Wisconsin Pharmacy Cost Study Committee Report

Options and Obstacles for Leveraging State Purchasing Power

Executive Summary

In 2017, staff from the Department of Corrections (DOC), Employee Trust Funds (ETF), and Health Services (DHS) began meeting to share strategies to address the high costs of prescription drugs and determine if there were opportunities to collaborate. In 2019, this working group applied for funding from the National Governor's Association (NGA), and with the addition of representatives from the Governor's office and the Office of the Commissioner of Insurance (OCI), formally became the Wisconsin Pharmacy Cost Study Committee (Committee).

The Committee has worked for the last year to develop options that leverage the combined volume of each agency. The Committee identified three primary approaches to save money on prescription drugs:

1. DHS & DOC partnership to pass through 340B pricing for medications for inmates;
2. DHS, DOC, & ETF formulary or preferred drug list (PDL) alignment to create pseudo-pooled purchasing; and
3. DHS, DOC, & ETF combined purchasing of certain specialty medications in order to lower prices for ETF and DOC.

The Committee has facilitated pursuing the first of these three approaches. It further discussed the logistics behind the second two, ultimately determining that they were not feasible to move forward with at the present time. The Committee has also identified several barriers that limit effective pooled purchasing:

- Inability of Medicaid to share net cost of drugs purchased;
- Differing mechanisms or points of purchase in the supply chain;
- General lack of transparency of costs within the purchasing system;
- Existing contracts that limit the usefulness of carving out one or a handful of drugs;
- Lack of a single purchasing authority amongst State of Wisconsin agencies.

The following paper provides background information on the current state of drug purchasing amongst the agencies working on this project, the relevant statutory provisions that allow for or limit certain activities related to drug purchasing, details on the options and barriers described above, and general Committee recommendations outside of the Committee's scope for how the state might proceed to continue lowering costs for agencies, patients, and taxpayers generally.

Background

Prescription drug spending represents 10% of all healthcare spending in the U.S. While overall growth in prescription drug spending has slowed somewhat in recent years (3.4% in 2017 versus 13$ in 2014[1]), increasing prices of brand name drugs and the introduction of new, high-cost specialty drugs continues to drive cost growth.[2]

It was this trend that encouraged several Wisconsin state agencies to begin meeting in late 2017 to discuss how they might align policies and purchasing strategies in order to save money on prescription drugs for the populations they serve. In 2018, ETF, DOC, and two divisions of DHS began meeting monthly to share data and strategies. The agencies applied for and were awarded a technical assistance grant from the National Governor's Association (NGA) in 2019 to support this work, and at that time formally established the Wisconsin Pharmacy Cost Study Committee (Committee).

The Committee's work has generally focused on the purchasing done by three agencies—ETF, DOC, and DHS. Specifically within DHS, the Committee focused its review on drugs purchased by the Wisconsin Medicaid program (Medicaid) and the Division of Care and Treatment Services (DCTS) which manages state-run inpatient facilities. In total, these agencies provide prescription drugs or drug coverage for more than two million Wisconsin residents. In order to identify opportunities to collaborate and save costs, the Committee reviewed the purchasing regulations and current practices of each agency.

Current Agency Purchasing & Regulations

Medicaid

Under Wis. Stats. §49, and DHS 107.10, the DHS provides access to prescription drugs for individuals enrolled in its Medicaid programs, including BadgerCare and SeniorCare. DHS 107.10 specifies the drugs covered under the Medicaid programs, which drugs are subject to prior authorization, any dispensing limitations, and pharmacist drug utilization review requirements. Wisconsin Medicaid is the largest single purchaser of prescription drugs in the state.

In FY18, DHS spent $1.26 billion before rebates for prescription drugs on behalf of Medicaid members. It does not include drugs administered in a physician's office or clinic, or drugs received by members while in an inpatient or outpatient facility. DHS contracts with DXC Technology to process claims from retail pharmacies for its Medicaid programs, as well as smaller programs administered by DHS, including the Wisconsin Chronic Disease Program and Ryan White AIDS program.

Wisconsin's Medicaid program participates in the Medicaid Drug Rebate Program (MDRP), which is administered by U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS). Pharmaceutical manufacturers are required to enter an MDRP agreement to have their drugs covered under state Medicaid programs. If a manufacturer enters into such an agreement, then

[1] U.S. Center for Medicare and Medicaid Services, Office of the Actuary, "CMS Office of the Actuary Releases 2017 National Health Expenditures," December 6, 2018, https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-national-health-expenditures

[2] Hernandez, Immacula, et al, "The Contribution Of New Product Entry Versus Existing Product Inflation In The Rising Costs Of Drugs," Health Affairs, January 2019, https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05147

state Medicaid programs must cover any outpatient drugs produced by that manufacturer. Pharmacy coverage is an optional benefit under federal Medicaid law, but all states currently provide coverage for outpatient prescription drugs.

Under MDRP, rebates are determined based on a statutory formula which requires that the Medicaid programs will get the best price per unit from pharmaceutical manufacturers for brand name drugs[3]. The MDRP includes the "best price requirement," meaning that the lowest discount offered by any manufacturer to any other purchaser must be offered to all state Medicaid programs. The "best price requirement" has been a barrier in negotiating directly with manufacturers for specific populations because the manufacturer would have to give that same discount to every other state Medicaid program. The Medicaid best price is considered confidential and cannot be divulged to any third party.

In addition to rebates received under the Medicaid Drug Rebate Program, Medicaid receives supplemental rebates by participating in The Optimal PDL Solution Program (TOP$), a multistate Medicaid purchasing pool administered by Provider Synergies LLC, an affiliate of Magellan Medicaid Administration. Together, the federal MDRP and supplemental rebates offset about 60% of the costs of payments made to retail pharmacies.

DCTS

DHS also purchases drugs for residents in its care and treatment facilities; the state's two psychiatric hospitals, three centers for individuals with intellectual/developmental disabilities, and two secure treatment centers. In FY2017, the average population in all facilities totaled 1,558. Total spending on drugs for all of the facilities totaled $7.8 million in FY18. The non-secure facilities bill other insurance, including Medicaid, when available.

The table below shows the average population in FY2017 and total spending on drugs in FY2018 by DHS facility.

[3] 42 U.S.C. 1396r-8 (c)(1)(C)

DHS Division of Care and Treatment Facilities		
Facility Name	FY17 Average Population*	FY2018 Drug Spending
Winnebago Mental Health Institute	187	$1,785,867
Wisconsin Resource Center	376	1,740,716
Mendota Mental Health Institute	282	1,216,533
Sand Ridge Treatment Center	351	836,224
Southern Wisconsin Center**	134	78,000
Northern Wisconsin Center**	13	16,050
Central Wisconsin Center	215	2,158,199
	1,558	$7,831,590
* Based on FY2017 Annual Report		
*Based on Purchase Orders		

Each of these facilities purchases drugs a little differently. Most facilities purchase most drugs through the MMCAP program; the same program the Department of Corrections uses. Whether the drugs are shipped directly to the facility or to a local pharmacy for dispensing depends on whether the facility has an on-site pharmacy. Where the facility does not have an on-site pharmacy, such as Sand Ridge Secure Treatment Center, the facility incurs an additional dispensing charge from the local pharmacy that receives the drugs and prepares them for dispensing to individual residents. Southern Wisconsin Center does not use MMCAP but rather purchases its drugs through CVS, the national pharmacy chain.

ETF

Under Wis. Stats. §40, ETF provides access to prescription drugs for employees, retirees, and their dependents participating in the state Group Health Insurance Program (GHIP) for state and participating local units of government, on behalf of the Group Insurance Board (Board). The GHIP prescription drug benefit was first carved out of the medical benefit in 2004 as a self-insured benefit. The Board contracts with Navitus Health Solutions, LLC (Navitus), a pharmacy benefit manager (PBM), to administer the GHIP prescription drug benefit programs. This includes managing drug lists, processing claims, managing pharmacy networks, negotiating drug pricing and administering clinical programs. In FY18, the GHIP spent $326 million (before rebates) on prescription drugs.

Navitus covers prescription drugs dispensed through retail pharmacies, mail-order services, and specialty pharmacies. It does not include drugs that GHIP participating health insurance plans cover, such as IV-drugs administered in a physician's office or drugs received by members while in an inpatient facility. In addition to managing a pharmacy network, Navitus negotiates rebates with pharmaceutical manufacturers. All revenues, including rebates are subject to a full-pass-through contracting model, meaning Navitus does not retain any portion of the rebates earned from pharmaceutical manufacturers. Retained rebates are used by ETF to lower costs for members. Navitus' sole revenue retained is through the administrative fees ETF pays per member per month.

DOC

Under Wis. Stats §302.38, the Department of Corrections (Corrections) is required to provide appropriate care or treatment, "if a prisoner needs medical or hospital care or is intoxicated or incapacitated by alcohol or another drug." Unlike Medicaid and ETF, DOC purchases and distributes drugs directly to the inmate population.

In 2018, Corrections spent $33.8 million on prescription drugs for its inmate population. 85% of these drugs were purchased through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP). Under MMCAP, requests-for-proposal (RFPs) are issued every five years by participating agencies seeking wholesale distributors. Wisconsin has selected Cardinal Health as its wholesaler. The Department of Administration (DOA) is the contracting agency and Corrections accesses the contract through an inter-agency agreement with DOA. The current contract expired in October 2019. A total of 263 Wisconsin state and local government agencies purchase pharmaceutical and medical supplies through MMCAP with sales totaling approximately $57.8 million in FY18.

Prescription drugs purchased through Cardinal Health are initially distributed to Corrections Central Pharmacy unit located in Waupun, and then distributed to correctional facilities located across the state. Licensed health care staff located at the facilities then dispense the medications as appropriate to patients.

In FY 2018, the Department of Corrections spent $1.5 million on specialty drugs not available through Cardinal Health and the MMCAP program. Often such drugs are only available through limited channels requiring Corrections to work with multiple wholesalers or specialty pharmacies to procure, and often with minimal discounts.

Finally, 2.5% of Corrections' prescription drug budget is spent on medications purchased on state purchasing cards. Corrections staff use these purchasing cards only when Central Pharmacy is closed or a certain medication is out-of-stock. Each facility has an arrangement with a local 24-hour retail pharmacy when a facility does not have a medication an inmate needs.

Other Wisconsin Governmental Purchasers

ETF, functioning as lead agency for this project, reached out to the Department of Veterans' Affairs (DVA) in 2019 to request information on their purchasing for their veterans' homes. DVA provides both clinical medical services for military servicepeople as well as longer-term care services through three nursing homes located in Wisconsin. DVA responded to ETF's request indicating that their purchasing was conducted through the US Department of Veterans' Affairs Federal Supply Schedule. The MDRP requires that manufacturers also enter into participation agreements with the Federal Supply Schedule, and this pricing is also confidential under federal law. DVA indicated that their purchasing was very restricted and therefore they would likely not be able to participate in any collaborative purchasing work with the Committee.

Comparison of State Agency Drug Expenditures

In order to compare the pricing each agency receives under current purchasing arrangements, the Committee compared their top 50 drugs by total expenditures for ETF, DOC, and DHS. The comparisons were based on information provided by each agency for its top 50 drugs based on total spend before rebates. Among the top 50 drugs for each agency, only seven drugs were common across all three agencies. The table in Attachment A shows the common drugs across agencies, including utilization and costs after rebates. The drug mix included in the individual agencies' top 50 lists reflect the clinical needs of their unique populations. ETF's top 50 drugs included many specialty drugs used to treat diabetes, multiple sclerosis, rheumatoid arthritis, and cancer. DOC and DHS populations had more significant use of medications to treat mental health conditions, HIV and Hepatitis C.

The Committee noted several challenges in completing a comparison analysis between agencies. First, as mentioned in the description above of Medicaid regulations, MDRP prevents Medicaid from sharing the actual rebate amounts received for drugs. The amounts shown in Attachment A of this paper are aggregate for the class, but actual rebate amounts can differ based upon which specific form of the drug is being supplied and in what quantity. Defining quantity also presented a challenge. ETF and Medicaid provide coverage for drugs received at retail pharmacies and there are a variety of ways that a drug can be prescribed, both in terms of delivery mechanism and dose. The specifics can be derived from National Drug Codes or NDCs, used to denote what has been prescribed on a drug claim. As mentioned earlier, Medicaid is unable to provide rebate values to this level of specificity, but they are able to provide this level of unit specificity and pre-rebate costs. DOC, however, purchases drugs differently than Medicaid and ETF, and tracks drugs via a shipped quantity, which may or may not be a comparable dose. Finally, both ETF and Medicaid receive rebates quarterly; this can skew the cost per prescription depending upon the volume of rebates received for the prior quarter versus the volume of prescriptions filled in the present quarter. Any comparisons made of these costs should be reviewed with this in mind, as well as any proposed solutions for combined purchasing.

The data available does appear to verify that DHS by and large receives substantial discounts versus DOC and ETF. In some instances, particularly for adalimumab and albuterol sulfate, it also appears that ETF receives lower pricing after rebates than DOC does through MMCAP. ETF and DOC also have sufficient volumes of these drugs that combining purchasing efforts could result in additional cost savings to each agency. With advisement from NGA, the agencies began to investigate options for both combining purchasing power as well as individually seeking methods for reducing drug costs.

Individual Agency Purchasing Options

In reviewing current agency purchasing practices versus practices in other states, the Committee identified two options that individual agencies could undertake that could present savings opportunities.

Leveraging 340B Pricing

The 340B Drug Pricing Program, authorized under Section 340B of the U.S. Public Health Services Act, is a drug discount program administered by the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services. Under the program, eligible safety net providers can purchase drugs at significant discounts if the drug's manufacturer participates in the MDRP. Discounts

provided under the 340B program are exempt from the MDRP best price requirements, and so could in theory be lower than the Medicaid best price. 340B prices are also considered confidential under federal law, however, and so cannot be verified.

NGA proposed three options for leveraging 340B pricing for the Committee's consideration[4]:

- Creating hospital centers of excellence with facilities that are 340B entities;
- Requiring 340B entities to bill at acquisition cost; or
- Establishing a Section 318 subgrantee relationship between state Public Health authorities and DOC.

Hospital Centers of Excellence

Under a centers of excellence program, each agency could contract with 340B hospitals to exclusively treat patients who need high-cost drugs that the 340B entity can purchase at a reduced price. 340B-eligible providers may provide 340B drugs to those patients who are considered patients of the 340B provider, as demonstrated by providing a certain amount of care and having medical records documented by the provider. A contract with such entities would stipulate that the 340B entity would pass the acquisition cost back to the agencies in exchange for care and drug reimbursement.

The NGA memo notes challenges for Medicaid programs in executing such contracts due to requirements in the Medicaid program to allow provider freedom of choice. Some states have sought waivers for these arrangements, but Wisconsin Medicaid has not yet done so in part due to access concerns between rural and urban parts of the state that might limit the ability to implement such waivers equitably.

ETF could pursue this type of arrangement but would face limits under its current pharmacy contracting model. ETF has a fully transparent pharmacy contract, which allows ETF to see all discount contracts between its PBM and manufacturers. ETF's position is that this transparency is critical in order to fulfill its fiduciary duty to members. 340B prices are required to be confidential under federal law, and so ETF could not maintain its fully transparent model for these contract arrangements. ETF may also have to either carve out medical care to ensure that patients become patients of record and that the full savings rate is passed through. This could disrupt continuity of care for other medical services received by the member if the 340B entity is not integrated into the member's regular health plan network.

DOC has an existing contract relationship for some services through the University of Wisconsin Hospitals and Clinics (UWHC), and that contract includes the ability to share access to 340B pricing for inmates who meet the definition of patient of the provider. In the case of DOC, the majority of care is provided by in-house medical staff, although some conditions do require inmates to be transported to a hospital for care. UWHC's access to 340B pricing is limited to certain conditions; their patient mix does not make them eligible for full 340B pricing. UWHC and DOC have investigated expanding both services and 340B pricing access in the past, but determined that this would be limited by logistical challenges. For UWHC, this would require they hold a separate, secure wing of their facilities to accommodate DOC inmates who are transported for care in order to provide adequate security. There are generally not enough DOC inmates who would need care that would fully occupy an entire hospital wing, and so these

[4] National Governor's Association. Review of 340B Options. Wisconsin Pharmacy Cost Study Committee Meeting Presentation, October 31, 2020. https://etf.wi.gov/boards/wpcsc/2019/10/31/item3/direct

rooms would not be fully utilized. UWHC's other patients would not be able to use those rooms, and so this would result in loss of access to other patients. DOC would also incur costs to transport inmates to and from appointments both in travel costs and staff time. Also, the majority of DOC facilities are outside of Dane County, and so DOC would either need to seek other 340B institutions to partner with or would need to transport inmates a significant distance to bring them to UW Hospital in Madison. The value of transporting inmate patients to UWHC to increase access to a limited set of 340B drugs may be less than the cost of the facilitating the transfers over time.

Upon review, the Committee opted not to advise any of the three agencies to pursue this option.

340B Entity Billing

The second recommendation provided by NGA was to ensure that 340B entities are billing state programs at acquisition cost for 340B drugs. As stated earlier, 340B pricing confidentiality requirements prevent any of the three agencies from determining what the rue acquisition cost is. ETF's fully transparent model further would require that prices be available to ETF's auditor in order to verify that claims were correctly processed and this arrangement would likely violate the 340B confidentiality rule. For Medicaid, the Medicaid Average Manufacturer Price (AMP) is confidential to Medicaid and cannot be shared, which further complicates a lower-of pricing requirement. Given the limitations surrounding price-sharing, the Committee also did not recommend that any of the agencies move forward with this option at this time.

Public Health and DOC Partnership

The final option provided by NGA was to investigate partnerships where DOC could access 340B pricing. Most other states who have created these arrangements for the Correctional authorities use some type of partnership with a 340B eligible hospital, but some states entered into subgrantee relationships with their departments of public health to access 340B drugs.

340B statutes allow entities receiving funding under Section 318 of the Public Health Service Act (PHSA) for treatment of sexually-transmitted diseases (STDs) and under Section 317 for tuberculosis are considered 340B covered entities if certified by the Secretary of the federal Department of Health and Human Services (HHS). According to CMS, STDs with drugs eligible for 340B treatment include HIV and Hepatitis C treatments, which are often treated with very high cost drugs. In order to be a subgrantee of a public health entity, an agency would need to establish a treatment relationship with the public health entity. This can be as expansive as full health care provision by the public health entity or as narrow as receiving in-kind materials from the agency related to STD treatment (e.g. test kits). DOC currently receives STD testing kits from the Wisconsin Department of Health Services' Division of Public Health (DPH). DOC pays for these kits currently, but the Health Resources and Services Administration (HRSA), the arm of HHS that administers 340B certification, has indicated that even a discounted payment rate for STD kits can be treated as an in-kind arrangement.

To initiate the subgrantee arrangement, DOC must make its intentions known to DPH and document the nature of their current partnership, adjusting the in-kind relationship if needed. DOC can then apply

directly to HRSA for subgrantee status. HRSA will contact DPH to verify the relationship and that DPH is receiving funds under Section 317 and 318.

Once awarded the subgrantee status, DOC will be able to enroll as a 340B entity and use 340B drugs to fill client prescriptions as long as the client is receiving services that are within the scope of STD or tuberculosis treatments. DOC would need to be able to separately account for drugs that are provided under 340B, either through a separate physical inventory or through software solutions. According to an analysis provided to the state of North Carolina, who like DOC purchases drugs through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), enrolling in 340B will not impact the volume discounts received from purchasing through MMCAP. In the same North Carolina analysis, HRSA's vendor, Apexus, indicated that Section 318 grantees can dispense any 340B drug to an individual who is eligible for treatment under the Section 318 subgrantee status. This means that a client who has both an STD and another condition can receive all treatment drugs at 340B prices.

This option was presented to the Committee at their December 2019 meeting, and the Committee recommended that DOC pursue subgrantee status in partnership with DPH. DOC had originally planned to pursue the arrangement for July 1, 2020, but the COVID-19 pandemic has delayed their plans. DOC still intends to implement this arrangement and will seek credentialing in the second half of 2020.

Value-Based Contracting

NGA also submitted an analysis of value-based purchasing approaches[5] to the Committee for consideration, highlighting the approaches taken by two states—Louisiana and Washington. Both models use a "subscription model," wherein the states pay a certain dollar amount to a manufacturer per month for unlimited access to a high-cost medication. Certain drugs, particularly those who are cures rather than maintenance medications may be better suited to subscription-type arrangements, as well as drugs that are either the only treatment available or one of few treatments available in a particular class of medications. For this reason, the first subscription arrangements have been centered around treatments for Hepatitis C. Louisiana's subscription arrangement is approximately one year old at the writing of this paper, and the term of the subscription contract is five years. Data on the outcomes of this model were not available at the time the option was reviewed by the committee.

The Committee also discussed an outcomes-based purchasing model that has been undertaken by the state of Oklahoma. Oklahoma has outcomes-based contracts for five different drugs with manufacturers of high-cost, generally sole-source drugs. NGA reported that the number of drug classes for which this approach will work may be limited due to challenges in defining meaningful outcomes and measurement. Often measurement is limited to claims data; electronic health records data can be very hard to access and so clinical outcomes are harder for states to track. In addition, NGA noted that states who are interested in these arrangements should consider the costs of data collection, analysis, and agreement management when looking at outcomes-based arrangements, as these administrative costs may overtake much of the additional savings. Finally, as noted, few manufacturers have actively engaged with this type of contracting. Oklahoma has approached 30 different manufacturers to work on

[5] National Governor's Association. State Value-Based Purchasing Agreements with Biopharmaceutical Manufacturers. Wisconsin Pharmacy Cost Study Committee October 31, 2019 Meeting. https://etf.wi.gov/boards/wpcsc/2019/10/31/item4/direct

such contracts, and the arrangements are very different than those larger manufacturers are accustomed to. They are complex and require a substantial amount of complex analysis to develop.

Due to the inherent complexities of these arrangements, lack of outcomes from states who have tried them, and uncertain savings opportunity, the Committee did not recommend that any of the agencies continue to pursue value-based contracting.

Combined Agency Purchasing Options

The primary driver in the three agencies' convening of the Committee focused on opportunities to pool their purchasing power in order to leverage better pricing on drugs. Following the review of individual agency options, the Committee refocused its review on opportunities to combine their respective purchasing volume.

Each of the agencies currently participates in some manner of purchasing pooling currently, as reviewed above: DOC and DCTS with MMCAP, Medicaid with TOP$, and ETF with Navitus. MMCAP and TOP$ are both inter-state pooling arrangements where multiple states all purchase through the same provider in order to increase either discounts or rebates. The Committee also heard a presentation from another inter-state pooling group, the Northwest Prescription Drug Consortium (NPDC), which Oregon and Washington states both organize and participate in. Similar to MMCAP, NPDC offers group purchasing arrangements for both entities, covering more than 1.1 million members. Benefits to these arrangements include expanding the number of potential lives covered under the group purchasing arrangement. However, the Committee lacks data transparency to complete a full analysis of current drug costs as mentioned earlier in this paper. While the option to combine volume for lower prices is innately attractive, there was hesitance on the part of DOC and ETF to completely move purchasing to a new vendor without being able to verify pricing. In addition, DOC and ETF currently use different statutory purchasing authorities to enter into their pharmacy purchasing contracts, and a fuller analysis of purchasing authority would need to be undertaken before such a move could be made.

Another approach would be to create an intra-state purchasing collaborative, where all three agencies combine volume to leverage greater discounts on drugs. Washington state internally does this as well through the centralized Washington State Healthcare Authority. Benefits to these arrangements include internal transparency on pricing between the various contracts, which provide a more holistic picture when negotiating prices. These arrangements may also lower administrative costs. This option was determined to be outside of the Committee's current scope of authority—no single agency involved in this discussion felt that they could take on purchasing authority for the others, nor did any agency have the authority to create a single, encompassing purchasing authority to govern purchasing across agencies.

Short of fully combining all purchasing for drugs, the Committee also looked at options to pursue combined purchasing arrangements for specific drugs where each agency has common utilization. Returning to the comparison of agency drug expenditures, the Committee focused on three drugs where there appeared to be the most opportunity available both in terms of price reduction and volume of use:

- Adalimumab: Adalimumab is more commonly known by the brand name Humira, and is used to treat arthritis, plaque psoriasis, and Chrohn's disease. Across the agencies, there were 9,715 prescriptions for this drug. The average cost per prescription for ETF was $4,556 and for DOC was $4,848 (Medicaid's price post-rebate was $296, but agencies agreed this price was likely not a good reference due to the best price rule). Conservatively, if DOC were able to simply reduce to ETF's prices, this could save $1.8M over a similar six-month time period. Additional savings could also possibly be negotiated for Medicaid through supplemental rebates if they were to be included in pooled purchasing and the additional volume would help their supplemental rebate negotiations.
- Insulin: Insulin in its various forms is used to manage diabetes. Use is common across all agencies (a total of 60,213 prescriptions were recorded during the six-month period of analysis), and diabetes is further known to be a general area of public health concern statewide. In this instance, DOC appears to get a lower price ($146) than ETF ($314). If ETF was able to obtain the lower DOC price, ETF could save $1.4M on insulin over a similar six-month period. Medicaid could also potentially leverage additional supplemental rebates is pooled and negotiated at the same time.
- Albuterol sulfate: Albuterol sulfate is used in inhalers for people with asthma. A large number of patients across programs use albuterol sulfate (212,825 prescriptions total), but costs for these drugs is relatively low, ranging among agencies from $30 per prescription to $41. If DOC were able to leverage ETF's $30 price per prescription, their costs would have been approximately $84,000 cheaper over the same six-month period.

In each of these instances, the Committee identified several risks associated with pursuing pooled purchasing. For ETF, removing drugs from manufacturer contracts under the PBM could risk other manufacturer discounts; for DOC, as the largest Wisconsin member of MMCAP, redirecting any large volume of drugs out of the MMCAP arrangement may reduce the discount amounts received by other, smaller municipalities who participate in MMCAP, causing them budget disruption. Also, the savings values are relatively small in the overall costs of each program, and should be weighed versus the cost to administer the programs, similar to what is noted in the value-based contracting review above. The DOC savings numbers in particular are not adjusted for the savings that will result when DOC moves to 340B pricing for higher cost drugs, and so will likely be much lower than the initial estimates.

Questions also still remained for the committee regarding pricing and pooling arrangements. Medicaid prices are still able to be shared at the granular level needed to determine best pricing, and the delayed rebate values cause some aberrations in the data—for example, some rebate values reduced the prices of certain drugs to less than $0, while the values for albuterol sulfate made it appear as if ETF receives a better price than Medicaid, an arrangement that is not technically legal. The other major question remains around contract ownership between independent agencies. The Committee determined that the Department of Administration (DOA) might be the more correct owner for a pooled purchasing arrangement, but assigning that responsibility was deemed outside of the scope of the committee.

Committee Recommendations & Agency Action

Following extensive review with the support of the National Governor's Association, the Committee determined the only appropriate action available under current law and agency structure was to

support DOC in pursuing 340B pricing. DOC continues to work on this project as of the drafting of this memo.

While other savings opportunities appear to exist, all were determined to be either beyond the scope of the agencies that formed the Committee, or of uncertain or small savings value, such that agencies are not comfortable disrupting their existing purchasing arrangements due to downstream impacts.

Additional Recommendations Outside of the Committee's Scope

Throughout their analysis, the Committee continued to encounter roadblocks as well as opportunities that were outside of its scope of control. The following details some of the items of greatest potential for broader intervention at the state or national level.

Price Transparency

In attempting to analyze how much each agency spends on pharmaceuticals in any given period, the Committee continually encountered barriers to sharing cost information, particularly from Medicaid and DVA. Federal law, as mentioned earlier, prohibits the disclosure of Medicaid best price and the Federal Supply Schedule. One unfortunate side effect of DOC moving drugs to 340B is that they may no longer be able to share their costs with the same level of transparency with which they were able to during the course of this project since 340B pricing is also confidential. The Committee and its supporting workgroup noted again and again how at the very least it seemed that, as stewards of state tax dollars, agencies should at least be able to share cost information internally to ensure they were appropriating tax funds responsibly. Unfortunately, confidentiality rules bar even this level of sharing.

Several states have looked to enact some level of price transparency laws to require manufacturers to regularly report drug pricing. The scope of legislation varies in terms of what reporting is needed and what penalties apply for non-reporting. Such legislation is based on the premise that the process pharmaceutical manufacturers use to price drugs is opaque and that price increases for both brand and generic medications are unsustainable. Requiring manufacturers to report prices would give states a data source from which state purchasers can develop strategies to combat price increases.

The Center for State Drug Pricing at the National Association of State Health Policy (NASHP) has developed model legislation to help guide states.[6] The NASHP model legislation requires manufacturers to report if the Wholesale Acquisition Cost (WAC) increases by more than 10% in a 12-month period or a drug will be introduced with a WAC of $30,000 or more for an annual course of treatment. Manufacturers would have to report WAC increases for generic drugs if they exceed 25% or $300 in a 12-month period or if the manufacturer will market a drug with a WAC that exceeds $3,000 in a 12-month period. Notices must be provided at least 30 days prior to the increases' effective date and must include a justification for the price increase.

The NASHP model legislation would also require manufacturers to report on any price discounts or rebates provided to PBMs. Hospitals participating in the federal 340B drug discount program would also have to report on the margins received under that program and how the margin was spent by the hospital. The legislation would require manufacturers to report on patient assistance programs,

[6] National Academy of State Health Policy. *Comprehensive Transparency Model Legislation.* https://www.nashp.org/wp-content/uploads/2020/02/revised-transparency-rx-Model-Leg-2.13.20.pdf

including program terms, the number of prescriptions provided to state residents under such programs, and the market value of such programs.

NASHP reports that as of June 2020, 59 total bills have been brought across 23 states related to drug price transparency. Few have passed or been signed, and most have been challenges by pharmaceutical companies or otherwise stalled during the legislative process.[7] In states where bills have passed pharmaceutical manufacturers are litigating efforts to require price reporting, arguing that the legislation violates the Commerce Clause of the U.S. Constitution, since it is attempting to regulate national pricing, not just state pricing. In April of 2019, Maryland's anti-gouging legislation was found unconstitutional by the Fourth Circuit Court of Appeals.[8] Additional appeals are expected. California and Nevada's laws have also been subject to litigation, although the lawsuit against Nevada's legislation was dropped when the state agreed to allow manufacturers to request that certain information be kept confidential because the information is a trade secret.[9]

In May of 2018, the Trump administration released the American Patients First blueprint[10], which included some federal level transparency efforts. The Blueprint would have required drug companies to include pricing in their television advertisements. In June of 2020, a federal appeals court upheld a lower court ruling that drug pricing disclosure is outside of the authority of the Department of Health and Human Services to require manufacturers to disclose.[11] The rule to date has not been enacted.

If Wisconsin opted to pursue transparency legislation, it would need to determine which state agency should collect the information reported by manufacturers under the bill. Suggested agencies include the Officer of the Commissioner of Insurance, DHS, the Department of Agriculture and Consumer Protection, and the Department of Administration. Legislation may specify that the administering agency create rules on the method and format of data to be submitted and that such data be included in a searchable database for use by state and private purchasers of prescription drugs, including health care providers and licensed health insurers. Based on Nevada's experience, the legislation and/or administrative rules could specify what information would be disclosed to hedge against lawsuits.

Drug Reimportation

Some states have identified drug importation from Canada or Mexico as options to combat price increases for select drugs. Federal law allows the importation and reimportation of drugs from other countries as long as certain requirements are met and that the Secretary of the U.S. Department of Health and Human Services certifies to Congress that such a program poses no additional risk to the

[7] NASHP Rx Legislative Tracker. https://www.nashp.org/rx-legislative-tracker/
[8] "Frosh v. Association for Accessible Medicines," U.S. Court of Appeals for the Fourth Circuit
[9] Mahinka, Stephen Paul and Sanchez, Amaru J., "State Drug Price Transparency Laws Present Reporting Issues for Biopharma," November 09, 2018, www.morganlewis.com/pubs/state-drug-price-transparency-laws-present-reporting-issues-for-biopharma
[10] Department of Health and Human Services. *CMS Drug Pricing Transparency Fact Sheet*. https://www.hhs.gov/about/news/2019/05/08/cms-drug-pricing-transparency-fact-sheet.html
[11] The National Law Review. *Federal Appeals Court Affirms Lower Court Ruling: Drug Pricing Transparency Rule Exceeds HHS's Regulatory Authority*. June 18, 2020. https://www.natlawreview.com/article/federal-appeals-court-affirms-lower-court-ruling-drug-pricing-transparency-rule

public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer.[12]

In 2018, Vermont became the first state to adopt legislation to authorize importing drugs from Canada. This legislation is designed to provide savings to Vermont consumers. In January 2019, as required by Act 133, the Vermont Agency for Human Services released its report on the initial design of the program. The report estimated that commercial insurers in Vermont could save between $1 - $5 million by importing drugs from Canada.[13]

The report strongly recommends that the state create two new categories of licensure to ensure no additional risk to health or safety: one for Canadian distributors and another for state-based wholesalers that would be allowed to import the drugs. The legislation authorizes the state to become the state-based licensed wholesaler or to contract with a private entity. The legislation allows for a price per drug to be added to the cost of the drugs imported that would pay for the states' costs to administer the drug importation program.

Short of legislation, the Utah state employee health insurance program began to send employees to Mexico in 2019 to purchase high-cost drugs[14]. Utah's program has found that, even inclusive of airfare and lodging costs, it is less expensive to send employees to Tijuana to purchase medications. Employees fly from Salt Lake City to San Diego and then are escorted across the border. There, they have a medical appointment with a doctor in Mexico, receive a prescription, and pick up their medications. After that, they are shuttled back to the airport and return home. Utah has found no reduction in quality effectiveness for drugs purchased this way. The program provides a $500 per-trip bonus to employees willing to make the trip. ETF has discussed this program with Utah in the past, but the longer flights, coupled with the 2020 COVID-19 outbreak, have slowed further discussion.

Legislation could require a state agency to issue a report on the design of a drug importation program, like Vermont's Act 133 did, and/or it could authorize selected state agency to promulgate rules to establish the program, including:

- how the program would ensure that importation would not provide an additional risk to health and safety;
- who would be eligible to purchase the imported drugs;
- what, if any, provisions would ensure that savings are passed along to consumers; and
- what, if any, additional charges would apply to the drugs to cover the state's operating costs.

The current federal administration has indicated it is researching opportunities to allow for the importation of drugs from other countries and has established a workgroup to study the idea.[15] This

[12] Vermont Agency for Human Services, "Wholesale Importation Program for Prescription Drugs Legislative Report," December 31, 2018
[13] Ibid.
[14] Whitehurst, Lindsay, "Utah sends employees to Mexico for lower prescription drug prices." February 9, 2020. https://abcnews.go.com/Health/wireStory/utah-sends-employees-mexico-lower-prescription-prices-68861516
[15] McGinley, Laurie, "Trump Administration to Explore Drug Imports to Counter Price Hikes," Washington Post, July 19, 2018, https://www.washingtonpost.com/news/to-your-health/wp/2018/07/19/trump-administration-to-explore-drug-imports-to-counter-price-hikes/?utm_term=.75ede28d6e14

suggests that the federal administration could be open to a state-based proposal to do so. It is possible that pharmaceutical manufacturers could respond to such legislation by limiting distribution of drugs to countries exporting drugs to the U.S. making it less likely that distributors in other countries would be willing to export to the United States.

Sole Statewide Purchasing Entity

Another repeated challenge identified by the Committee was determining which agency would have the authority to view pricing across agencies and/or purchase on behalf of all agencies. DOA could potentially do so, but for entities such as ETF that are non-cabinet, the authority may not be as clear. A simpler means of creating the authority as well as ensuring subject matter expertise could be to create a single purchasing entity for the State of Wisconsin. The entity could either provide administrative authority, such as the Washington Health Care Authority, or could even be expanded to provide general pricing oversight as in the review boards currently run in states like Maine and Maryland. The Washington Authority is able to review and make coverage and drug preference decisions for all people in Washington state who are on a government-run health program, including state employees and Medicaid members. Maine and Maryland convene drug affordability review boards that limit how much all state residents may pay for certain high-cost drugs[16]. These boards have not gone un-challenged and implementing either a statewide authority or an affordability review board may require legislative action.

Public Health Purchasing of Drugs for Chronic Disease

One additional option that could be considered for drugs that address chronic illnesses such as albuterol sulfate or insulin is a public health purchasing model. In this option, similar to the Vaccines for Children (VFC) program, a state public health authority would purchase a supply of a particular medication and distribute it to eligible individuals.

In the case of VFC, the program is federally-funded and provides vaccines at no cost to children whose families may be unable to pay for or otherwise obtain vaccinations through insurance. The Centers for Disease Control (CDC) purchases vaccines at a discount and distributes them to grantees such as health departments which then distribute them at no charge.[17] VFC limits eligibility currently to children who are Medicaid of Children's Health Insurance Program (CHIP) eligible, children who are uninsured or underinsured, and to children of American Indian or Alaska Native descent as authorized by the Indian Health Care Improvement Act.[18] This program has generally been deemed effective at providing access to childhood immunizations and reducing the spread of vaccine-preventable disease.

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[16] NASHP. Administrative Actions. https://www.nashp.org/policy/prescription-drug-pricing/administrative-actions/#toggle-id-3

[17] Centers for Disease Control and Prevention. Vaccines for Children. https://www.cdc.gov/vaccines/programs/vfc/index.html

[18] National Center for Health Research. The Vaccines for Children Program. http://www.center4research.org/vaccines-children-program-vfc/

There is no similar federal program currently offered to help adults manage chronic conditions. In Wisconsin there is the Wisconsin Chronic Disease Program (WCDP) which is funded entirely by the state. WCDP is the payer of last resort for treatments related to chronic renal disease, hemophilia, and adult cystic fibrosis. Members who make up to 300% of the federal poverty level (FPL) do not have copayments or deductibles under the program. Members who make more than 300% FPL will have a certain amount out of pocket due before coverage begins.[19]

Several states have looked into bills to ensure that patient costs for insulin under their health plans stay within limits, but these bills do not control the actual costs of the drugs. This means that insurers assume more of the drug costs, and these costs are ultimately passed back to members in health insurance premiums, or to taxpayers in the cases of public payer programs like Medicaid. Minnesota has pursued a cost control program at retail that limits the costs that individuals pay for emergency insulin supplies, and manufacturers must reimburse pharmacies for insulin dispensed under the new law or to send them replacement insulin at no cost. There are also longer term provisions for manufacturers to provide insulin at copays not to exceed $50.[20]

The utilization of drugs to treat asthma and diabetes in ETF, DHS, and DOC populations reflects the prevalence of these conditions in the Wisconsin population at large. The state may have a population health interest in controlling these conditions in order to promote worker health and productivity. Another option beyond setting cost limits could be for states to negotiate the bulk purchase of insulin or other drugs like albuterol sulfate through public health entities, who could then provide the drugs to all state residents at either no or very low costs. Drugs could be distributed by local public health authorities who could also provide simple testing and education to patients in how to manage their conditions. The state could also potentially create cooperative arrangements with 340B hospitals to provide drugs and associated care at reduced prices in exchange for passing through the 340B contracted rate for chronic disease management drugs. An extensive review of legal and logistical limitations would need to be conducted regarding this option.

Other Options Considered but Not Recommended

Other options were reviewed by the Committee for initial consideration as in scope, but were ruled out early on as either not feasible or impractical. A list of those proposals and brief descriptions are available in Attachment B.

[19] Department of Health Services. Wisconsin Chronic Disease Program. https://www.dhs.wisconsin.gov/forwardhealth/wcdp.htm

[20] Walz, Tim. *Governor Walz Signs Alec Smith Insulin Affordability Act*. https://mn.gov/governor/news/?id=1055-428439

Attachment B: Other Options

The Committee considered other approaches to reducing drug costs across state agencies early in the process that were ruled out early on as not feasible or as having limited savings potential. Below are descriptions of the approaches considered but not being recommended at this time.

Mail Order RFP

DHS and ETF could release a joint request-for-proposal for a vendor to administer mail order prescriptions for both the DHS and ETF programs. The vendor would have to integrate with both DHS and ETF systems and vendors but could be structured to not pose a risk to Medicaid's existing rebates. DOC, DVA, and DHS facilities were not considered for this approach since such a model would not work with their dispensing models. The Committee is not recommending this approach because several federal and state Medicaid regulations make this approach unlikely to generate savings for the Medicaid program.

Orphan Drug Direct-to-Manufacturer Purchasing

DHS, ETF and DOC could work directly with orphan drug manufacturers to obtain orphan drugs at extremely reduced prices. In exchange for these savings, the departments would make data available for the subset of patients who take the medication or may request study participation of the patient on behalf of the manufacturer. This data would help the manufacturer gain access to a larger study population for drugs that are only available to a small population. The Committee is not recommending this approach because of a lack of proof of concept and significant concerns over the sharing of patients' data with pharmaceutical manufacturers.

Specialty Drugs Site of Care

DHS and ETF could research which sites of care are the least expensive to provide specialty drugs and direct members to purchase drugs through those sites of care through the benefit design. Currently, many specialty drugs are dispensed by physician clinics and billed through the medical benefit. Often, these same drugs could be purchased through a specialty pharmacy for a better price and ensuring manufacturer rebates are available to offset costs. Corrections, DVA and the DHS facilities are not likely candidates for participation unless on-site infusions were available at every location, which would likely make it cost prohibitive for facilities. While the members of the Committee agree that the differences in the costs of drugs depending on the site of care is an important issue to address, the Study Committee is not recommending this approach at this time because it could not identify a benefit to working together on such an approach. Both ETF and Medicaid will continue to focus on making sure that patients are receiving their drugs in the most cost-effective and appropriate setting.