healthcare Foundation (AHF). If adopted by Ohio voters, it will impact an estimated:

- more than 3.7 million individuals currently receiving drugs and vaccines for their health care through state pharmacy programs;
- an additional 134,000 individuals who could receive affected health care services and drugs through several state pharmacy programs, though they do not currently participate in this coverage (for example some employees of state universities and community colleges);
- approximately 41,000 individuals admitted for inpatient hospital services annually at OSU Wexner Medical Center;
- a significant number of children and other individuals who have received or could receive approximately 67,000 doses of vaccines; and
- more than 225,000 employers who rely upon the Ohio Bureau of Workers' Compensation state insurance fund program to provide essential health services to injured workers.[9]

In total, the Proposed Statute would directly impact more than 4 million Ohioans—specifically, newborn babies and other children needing vaccines for hepatitis, diphtheria tetanus and the flu; people with HIV/AIDS; college students; individuals with intellectual and other developmental disabilities; people receiving inpatient psychiatric hospital care or other inpatient hospital care for cancer and other medical conditions; incarcerated youth and adults; state employees and their families; state retirees and their spouses; injured workers; and employees of colleges and universities. In addition; others could be impacted indirectly, including employees of some city and county governments, and a variety of other Ohioans.

The authors of this report were hired by the Pharmaceutical Research and Manufacturers of America (PhRMA) to conduct an independent, objective analysis of the likely impact of the Proposed Statute on the state and the people of Ohio. This analysis was generated following reviews of existing policy, comparative analysis and a series of interviews with Ohio state agency officials. Research was designed to determine how impacted state programs currently operate, consider key questions and possible responses from the affected entities, and make some conclusions about the impact of the Proposed Statute.

2. THE ISSUE: OHIO DRUG PRICE RELIEF ACT

The Ohio Drug Price Relief Act is a proposed initiated statute that is expected to appear on Ohio's statewide ballot in November 2017. If approved by Ohio voters, it would become state law. The proponent of the Proposed Statute is the AIDS Healthcare Foundation (AHF), a California-based global organization that operates managed care plans, pharmacies and HIV/AIDS testing and treatment facilities, with two facilities in Ohio. The stated goal of the Proposed Statute is to reduce the prices paid by the state of Ohio for prescription medications distributed by state government agencies for beneficiaries using those programs. The Ohio Act is similar to a drug pricing initiative being pursued by AHF in California that will appear on the ballot in November 2016.

[9] See Figure 3 for details and references.

Generally, the Proposed Statute would prohibit the state from agreeing to pay, directly or indirectly, for the purchase of a prescribed drug unless the net cost of the drug, inclusive of rebates, discounts, and other price concessions, is the same as or less than the lowest price paid for the same drug by the U.S. Department of Veterans Affairs (VA). The summary provided in the petition sent to Ohio Attorney General Mike DeWine reads as follows:

> The Act would enact Section 194.01 of the Ohio Revised Code to require that notwithstanding any other provision of law and in so far as permissible under federal law, the State of Ohio shall not enter into any agreement for the purchase of prescription drugs or agree to pay, directly or indirectly, for prescription drugs, including where the state is the ultimate payer, unless the net cost is the same or less than the lowest price paid for the same drug by the VA. [10]

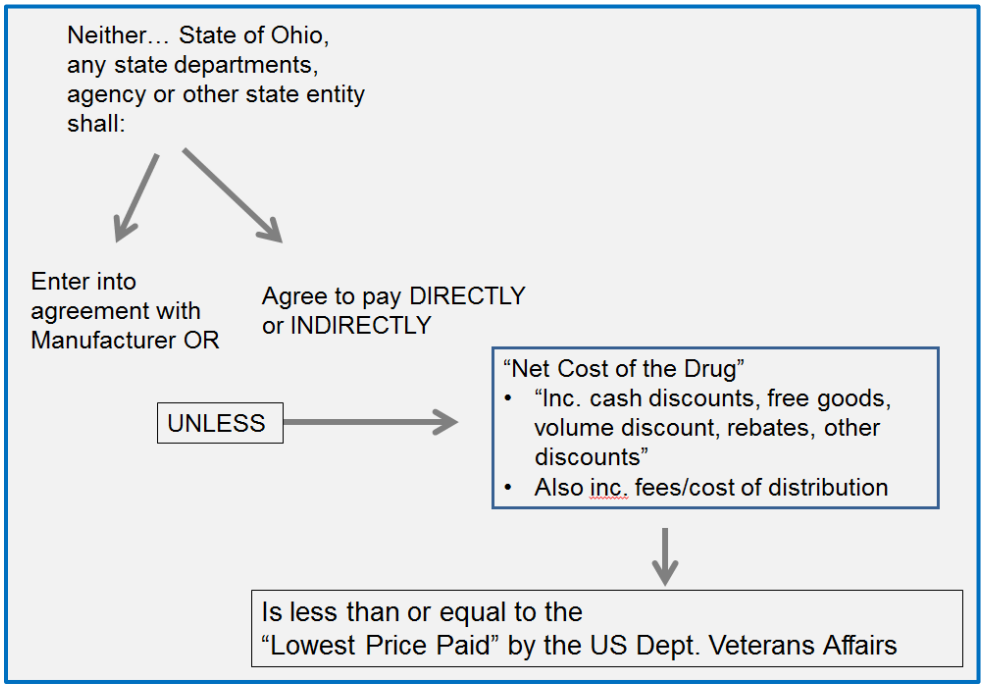
Further, the Proposed Statute states that it also applies to all programs in which the state of Ohio or any state agency or entity is the ultimate payer for the drug, even if the agency or entity did not purchase the drug directly. In this section, two state programs – the Ohio Best Rx Program and the Ohio HIV Drug Assistance Program – are specifically named. See Appendix 1 for the complete text of the Proposed Statute.

3. ANALYSIS OF PROPOSED STATUTE, ASSUMPTIONS AND METHODOLOGY

The following section summarizes the assumptions and logic used to analyze the Proposed Statute, assess its impact on the affected entities, and examine what it would take to operationalize the Proposed Statute's requirements. A fiscal analysis of the Proposed Statute's impact was not conducted, nor was one made available by the proponent. The actual language of the Proposed Statute is included in Attachment 1. A detailed outline of the language and assumptions is provided in Attachment 2. Figure 1 provides a schematic of the language.

[10] http://www.sos.state.oh.us/sos/upload/ballotboard/2015/2015-07-21-petition.pdf

Figure 1 Schematic of the Language of the Proposed Statute



The Proposed Statute would create a *new Chapter 194* in Title 1 of the Ohio Revised Code (O.R.C.) that would apply to any program or entity throughout Ohio law. Further, as written, the Proposed Statute contains *no definitions of the key terms and* no cross-references to other sections of law that might provide guidance or clarity. As is normally required, we would expect most of the affected state departments or other entities would develop rules to specify how implementation would occur. This may lead to questions of interpretation that would ultimately need to be resolved by each impacted state entity and would likely be subject to regulatory and/or legal challenges.

The Proposed Statute states that the language of the Act should be "*liberally construed* to effectuate its purpose." This mirrors a common legal principle, instructing that, if the words are not clear, the deemed or stated purpose should be taken into account. (Black's Law Dictionary). Given this, we assume that the intent is to include the greatest number drugs and to apply the Veterans Affairs (VA) lowest-price-paid benchmark as broadly as possible.

The combination of these facts requires *that our analysis take a broad but reasonable and professionally informed assessment* of the meaning.

A. Key Definitions and Interpretation of the Proposed Statute

As previously stated, the Proposed Statute does not include definitions of any key terms. For purposes of our analysis, we have made the following assumptions to guide our interpretation of the Proposed Statute.

1) There are a variety of definitions of "drug" within the Ohio Revised Code. For this analysis, we have adopted the definition of drug used by the Ohio Board of Pharmacy, O.R.C. § 4729.01. This definition includes outpatient drugs and vaccines, as well as other drugs administered in a hospi-

tal or office, and/or physician administered drugs. Further, the definition for "prescribed drug" was assumed to include both drugs for which a prescription is required by law for dispensing and drugs for which a prescription is required by a third party payer or program as a condition of reimbursement. See Attachment 2 for additional discussion.

2) "State entity" is a concept used in multiple contexts in Ohio law so there is no generally applicable statutory definition. For purposes of this analysis, we used the definition specified in O.R.C. § 2743.01,[11] which relates to the definition of state liability, to guide which entities were included or excluded from consideration. Therefore, this analysis assumed that the application of the Proposed Statute to the "state of Ohio, any state departments, agency or other state entity" includes all cabinet agencies and boards, as well as other state entities, including state universities and colleges, state retirement systems, and state-owned or operated medical facilities or pharmacies, that directly or indirectly purchase prescription drugs. Further, this analysis excludes county governments, municipalities, and other political subdivisions within the state of Ohio.[12] However, even if counties or other political subdivisions were not considered "state entities," they may be impacted by the Proposed Statute by virtue of state funding or state contracts being used to pay for prescription drugs in local programs. In these cases, the state may be paying "indirectly."

   Specifically included would be:
   a. Any health care or health insurance function covering prescribed drugs paid for in part or whole by a state entity.
   b. Programs which had an appropriation for purchase of drugs through a state budget act, even if the funds were from a federal source.
   c. Programs specifically named in the language of the Proposed Statute: The Ohio Best Rx Program and the Ohio HIV Drug Assistance Program. These programs are referenced in the text of the Proposed Statute in Section 194.01 (D)(2) as examples of programs where the state is the "ultimate payer" for prescription drugs. "Ultimate payer" is an otherwise undefined term. It is unclear what distinction is being made through the specific inclusion of these programs as "ultimate payers." This analysis found that the Ohio HIV Drug Assistance Program is a direct purchaser of drugs and should be included by virtue of the language of the Proposed Statute in Section 194.01(D)(1). In contrast, the Ohio Best Rx program operates as a discount drug card program, with no state appropriation to directly or indirectly purchase drugs and with only the state's contracted vendor having any agreements directly with manufacturers. Nevertheless, we have assumed the Ohio Best Rx program is included because it is specifically named in the Proposed Statute, even though the state does not pay directly or indirectly for prescription drugs under this program.

3) The Ohio Bureau of Workers' Compensation program consists of two components: a self-funded program and a state insurance fund program. The state insurance fund program was included in this analysis as being clearly impacted by the Proposed Statute. With regard to the self-funded program, there is no state involvement as a "direct or indirect" payer. The state does provide oversight to the self-funded program (e.g., it must approve employer participation and has regu-

[11] O.R.C. § 2743.01 State liability definition, Court of Claims Act. This definition, in the context of defining state liability, provides a useful framework to analyze how the legislature and courts have classified various state entities, though not specifically in this context.
[12] See FN 3.

lations regarding pharmacy reimbursement). While the self-funded program was not included as part of this analysis, it is an example of a program where the lack of clarity in the Proposed Statute could lead to challenges in implementation.

4) Other important terms which we relied upon to facilitate the analysis and are included, but undefined in the Proposed Statute:
    a. "Brand name drug" is another term for an innovator drug, which is a new chemical entity or formulation originally marketed under an original new drug application approved by the Food and Drug Administration (FDA).
    b. "Generic drug" is another term for a non-innovator drug, which has the same active ingredients as a brand name drug.
    c. "Drug formulary" is the list of generic and brand name drugs preferred by the health plan or health program. If a drug is not included on the formulary, most health plans will have a mechanism to request a review and approval of the drug for a specific patient, usually at a higher cost to the consumer.
    d. "Supplemental rebates" are voluntary rebates negotiated by state Medicaid programs with manufacturers that are over and above federally mandated rebates.

5) The Proposed Statute does not specify how state pharmacy programs should address drugs that the VA does not purchase in any given time period. The plain language of the proposed statute establishes the benchmark as "the lowest price ***paid***" for a drug by the VA, not the "lowest price ***available***." Thus, only drugs actually ***purchased and paid for*** by the VA establish the benchmark that impacts entities subject to the Proposed Statute. It might be argued that drugs that do not have a "lowest price paid for the same drug" by the VA cannot be made available under state programs. Another interpretation might be that state programs can purchase these drugs, but that they are subject to a net cost benchmark of whatever price might have been available to the VA. However, *this report interprets the language of the Proposed Statute as providing that drugs not purchased by the VA* ***can*** *be purchased by state entities, and the state entities are free to negotiate pricing arrangements for these drugs without the constraint of the Proposed Statute*. While this interpretation adds some flexibility for state programs in terms of the drugs they can purchase, and at what price, this interpretation could be a point of legal dispute that could further complicate implementation of the Proposed Statute.

B. Comparison of the Ohio and California Statutes

The language of the Ohio Proposed Statute is very similar to the California language. However, there are three substantive differences that are important to consider.

First, the California language[13] is placed in an existing section of the California Welfare and Institutions Code,[14] thereby incorporating some definitions of terms that already exist in California statute and making it applicable only to programs offered under that chapter or division of the law. In Ohio, the Proposed Statute would be established in a new chapter of the law, thereby applying broadly to Ohio programs and lacking cross references to existing definitions of terms.

[13] The new section 14105.32 is placed in Article 3 Administration, within Chapter 7 Basic Health Care, which is within Part 3 Aid and Medical Assistance, which is within Division 9 Public Social Services of the California Code.
[14] http://www.leginfo.ca.gov/cgi-bin/calawquery?codesection=wic

Further, the California language includes the following phrase, *"The requirements of this section shall not be applicable to drugs purchased or procured or rates developed pursuant to or under any MediCal managed care program."* MediCal is the California Medicaid program. This managed care exclusion language significantly narrows the impact of the California provision since much of MediCal is provided through managed care arrangements. This same exclusion of Ohio's Medicaid managed care arrangements is not in the Ohio Proposed Statute.

Finally, the phrase *"*...or agree/agreement to *pay directly or indirectly* for prescribed drugs*..."* is included in Ohio's proposed language twice, in (D)(1) and (D)(3), but never in the California language. This language adds a significant *lack* of clarity regarding the meaning and also broadens the scope of the Ohio language. The lack of clarity comes with how to distinguish between a state program that pays "directly or indirectly" and a state entity that is the "ultimate payer," which is a term included in both the California initiative and the Ohio Proposed Statute. Two assumptions were made for the purposes of this analysis. First, even state programs that do *not have direct agreement*s with drug manufacturers, but which fund third party reimbursement for drugs, are included under the Proposed Statute. Second, from a practical point of view, the terms "ultimate payer" and "direct or indirect payer" were treated as having the same meaning. However this is an issue that might result in legal challenge if the term "ultimate payer" is interpreted to have a different or unique meaning.

4. THE PROPOSED BENCHMARK: STATE NET COST VS. VETERANS AFFAIRS LOWEST PRICE PAID

The Proposed Statute establishes a net cost benchmark that state drug programs must not exceed. This benchmark is the lowest price paid for the same drug by the U.S. Department of Veterans Affairs (VA). To understand the lowest price paid, it is important to understand how the cost of drugs is established within the VA system.

The VA's health care system is a relatively "closed" system of delivering health care, primarily using its own health care personnel and health care facilities for providing services to veterans. In 2013, over 99% of VA covered drugs were dispensed to veterans through the VA system itself rather than through retail pharmacies. The VA often acquires drugs in bulk or otherwise directly from wholesalers and then dispenses drugs at VA-operated medical facilities or through the VA's own mail order system. The VA uses a formulary of preferred drugs that reflect the needs of the veterans served, but it will also purchase drugs off-formulary when medically necessary. The VA reported a cost of $3.3 billion for drugs in 2013.[15] This cost *does not include the cost of dispensing those drugs* to veterans through the VA system.

The Veterans Health Care Act of 1992[16] (VHCA) was enacted by Congress to reduce the cost of drugs purchased by the VA and certain other federal agencies that have major drug spending. The VHCA was in part a response to the creation of a federal pharmacy rebate program for the Medicaid program under the 1990 Omnibus Budget Reconciliation Act, or OBRA 1990,[17] which required that, in order to participate in Medicaid, drug manufacturers would be required to pay a significant rebate to state Medicaid programs for outpatient drugs purchased under Medicaid. Initially, OBRA established the Medicaid rebate for brand name drugs as the greater of a fixed percentage of the OBRA-defined average manufac-

[15] Overview of the VA Drug Formulary Management Program http://mldc.whs.mil/public/docs/library/health/20140507-VA-Drug-Formulary-Briefing-to-MCRMC.pdf
[16] Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943
[17] Omnibus Budget Reconciliation Act of 1990 (OBRA '90)

turer's price (AMP) or the difference between AMP and "best price"[18], also requiring additional rebates if the price of a drug escalated beyond the Consumer Price Index of all Urban Consumers (CPI-U)[19]. Rebates for generic drugs were also required. In exchange, manufacturers were assured that all of their FDA-approved covered outpatient drugs would be available under the Medicaid outpatient pharmacy program.

When OBRA 1990 took effect, it caused a major shift in the market that impacted the price of drugs being offered to other federal purchasers. Because the OBRA 1990 best price reporting requirement initially included the VA's negotiated Federal Supply Schedule (FSS) pricing in the determination of best price, the VA discounts caused Medicaid rebates to be higher. As a result, manufacturers began to reduce the discounts provided to federal purchasing agencies, including the VA.[20] With enactment of the VHCA in 1992, Congress sought to reverse these effects, requiring manufacturers to make brand name drugs available on the FSS contracts and creating a Federal Ceiling Price (FCP) equal to 76% of the VHCA-defined AMP (called the non-federal average manufacturer's price or non-FAMP). This new FCP applied to the so-called "Big Four" federal purchasers: the VA, the Department of Defense, the Public Health Service, and the Coast Guard. The VHCA exempted sales made to federal agencies from being included in the calculation of best price for purposes of Medicaid rebate calculations, which mitigated the disincentive for manufacturers to offer reduced prices to the Big Four federal purchasers. The VHCA also provided that a manufacturer which failed to comply with its terms would be precluded from receiving federal funds under various federal health programs, including Medicaid, 340B, and the Big Four agencies' programs. This history provides a useful illustration of the important interplay between the federal programs, and their respective statutory pricing provisions, for the large volume of prescription drugs purchased.

While the FCP provides the VA with a significantly reduced price for a wide range of drugs, the VA may purchase drugs at prices that are even lower than the FCP. This is because the VA may receive additional discounts through 1) their national contracts, which are committed contracts that generally are extended in connection with preferred formulary positioning for manufacturers, 2) prime vendor (wholesaler) "negative fees" that result in discounts on product cost, and 3) time-bound discounts (could change daily or weekly) that manufacturers offer to the VA and/or other federal agencies for specific drugs.

5. STATE PHARMACY PROGRAMS: CONSIDERATIONS RELATED TO THE PROPOSED STATUTE

A. Methodology

Because the Proposed Statute in Ohio would apply to a broad range of state entities and pharmacy programs, the first challenge for this analysis was to understand the specific program requirements and the

[18] Best price is generally defined as, for a single source or innovator multiple source drug, the lowest price available from the manufacturer to a list of statutorily-defined entities, including any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States in any pricing structure (including capitated payments). 42 U.S.C. § 1396r-8(c)(1)(C); 42 C.F.R. § 447.505(a). Best price generally includes all rebates, discounts and other price concessions provided by the manufacturer to the relevant statutorily-defined entities.

[19] CPI-U is the price index prepared by the Bureau of Labor Statistics (BLS). It represents changes in prices of all goods and services purchased for consumption by urban households. http://www.bls.gov/cpi/

[20] Jacobson, Panangala and Hearn, Cong. Research Serv., RL 31340, Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid and Medicare Policies (2007).

prescription drug purchasing and distribution models that impact the net cost of prescription drugs for affected state programs. Utilizing publicly available information and drawing upon experience with state government,[21] this analysis identified all possible entities that would meet the criteria for inclusion, based on the language of the Proposed Statute and the interpretation as described above.

Figure 2 is a summary of the state entities and associated programs affected by the Proposed Act and Figure 3 provides the detailed listing of individual departments and affected entities. This includes state departments, state universities and colleges, state retirement systems and other state entities. It may also include health services offered by universities or colleges under certain circumstances, as well as hospital medical centers that are operated in conjunction with a public university.

Figure 2 State Entities and Associated Programs Affected by the Proposed Act: Summary of Total Lives, Employers and Doses. [22]

Covered Lives[i]	
• **Medicaid**	**3,025,790**
• **Other programs**	**799,315**
Potential Covered Lives[ii]	**134,422**
Employers	**225,466**
Doses of Vaccine	**~67,000**

While it was not possible to obtain information from every entity in a consistent form that would readily allow them to be added together, the figure illustrates the scope of individuals impacted by these programs, indicating that roughly 4 million Ohioans would be impacted.

[21] Appendix 6 includes a brief biography for each author.
[22] Sources for Figure 2 and Figure 3 are provided as endnotes to the report.

Figure 3 State Entities and Associated Programs Affected by the Proposed Act: Detail of Total Lives, Employers and Doses.

State Entities and Associated Programs[iii]	Scope Number of Lives or Program Size
Ohio Department of Medicaid	3,025,790 covered lives[iv]
Ohio Department of Health Programs, including:	
• Children with Medical Handicaps	20,000 covered lives[v]
• Vaccine Program	
- Childhood vaccines	42,289 doses[vi]
- Influenza vaccines	25,000 doses[vii]
• AIDS Drug Assistance Program (ADAP) Ryan White Programs	4,900 covered lives[viii]
• Family Planning Program	35,000 covered lives[viii]
• Bioterrorism Program	500,000 doses[viii]
Ohio State Retirement Systems, including:	
• Ohio Public Employees Retirement System	70,000 covered lives[ix]
• School Teachers Retirement System	129,717 covered lives[x]
• School Employees Retirement System	44,500 covered lives[xi]
• Highway Patrol Retirement System	3,000 covered lives[xii]
• Ohio Police and Pension Fund	27,963 potential covered lives[xiii]
Ohio Department of Mental Health and Addiction Services (ODMHAS): Ohio's Pharmacy Service Center sells and distributes to:	
• State ODMHAS hospitals	45,102 covered lives[xiv]
• Non-state governmental entities, including community mental health agencies	11,621 covered lives[xv]
• Other State Departments[xvi], including:	
- Ohio Department of Rehabilitation & Correction	51,001 covered lives[xvii]
- Ohio Department of Youth Services	960 covered lives[xviii]
- Ohio Department of Developmental Disabilities	888 covered lives[xix]
Ohio Department of Administrative Services **State Employee Health Insurance**	114,900 covered lives[xx]
Ohio Department of Aging -Ohio Best Rx Program	182,726 covered lives[xxi]
Ohio Bureau Workers Comp (BWC)	225,466 employers[xxii] 44,000 covered lives[xxiii]
Ohio Department Higher Education	
• Employees of State University and Community Colleges	106,459 potential covered lives[xxiv]
Ohio State Wexner Medical Center	$252M for drugs only and 41,000 admissions (unduplicated) in FY16[xxv]

Officials within key state pharmacy programs were interviewed to explore in more depth how current programs operate, focusing in particular on the mechanics of the various purchasing relationships. See Attachment 5 for more information on the interview methodology.

B. Overview of State Pharmacy Program Purchasing

The state departments, agencies, and other entities involved with the direct or indirect purchase of prescribed drugs employ a variety of approaches and strategies in the operation of their programs. Most of these state programs do not purchase drugs in bulk or otherwise purchase directly from wholesalers and then dispense through their own medical and mail order facilities, like the VA does Rather, most state programs have arrangements that use private vendors to negotiate and sometime process and pay claims for the cost of prescription drugs dispensed to program participants through retail pharmacies or other medical facilities (e.g., public or private clinics). Private vendors generally include pharmacy benefits mangers (PBMs) but may also include insurance companies or managed care plans (MCPs)[23]. Only a few of these arrangements involve the state entering into a direct agreement with manufacturers regarding discounts or rebates for the purchase of drugs, though many programs may benefit from discounts or rebates negotiated by the contracted PBM, insurer, or MCP.

While the details of arrangements for each program are different, as are the state or federal statutes and regulations under which the programs operate, this analysis generally grouped each program reviewed into one of four basic models. Figure 3 below summarizes which of the four models of purchasing relationships best describes the impacted state entities.

Figure 4 Models of State Entity Purchasing Relationships

Model Number and Title	Affected State Entities
Model 1: State Entity Contracts with 3rd Party (at risk) Insurer	• Ohio Department of Medicaid, managed care program • Ohio University, student health plan and possibly other university health plans
Model 2: State Entity Contracts with Pharmacy Benefit Manager (PBM)	• Ohio Department of Medicaid, fee-for-service program • Ohio Department of Administrative Services, state employee benefits program • Ohio Bureau of Workers' Compensation • RxOC Members, including[24]: - Ohio Public Employees Retirement System - School Employees Retirement System - State Teachers Retirement System of Ohio - Highway Patrol Retirement System of Ohio - The Ohio State University - A number of other state universities - A number of local, non-state entities participate in RxOC

[23] Also referred to as managed care organizations, MCOs. This is an arrangement between an insurer and a selected network of health care providers, often for a per member per month payment; e.g. a monthly capitation payment.
[24] See listing of all members of the RxOC in Attachment 4

Model 3: State Entity Contracts with Wholesaler and/or Manufacturer, includes direct purchase of drugs	• Ohio Department of Mental Health and Addiction Services, Pharmacy Service Center • Ohio Department of Health, Immunizations Program • Ohio Department of Health, HIV Drug Assistance Program • Ohio Department of Health, Family Planning Program • Ohio Department of Health, Bioterrorism Program • Ohio State University Wexner Medical Center
Model 4: State Entity Contracts for Pharmacy Discount Card	• Ohio Department of Aging, Best Rx Program

The following figures illustrate the four models.[25]

Figure 5: Model 1 State Entity Contracts with 3rd Party/At Risk Insurer
Figure 6: Model 2 State Entity Contracts with Pharmacy Benefit Manager (PBM)
Figure 7: Model 3 State Entity Contracts with Wholesaler and/or Manufacturer, includes direct purchase of drugs
Figure 8: Model 4 State Entity Contracts for Pharmacy Discount Card, Best Rx

As depicted, the key issues include the negotiation and payment flow, the rebates and discount flow, and the product flow. These models demonstrate the complexity and nuances of state entities' drug purchasing programs.

[25] Pete Abilla, 4 Things You Didn't Know about the Pharmaceutical Supply chain, 2011 http://www.shmula.com/pharmaceutical-supply-chain-things-you-didnt-know/8503/

Figure 5 Model #1 State Entity Contracts with 3rd Party/At Risk Insurer

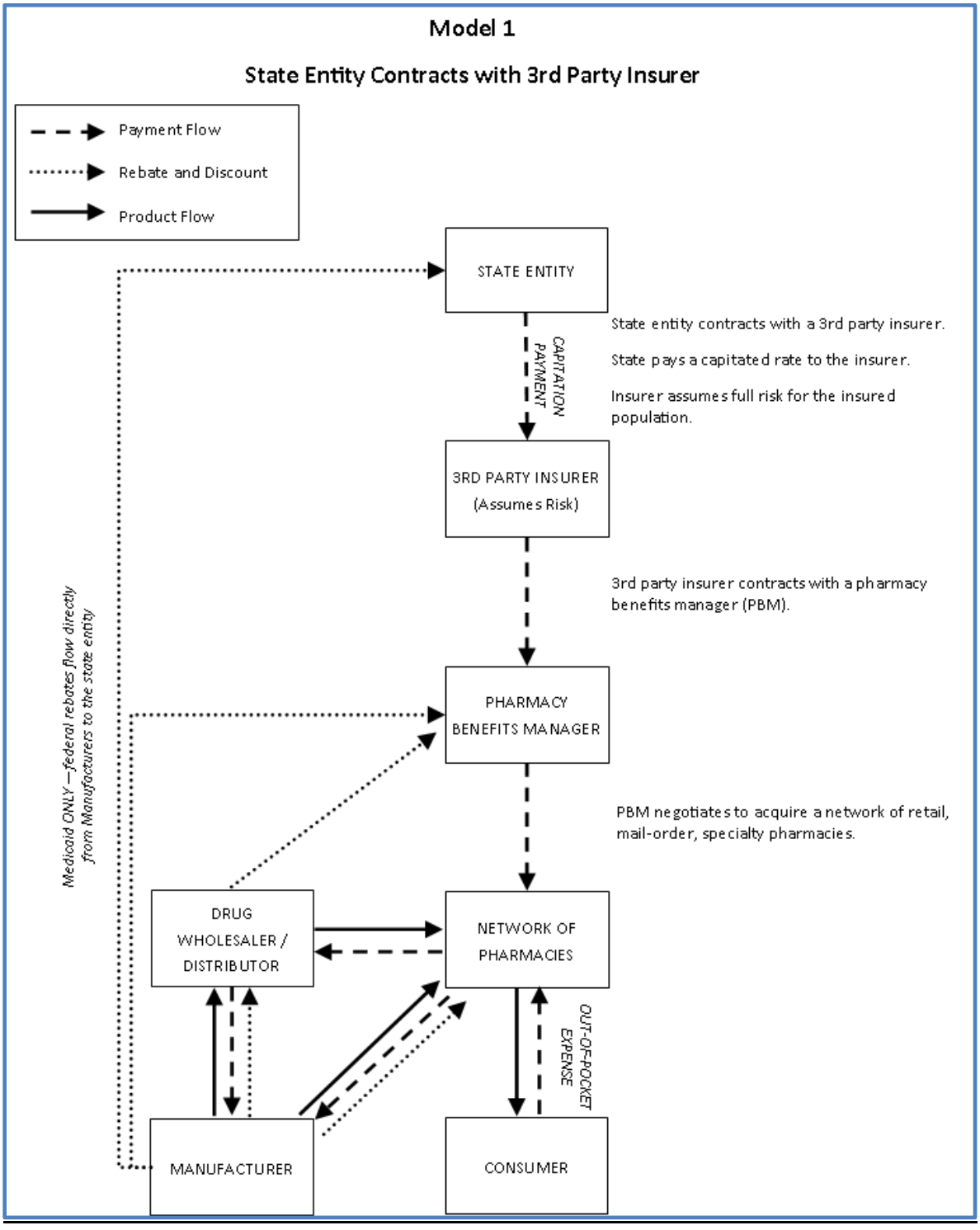


Figure 6 Model #2 State Entity Contracts with Pharmacy Benefit Manager (PBM)

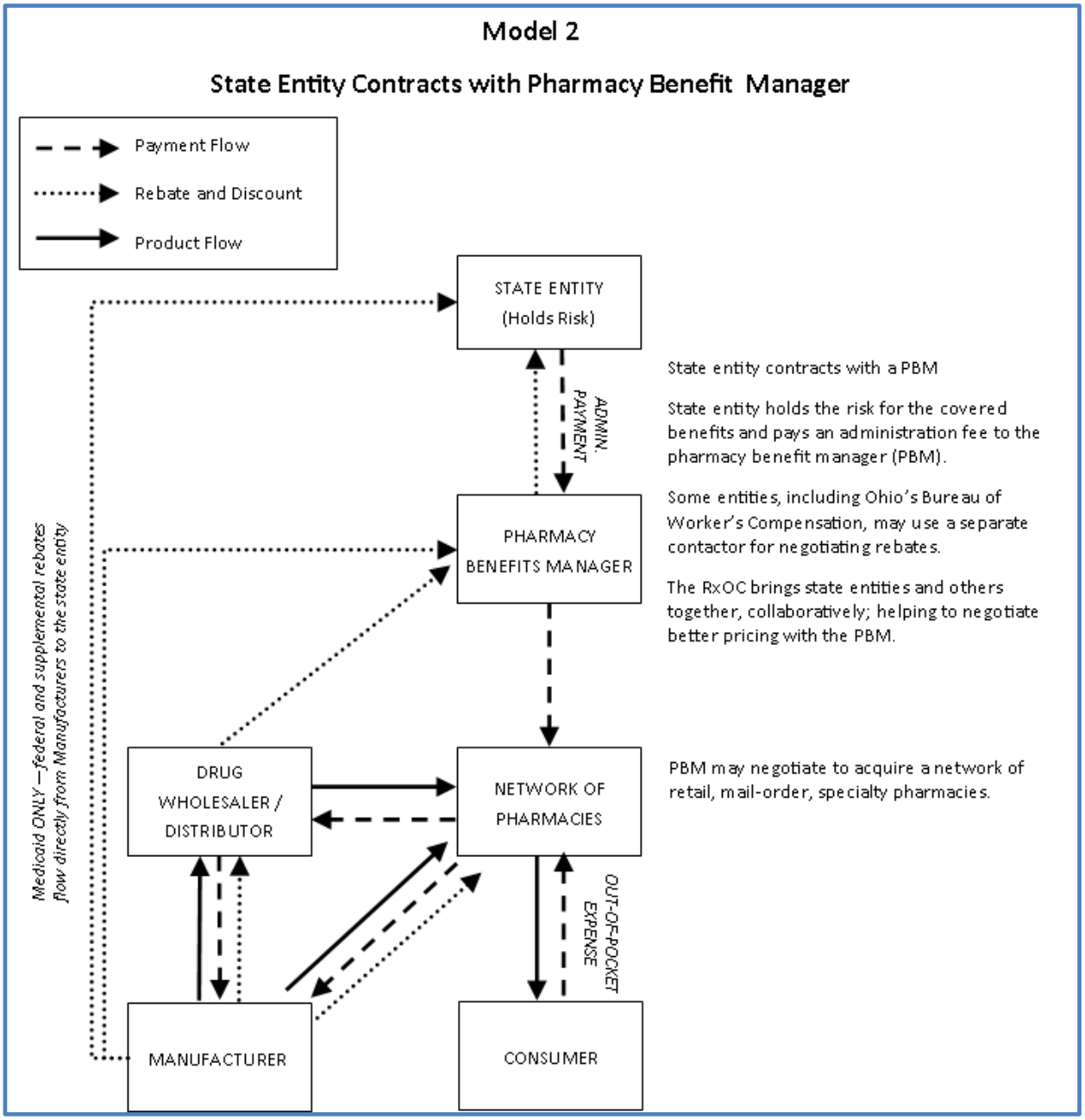


Figure 7 Model #3 State Entity Contracts with Wholesaler and/or Manufacturer, Including Direct Purchase of Drugs

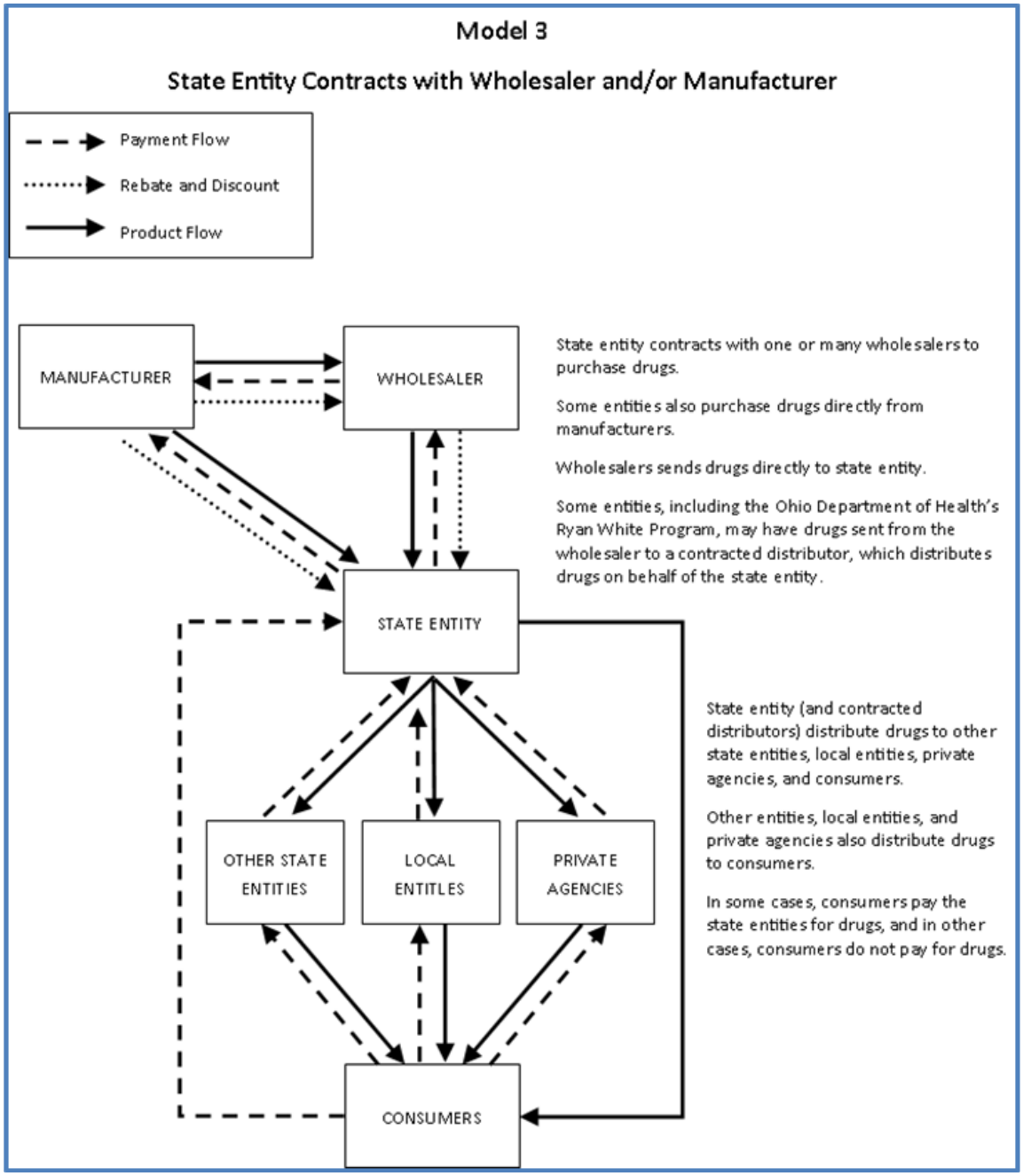
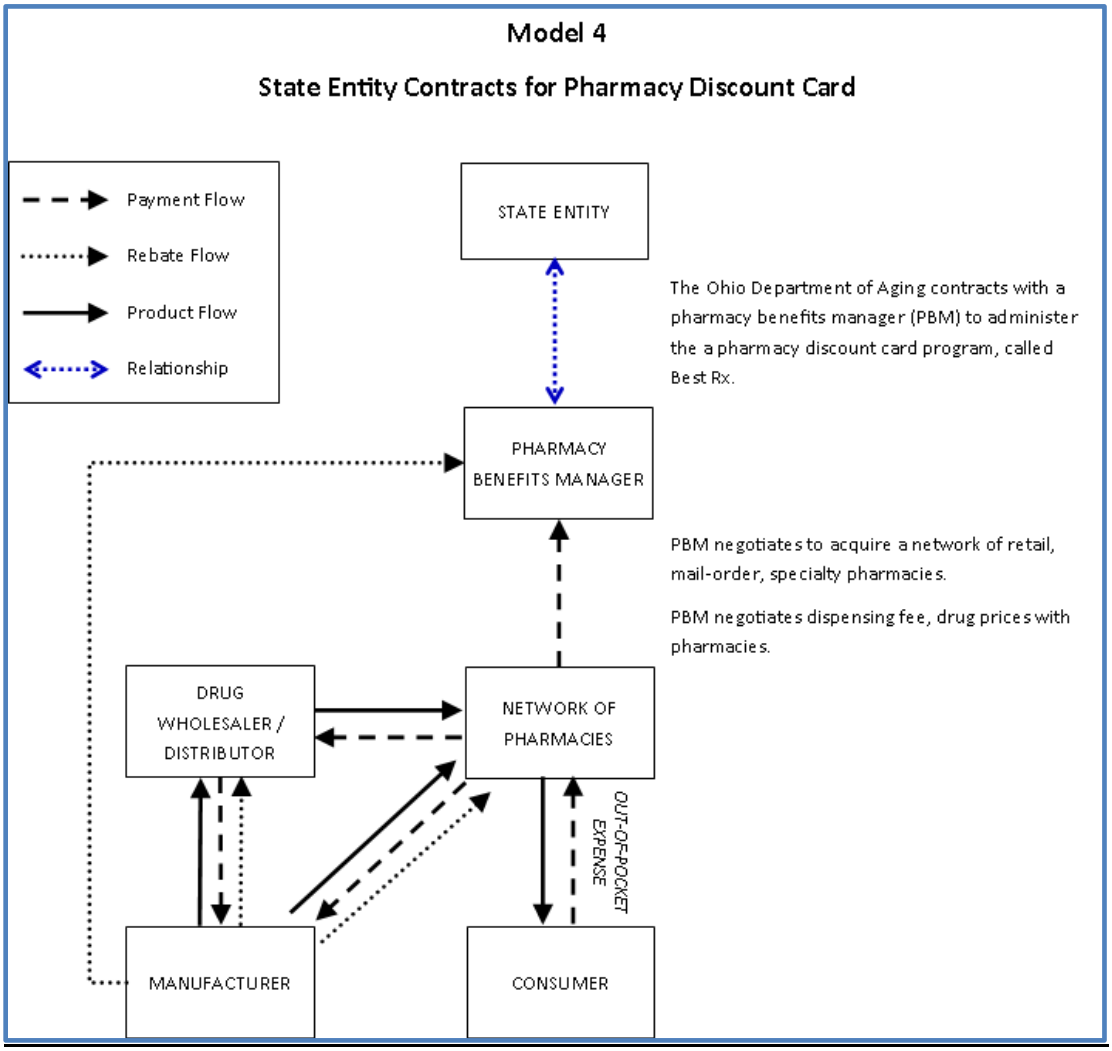


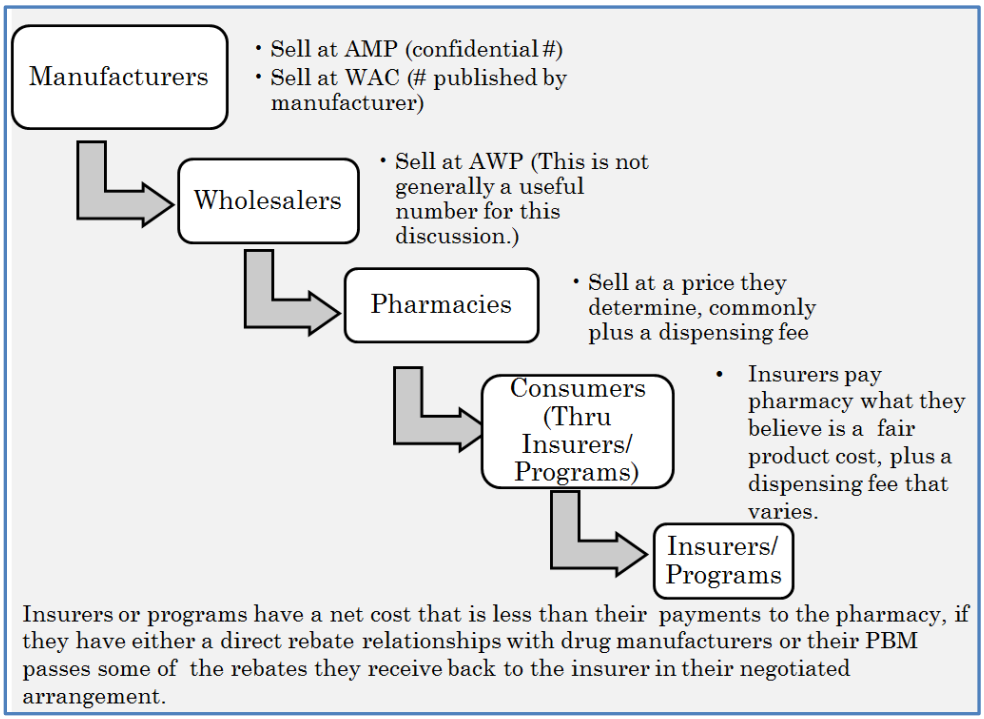
Figure 8 Model #4 State Entity Contracts for Pharmacy Discount Card, Best Rx



C. Analysis of the Models: How the cost of a drug is determined

To understand the net cost incurred by any state entity, it is important to have an understanding of how the prescription drug supply system operates. There are generally multiple entities playing a role in the pharmaceutical supply chain. As a general rule, each entity experiences a different cost for the drug product, and each entity seeks to recover its own costs in the subsequent sale of the drug to the next entity in the supply chain. This framework generally applies to most programs and payers, e.g., commercial insurance, public health programs like Medicaid and Medicare, and self-funded employer health plans, though there is some variability across programs, as will be discussed. Figure 9 provides an illustration of the supply chain and the critical pricing elements.

Figure 9 The Supply Chain and Summary of Pricing Considerations



Notes:
AWP*-Average Wholesale Price.* ***AMP****-Average Manufacturer's Price.* ***PBM****-Pharmacy Benefit Manager.* ***WAC****-Wholesale Acquisition Price*

At the beginning of the prescription drug supply chain is the biopharmaceutical manufacturer that develops and produces the drugs. Manufacturers generally sell their drugs to wholesalers, such as Cardinal Health or McKesson, who further distribute product to retail pharmacies, where they are dispensed to patients upon receipt of a valid prescription from the prescriber. While this is generally true for many products, some drugs are sold by manufacturers directly to pharmacies or other points of distribution, such as doctor's offices and hospitals.

Cost to the wholesaler is how much that wholesaler has to pay the manufacturer for the product that the wholesaler will distribute to pharmacies. The wholesale acquisition cost (WAC) is the published sales price from manufacturers. The WAC can be found in various drug compendia.. The price of drugs sold to wholesalers is subject to negotiations between the manufacturer and the wholesaler, and actual transaction prices may vary due to other discounts offered by the manufacturer. For example, a manufacturer may offer a prompt-pay discount.

Federal Medicaid law and the VHCA[26] require manufacturers to report an Average Manufacturers' Price (AMP) for each drug sold. The AMP generally reflects the actual prices paid to manufacturers by

[26] VHCA See FN 9

wholesalers for drugs distributed to retail pharmacies and is the basis of each program's calculation of required discounts. AMP is a confidentially reported price that is not disclosed by federal programs.[27]

Cost to the pharmacy reflects how much the pharmacy has to pay the wholesaler (or manufacturer, if it is a drug sold directly from the manufacturer to the pharmacy) to purchase a drug. The average wholesale price (AWP), published by various drug compendia, reflects an estimate of the price at which wholesalers are selling to pharmacies. AWP generally is assumed to represent a 20% mark-up over WAC. In reality, negotiations between pharmacies and wholesalers result in a range of prices.

For insured consumers picking up a prescription at a pharmacy, cost generally means the amount of co-payment or co-insurance they are required to pay under their insurance policy or coverage program. Many insurance companies "tier" covered drugs, charging lower co-payments for "preferred" (generally less expensive but still effective) drugs and higher co-pays for high-cost drugs.

At the end of the chain is the insurer. This could be a private insurer, or in the case of the Proposed Statute, state entities that finance or arrange pharmacy coverage programs, funded in part or in whole by Ohio tax dollars. These third-party payers generally negotiate prices with individual pharmacies or chains of pharmacies, leveraging volume purchasing to get lower than the full retail price. Historically, most third-party payers used AWP to set prices (reimbursement rates) paid to pharmacies, generally setting a price at some percentage below the published AWP. Many third party payers have moved away from using the AWP as the basis for negotiating retail pharmacy prices. Some may use WAC as the starting point for price development (adding a percentage). In addition, the federal Medicaid program has created a new data source, built from a national survey of pharmacies, to provide states with drug-specific information on pharmacy acquisition prices.[28]

Rebates

Third-party payers also often seek additional discounts off the retail price by negotiating rebate deals directly with manufacturers or through their PBM or other contractor. As noted above, state Medicaid programs have benefited from a federally mandated national rebate program, where manufacturers are required to provide rebates for covered outpatient drugs in exchange for a state's coverage of the drug.

In addition, Ohio and many other states negotiate "supplemental" rebates directly with manufacturers to further reduce the net cost of the pharmacy benefit to Medicaid. Many other private and public purchasers of pharmacy services, including PBMs who work for insurance companies as well as public payers, managed care plans, and hospitals, also negotiate rebates or other discount arrangements directly with manufacturers.

Rebate arrangements, especially for large volume payers, can significantly reduce the net cost of a drug. Medicaid, through the national drug rebate program, receives a minimum of 23.1% of AMP in rebates for brand name drugs. For generic drugs the rebate is 13% of AMP. As noted, Ohio Medicaid also negotiates additional supplemental rebates. The result, according to the CMS64 (a federal financial report on

[27] Drug-specific rebate information is proprietary information that must be protected from disclosure in a manner that is consistent with Social Security Act §1927.

[28] See results from National Average Drug Acquisition Cost survey https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/pharmacy-pricing.html

state Medicaid spending)[29] was that the Ohio Medicaid program received $768,002,258 in rebates in FY 2014. Other state programs, including but not limited to the Bureau of Workers Compensation and the Ohio Public Employee Retirement System, reported that they benefited from rebate arrangements, generally negotiated by PBMs or other contractors rather than by the state entity directly. These voluntarily negotiated rebates between PBMs and manufacturers, as shared with state entities, are on a significantly smaller scale as a percentage of AMP than what the Medicaid program receives under its federally mandated rebate program. Another important difference from Medicaid is that, many times, the rebates represent a fixed per-transaction rebate paid by the PBM to the state entity, regardless of the specific drug or manufacturer, rather than a drug-specific discount. For example, the PBM agrees to pay the state entity one dollar for every transaction, without regard to whether the individual drug cost $10 or $1000 or whether the actual rebate is $0.25 or $25.00. Since the Proposed Statute requires the benchmark to be the lowest price paid for each drug, drug-specific rebate information would be required to comply with the Proposed Statute, further adding to the complexity of implementation.

State Entity Contracts with Wholesaler and/or Manufacturer

The state entities included in Model 3 most closely resemble the arrangement used by the VA as a direct purchaser of drugs that are dispensed separately from the program's purchase of the drug. The Department of Mental Health and Addiction Services, several Department of Health programs, and the OSU Wexner Medical Center all purchase drugs in bulk and then distribute those drugs to pharmacy operations, which in turn dispense to consumers. The net cost of the drug would be calculated based on the acquisition of the drugs, in bulk (reflecting any discounts at point of purchase) minus any rebates received after purchase. There might be some costs of wholesalers or other contractors involved in obtaining the bulk purchase reflected in the net cost of drug acquisition in these arrangements. However, the costs of warehousing and distributing the drugs to pharmacies and the cost of dispensing the drugs to consumers are not included in the net cost of acquiring the drug under these arrangements because those costs occur later in the supply chain.

State Entity Contracts with a Third Party Insurer or PBM

In Models 1 and 2, which represent the large majority of the impacted population for pharmacy coverage (including Medicaid managed care and fee-for-service [FFS] arrangements, state employee plan beneficiaries, and retirees), the state's approach to purchasing drugs is to provide a third party reimbursement for drugs dispensed through the retail pharmacy system. In Model 1, the state entity passes the risk of the actual cost of pharmacy to another entity (e.g., a Managed Care Plan). In Model 2, the state entity continues to hold the risk but uses a vendor for various tasks, including negotiating prices and/or processing claims.

For the purchasers of drugs in Model 1 and Model 2, the net cost of the drug to the state program is the amount reimbursed to the pharmacy (which reflects price discounts as well as any copayments made by consumers at point of purchase), minus any rebates received after reimbursement is made to the pharmacy. This means that the net cost to these state programs includes costs that have been added throughout the supply chain, beyond the original sales price from the manufacturer to the wholesaler (or pharmacy), including the pharmacy dispensing fee.

[29] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/MedicaidBudgetExpendSystem/CMS-64-Quarterly-Expense-Report.html

Figure 10 provides a description of the types of strategies used by third party payers and PBMs to reduce the net cost of drugs dispensed to the public. Examples of all of these strategies were found to be used by state entities providing pharmacy coverage in Ohio.

Figure 10 Cost Management Strategies Used by Providers of Pharmacy Benefit

Cost Management Strategy	Description
Formularies	Many purchasers implement formularies that contain preferred drugs that reflect value for the purchaser. That is, they select the most clinically appropriate and cost effective drugs for their formulary.
Purchasing Collaboratives	Some purchasers have joined purchasing collaboratives to realize better pricing based on a larger number of lives. For example, the Ohio Public Employees Retirement System has approximately 70,000 covered lives comprised of retirees not covered by Medicare. . By joining the Rx Ohio Collaborative (RxOC), they are now part of a group of 125 member organizations representing over 625,000 lives, and their purchasing power is enhanced.
Co-pays	Co-pays shift a portion of the prescription cost to the consumer. Many times they are used to incentivize the consumer to use a generic or preferred drug. For example, state of Ohio employees pay $10 for a generic drug, $25 for a preferred brand-name drug, $50 for a non-preferred brand-name drug when a generic is unavailable, and $50 plus the difference between the cost of the brand-name and generic drug when a generic is available. At the VA, the co-pay is either $8 or $9 for eligible individuals required to make a co-payment, and it is the same for a formulary or non-formulary drug.
Utilization management	Utilization management strategies such as prior authorization and prospective drug utilization review are intended to help deliver a clinically appropriate and cost effective drug benefit.
Negotiation	Negotiation can mean many things and take many forms. Purchasers may negotiate rebates or discounts directly with drug manufacturers or wholesalers. They may also obtain volume or prompt payment discounts from wholesalers if they are purchasing drugs directly. Most state entities are purchasing from retail pharmacies and are negotiating a price that will be paid to the pharmacy that will cover the pharmacy's product acquisition cost plus a professional dispensing fee.
Statutory discounts	Public programs such as Medicaid and the VA receive federally mandated discounts/rebates that reduce their costs.
Pharmacy benefit manager (PBM)	Most state entities utilize a PBM to help them manage their pharmacy benefit. PBMs perform formulary management, drug pricing, discount negotiations, and utilization management.

State Entity Contracts for Pharmacy Discount Card, Best Rx

In the case of Model 4 for Ohio's Best Rx, the state entity contracts with a vendor that has negotiated price discounts within the pharmacy system on behalf of a large group of individuals who are self-pay. Notice that, while a business relationship exists, there is no state appropriation to directly or indirectly purchase drugs. As described in section 3(A) above, were it not for the specific inclusion of these programs by name in the language of the Proposed Statute, identified as "ultimate payers," this analysis would not have included them. Under this model, the net cost of a drug is presumed to be the price paid by the consumer at the retail pharmacy.

6. ANALYSIS OF KEY QUESTIONS RAISED BY THE PROPOSED STATUTE

There are several important questions that must be answered in order to assess whether the Proposed Statute can achieve its stated purpose. These questions relate to whether it is possible to implement the provisions of the Proposed Statute and the impact the Proposed Statute it would have, if implemented.

A. Is it possible to identify the lowest price the VA pays for a drug?
B. Is it possible to know what drugs the VA purchases?
C. If we could identify the lowest price paid for all drugs purchased by the VA, is it a reasonable net cost target for the state drug programs?
D. Will manufacturers voluntarily negotiate discounts/rebates with Ohio's state entities (or entities' vendors) to achieve the benchmark net cost?
E. What additional strategies might state pharmacy programs employ to achieve compliance with the Proposed Statute?
F. What is the potential impact on entities with pharmacy programs that are not the intended targets of the Proposed Statute?

Each question is addressed below.

A. Is it possible to identify the lowest price the VA pays for a drug?

Conclusion

No. The full set of information required to make the comparison is not publicly available. While the FSS contract prices are published within the VA's public contracts database, the publicly published prices for the Big Four federal entities are not inclusive of all discounts and may not be the lowest price paid by the VA for drugs.

Discussion

The VHCA requires manufacturers to offer the VA a price for drugs that is at least 24% off the VHCA-defined AMP on brand name drugs. However, as explained in more detail under section 4 above, the VA does not generally pay the published Big Four or FSS price for drugs. The published pricing is not always modified to reflect the additional (and often time-bound) discounts that further reduce the VA's actual price paid at any given time. Therefore, the lowest price paid by the VA for any drug is likely to vary frequently (even potentially daily) and is not always publicly available. This seriously impedes the ability of state entities and their vendors to know the price benchmark. Additionally, the variation in drug pricing over time makes it unclear when or how states will know the VA's lowest price paid.

Figure 11 depicts all the components of pricing information that must be readily available in order to comply with the Proposed Statute's benchmark price, e.g. the lowest price paid for a drug by the VA.

Figure 11 Can state entities know the Lowest Price Paid by the VA?

Can State Entities know the lowest price paid by the VA?

Ohio Drug Price Relief Act says state entities shall not... "Purchase a prescribed drug... unless the net cost of the drug,... is the same as or less than the **lowest price paid for the same drug** by the United States Department of Veteran Affairs"

Type of Discount	Description	Is it Publicly Available?
"Big 4" Price	Reflects at least the federally required discount of 24% off VHCA defined AMP minus CPI-based additional discount for brand name drugs, and any voluntary discount for generics	Yes
National Contract Price	Reflects deeper discounts, based on the VA's commitment to purchase specific drugs	Yes
Temporary Price Discounts	Reflects time-bound discounts below the "Big 4" price and the FSS price	No
Prime Vendor Discount	Reflects additional discounts offered by the prime vendor	No
Lowest Price Paid for a Purchased Drug	**Cost of a drug purchased by the VA, net of all discounts**	**NO**

B. Is it possible to know what drugs the VA purchases?

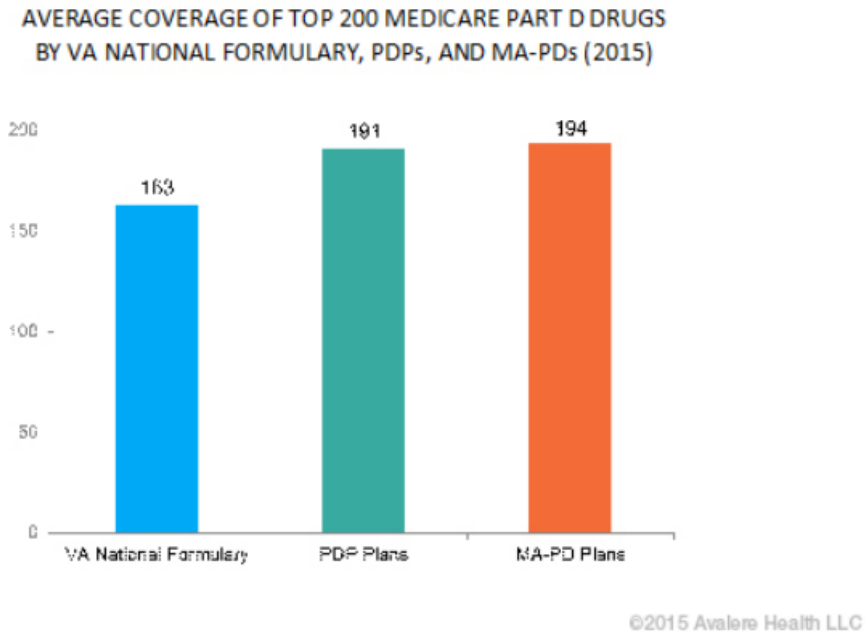
Conclusion

No. While the VA uses a formulary that includes many products that are of importance to the VA population, the VA also purchases "non-formulary" drugs on a case-specific basis when medically necessary. The actual purchasing behavior of the VA might be discoverable after the fact but is not publicly available in an operationally feasible timeframe.

Discussion

As discussed in section 4, the VA uses a formulary for its pharmacy coverage. A study conducted by Avalere compared the VA formulary with the top 200 Medicare Part D drugs by volume.[30] Figure 12 presents findings from this study, which illustrates the controlled nature of the VA formulary and the different profile of need within the veteran population served by the VA.

Figure 12 Average Coverage of Top 200 Medicare Part D Drugs by VA National Formulary, PDPs and MA-PDs



Not all drugs listed on the FSS are included on the VA formulary, but the VA will purchase off-formulary when medically necessary, using a prior authorization process. For example, of 111 psychiatric drugs on the FSS, 56 are on the VA formulary; however, the VA actually dispenses 95 of them. Some of the drugs that may not listed on the formulary are primarily used in the pediatric population and are not widely needed in the VA (e.g. ADHD drugs.)[31]

As described in section 3(A) above, this analysis assumes that only those drugs actually purchased by the VA – and which have an actual lowest price paid by the VA – are subject to the net-cost benchmark under the Proposed Statute. An immediate challenge to implementation is that it does not appear feasible for a state entity to actually know *what drugs have been purchased* by the VA, both on and off-

[30] Kelly Brantley, VA National Formulary Covers 16% Fewer Top Prescription Drugs than Medicare Part D Plans, (2015), http://avalere.com/expertise/managed-care/insights/a-recent-avalere-analysis-found-that-the-va-national-formulary-covers-fewer (accessed February 15, 2016). This study compares the VA national formulary with stand-alone Medicare prescription drug plans (PDPs) and integrated Medicare Advantage Prescription Drug Plans (MA-PDs). Used with the permission of the author.

[31] See FN 5

formulary, in order to know which drugs have a net cost benchmark that must be applied under the Proposed Statute. VA drug purchases, especially off-formulary, will likely vary from one time period to another. This information might be discoverable in a retrospective manner, but may not be publicly available in an operationally feasible timeframe. This significantly complicates implementation and raises questions about how state programs might approach coverage and reimbursement decisions, especially for populations, like children, whose drugs are not typically the focus of the VA program.

C. If we could identify the lowest price paid for all drugs purchased by the VA, is this a reasonable net cost target for the state drug programs?

Conclusion

No. The lowest price paid by the VA in acquiring drugs from wholesalers does not reflect all legitimate costs that state programs may incur in acquiring and dispensing drugs through the retail pharmacy system. In 2013 over 99% of VA covered drugs were dispensed to veterans through VA operated pharmacies (in medical facilities or by mail order); these distribution costs are not included in the required VA benchmark price but are included in the net cost incurred by most state programs. It is not an "apples to apples" comparison.

Discussion

Medicaid and most other state purchasers (with the exception of the programs described in Model 3 above) do not buy drugs in bulk or otherwise directly from wholesalers and then distribute these drugs through their own pharmacy system, as the VA does. Thus, public purchasers have costs associated with having drugs acquired and then dispensed by a retail pharmacy reflected in their "net cost" for a drug purchase. As a third-party payer, rather than as the operator of a pharmacy system, state entities must pay a cost that reasonably reflects the acquisition cost of a pharmacy (which may include the costs of the wholesaler) and a reasonable professional dispensing fee for the pharmacist's services. As described in 6 (B) above, the VA incurs costs related to the dispensing of drugs to veterans, but these costs are not reflected in the benchmark price established in the Proposed Statute. Thus, the comparison is unequal and makes it impossible for state entities to achieve the Proposed Statute's standard.

Figure 13 illustrates the costs included and excluded in the lowest price paid for the same drug by the VA, which is the benchmark identified in the statute, compared to all the costs included in the net cost of a drug to state agencies.

Figure 13 Price Comparison: What is included in the Lowest Price Paid by the VA vs. Net Cost to the State Entities

State Entities must have a Net Cost that is Less Than or Equal To the Lowest Price Paid by the VA, but these Measures Include Unequal Supply Chain Costs	
VA	**STATE ENTITIES**
Manufacturer Required by P.L. 102-585 to offer a price to the VA for brand name products that is no more than VHCA defined AMP[32] minus 24%. The price also may be inclusive of a consumer price index (CPI)-based additional discount. May offer discounted prices for generics. **INCLUDED**	**Manufacturer** Only Medicaid, the Ryan White grantees, and 340B[33] entities have statutorily required discounts. Most other state entities do not have a direct relationship with manufacturers. They may benefit from some discounts/rebates negotiated by a PBM or other entity on their behalf. **INCLUDED**
Prime Vendor Sells to the VA at the price negotiated between the manufacturer and the VA minus prompt pay discounts applied/extended by the prime vendor. **INCLUDED**	**Wholesalers** Purchase drugs at some negotiated discount off WAC from a manufacturer, but have no statutory power to get drugs at VA price. The wholesalers then sell to retail pharmacies at some price above their cost. Wholesalers will negotiate discounts with pharmacies such as prompt pay, volume discounts, and product-specific specials. **INCLUDED**
Pharmacy Distribution Costs of operating VA mail order and clinic pharmacies. **NOT INCLUDED**	**Pharmacy Distribution** Pharmacies negotiate reimbursement with third party payers or their PBMs designed to cover the **cost of acquiring and dispensing drugs** to enrollee/ covered lives. **INCLUDED**
Copays Charged for some drugs, but *does not* reduce the calculation of the lowest price paid by the VA**.** **NOT INCLUDED**	**Copays** Paid by some, but *does* reduce the calculation of the net cost (to the state) of the drug. **INCLUDED**
LOWEST PRICE PAID	**NET COST**

[32]Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943. VHCA defined AMP is Average Manufacturer's Price as defined by the Veterans Health Care Act of 1992 (P.L. 102-585).

[33] The 340B program applies to "covered outpatient drugs," which are defined as prescription drugs and biologics other than vaccines (Social Security Act, Section 1927 (k)). This includes over the counter drugs prescribed by a physician and covered by the Medicaid program.

D. Will manufacturers voluntarily negotiate discounts/rebates with Ohio's state entities (or entities' vendors) to achieve the benchmark net cost?

Conclusion

It is not reasonable to assume that large numbers of manufacturers would be willing to negotiate voluntarily the significant additional discounts with Ohio state entities or with vendors on behalf of Ohio state entities. Manufacturers would be reluctant to cooperate given the potential national precedent that could be set regarding state pharmacy programs as well as the potential impact these discounts could have on the federally established discount programs for the VA and other federal buyers. Further, without the additional discounts needed, Ohio Medicaid would be unable to enter into direct rebate agreements and could lose existing supplemental rebates.

Discussion

The Big Four agencies and the Medicaid program—which all are significantly larger volume drug purchasers than Ohio state entities—achieved their current baseline arrangement with manufacturers only through laws enacted by Congress that mandate manufacturer discounts or rebates and, in the case of Medicaid, also guarantee access to their products in exchange for the provision of rebates.

This challenge is exacerbated since, for the state entities that act as/contract with third party payers (Models 1 and 2), or are negotiating on behalf of self-pay consumers within the retail pharmacy system (Model 4), the entities must achieve discounts sufficiently *below* the VA's lowest price paid to assure that the necessary costs of dispensing drugs to consumers, which are part of these state entities' net cost, can also be accommodated within the required target price.

Since Medicaid and many other state entities may need significantly larger discounts off AMP to achieve a net cost equal to or less than the VA's drug acquisition cost, the potential impact of ever-increasing discounts makes it unlikely that manufacturers would agree. For example, if additional discounts were given in significant enough volume that the AMP (an average commercial price to the retail sector) were reduced, then the VA price could also go down, triggering the need to further reduce the price for state entities to remain compliant—creating a downward price spiral. Further, it is reasonable to assume that manufacturers and others would have concerns regarding Ohio's rates becoming the precedent for the nation as a whole, possibly threatening the structure of existing federal rebate statutes. For example, in the event that the downward spiral creates a new best price for the Medicaid program, then all state Medicaid programs would access the increased rebates, changing the dynamics of the law in an unanticipated way.

Finally, because the Proposed Statute prohibits a state entity from entering into any agreements with manufacturers for the purchase of a prescription drug unless the net cost to the state entity does not exceed the lowest price paid by the VA for the drug, Ohio Medicaid would be unable to enter into direct rebate agreements for any drugs for which they fail to achieve any additional discounts needed to comply with the Proposed Statute. . The state would still have to purchase the drug to comply with federal Medicaid requirements, but the Proposed Statute would prohibit the state continuing its agreement for the existing supplemental rebates. Therefore, the net cost to the state of Ohio would increase from the loss of existing supplemental rebates for drugs that must be purchased to comply with federal regulation regardless of the language of the Proposed Statute.

E. What additional strategies might state pharmacy programs employ to achieve compliance with the Proposed Statute?

Conclusion

If state entities cannot achieve the benchmark price through voluntary negotiation or discounts, then they will be forced to implement other restrictions in these programs in an attempt to reach the net cost benchmark established in the Proposed Statute.

Such actions could reduce access to prescription drugs for consumers. For example, state programs may have to use more restricted formularies, drop coverage of drugs for which the benchmark net cost is not achieved (where allowed under federal laws), restrict network pharmacy availability, lower pharmacy reimbursement rates, or raise co-payments for consumers.

Discussion

If the Proposed Statute becomes law in Ohio, state pharmacy programs would make a good faith attempt to implement the provisions of the Statute. As described in questions identified in section 6 above, the state entities would be faced with significant challenges to implementation – both operational and in their ability to obtain manufacturers' agreement to the Proposed Statute's discounts for drugs.

This could result in state entities pursuing extensive administrative regulations in an attempt to operationalize a reasonable interpretation of the Proposed Statute (e.g., defining terms to be more achievable and creating work-arounds for information not publicly available, which might include retrospective adjustments to pricing and payment arrangements). These solutions could create significant additional administrative costs that would have to be incurred by each program or shared across programs.

Existing contracts with insurers, MCPs, and PBMs would have to be re-procured, and for Medicaid, new rebate negotiations would be required. There are a variety of pharmaceutical contracts currently in effect, administered through the Ohio Department of Administrative Services. These resulted from a competitive bidding process required by Ohio law. The resulting contracts typically have a life of three or five years, all terminating in different years. Since drug pricing and/or rebate amounts are key components of these arrangements, the new requirements of the Proposed Statute would create a need to change the performance requirements in the contracts. This would likely require that the contracts would have to be reprocured, at one time. Further, most programs operate under regulations that go through a structured rule-making that involves public and legislative review processes. Regulations would be especially critical to implementation of the Proposed Statute, since state programs would need to define terms that are not defined in the Proposed Statute and to clarify the state entity's interpretation of unclear language. Both the promulgation of regulations and the process required for public contract procurement would likely require many months of effort on the part of state entities. The rule-making process could be especially lengthy, since state program interpretations might be subject to debate and even legal challenge. These processes alone will make implementation challenging.

Given the conclusion in section 6(D) above that manufactures are unlikely to agree voluntarily to the level of additional price concessions that would be required for most state pharmacy programs to meet the benchmark net cost, state programs would have to consider other options for fully achieving the lev-

els of savings mandated. Alternatively, state programs would have to implement changes to their pharmacy programs if they could not achieve the benchmark net cost.

The analysis in section 7 below provides more specific examples of how the various state programs might be impacted by this challenge. Based upon the program-specific analysis, it is anticipated that state entities would seek to combine various strategies, as described in Figure 10 above, within the permissible bounds of their federal or state authorities.

No single tool is likely to satisfy the requirements. Options include the following:

- negotiating below the target VA price with manufacturers, so that distribution costs can still be accommodated within the state's net costs;
- using additional utilization management or other prescriber education/interventions in order to steer medication use;
- putting restrictions on the types and selection of drugs that would be available through a closed or limited formulary;
- reducing the cost of distribution (e.g., lowering pharmacy reimbursement, or reducing or eliminating retail pharmacies and using mail order exclusively), and eliminating value-added services, such as data analytics or health navigation assistance to members;
- increasing the co-payments or otherwise shifting costs to the end-consumer (employee, child, or individual with a disability or health condition);
- eliminating the pharmacy program altogether; and
- invalidating existing state contracts or purchasing agreements, restructuring the procurement, and revising the associated relationships, in order to remove as much cost as possible; then creating a different way for those costs to be paid, such as a separate fee or agreement.

F. What is the potential impact on entities with pharmacy programs that are not the intended targets of the Proposed Statute?

Conclusion

In addition to those state entities that are intended targets of the Proposed Statute, there are other pharmacy programs that could also be impacted—"non-targeted entities," including third party payers such as private insurers. If the state must seek deep price concessions from manufacturers, wholesalers and pharmacies, it is conceivable that these entities might compensate by raising prices for non-target entities and equally conceivable that those increases could be passed along to consumers in the form of higher copays.

There are also significant concerns about the impact that the Proposed Statute could have on future VA drug prices. If states attempt to use the VA price concessions as a benchmark, manufacturers may be less willing to negotiate more generous discounts beyond those required by VHCA for active military, military retirees, and other veterans. Finally, individuals currently relying on collaborative negotiations through the RxOC—including some Ohio cities, counties, school districts, health consortiums, and others—could experience higher drug prices if significant numbers of state programs leave the collaborative and thereby reduce the purchasing power of the remaining programs to negotiate the most favorable pricing.

Discussion

While it is not believed that negotiations with manufacturers and others in the supply chain would be sufficient to generate the significant additional discounts to achieve the benchmark net cost, state entities would be expected to do their best to achieve additional discounts or cost reduction, as discussed in section 5 above. It should be expected that manufacturers, wholesalers, and pharmacies would seek to recover any price concessions they provide to state purchasers through increased costs (reduced discounts) to other third-party payers. This could impact the discounts offered to employer-sponsored benefit plans and other payers.

There is also significant concern being expressed by some veterans groups[34] that, based upon the experience following the 1990 enactment of the federal Medicaid rebate program, any effort to achieve the VA discounts for other large purchasers (like states) would be expected to result in higher costs for the VA. While the underlying price concessions for the Big Four federal agencies are now mandated in federal law, it should be expected that the additional discounts the VA negotiates today could be jeopardized if manufacturers actually begin to offer significant additional price concessions to other purchasers. In fact, an internal memo prepared by the Department of Veterans Affairs identifies the threat of a loss to the VA in the amount of $3.8 billion dollars. The memo cites both the California ballot measure and the Ohio initiative, and suggests that the passage of the California ballot measure would result in the elimination of *all* non-statutorily required and *all* non-contractually required discounts; e.g. $3.8 billion dollars.[35] Increased costs to an already stressed VA system would be a significant consequence and, if these increased costs are passed on to veterans who rely on the VA for pharmacy coverage, could impact veterans' access to drugs.

Further, collaborative purchasing relationships, such as the RxOC, Ohio's Best Rx, and the Ohio Pharmacy Service Center, bring together many entities in order negotiate lower drug prices. For example, in the case of the RxOC, this includes cities, counties, school districts, health consortiums and others local entities and organizations[36] which benefit today from the participation of state programs. If state entities are not able to continue these arrangements (see more detailed program-specific discussion below in section 7), the loss of this purchasing power could result in higher prices for both the targeted state and non-targeted entities, in turn, affecting access.

7. ANALYSIS OF INDIVIDUAL PROGRAMS AND STATE ENTITIES IMPACTED BY THE PROPOSED STATUTE

This section provides a brief analysis of the potential impact of the Proposed Statute on the specific state pharmacy programs that were interviewed for this report. Any comments or conclusions presented here should not be considered as reflecting official program policy, nor is this report attempting to predict with certainty what any state entity would do under the Proposed Statute. Further, the purpose of this

[34] National Military and Veterans Alliance. Letter to Secretary McDonald, U.S. Department of Veterans Affairs. Dated April 26, 2016, stating "We write to express serious concerns about pending ballot measures in California and Ohio that would, we believe, increase the cost of prescription drugs for veterans, active duty military, their dependents and military retirees.

[35] VHA Issue Brief, Department of Veterans Affairs, *Threat to Department of Veterans Affairs' Pharmaceutical Discounts* (http://www.noprop61.com/pdfs/VA-Memo-re-Impact-of-Prop-61-Given-to-LAO.PDF)

[36] See Attachment 4 for a complete listing of the RxOC members.

report was *not* to conduct a detailed analysis of the *financial impact* of the Proposed Statute on any specific program. Rather, the priority was to understand how the program currently operates and assess the potential impact.

A. Drug Pricing in the Medicaid Program

Medicaid is by far the largest state program impacted by the Proposed Statute. In State Fiscal Year (SFY) 2016 year to date, over 3 million Ohioans were insured by Medicaid. Roughly 80% of them received care through one of five managed care plans. For those served in managed care, the pharmacy benefit is part of the managed care benefit and included in the per member per month payment made to MCPs. In Federal Fiscal Year (FFY) 2014 about $1.5 billion was spent on pharmacy services between the managed care plans and Medicaid FFS. Almost $750 million in rebates were invoiced to drug manufacturers. With this information in mind, it is important to understand the similarities and differences between the VA, Medicaid FFS, and Medicaid managed care.

Today, the VA's and Medicaid's statutorily protected price for innovator drugs is about the same: 24% off the VHCA-defined AMP[37] (called the non-federal average manufacturer's price or non-FAMP) for the VA and 23.1% off AMP for Medicaid for drugs provided through both the FFS and managed care delivery systems. While the calculation of the AMP for the VA and the AMP for Medicaid is not identical, a Congressional Budget Office (CBO) 2005 analysis found significant similarity in the price results per drug.[38] Unlike the VA, Medicaid also receives 13% off AMP for generic drugs provided through both the FFS and managed care delivery systems. While many manufacturers offer the VA a discounted price on generic drugs, they are not required to do so by law.

Further, as discussed in section 6(A) above, the VA may receive additional discounts beyond those reflected in the FSS price and their national contracts, such as for time-bound discounts on specific drugs. State Medicaid programs, in turn, may realize additional rebates for drugs through state-level supplemental rebate agreements with manufacturers. Medicaid's managed care plans may also negotiate additional discounts with manufacturers.[39]

Although the VA and Medicaid arrive at their net purchase prices in different manners, and not all discount information is publically available in either program,[40] it is reasonable to assume that *Medicaid and the VA are approximately equivalent in terms of the net discounts/rebates realized from manufacturers.* If this were the comparison being sought in the Proposed Statute, there would be little to nothing to be gained for Medicaid under the Proposed Statute except for the significant administrative cost of demonstrating compliance.

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[37] See FN 15

[38] Congressional Budget Office, Congress of the United States, Prices for Brand-Name Drugs Under Selected Federal Programs (2005).

[39] U.S. Gov't Accountability Office, GAO-14-578 (2014) GAO found that the state supplemental rebates, included in the 2010 MAX data, in aggregate, were equivalent to 4 percent of Medicaid expenditures for all drugs reimbursed in the 3rd calendar quarter.

[40] Drug-specific rebate information is proprietary information that must be protected from disclosure in a manner that is consistent with Social Security Act §1927.

However, unlike the VA, Medicaid does not buy drugs in bulk or otherwise directly buy from wholesalers and then distribute or dispense drugs through its own pharmacy system. So Medicaid has additional costs in its net cost paid for drugs that are associated with getting prescriptions filled by a retail pharmacy—costs that are not reflected in the benchmark VA price. Medicaid must pay a cost that reasonably reflects the cost of a pharmacy acquiring the drug (which may include the costs of the wholesaler as well as the pharmacy) and a professional dispensing fee.

There is further evidence that Medicaid already realizes a significantly beneficial net cost for drugs. The GAO compared Medicaid pharmacy purchasing nationwide to various federal government purchasers. The June 2014 GAO report found that "Medicaid paid a lower average net unit price—that is, the price after subtracting any beneficiary-paid amounts and post-purchase price adjustments across the entire sample of 78 prescription drugs and the subsets of brand-name and generic drugs."[41]

However, under the Proposed Statute Medicaid's benchmark for its net cost must be at or below the VA's lowest price paid. Therefore, Medicaid might be forced to find ways to reduce the price paid even further to offset the costs of distributing/dispensing drugs to beneficiaries. Options might include:

- a more limited preferred drug list (expanded use of prior authorization to achieve higher supplemental rebates in FFS);
- cuts to pharmacy reimbursement (this would require federal CMS approval under new regulations that require states to establish prices that reflect actual acquisition price of drug products, plus reasonable professional dispensing fees);[42]
- restriction in the use of retail pharmacy outlets (requiring or providing incentives for mail order); and/or
- higher co-pays for consumers (federal Medicaid law restricts state options with regard to cost-sharing, so this would never be a significant source of cost offset).

States are required by federal law to make available under the Medicaid program all FDA-approved covered outpatient drugs produced by a manufacturer that has entered into a rebate agreement. Therefore, states would not be able to implement a closed Medicaid formulary or refuse to purchase drugs, even if the benchmark price is not achieved. This could further reduce a manufacturer's willingness to negotiate significantly greater discounts with the state.

Further, *Medicaid might be at risk of losing valuable supplemental rebate arrangements currently in place with manufacturers*, since the Proposed Statute would prohibit the state from having any agreement with manufacturers for drugs that failed to reach the benchmark net cost after retail pharmacy costs are included. [43]

B. Ohio's HIV Drug Assistance Program

On August 18, 1990, Congress passed the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, named for an Indiana teen who lost his life to AIDS. The program provides a comprehen-

[41] U.S. Gov't Accountability Office, GAO-14-578, Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices (2014)
[42] Medicaid Covered Outpatient Drugs 81 Fed. Reg. 5169 (Feb. 1, 2016) (to be codified at 42 C.F.R. 447)
[43] See FN 21

sive system of care and essential support services for people living with HIV who are uninsured or underinsured. The U.S. Secretary of Health and Human Services establishes requirements for the core therapeutic products that must be provided by Drug Assistance Programs under Ryan White.[44]

Ohio's program is administered by the Ohio Department of Health (ODH) and serves approximately 4,900 individuals with incomes up to 300% of the federal poverty level (FPL). ODH purchases the drugs in bulk for the program and then distributes the drugs to a mail order pharmacy, which in turn dispenses to program participants. ODH is a member of the National Association of State AIDS Directors (NASAD), which negotiates on behalf of all AIDS programs to secure optimal drug pricing. Through this association, Ohio can access drugs at a price below the federal 340B price, to which they are also entitled under the federal law. See Attachment 3, Example# 2 for a diagram of current purchasing, rebate, and other product flow information for the Ohio HIV Drug Assistance Program.

While a complete review of the program pricing was not undertaken, state officials reported that a sample review found that Ohio's drug costs[45] are consistently below the Big Four and FSS prices. The Ohio program also receives some manufacturer rebates. Costs of mail order distribution would not be included in the net cost of the drug product, since that cost is incurred after the drug is purchased. Based on the feedback from ODH regarding the existing prices, it can be concluded that the Proposed Statute might have no impact on the drugs administered through this program. This seems to contradict what the sponsors of the Proposed Statute have indicated regarding reduced costs of drugs for HIV/AIDS treatment, at least with regards to the HIV Drug Assistance Program.[46]

C. The Impact of the Proposed Statute on Other State Entities

While this analysis concludes that it is reasonable to assume that the state Medicaid program and the Ohio HIV Drug Assistance Program already experience discounts and rebates on par with the VA (at least with regard to discounts off AMP), it was not found to be true for the pharmacy programs across most of the rest of the state entities we interviewed. However, as discussed above in section 6(D) above, it is not reasonable to believe that manufacturers would be willing to agree to significant additional discounts in order to meet the benchmark net cost for most programs.

Attachment 3 contains diagrams which represent the way in which drug prices are negotiated and reimbursed for several of the individual programs interviewed.[47] As depicted, the key components include price/rebate negotiation responsibility and payment flow, the rebates and discount flow, and the product flow. These models demonstrate the complexity and nuances of state entities' drug purchasing programs. Each of the arrows in the charts describes a relationship that would have to be reviewed, reprocured, renegotiated, and restructured if the Proposed Statute is to be implemented. All of this would be undertaken in an effort to eliminate cost and get below what is, for most state pharmacy programs, an unequal and unachievable target benchmark price: the lowest price paid for the same drug by the VA.

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[44] http://hab.hrsa.gov/manageyourgrant/files/habpartbmanual2013.pdf

[45] Ohio receives prices negotiated on behalf of a number of states by the National Association of State AIDS Directors (NASAD)

[46] Tracy Jones, Executive Director of the AIDS Taskforce of Greater Cleveland, quoted in the Business Wire, December 22, 2015. http://www.businesswire.com/news/home/20151222006046/en/AHF-Advocates-Submit-171205-Signatures-2016-Drug

[47] See FN 10.

With this in mind, the following is a brief summary of the interviews conducted and an assessment of what each entity would be able to do or might be forced to do, in order to comply with the Proposed Statute. Even if each entity were to take the listed actions below, it is highly unlikely that the entity's response would be adequate to achieve full compliance with the Proposed Statute's "net cost" requirements.

The interviews focused on how each program *currently operates*. Administrators were not asked to opine on how they *would* comply, so it is important to note that any conclusions are solely those of the report authors, based on an informed assessment of the possible or likely responses and recognizing that other responses are also possible. The conclusions do not purport to represent the views of any program or of the state administration.

1) ***Ohio Pharmacy Service Center operated by the Department of Mental Health and Addiction Services (ODMHAS)***. OPSC directly purchases drugs in bulk and then distributes drugs and other supplies to governmental and qualifying entities in Ohio. OPSC's net cost does not include its costs of distribution to other agencies. State entities, such as the Department of Rehabilitation and Corrections or Youth Services do, however, pay a price that reflects distributions costs when they receive drugs from OPSC. Unless the entire purchasing relationship could be legally reconfigured to separate the distribution costs (e.g., by creating a fee outside of the drug purchase), it is questionable whether the OPSC operation could achieve the net cost for the agencies it serves and continue to cover its own administrative costs without additional state funding. Absent a state appropriation for operating costs, OPSC might no longer be able to serve as a central administrative pharmacy resource for state entities that provide treatment to individuals and it is not clear what better alternative would be available to these entities to comply with the Proposed Statute. See Attachment 3, Example #1 for a diagram of current purchasing, rebate, and other product flow information.

   OPSC could continue the existing relationship with community behavioral health agencies (as non-state entities, these entities would not have to achieve the benchmark net cost target), if OPSC could at least achieve the additional deep discounts required to meet the benchmark net cost for its own acquisition. However, this represents only a small portion of their current business. If the operation of the OPSC cannot be sustained, this might increase prices to community behavioral health agencies, which benefit today from OPSC volume purchasing.

2) ***Ohio Department of Health (ODH)***. ODH operates a number of programs that both directly and indirectly purchase drugs for Ohioans, including vaccines, bioterrorism response, and Title X family planning.

   a) ***ODH Vaccines, including Hepatitis B immune globulin (HBIG), Diptheria Tetanus (DT) vaccines, a small amount of other childhood vaccines, and influenza vaccine; but excluding Vaccines for Children (VFC) vaccines and VFC influenza vaccine***. Most of the vaccines provided through ODH are obtained by ODH from federal sources at no cost to the state and would not appear to be impacted by the Proposed Statute. However, a small amount of vaccine is purchased by ODH using state contracts administered by the Department of Administrative Services (DAS). The DAS contracts would have to be rebid, in an attempt to negotiate net costs to be at or below the lowest price paid by the VA. Since most of these vaccines are distributed to health departments or hospitals, the cost of distribution is already

outside of the drug purchasing arrangement and would not be a factor. In light of the purposes of these medications and the relatively very small volume, it is hard to say whether or not the target price could be negotiated voluntarily. If the target net cost could not be obtained for the ODH purchases, the program might not be able to continue to provide this supply of vaccines.

b) ***ODH Bioterrorism response***. There probably would be no short-term impact on the doses of drugs maintained to treat first responders in the event of bioterrorism, because a significant stockpile exists currently.

c) ***ODH Title X family planning services***. Currently the state distributes federal funds combined with state matching funds to approximately 132 Title X grantees across Ohio, including health departments, and women's and other health centers, with the federal requirement to provide a "broad range of...methods and services."[48] The grantees purchase and dispense medications and are eligible for federal 340B drug pricing. Given the state's role in funding, the grantees would have to procure drugs consistent with the requirements of the Proposed Statute. If the 340B prices would not be as favorable as the VA prices,[49] additional price reductions would have to be secured or other changes made to achieve the net cost target. If the grantees could not secure these prices, there would be a question of whether the federal statutory requirements of Title X are specific enough to override the Proposed Statute. We do not assume that if it is a federal program, it would automatically be exempted from the Proposed Statute.

3) ***Ohio Department of Administrative Services (DAS)****:* DAS negotiates the contract for state employee prescription benefits. The Department operates the program through a PBM that reimburses for prescription drugs purchased by these individuals and their covered dependents.

If the state employee pharmacy program could not achieve the benchmark net cost through voluntarily negotiated additional price concessions from manufacturers, the benefit plan might have to consider changes to the benefit or the network. State employees already utilize a fair degree of mail order drugs, because mail order is less expensive than relying solely on retail pharmacies. An even greater reliance on mail order might need to be considered. Another option might be to shift additional costs to employees through higher copays. Finally, there could be further constraints on the formulary, with decreased access to certain drugs, either to drive better discounts on drugs included on the formulary or to exclude reimbursement for any drugs the state entity would be prohibited from purchasing if the benchmark net cost is not achieved. For many state employees, prescription drugs as well as other health care services are subject to collective bargaining negotiations, so any of these changes would likely have to be secured with other concessions.

Note: DAS also is responsible for the procurement of several state purchasing contracts, including many mentioned throughout this report. In light of this, it is important to understand that any change resulting from the Proposed Statute would begin with the procurement process administered by

[48] Title X of the Public Health Service Act, 42 U.S.C. 300, et seq.
[49] Elizabeth Hill, Legislative Analyst Office, California. "Lowering the State's Costs for Prescription Drugs." (February 2005).

DAS. However, for ease of understanding, each contract for drug procurement was addressed in the context of the entity with the day-to-day operating responsibility for a pharmacy program.

4) ***The Ohio State University Wexner Medical Center****:* The medical center associated with The Ohio State University is the only public university hospital in the state. As a state entity, it would be subject to the Proposed Statute. The medical center directly purchases drugs in bulk for both inpatient and outpatient use at its facilities, as well as for dispensing to consumers through its retail pharmacy. The medical center negotiates directly with wholesalers and manufacturers to obtain its supply of drugs. See Attachment 3, Example #3 for a diagram of current purchasing, rebate and other product flow information.

   It is not clear that the medical center would be more successful than other state entities in negotiating the additional deep discounts needed in order to continue to purchase drugs for use in the medical center and its retail pharmacy under the provisions of the Proposed Statute. While the medical center may use a formulary of preferred drugs, both to promote quality and also to obtain favorable pricing concessions, it is inconceivable that the medical center could operate without having access to the full of array of medically necessary drugs for treatment of the complex array of conditions seen at the medical center. Since federal Medicare conditions-of-participation requirements specify that a hospital must have a process to approve and procure medications that are not on the hospital's medication list,[50] this would appear to preempt the Proposed Statute, at least in part. The medical center's retail might not be exempted.

5) ***Rx Ohio Collaborative (RxOC)****:* The RxOC is a purchasing collaborative that was founded by the Retirement Systems of Ohio and The Ohio State University. Over 125 organizations are engaged with the RxOC to achieve lower costs and other value-added services for their pharmacy coverage programs. These include the Ohio Public Employees Retirement System, the School Employees Retirement System, the State Teachers Retirement System of Ohio, The Ohio State University, the Highway Patrol Retirement System of Ohio, and a number of other state universities. In addition to the state level entities, participants include some county governments, schools, health consortiums and others. See Attachment 3, Example #4 for a diagram of current purchasing, rebate and other product flow information.

   Each member or plan sponsor of the RxOC has a contract with a PBM for pharmacy benefit administration. Each plan sponsor has control over the benefit design, including formulary, prior authorization, and determining the level of co-payments. The RxOC provides a variety of "value-added services" to participating members, including data analytics, administering the collaboration, providing health navigation assistance for members and families, and providing medication management or other health programs. Fundamentally, the RxOC brings together more than 625,000 lives[51] collaboratively, in order to negotiate with the PBM for advantageous drug pricing. The PBM then administers the benefit and distributes the product, through a network of retail, mail order, and specialty pharmacies.

[50] CFR §482.25 (b)(9) and Interpretive Guidelines.
[51] See Attachment 4 for a listing of all member organizations participating in the RxOC.

The state entities that participate in the RxOC would each be required to meet the net cost benchmark of not greater than the lowest cost paid for the same drug by the VA. If the RxOC negotiated arrangements could not achieve this net cost, the entities would need to identify alternative strategies. There is no reason to assume that these entities could be more successful in negotiations on their own than through this collaboration, which is intended to increase the market leverage of these state programs. It was clear from the interviews that the current net cost realized by the state entities participating in the collaborative were significantly short of the price guaranteed to the VA under the VHCA, even before additional discounts to the VA are considered.

Some entities might find they no longer could afford the costs of the value-added services currently obtained through RxOC participation, because these services are financed today through a fee that is assessed as a part of each drug reimbursement transaction (in effect, a share of the savings realized as a result of the RxOC collaborative negotiation). The loss of participation of the state programs could greatly reduce the purchasing leverage of the collaborative for the non-targeted entities that currently participate. These entities could see their drug prices increase. Alternatively, the RxOC would need to find a legal way to restructure its financing so that the costs of participation in value added services are separated from the net cost of the drug purchase transaction and therefore not included in the net cost calculation.

Again, these state entities could also attempt to reduce net cost for drugs through cost shifting to consumers through higher co-payments, but it is expected these efforts would fall far below what would be needed to bring the net cost to the VA benchmark. Therefore, these programs could be required to limit access to drugs, either through tighter formularies to drive better discounts or, if they cannot achieve the benchmark net cost, through eliminating some drugs from coverage.

6) ***Ohio Public Employee Retirement System (OPERS):*** OPERS and the other state employee retirement systems pay for drugs by providing an outpatient pharmacy benefit to some state retirees and covered dependents enrolled in its health care plan. Generally, the majority of these drugs are provided through a PBM arrangement, collaboratively negotiated with the RxOC. Like other third-party payer programs, options would include those outlined in section 6 (E) above. See the discussion of the RxOC above.

7) ***Ohio Bureau of Workers' Compensation (BWC):*** BWC operates two funds for the purposes of assisting injured workers: a state insurance fund that provides coverage for most employers in the state and a program where some employers can be self-insured for coverage under the state law. The assessment indicates that the self-insured arrangements do not involve the state as a direct or indirect purchaser of prescription drugs and would therefore not be subject to the Proposed Statute. However, the drug coverage provided under the state insurance fund would be impacted by the Proposed Statute. The BWC contracts with a PBM to administer pharmacy claims for the state insurance fund. The reimbursement for drugs dispensed to injured workers under this arrangement is established in regulations promulgated by the BWC.

BWC currently uses a separate contractor to obtain rebates from manufacturers for brand name drugs, but these rebate arrangements would need to be dramatically larger to achieve the net cost benchmark. Beyond seeking additional rebates, the entity's options would be similar to the other entities that are third party payers. However, the biggest difference is that BWC also would have to

amend its current regulations to seek additional discounts for its retail pharmacy prices to further reduce the net cost paid for drugs dispensed to injured workers. BWC might be forced to further limit the drugs available under the program but presumably would not be able to impose non-clinically appropriate limitations without jeopardizing the effectiveness of the workers compensation program in treating injured workers.

8) ***Ohio University (OU):*** The University is one among many state colleges and universities that offer insurance coverage that includes a pharmacy benefit for students who are otherwise not covered by health insurance. While there does not appear to be a specific appropriation that specifically supports the purchase of drugs at Ohio University, the University is closely involved in the design and selection of the benefit package and also provides significant administrative support for the administration of the coverage (e.g., collects premium amounts from students and passes funds to the insurer, which reduces administrative costs for the insurer). This assessment concluded that the program could potentially be impacted by the Proposed Statute. See Attachment 3, example #4 for a diagram of purchasing, rebate and other product flow information.

   If such an arrangement would be required to comply with the net cost benchmark, the University would have a variety of options to consider. One option might be to find a way to extricate itself from its close involvement/administration of the arrangement. It is hard to estimate to what degree a loss of administrative support from the university might impact the cost of coverage for participating students, but it could certainly increase the administrative costs for the insurer, and these costs would likely be passed on to students.

9) ***BestRx Program:*** The BestRx program contracts with a PBM to obtain discounted drug pricing and rebates at participating pharmacies and through mail-order pharmacies. There is no state appropriation supporting the actual purchase of drugs; instead, individual consumers pay out-of-pocket for drugs at participating pharmacies. As a voluntary discount program, there is no guarantee of the types of drugs that are made available. Only negotiated drugs are available at a discount. See Figure 8 for a diagram of contracting, rebate and other product flow information.

   To comply with the Proposed Statute, there would need to be a re-procurement to assure that only those drugs that meet the net cost benchmark are available. This presumes that the net cost to the state entity would be calculated as equal to the cost to the consumer who purchases the drug. Given the drug price cuts that would be needed and the relatively small number of actual users of the discount card, it is unlikely that the current scope of agreements with manufacturers could be maintained, which would reduce the number of drugs available at discount. It is questionable whether this program would continue to be viable under the Proposed Statute.

8. FINAL CONCLUSIONS

Our research, interviews and prior experience leads us to several conclusions regarding the Proposed Statute. In summary, we find that it is highly unlikely that the Proposed Statute could be implemented and highly unlikely, in any case, that it would achieve its stated purposes of lowering prescription drug prices for consumers. We further find that the Proposed Statute would negatively impact pharmacy programs that are not the intended target, including those serving veterans and those covered by private insurance, as well as potentially increase the cost to school districts, senior citizens, and some retirees who

would lose existing collaborative purchasing arrangements. Finally, we conclude the Proposed Statute could limit access to certain drugs for some individuals, cause of a loss of state Medicaid supplemental rebates and potentially limit the use of local pharmacies in some programs.

A. It is highly unlikely the Proposed Statute could be implemented.

First, complete information regarding what drugs the VA purchases and the lowest price the VA pays is not generally available. Second, even if all necessary information could be obtained, the VA's lowest price paid is not a reasonable net cost target for state drug programs. Third, it is not reasonable to assume that a large number of manufacturers would be willing to voluntarily negotiate the deeper discounts/rebates needed to achieve the benchmark net cost.

B. Even if it could be implemented, it is highly likely that the Proposed Statute would fail to achieve its purpose.

Medicaid, with roughly three million people and $1.5 billion in retail pharmacy expenditures, is the largest state program targeted by the Proposed Statute. Ohio's HIV Drug Assistance Program is also mentioned prominently by proponents as a program that will benefit, suggesting that it will cost the state less to serve individuals with HIV/AIDS.

Although the VA and Medicaid arrive at their net purchase prices in different manners, and not all discount information is publically available in either program, it is reasonable to assume that Medicaid and the VA are approximately equivalent in terms of the net discounts/rebates realized from manufacturers. As such, there would be little to nothing to be gained for Medicaid under the Act, though at a significant administrative cost of demonstrating compliance.

In addition, if the state would be prohibited from maintaining rebate agreements for drugs that failed to reach the benchmark net cost after retail pharmacy costs are included, then Medicaid might be at risk of losing valuable supplemental rebate arrangements currently in place with manufacturers.

State program officials at Ohio's HIV Drug Assistance Program indicated that when comparing their current prices, Ohio's drug costs are already consistently below the Big Four and FSS prices. The Ohio program also receives some manufacturer rebates. Based on the feedback from ODH regarding the existing prices, we conclude that the Proposed Statute might have no impact on the drugs administered through this program. This seems to contradict what the sponsors of the Proposed Statute have indicated regarding reduced costs of drugs, at least with regards to the HIV Drug Assistance Program.

In addition to the potential of losing existing supplemental Medicaid rebates, the potential also exists that the state could decide to forego other federal funds, where compliance is not possible[52] or the administrative cost outweighs the federal program funding.

[52] Federally funded programs are not exempt from the Proposed Statute. A deeper analysis would be needed to determine whether the requirements and statutory language of the federal program is specific enough to override the language of the Proposed Statute, to be exempted.

Beyond Medicaid and the Ohio HIV Drug Assistance Program, the remaining state entities would need to take other extreme measures in an attempt to comply with the mandate. No single approach would be possible or even allowable in all cases. Possible responses and unintended consequences include:

1. negotiating below the target VA price with manufacturers, so that distribution costs can still be accommodated within the state's net costs;
2. using additional utilization management or other prescriber education/interventions in order to steer medication use;
3. putting restrictions on the types and selection of drugs that would be available through a closed or limited formulary;
4. reducing the cost of distribution (e.g., lowering retail prices or reducing or eliminating retail pharmacies and using mail order exclusively), and eliminating value-added services, such as data analytics or health navigation assistance to members;
5. increasing the copayments or otherwise shifting costs to the end-consumer (employee, child, or individual with a disability or health condition;
6. eliminating the pharmacy program altogether; and/or
7. invalidating existing state contracts or purchasing agreements, restructuring the procurement, and revising the associated relationships, in order to remove as much cost as possible, and then creating a different way for those costs to be paid, such as a separate fee or agreement.

C. It is also highly likely that pharmacy programs of non-targeted entities would be negatively impacted.

Pharmacy programs of entities that are not the intended target of the Proposed Statute would likely be impacted as a result of potential cost-shifting across the supply chain as manufacturers, wholesalers, and pharmacies attempt to respond to the state's seeking deeper price concessions. There are also significant concerns about the impact on future VA drug prices.[53] If states attempt to use the VA price concessions as a benchmark, manufacturers may be reluctant to continue to negotiate additional VA discounts for brand name drugs beyond the FCP guaranteed by the VHCA for active military, military retirees, and other veterans. They may also be less favorably inclined to extend negotiated discounts on generic drugs. Further, as noted in the VA memo,[54] the loss of the additional discounts is estimated to be $3.8 billion dollars. Increased costs to an already stressed VA system would be a significant consequence and, if these increased costs are passed on to veterans who rely on the VA for pharmacy coverage, could impact veterans' access to drugs.

Finally, if state programs cannot continue their participation in the collaborative, higher drug prices could be likely for those organizations currently relying on collaborative purchasing through the RxOC, including Ohio cities, counties, school districts, health consortiums and others.

[53] National Military and Veterans Alliance. Letter to Secretary McDonald, U.S. Department of Veterans Affairs. Dated April 26, 2016, stating "We write to express serious concerns about pending ballot measures in California and Ohio that would, we believe, increase the cost of prescription drugs for veterans, active duty military, their dependents and military retirees.
[54] See FN 27

LIST OF ATTACHMENTS

1. Language of the Proposed Statute: Ohio Drug Price Relief Act

2. Detailed analysis of the language of the Proposed Statute

3. Flow charts Examples of Purchasing relationships from Selected State Interviews
    a. Example #1 Wholesale Contract: ODMHAS Pharmacy Service Center
    b. Example #2 Wholesale and Dispensing Contracts: ODH HIV Drug Assistance Program
    c. Example #3 Wholesale Contract: Ohio State University Wexner Medical Center (OSUWMC)
    d. Example #4 PBM Contract: Rx Ohio Collaborative for Retirement Systems, Some State Universities, Others

4. List of member organizations participating in the RxOC

5. Methodology: Interviews with Key Programs

6. VHA Issue Brief, Department of Veterans Affairs, Threat to Department of Veterans Affairs' Pharmaceutical Discounts

7. Brief biographies for the authors of this report

ATTACHMENT 1: Text of the Ohio Drug Price Relief Act (the "Proposed Statute")

Be it Enacted by the People of the State of Ohio that the following chapter and section are added to Title I of the Revised Code.

Chapter 194: Drug Price Relief

Section 194.01

A. **Title.** This Act shall be known as "The Ohio Drug Price Relief Act" (the "Act").

B. **Findings and Declarations**. The People of the State of Ohio hereby find and declare all of the following:
1) Prescription drug costs have been, and continue to be, one of the greatest drivers of rising health care costs in Ohio.
2) Nationally, prescription drug spending increased more than 800 percent between 1990 and 2013, making it one of the fastest growing segments of health care.
3) Spending on specialty medications, such as those used to treat HIVIAIDS, Hepatitis C, and cancers, are rising faster than other types of medications. In 2014 alone, total spending on specialty medications increased by more than 23 percent.
4) The pharmaceutical industry's practice of charging inflated drug prices has resulted in pharmaceutical company profits exceeding those of even the oil and investment banking industries.
5) Inflated drug pricing has led to drug companies lavishing excessive pay on their executives.
6) Excessively priced drugs continue to be an unnecessary burden on Ohio taxpayers that ultimately results in cuts to health care services and providers for people in need.
7) Although Ohio has engaged in efforts to reduce prescription drug costs through rebates, drug manufacturers are still able to charge the State more than other government payers for the same medications, resulting in a dramatic imbalance that must be rectified.
8) If Ohio is able to pay the same prices for prescription drugs as the amounts paid by the United States Department of Veterans Affairs, it would result in significant savings to Ohio and its taxpayers. This Act is necessary and appropriate to address these public concerns.

(C) Purposes and Intent.

The People of the State of Ohio hereby declare the following purposes and intent in enacting this Act:

1) To enable the State of Ohio to pay the same prices for prescription drugs as the prices paid by the United States Department of Veterans Affairs, thus rectifying the imbalance among government payers.
2) To enable significant cost savings to Ohio and its taxpayers for prescription drugs, thus helping to stem the tide of rising health care costs in Ohio.
3) To provide for the Act's proper legal defense should it be adopted and thereafter challenged in court. for the same drug by the United States Department of Veterans Affairs.

(D) Drug Pricing.

1) Notwithstanding other provision of the law and insofar as may be permissible under the federal law, neither the State of Ohio, nor any state department, agency or other state entity including, but not limited to the Ohio Department of Aging, the Ohio Department of Health, the Ohio Department of Insurance, the Ohio Department of Jobs and Family Services and the Ohio Department of Medicaid shall enter into any agreement with the manufacturer of any drug for the purchase of a prescribed drug, or agree to pay, di-

rectly or indirectly, for a prescribed drug, unless the net cost of the drug, inclusive of cash discounts, free goods, volume discounts, rebates, or any other discount or credits, as determined by the purchasing department, agency or entity, is the same as or less than the lowest price paid for the same drug by the United States Department of Veterans Affairs.

2) The price ceiling described in subsection (1) above also shall apply to all the programs where the State of Ohio or any state department, agency or other state entity is the ultimate payer for the drug, even if it did not purchase the drug directly. This includes, but is not limited to, the Ohio Best Rx Program and the Ohio HIV Drug Assistance Program. In addition to agreements for any cash discounts, free goods, volume discounts, rebates, or any other discounts or credits already in place for these programs, the responsible department, agency or entity shall enter into additional agreements with drug manufacturers for further price reductions so that the net cost of the drug, as determined by the purchasing department, agency or entity is the same as or less than the lowest price paid for the same drug by the United States Department of Veterans Affairs.
3) All state departments, agencies and other state entities that enter into one or more agreement with the manufacturer of any drug for the purchase of prescribed drugs or agreement to pay directly or indirectly for prescribed drugs shall implement this section no later than July 1, 2017.
4) Each such department, agency or other state entity, may adopt administrative rules to implement the provisions of this section and may seek any waivers of federal law, rule, or regulation necessary to implement the provisions of this section.
5) The General Assembly shall enact any additional laws and the Governor shall take any additional actions required to promptly carry out the provisions of this section.

(E) Liberal Construction.

This Act shall be liberally construed to effectuate its purpose.

(F) Severability.

If any provision of this Act, or part thereof, or the applicability of any provision or part to any person or circumstances, is for any reason held to be invalid or unconstitutional, the remaining provisions and parts shall not be affected, but shall remain in full force and effect, and to this end the provisions of this Act are severable. If this Act and another law are approved by the voters at the same election with one or more conflicting provisions and this Act receives fewer votes, the non-conflicting provisions of this Act shall go into effect.

(G) Legal Defense.

If any provision of this Act is challenged in court, it shall be defended by the Attorney General of Ohio. The People of Ohio, by enacting this Act, hereby declare that the committee of individuals responsible for the circulation of the petition proposing this Act ("the Proponents") have a direct and personal stake in defending this Act from constitutional or other challenges. In the event of a challenge, any one or more of the Act's Proponents shall be entitled to assert their direct and personal stake by defending the Act's validity in any court of law, including on appeal. The proponents shall be indemnified by the State of Ohio for their reasonable attorney's fees and expenses incurred in defending the validity of the challenged Act. In the event that the Act or any of its provisions or parts are held by a court of law, after exhaustion of any appeals, to be unenforceable as being in conflict with other statutory or constitutional provisions, the Proponents shall be jointly and severally liable to pay a civil fine of $10,000 to the State of Ohio, but shall have no other personal liability to any person or entity.

ATTACHMENT 2: Analysis of the Language of the Proposed Statute

A. General comments

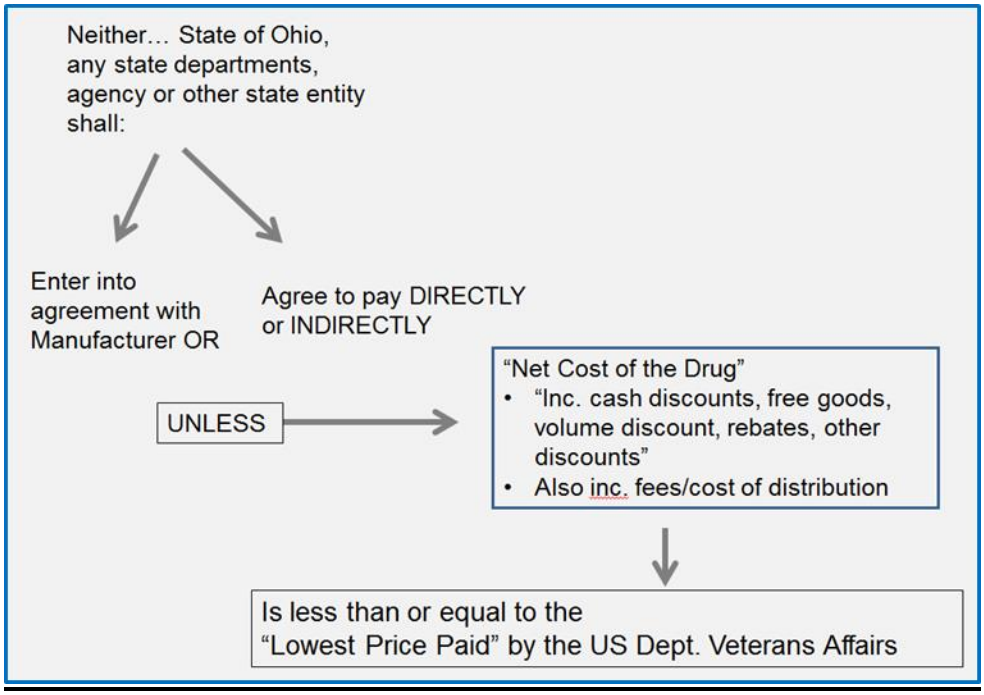
- **Chapter 194 is new chapter** of Title 1 of the Ohio Revised Code (O.R.C.), State Government. As such, it would apply broadly to the functions and programs of state government, with no existing definitions or cross references to existing statutory definitions which would apply, other than the language of the Ohio Drug Price Relief Act (the Proposed Statute) itself.
- "The Act shall be **liberally construed** to effectuate its purpose." This is a common legal principle, instructing that, if the words are not clear, the deemed or stated purpose should be taken into account. (Black's Law Dictionary). For this purpose we assume that the intent is to include the most drugs, and to apply the VA price as broadly as possible.
- The combination of these two facts requires that **our analysis take a broad, but reasonable and professionally informed assessment** of the meaning. Assuming that the language is adopted, without legislative clarification, the only true determination of the meaning will be made by the courts through litigation.

The Petition: (D)(1) Text

- *Notwithstanding any other provision of law and*
- *Insofar as may be permissible under federal law,*
- *Neither the State of Ohio, nor any state department, agency or other state entity,*
    - *Including, but not limited to,*
        - *the Ohio Department of Aging,*
        - *the Ohio Department of Health,*
        - *the Ohio Department of Insurance,*
        - *the Ohio Department of Jobs and Family Services, and*
        - *the Ohio Department of Medicaid,*
- *Shall enter into any agreement*
    - *with the manufacturer for any drug*
        - *For the purchase of a prescribed drug OR*
- *Agree to pay,*
    - *Directly or*
    - *Indirectly,*
        - *For a prescribed drug,*
- *Unless the net cost of the drug, inclusive of cash discounts, free goods, volume discounts, rebates, or any other discounts or credits,*
    - *As determined by the purchasing department, agency or entity,*
    - *Is the same as or less than the lowest price paid for the same drug by the United States Department of Veterans Affairs.*

The following is a graphic representation of this language.

Figure 1 Schematic of the Language of the Ohio Drug Price Relief Act (The Proposed Statute)



B. Key Definitions and Interpretation of the Proposed Statute

Since the Proposed Statute is fashioned as a new chapter of the Ohio Revised Code (O.R.C.) no definitions are provided or incorporated by reference, other than the language of the Act itself. In the absence of definitions, the following identifies key definitions that we have adopted to guide our interpretation of the Proposed Statute.

1) State Department, state entity, state universities and state retirement systems are directly impacted by the Proposed Statute.
   a) The Act specifically references the "*State of Ohio, any state department, agency or other state entity."* Hereafter, we'll refer to this collection of entities as "State/Other Entities."
   b) The definition of "state department" is fairly straight forward. O.R.C. § 121.02 lists the administrative departments of state government.
   c) "State entity" is a concept used in multiple contexts, including immunity, prevailing wage, PERS, etc. As such, there is no generally applicable statutory definition. Given this, we have adopted the definition of "state" as defined in O.R.C. § 2743.01, the Court of Claims Act. This definition, in the context of state liability, provides a useful framework to analyze how the legislature and courts have classified various state entities, though not specifically in this context. Further, the definition is broad, which seems to be a reasonable assumption in light of the requirement to "liberally construe" the Proposed Statute.
      a. O.R.C. § 2743.01 State liability definition.
      As used in this chapter:

(A) "State" means the State of Ohio, including, but not limited to, the general assembly, the Supreme Court, the offices of all elected state officers, and all departments, boards, offices, commissions, agencies, institutions, and other instrumentalities of the state. "State" does not include political subdivisions.

(B) "Political subdivisions" means municipal corporations, townships, counties, school districts, and all other bodies corporate and politic responsible for governmental activities only in geographic areas smaller than that of the state to which the sovereign immunity of the state attaches.

d) State universities are also included under the definition of "state." A number of legal cases establish the proposition that a state university is an "instrumentality of the state" for purposes of defining "state" under O.R.C. § 2743.01.[55]

   a. O.R.C. § 3345.12 (A)(1) and (A)(2) "State institution of higher education" includes universities listed above, but also includes NE Ohio Medical University; community colleges; state community colleges; and technical colleges.
   b. O.R.C. §3345.011 State university is defined as follows*: "State university" means a public institution of higher education which is a body politic and corporate. Each of the following institutions of higher education shall be recognized as a state university: State university" means a public institution of higher education which is a body politic and corporate. Each of the following institutions of higher education shall be recognized as a state university: university of Akron, Bowling Green state university, Central state university, university of Cincinnati, Cleveland state university, Kent state university, Miami university, Ohio university, Ohio state university, Shawnee state university, university of Toledo, Wright state university, and Youngstown state university.*

e) County governments, municipalities, other political subdivisions are excluded from the definition of state department or entity, per the definition of O.R.C. § 2743.01 above. However, even if counties or other political subdivisions are not considered "state entities," they may be impacted by the Proposed Statute by virtue of state funding being used to pay for prescription drugs. In these cases, the state may be paying "indirectly".

f) There are several pension systems that provide health care for public sector members and or retirees. The pension systems are also included in our working definition of "state entity," relying on the definition of "state" in the Court of Claims Act. [56]

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[55] See "Mech. Contrs. Ass'n of Cincinnati, Inc. v. Univ. of Cincinnati", 152 Ohio App. 3d 466, 2003-Ohio-1837, 788 N.E. 2d 670, ¶ 41 (10th Dist.) ("The university, as a state institution, is an instrumentality of the state of Ohio within the meaning of the statute."); "Collins v. Univ. of Cincinnati", 3 Ohio App. 3d 183, 184, 444 N.E. 2d 459 (1st Dist. 1981) ("Under the Act, a state university is considered to be an instrumentality of the state, thus amenable to suit" in the Court of Claims); "Boggs v. State", 8 Ohio St. 3d 15, 17, 455 N.E. 2d 1286 (1983); "Conner v. Wright State Univ.", 10th Dist. Franklin No. 13AP-116, 2013-Ohio-5701, fn. 1 ("WSU is a state university created pursuant to R.C. 3352.01, and therefore, for the purposes of [the Court of Claims Act], falls within the definition of the state.")

[56] O.R.C. § 2743.02(A)(1) provides that the state waves its immunity from liability, and consents to be sued in the Court of Claims. However, to the extent that the state has previously consented to be sued, the chapter has no applicability. By virtue of O.R.C. § 145.09, the PERS board "may sue and be sued." Although it is not subject to the jurisdiction of the Court of Claims, as an entity which consented to being sued prior to the enactment of the Court of Claims Act, PERS satisfies the statutory definition of "state" in the Court of Claims Act. See "Jackson A&E Assocs. v. Public Emples. Ret. Sys.", 2003-Ohio-7033 (Ohio Ct. App. 10th Dist. 2003).

g) Using this set of definitions, Figure 3 above includes a listing of all entities that we have included as a state department or state entity, or where the state is indirectly paying for prescription drugs.

2) Definition of "drug."

There are a variety of definitions of "drug" which vary depending on the particular chapter or use of the term in the Ohio Revised Code.

O.R.C.§ 4729.01 is the definition used by Ohio's Board of Pharmacy. This is the definition that was used for this analysis. Note that this definition is very similar to that used by the FDA.[57]

> *a. "Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;*
>
> *b. Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;*
>
> *c. Any article, other than food, intended to affect the structure or any function of the body of humans or animals;*
>
> *d. Any article intended for use as a component of any article specified in division (E)(1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories."*

a) Note that the definition also includes biologics and biosimilars, such as vaccines.
b) In the absence of any specificity or indication to the contrary, this analysis is not limited to outpatient drugs and includes inpatient hospital drugs.
c) Also note that the definition of drug includes animal drugs, as well as human drugs. There is no basis to exclude animals, but purely for the efficiency of the analysis, veterinary drugs were not incorporated in this analysis.

3) Definition of a "prescribed drug."

This is another term that has a variety of definitions, depending on the statutory use. For this analysis the definition of "prescribed drug" includes all of the following:

a) A "drug" which requires a physician's prescription at the point that it will be dispensed.
b) Any "drug" where a prescription is required for a given health care program, even if the drug is otherwise available over the counter (OTC). For example, Medicaid will pay for OTCs if there is a prescription. Similarly, health savings accounts (HSAs) will consider OTCs as an allowable health care expense, if there is a prescription.
c) Another area of considerable ambiguity is formulas. Referencing the definition of drug above, would suggest that formulas are "food." However, specialized formulas for metabolic disorders or other special considerations might be ordered using a prescription as a matter of

[57] 21 U.S.C. §321(g)(1) (2014)

practice. Both formulas and specialized formulas are not regulated as a drug by the FDA, so neither was considered for the purposes of this analysis.[58]

d) For "drugs" administered in a hospital or office or physician administered drugs there was no basis to exclude these types of drugs; but given the complexity of the analysis, it was not attempt to describe the impact. Note that this group of drugs would be extraordinarily difficult to identify and to define their impact. These are typically included in the medical benefit of a health insurance plan, rather than in pharmacy benefit. Hospital administered drugs would rarely and inconsistently be itemized on a patient claim or bill.

C. Additional Key Definitions and Interpretation of the Proposed Statute

The Petition: (D)(2) Text

- *The price ceiling described in subsection (1) above also shall apply to all programs*
  - *Where the State of Ohio or any state department, agency or other state entity is the ultimate payer for the drug,*
    - *Even if it did not purchase the drug directly.*
  - *This includes, but is not limited to,*
    - *The Ohio Best Rx Program and*
    - *The Ohio HIV Drug Assistance Program.*
- *In addition to agreements for any cash discounts, free goods, volume discounts, rebates, or any other discounts or credits already in place for these programs,*
  - *The responsible department, agency, or entity*
  - *shall enter into additional agreements with drug manufacturers*
    - *For further price reductions*
    - *So that the net cost of the drug,*
      - *As determined by the purchasing department, agency or entity,*
      - *Is the same as or less than the lowest price paid for the same drug by the United States Department of Veterans Affairs.*

The Petition: (D)(3) Text

- *All state departments, agencies and other state entities*
  - *That enter into*
    - *one or more agreements with the manufacturer of any drug for the purchase of prescribed drugs or*
    - *agreement to pay directly or indirectly for prescribed drugs*
- *Shall implement this section no later than July 1, 2017.*

[58]FDA, Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm (accessed June 20, 2016)

D. What are "programs" for the purposes of (D)(2)?

When considering the state departments and other entities identified in Figure 3 above, the nature of the program and funding related to drugs was further examined.

a. Any health care or health insurance function that is operated, administered, or paid for, in part or wholly, by the state/other entities was included.
b. If the state/other entity received federal funds that are appropriated through a state budget act, these were included.
c. If the entity incurred an expense in administering the program, even if the premium was not paid by the entity, it was determined that such expenses would be covered by the Proposed Statute.
d. The Ohio Workers' Compensation program has two components: a self-funded program and a state fund program. The state fund program was included. With regard to the self-funded program, there no direct state involvement was found; therefore, this was excluded from this analysis. However, it is important to note that while there is no contract for the self-funded component, there are extensive state regulations that address pricing.

E. "Ultimate Payer."

"Ultimate payer" is also an undefined term, but suggests that (D)(2) be interpreted differently from (D)(1). The use of the term ultimate payer is emphasized by the specific references to Ohio Best Rx and the Ohio HIV Drug Assistance Program. Both the Ohio Best Rx and Ohio HIV Drug Assistance Program are included in this analysis, because the plain language of the Statute identifies them. However, in the case of the Best Rx program, were it not for the named inclusion, it would not have been included, as it operates as a discount drug card.

ATTACHMENT 3: Examples of Purchasing Relationships from Selected State Interviews

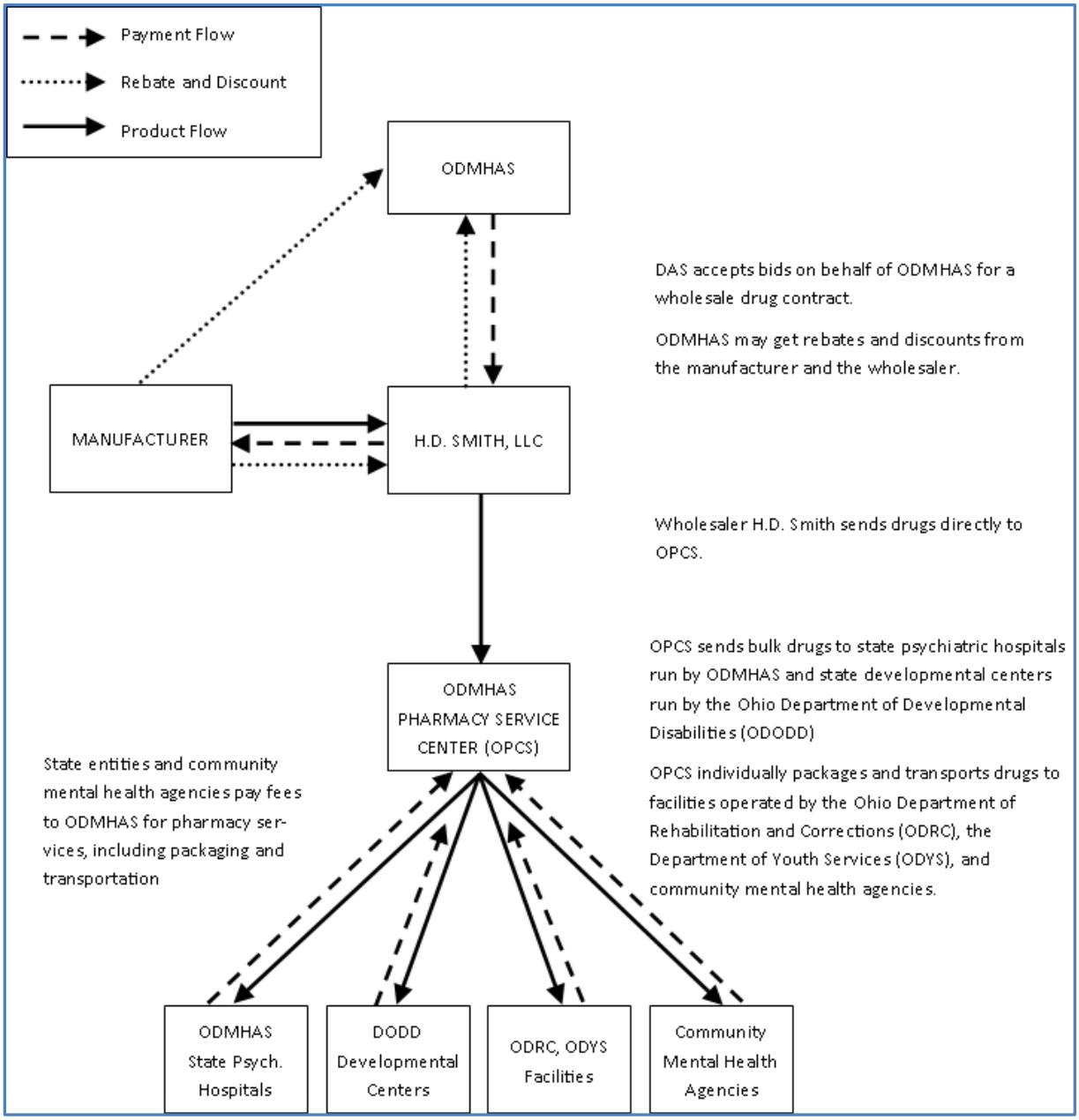
A. Example #1 Wholesale Contract: ODMHAS Pharmacy Service Center

B. Example #2 Wholesale and Dispensing Contracts: ODH HIV Drug Assistance Program

C. Example #3 Wholesale Contract: Ohio State University Wexner Medical Center (OSUWMC)

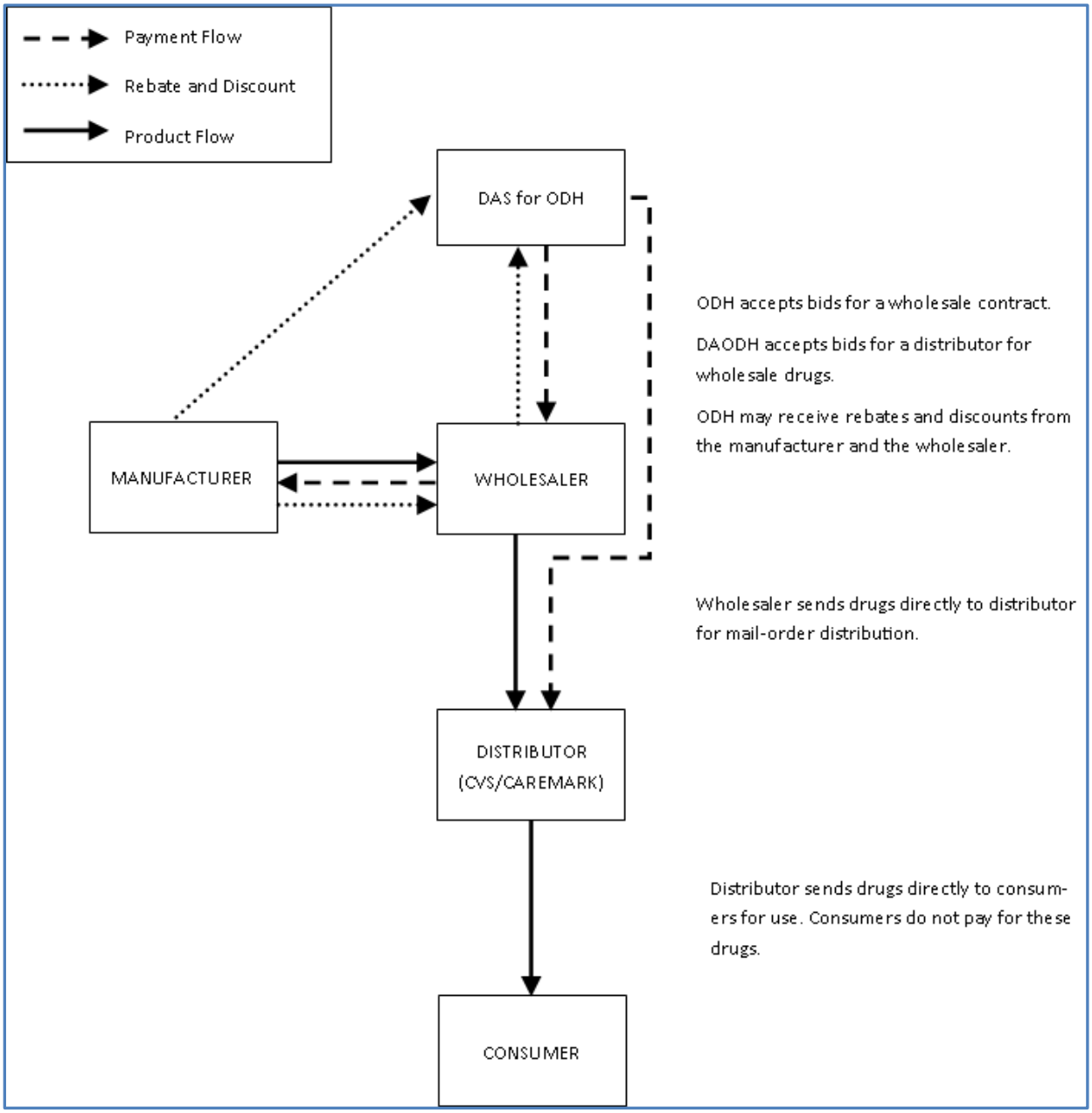
D. Example #4 PBM Contract: Rx Ohio Collaborative for Retirement Systems, Some State Universities, Others

ATTACHMENT 3: Example #1
Wholesale Contract: ODMHAS Pharmacy Service Center



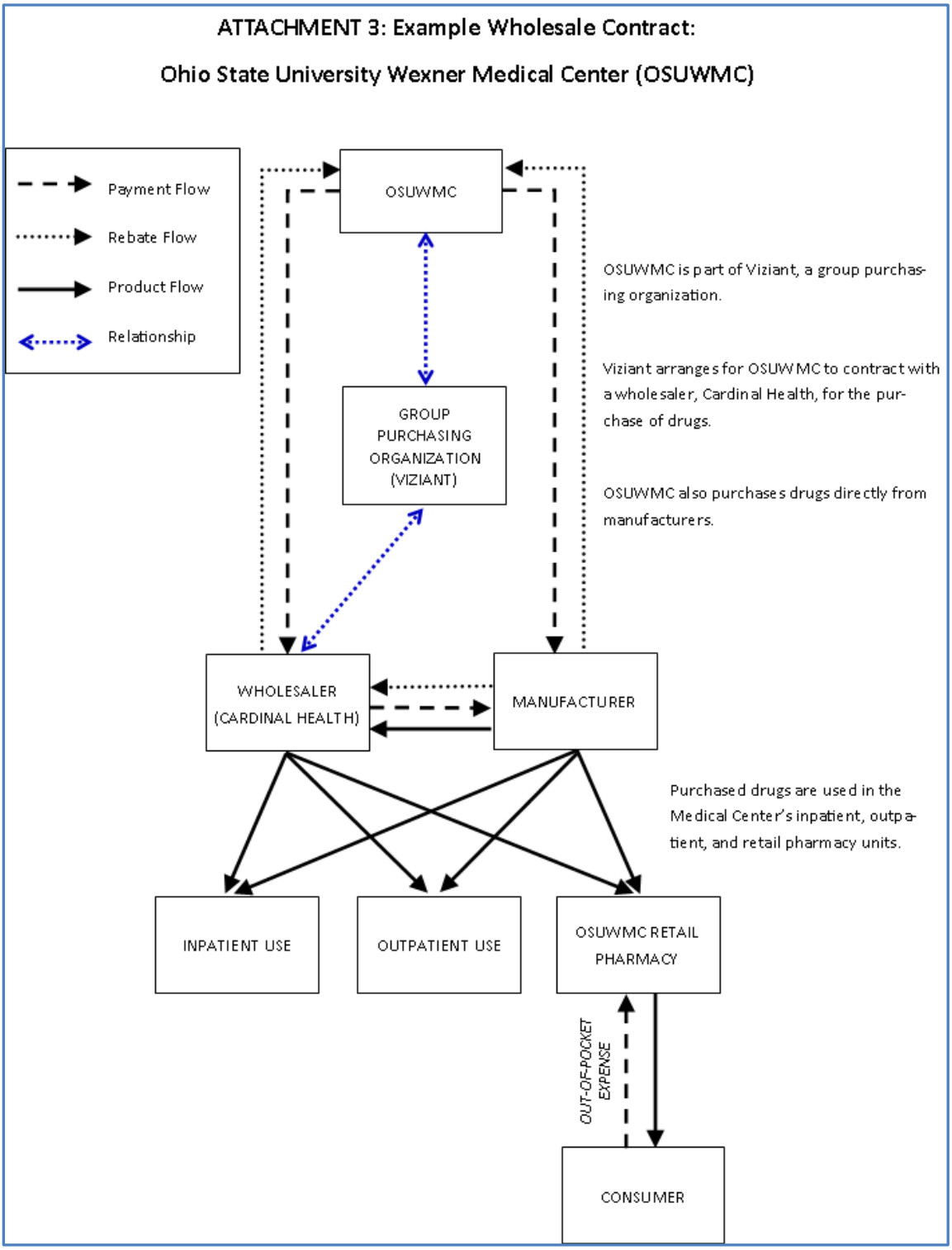
ATTACHMENT 3: Example #2

Wholesale and Dispensing Contracts: Ohio HIV Drug Assistance Program



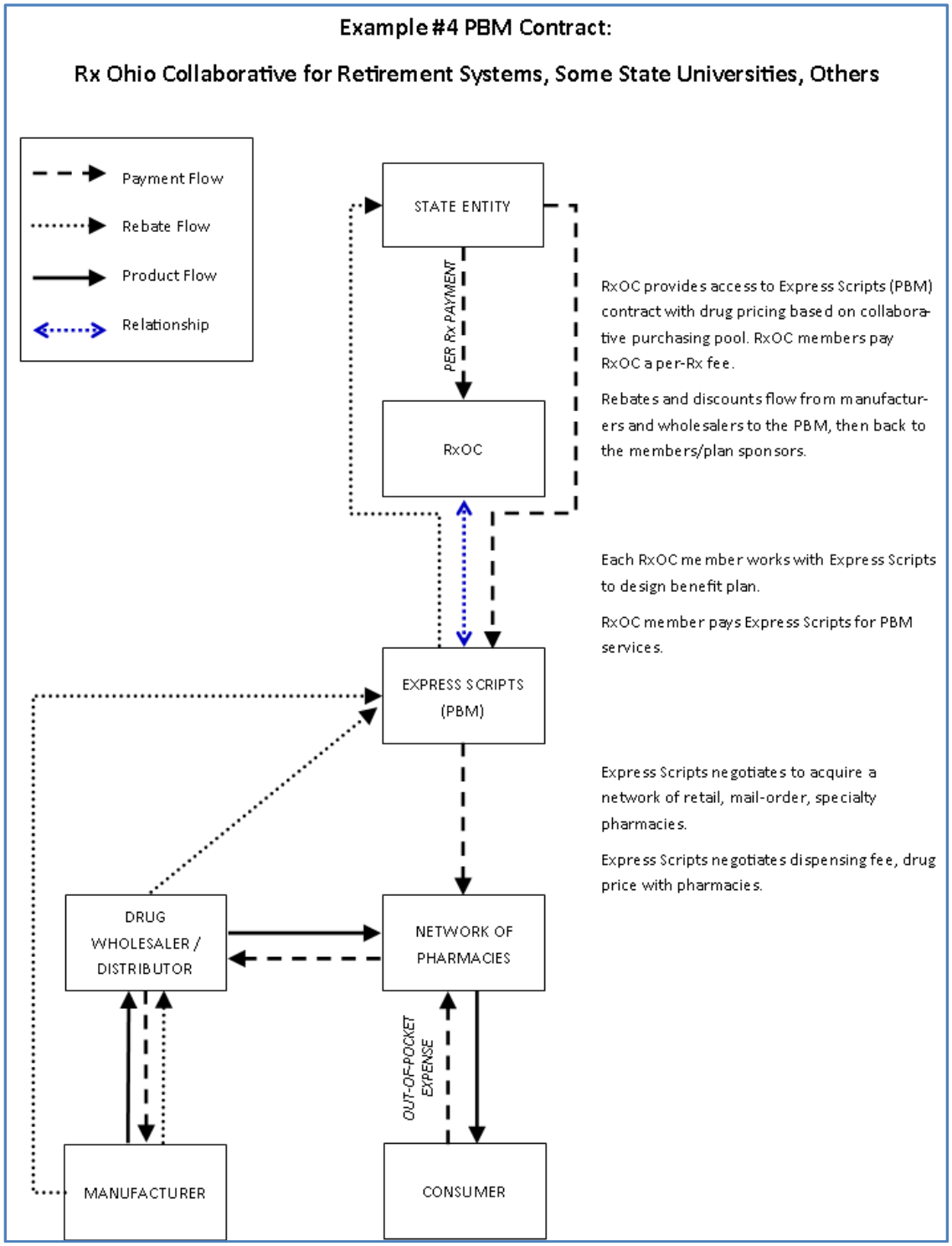
ATTACHMENT 3: Example #3

Wholesale Contract: Ohio State University Wexner Medical Center (OSUWMC)



ATTACHMENT 3: Example #4

PBM Contract: Rx Ohio Collaborative for Retirement Systems, Some State Universities, Others



ATTACHMENT 4: Member Organizations of the RxOC

- Akron City Schools
- Alkon Corporation
- Athens City School District
- Athens County School Consortium
- *Alexander Local Schools*
- *Athens Meigs Educational Service Center*
- *Federal Hocking Local Schools*
- *Nelsonville-York City Schools*
- *Tri-County Career Center*
- *Trimble Local Schools*
- Bowling Green State University
- Central Ohio Health Care Consortium
  - *Belmont County*
  - *Brown County*
  - *City of Canal Winchester*
  - *City of Gahanna*
  - *City of Grove City*
  - *City of Obetz*
  - *City of New Albany*
  - *City of Washington*
  - *City of Worthington*
  - *Madison Township*
  - *Paulding County*
  - *Sandusky County*
  - *Shelby County*
  - *Village of Granville*
- City of Green
- City of Lebanon
- Columbus City Schools
- County Employee Benefits Consortium of Ohio
  - *Allen County*
  - *Ashland County*
  - *Ashtabula County*
  - *Athens County*
  - *Butler County*
  - *Carroll County*
  - *Champaign County*
  - *Clark County*
  - *Clinton County*
  - *Darke County*
  - *Delaware County*
  - *Fulton County*
  - *Geauga County*
  - *Hardin County*
  - *Hocking County*
  - *Lawrence County*
  - *Logan County*
  - *Madison County*
  - *Marion County*
  - *Morrow County*
  - *Preble County*
  - *Putnam County*
  - *Ross County*
  - *Scioto County*
  - *Seneca County*
  - *Union County*
  - *Washington County*
  - *Williams County*
- Crown Equipment
- Fremont City School District
- Hancock County School Consortium
  - *Arcadia Local Schools*
  - *Arlington Local Schools*
  - *Blanchard Valley Center MRDD*
  - *Cory-Rawson Local Schools*
  - *Hancock County Board of DD*
  - *Hancock County ESC*
  - *Liberty Benton Local School District*
  - *McComb Local School District*
  - *Van Buren Local School District*
  - *Vanlue Local School District*
- Highway Patrol Retirement System of Ohio
- Installed Building Products (IBP)
- Kent City School District
- Kenyon College
- Licking County
- Mason City Schools
- Memorial Hospital of Union County
- Mercer-Auglaize Benefit Trust
  - *Auglaize County ESC*
  - *Celina City School District*
  - *Coldwater EV School District*
  - *Fort Recovery Local School District*
  - *Marion Local School District*
  - *Mercer County ESC*
  - *Minster Local School District*
  - *New Bremen Local School District*
  - *New Knoxville Local School District*
  - *Parkway Local School District*
  - *St Henry Local School District*
  - *St Marys City School District*
  - *Waynesfield-Goshen Local School District*
- NMC Group
- Ohio University
- Perrysburg Schools
- Pittsburgh Glass Works
- Ross County Schools
  - *Huntington Local School District*
  - *Paint Valley Local School District*
  - *Pickaway-Ross Career & Technology Center*
  - *Ross Pike County ESC*
  - *Southeastern Local School District*
  - *Union-Scioto Local School District*
  - *Zane Trace Local School District*
- Shaker Heights Schools
- Shawnee State University

Springfield City Schools
Suburban Health Consortium
- *Bay Village City School District*
- *Brecksville-Broadview Heights City School District*
- *Brunswick City Schools*
- *Cuyahoga Heights Schools*
- *Cuyahoga Valley School District*
- *Garfield Heights City Schools*
- *Independence Local School District*
- *Lakewood City School District*
- *North Royalton City School District*
- *Oberlin City School District*
- *Orange City School District*
- *Polaris School District*
- *Rocky River City School District*
- *South Euclid-Lyndhurst City School District*
- *Warrensville Heights School District*
- *Westlake City Schools*

Toyota Industrial Equipment Manufacturing
Warren Local Schools

ATTACHMENT 5: Methodology: Interviews with Key Programs

In order to more fully understand the current operation of state programs that would be impacted by the Proposed Statute, and in particular to explore the mechanics of the various purchasing relationships, we interviewed officials with key programs. We developed a tool to guide the interviews and enable us to collect consistent information across wide-ranging program designs. Most interviews were conducted by telephone, with at least two members of our team participating. The interviews we conducted represented a subset of all the potentially impacted entities, and were prioritized based on 1) those entities that would allow us to explore what we viewed as one-of-a kind programs with a significant drug purchasing volume and 2) those that we expected would be representative of other similar programs. So, for example, officials with the Ohio Public Employee Retirement System were interviewed, assuming OPERS would be sufficiently illustrative of the state's five public employee retirement systems. The following entities were interviewed.

Interviews of Unique Programs

- Ohio Department of Medicaid (ODM), Medicaid Fee for Service and Medicaid Managed Care
- Ohio Department of Mental Health and Addiction Services (ODMHAS) Pharmacy Service Center
- Ohio Department of Health (ODH) and their various health programs
    - Immunizations:
    - AIDS Prevention and Treatment – Ohio HIV Drug Assistance Program
    - Children with Medical Handicaps (CMH)
    - Family Planning and Reproductive Health
    - Bioterrorism
- Ohio Department of Administrative Services
    - State employee health insurance
- Ohio Bureau of Workers' Compensation (BWC)
- Ohio BestRx Program
- Ohio State University Wexner Medical Center (OSUWMC)[59]

Interviews of "Representative" Programs

- Ohio Pension and Retirement Systems –OPERS health care
    - Similar programs include: STRS (State Teachers Retirement System), SERS (School Employees Retirement System), Highway Patrol Retirement System and Ohio Police and Pension Fund.
- Ohio University (OU)
    - Similar programs include an undetermined number of other colleges and universities that offer health insurance for their students. Further, among those that offer health insurance, a deeper examination of the role of the university in the design, selection and administration of the health insurance would be needed in order to determine whether they would be impacted by the Proposed Statute.

[59] There are other public universities in Ohio. However, the OSU and associated medical center are the only truly public hospital entity that exists and would be directly impacted by the Act.

ATTACHMENT 6: VHA Issue Brief, Department of Veterans Affairs, Threat to Department of Veterans Affairs' Pharmaceutical Discounts.

California Legislature
Joint Committee on Rules

ROOM 3016 - STATE CAPITOL
P.O. BOX 942849
SACRAMENTO, CALIFORNIA 94249-0001
TELEPHONE: (916) 319-2804

August 19, 2016

Thomas Hiltachk
Bell, McAndrews & Hiltachk
455 Capitol Mall, Suite 600
Sacramento, CA 95814

Re: Legislative Open Records Act Request

Dear Mr. Hiltachk:

We are in receipt of your request for records under the California Public Records Act (Gov. Code, § 6250 et seq.) sent by e-mail to the Legislative Analyst's Office on August 12, 2016. The Legislature is not subject to the California Public Records Act (see Gov. C., § 6252(f)). As the Legislative Analyst's Office is appointed by the Joint Legislative Budget Committee (see Gov. C., § 9143 and Rule 37 of the Joint Rules of the Senate and Assembly), it is considered legislative staff and is also not subject to the California Public Records Act. However, we have construed your request as one made pursuant to the Legislative Open Records Act (Gov. Code, § 9070 et seq.).

Under the Legislative Open Records Act, requests to inspect legislative records must be directed to the appropriate Committee on Rules of each house of the Legislature, the Joint Committee on Rules, or the Joint Legislative Audit Committee, as those committees are the only entities deemed to have custody of legislative records and have sole responsibility for making legislative records available for inspection (see Gov. C., § 9074). Thus, this letter responds to your request on behalf of the Joint Committee on Rules.

In your request, you reference a statement made in a declaration submitted recently by Deputy Legislative Analyst Mark Newton in opposition to a petition to modify the Legislative Analyst's analysis for Proposition 61. Specifically, you reference Mr. Newton's statement, pursuant to discussions with the U.S. Department of Veterans Affairs ("VA"), that overall drug prescription drug spending by the VA would increase by $3.8 billion annually if VA drug prices were increased to the limits imposed by federal price caps. You asked for any documents provided

by the VA stating or providing the $3.8 billion estimate.

Enclosed is an internal opinion by the VA that is responsive to your request.

Sincerely,

Debra Gravert
Chief Administrative Officer
California Legislature
Joint Committee on Rules

Enclosure

cc: Office of Legislative Counsel
Sarah Kleinberg, Legislative Analyst's Office

VHA ISSUE BRIEF

Issue Title: Threat to Department of Veterans Affairs' Pharmaceutical Discounts

Brief Statement of Issue and Status: There is very likely going to be a ballot measure in California in November 2016 which specifies that the State of California shall not pay more for prescription drugs than the lowest price paid for the same drug by the U.S. Department of Veterans Affairs (California Drug Price Relief Act. Attorney General Initiative #15-0009. http://www.aidshealth.org/#archives/23835). Excerpt follows:

I/(a) ... neither the State of *California, nor any state administrative agency or other state entity, including, but not limited to, the California Department* of *Health Care Services, shall enter into any agreement with the manufacturer* of *any drug for the purchase* of a *prescribed drug unless the net cost* of *the drug, inclusive* of *cash discounts, free goods, volume discounts, rebates, or any other discounts or credits, as determined by the California Department* of *Health Care Services, is the same as or less than the lowest price paid for the same drug by the United States Department* of *Veterans Affairs."*

"(b) The price ceiling described in subsection (a) above also shall apply to all programs where the State of *California or any state administrative agency or other state entity is the ultimate payer for the drug, even if it did not purchase the drug directly. This includes, but is not limited to, California's Medi-Cal fee-for-service outpatient drug program, and California's AIDS Drug Assistance Program. In addition to agreements for any cash discounts, free goods, volume discounts, rebates,* or *any other discounts or credits already in place for these programs, the responsible state agency shall enter into additional agreements with drug manufacturers for further price reductions* so *that the net cost* of *the drug, as determined by the California Department* of *Health Care Services, is the same as or less than the lowest price paid for the same drug by the United States Department* of *Veterans Affairs. The requirements* of *this Section shall not be applicable to drugs purchased or procured, or rates developed, pursuant to or under any Medi-Cal managed care program.* II

Discussion: Drug discounts are very popular with the public and if approved by California voters, this measure has the potential for significant negative financial impact to VA if drug manufacturers stop providing VA with the large discounts it is currently able to negotiate.

The concern over the potential negative financial impact on VA is real. The Pharmacy Benefits Management Service office (PBM) has already had a company balk at providing a discount, specifically citing the California ballot measure as well as a similar Ohio initiative. The California ballot measure is a nearly parallel situation to the federal government's 1990 Omnibus Budget reconciliation Act (OBRA '90) that specified ALL government purchases of pharmaceuticals will be made at the lowest price offered to any SINGLE government purchaser.

In response to OBRA '90, pharmaceutical manufacturers responded predictably. Instead of offering the lowest prices to all federal purchasers, they eliminated all except

the highest prices, avoiding lost revenue and in some cases actually increasing revenue. To counter the pharmaceutical industry's reaction to OBRA '90, the federal government implemented PL 102-585 to mandate a 24% discount from manufacturers. The financial impact of the loss of Temporary Price Reduction discounts alone could reach $2.3B per year. As national contracts expire and VA is unable to negotiate deep discounts, this could result in losses of an additional $1.5B per year.

Summary: For financial planning purposes, VA should assume the California ballot measure will be endorsed by voters and that the pharmaceutical industry will react by eliminating all non-statutorily required and non-contractually required VA pharmaceutical discounts. In addition, VA should develop a broad array of counter measures that can be implemented should the ballot measure pass and the pharmaceutical industry react as expected.

References:

Unites States General Accounting Office (GAO/HRD-91-139): MEDICAID: Changes in Drug Prices Paid by VA and 000 Since Enactment of Rebate Provisions. September 1991.

United States General Accounting Office (GAOIT-HEHS-97-171): FEDERAL DRUG PRICES: Effects of Opening the Pharmaceutical Schedule Are Uncertain. July 1997

United States General Accounting Office (GAO/HEHS-00-118): PRESCRIPTION DRUGS: Expanding Access to federal Prices Could Cause Other Price Changes. August 2000.

For further Information Contact:

Michael Valentino
Chief Consultant, Pharmacy Benefits Management Services
Michael.Valentino@va.gov
202-461-7360

ATTACHMENT 7: Brief Bios for the Authors

Robyn Colby, Senior Consultant Health Management Associates

Ms. Colby has 30 years of health care policy and rate setting experience in Medicaid. As chief of policy she led sections devoted to strategic planning, research, and delivery system development for the Medicaid program. Robyn was responsible for fee-for-service program development and rate setting for hospital and non-institutional services such as physician, pharmacy, dental, clinic, FQHC and lab.

Robyn also led the procurement and state side implementation of the first pharmacy point of sale system for the Ohio Medicaid program and played a key role in the implementation of the most recent Medicaid Information Technology System (MITS), providing leadership for the configuration of the rules based engine and the McKesson ClaimCheck software that was utilized by MITS.

Robyn spent the last three years of her state career working on payment reform and innovation development. Ohio was one of seven states selected to be a part of the CMMI Comprehensive Primary Care Initiative, and Robyn was the CPCI project manager for Ohio Medicaid, where she developed the attribution methodology for the Ohio fee-for-service population, participated on the multi-payer data aggregation subcommittee, and collaborated with the other participating payers to align around a common set of quality measures. Led by the Office of Health Transformation, Ohio applied for, and was awarded, both a SIM design grant and subsequently, a testing grant. Robyn served as the Medicaid project manager and participated in the development of the initial SIM work, including developing a common set of quality metrics for episodes, and the framework for primary care medical homes.

Maureen Corcoran, President of Vorys Health Care Advisors

Ms. Corcoran is a veteran health care professional with more than 30 years of experience, both in and outside of state government, as a clinician, policy maker and administrator — along with her expertise in Medicaid programs, behavioral health, health care finance and quality improvement. She has a special interest in disability and children's policy, and the interface with Medicaid financing. She is a recipient of the 2016 American Network of Community Options and Resources (ANCOR) Legacy Award, which recognizes the most influential leaders in the field of intellectual and developmental disabilities.

Prior to joining Vorys Health Care Advisors, Ms. Corcoran directed policy and program initiatives for the Ohio's Medicaid program and served as the state's interim Medicaid director. She has additional state government experience as the Assistant Director of the Department of Mental Health, Chief of Budget and Cost Containment for the Department of Health, and as Human Services Policy Advisor to Governor Celeste. She played significant roles in writing and implementing two pieces of Ohio law that significantly reformed the state systems of developmental disabilities and mental health respectively.

Other positions that she has held include serving as President of the Ohio Provider Resource Association, an association of providers serving Ohioans with intellectual and other developmental disabilities. She also has served as Assistant Director of Nursing and Clinical Faculty at Case Western Reserve, where she received an MBA and Master's degree in Nursing. She teaches public budgeting and health policy at the Voinovich School of Ohio University.

Jim Downie, Principal Health Management Associates

Mr. Downie has over 28 years' experience covering all aspects of the Medicaid program, including Medicaid transition from fee-for-service payment systems to managed care systems, development of financial methodologies and systems, home and community-based services (HCBS) waiver development, Medicaid eligibility policy, provider relations, consumer and advocate outreach, and project management.

Mr. Downie has participated in the development and execution of many Federal reviews, including CMS HCBS Waiver renewals, Office of the Inspector General HiTECH reviews and system certification reviews. He has extensive project management experience and was responsible for leading many large, successful projects including the federal certification of Ohio's new Medicaid Management Information System, which lead to his role as Ohio Medicaid Portfolio Manager responsible for the coordination and prioritization of all Medicaid production-oriented projects.

Mr. Downie also served as Ohio's Interagency Contract Manager for Medicaid Programs responsible for maintaining relationships between agencies and ensuring compliance with federal and state Medicaid regulations. He has worked on many disability policy areas with a focus on attaining provider, consumer and advocate input. Mr. Downie has a Bachelor's of Science in Business from the Ohio State University.

Barbara Coulter Edwards, Principal Health Management Associates

Ms. Coulter Edwards is a nationally recognized expert in Medicaid policy, including managed care, long term care, behavioral health, and state and federal health care reform. As Director of the Disabled and Elderly Health Programs Group at the federal Centers for Medicare and Medicaid Services (CMS), she was responsible for a wide array of national Medicaid program policy and oversight, including Medicaid integrated service models; Medicaid pharmacy coverage and pricing; the application of essential health benefits to Medicaid expansion populations; and the development of a strong national focus on behavioral health care within the Medicaid program. In this role, she worked closely with states, stakeholders, and other federal partners, including SAMHSA, AHRQ, HUD, DOL, and DOJ.

Ms. Edwards served as Director of Ohio's Medicaid and CHIP programs, where she led significant program reforms, including implementation of Ohio's comprehensive strategy to promote access to home and community-based long term services and supports, development of the state's first Preferred Drug List for outpatient prescription drugs, expansion of managed care to serve Medicaid consumers, and implementation of Ohio's Children's Health Insurance Program.

Ms. Edwards also served as a Principal with Health Management Associates, serving public and private sector clients at a state, local and national level, with a particular focus on improved Medicaid program policy and operations for individuals with behavioral health and developmental disabilities. While with HMA, she served as the Interim Director of the National Association of State Medicaid Directors, providing services to the nation's Medicaid program and represented state interests before the CMS and on the Hill.

Marisa Weisel, Senior Advisor Vorys Health Care Advisors

Ms. Weisel is a seasoned policy analyst and advocate with consulting and government relations experience across a wide range of health care clients. Prior to joining Vorys Health Care Advisors, Ms. Weisel worked in government relations at the Ohio State Medical Association, where she served as Manager of Advocacy and Policy and focused on Medicaid and public health issues. While in that role, she drafted a research study on primary care reimbursement increases that was cited by *The New York Times*.

Ms. Weisel's expertise spans topics including state and federal health care reform,medical device regulatory affairs with the Food and Drug Administration, Center for Medicare and Medicaid Innovation (CMMI) grants, population health planning, value-based reimbursement, clinical integration, Medicaid reimbursement in a managed care environment, quality improvement and compliance, behavioral health, developmental disabilities, medical education, and clinical guidelines.

Ms. Weisel is also a skilled speaker, facilitator, and strategic planner, and she taught a graduate course at the University of Michigan on integrating disciplines of public health. Before moving to Ohio, Marisa worked as policy research fellow for the American Heart Association and as an associate regulatory affairs specialist for a medical device manufacturing company. She holds two degrees from the University of Michigan: a Master of Public Health in Health Management and Policy, and Bachelor of Sciences in General Biology.

NOTES for Figure 2 and 3: State Entities and Associated Programs

Including Scope, Number of Lives or Size of Program

[i] Calculation almost certainly contains duplicate individuals who receive prescription drug coverage through more than one affected state entity.

[ii] Includes individuals who are eligible, but may not be enrolled to receive prescription drug coverage through the Ohio Police and Pension Fund and through State University and Community Colleges.

[iii] The intent of this analysis is to provide a rough approximation of the impact of the Act. Data is based on information shared with the authors by the affected state entities and from publically available sources.

[iv] Includes fee-for service, managed care, and limited benefits. Based on State Fiscal Year 2016 average, July 2015 - May 2016. Per Monthly Caseload Report - May. Ohio Department of Medicaid. 2016. Available at http://medicaid.ohio.gov/Portals/0/Resources/Reports/Caseload/2016/05-Caseload.pdf

[v] Individuals eligible for CMH purchase of medication using Medicaid's fee-for-service drug purchasing contract for non-Medicaid enrollees. Number does not include Medicaid enrollees who are also served by the program. Information supplied by Ohio Department Health.

[vi] Doses distributed to local health departments, FQHCs, and maternity hospitals in 2015. This includes state purchase of pediatric DT vaccine, hepatitis B immune globulin, and other limited childhood vaccines. This does not include immunizations for the Vaccines for Children program (VFC), as VFC does not incur a state expenditure. Information supplied by Ohio Department Health.

[vii] While no state dollars are used to purchase the influenza vaccines, the use of a state contract and inclusion of federal dollars in the state budget (Fund 3920, ALI 440618) would make this influenza vaccine purchase subject to the Act. This figure does not include VFC-purchased influenza vaccines. Information supplied by Ohio Department Health.

[viii] Information supplied by Ohio Department of Health.

[ix] Covered lives for health care, including pharmacy benefit, in 2016. Information supplied by the Ohio Public Employees Retirement System.

[x] Covered lives for health care, including pharmacy benefit, as of June 2016. Information supplied by the School Teachers Retirement System.

[xi] Information supplied by School Employees Retirement System.

[xii] Information supplied by Highway Patrol Retirement System.

[xiii] Retirees and beneficiaries eligible to participate in the Ohio Police and Pension Fund's optional health care program for retirees and eligible dependents. 2015 Popular Annual Report. Ohio Police and Pension Fund. Available at https://www.opf.org/Files/2015annualreport.pdf.

[xiv] Unique number of individuals who received inpatient treatment during State Fiscal Year 2015. Information supplied by Ohio Department of Mental Health and Addiction Services.

[xv] Unique number of individuals served in outpatient settings in State Fiscal Year 2015. Information supplied by Ohio Department of Mental Health and Addiction Services.

[xvi] These state departments may also purchase drugs outside of the ODMHAS Pharmacy Service Center.

[xvii] Number of inmates as of June, 2016. Monthly Fact Sheet – June 2016. Ohio Department of Rehabilitation & Correction. Available at http://www.drc.ohio.gov/web/reports/FactSheet/June%202016.pdf.

[xviii] Individuals served in juvenile correctional facilities and alternative placements in SFY 2015. Fiscal Year 2015 Annual Report. Ohio Department of Youth Services. Available at http://www.dys.ohio.gov/DNN/LinkClick.aspx?fileticket=wfNZDRHJ4Mg%3d&tabid=102&mid=544.

[xix] Individuals served in state-operated developmental centers in SFY 2015. Fiscal Year 2015 Annual Report. Ohio Department of Developmental Disabilities. Available at http://dodd.ohio.gov/About/Documents/DODDAnnualReportFY2015.pdf.

[xx] Information supplied by Ohio Department of Administrative Services.

[xxi] 182,726 covered lives, 2,791 users in 2016. Based on 2016 totals from Utilization Summary for Ohio's Best Rx Program 2005 - May 2016. Report supplied by Ohio Department of Aging.

[xxii] Individual employers covered by BWC insurance fund in 2015. Fiscal Year 2015 Annual Report. Ohio Bureau of Worker's Compensation. 2016. Available at https://www.bwc.ohio.gov/downloads/blankpdf/AnnualReport.pdf.

[xxiii] 44,000 injured workers received prescriptions in 2015 through the state insurance fund. Information supplied by Ohio Bureau of Worker's Compensation.

[xxiv] Based on Employees by Appointment Status and Work Category, Fall 2012. Ohio Department of Education. 2015 Available at: https://www.ohiohighered.org/sites/ohiohighered.org/files/uploads/data/statistical-profiles/all_employee/all%20employ_2012.pdf.

[xxv] Information supplied by Ohio State Wexner Medical Center. https://wexnermedical.osu.edu/mediaroom/facts. The six hospitals that make up the medical center. Total operating revenue in 2015 was $2.37 billion.