



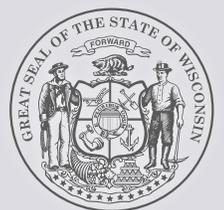
STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES



Report of the Governor's Task Force on Reducing Prescription Drug Prices

October 2020



Acknowledgments

The Governor's Task Force on Reducing Prescription Drug Prices is comprised of consumer advocates, state legislators, government agency representatives, and individuals representing industries involved with the development, pricing, distribution, and purchasing of prescription drugs including manufacturers, pharmacy benefit managers, pharmacies, health insurance carriers, hospitals, physicians, and free and charitable clinics.

The Office of the Commissioner of Insurance is the lead agency responsible for coordinating the work of the Task Force, Commissioner Mark Afable and Deputy Commissioner Nathan Houdek would like to thank the following individuals for supporting the work of the Task Force and contributing to this report:

Office of the Commissioner of Insurance: Jennifer Stegall, Megan Aubihl, Olivia Hwang, Kelsey McDermott, Jessica Carlson, Derek Spellman, and Jeff Grothman

National Governors Association: Hemi Tewarson, Kate Johnson, Sandra Wilkniss, and Jane Horvath

Acknowledgments

Introduction

October 2020

The Governor's Task Force on Reducing Prescription Drug Prices convened eight meetings to hear presentations from industry experts and discuss potential policy options from November 2019 through August 2020. The work of this Task Force has reinforced that the prescription drug development and supply chain is complicated, opaque, and, in many ways, intentionally confusing. This complexity makes it nearly impossible to understand how prices are set, how dollars flow through the supply chain, and, most importantly, why patients end up being charged exorbitant prices for some prescription medications.

I applaud Governor Evers for his commitment to addressing this important issue and for creating this Task Force as a forum for discussion, debate, and policy development. It is abundantly clear that it will require a sustained effort from all stakeholders to have a meaningful impact on addressing excessive prescription drug prices, and I encourage Wisconsin's public policymakers to continue developing and advancing new solutions with the goal of ensuring that all Wisconsin residents can afford and access the medications they need.

I greatly appreciate the willingness of the Task Force members to commit their time to this effort and for their active engagement throughout the entire process. I also want to acknowledge the many presenters who were willing to volunteer their time to share their knowledge and insights.

Throughout this process, the Task Force benefitted from hearing the personal experience stories of numerous Wisconsin residents who are struggling to afford their medications. These stories helped to reinforce the importance of the work of the Task Force, and I want to thank everyone who was willing to share their personal experiences, as well as Derek Spellman for gathering and recording those stories.

The work of this Task Force would not have been possible without the advice, guidance, and support of Jennifer Stegall, who was the driving force behind the research, analysis, and policy development throughout the entire process.

I also appreciate the support provided by the staff of the National Governor's Association. Hemi Tewarson, Kate Johnson, Sandra Wilkniss, and Jane Horvath were generous with their time and knowledge as we explored potential policy options and developed the Task Force workplan.

As a result of the COVID-19 pandemic, the Task Force temporarily paused its work in spring of 2020 and postponed the meetings that had been scheduled for March and April. After navigating unprecedented challenges, the Task Force revised its 2020 workplan and began holding meetings again in May with the remainder of the meetings being moved to a virtual format. I want to thank Megan Aubihl for managing the transition to virtual meetings and coordinating the participation of the members, presenters, and the public via the Zoom platform.

Acknowledgments

Members of the Office of the Commissioner of Insurance public affairs team – Olivia Hwang, Kelsey McDermott, Jessica Carlson, and Jeff Grothman – were instrumental in assisting with the external communications, copyediting, social media promotion, and creation of the final report.

I submit this report as a starting point for what I expect to be ongoing and evolving policy work toward a solution that ensures everyone who lives in the Badger State is able to access the medication they need at a reasonable cost.

Sincerely,

A handwritten signature in black ink, appearing to read "Nathan Houdek". The signature is fluid and cursive, with the first name "Nathan" and last name "Houdek" clearly distinguishable.

Nathan Houdek
Chair, Governor's Task Force on Reducing Prescription Drug Prices
Deputy Commissioner, Wisconsin Office of the Commissioner of Insurance

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Executive Summary

On August 20, 2019, Governor Tony Evers signed [Executive Order #39](#), creating the Governor's Task Force on Reducing Prescription Drug Prices (Task Force).

Indicating prescription drugs are estimated to cost Wisconsin residents over \$1.3 billion in 2019, the Executive Order requires the following:

The Task Force shall advise and assist the Governor in addressing excessive prescription drug prices and the financial burden that prescription drug prices place on Wisconsin residents. The Task Force shall do the following:

- a. Gather and analyze data and information relating to the development, pricing, distribution, and purchasing of prescription drugs.
- b. Review actions already taken by Wisconsin and other states to reduce prescription drug prices.
- c. Identify opportunities to coordinate with other states and the federal government.
- d. Recommend potential actions, which may include legislative, legal, regulatory, or community-based strategies, that can be taken to reduce prescription drug prices in Wisconsin.

Chaired by the Office of the Commissioner of Insurance (OCI) Deputy Commissioner, Nathan Houdek, the Task Force met eight times between November 2019 and August 2020. The Task Force heard presentations from each entity of the prescription drug supply chain to gain an understanding of each entity's role and the impact their practices have on the prices consumers ultimately pay for their medications. Recognizing that manufacturers set the initial sales price of their drugs and there are few state levers to impact that "list price," Mr. Houdek focused the Task Force on identifying practices within the supply chain where the state could effectuate change after the list price is set.

The recommendations and policy options compiled in this report represent varying levels of consensus and discussion by Task Force members, as described under each tier below. The recommendations and policy options are intended to provide initial direction to guide state action in creating building blocks to a strong foundation in addressing high prescription drug costs.

Assembly Bill 114/Senate Bill 100

The Task Force recommends the provisions in 2019 AB 114/SB 100, as amended by ASA 1, move forward in the next legislative session. Below is a list of the issues addressed in the bills and the specific recommendations.

Require pharmacy benefit managers (PBMs) to annually submit a report to OCI reflecting rebates received from manufacturers.

Require PBMs to either hold an Employee Benefit Plan Administrator (EBPA) license or a newly created PBM license.

Prohibit gag clauses in PBM contracts with pharmacists.

Ensure PBMs charge the lowest price available to the enrollee, at the point of sale (the cost either under the enrollee's health plan or purchased without, whichever is lower).

Executive Summary

Prohibit PBMs from retroactively denying or reducing a pharmacist's claim after adjudication, unless certain circumstances apply.

Establish requirements PBMs must adhere to when conducting audits of pharmacists and pharmacies.

Tier 1: Task Force Recommendations; Majority Task Force Member Support

There were several recommendations where a majority of the Task Force, after weighing the pros and cons of each, determined the recommended action to be a positive step toward reducing prescription drug prices. In some cases, the recommendation has a more direct impact on pricing and in others, a greater level of transparency is offered that will help inform future discussions. Those recommendations are listed below.

Statutorily limit the copay an insurer can charge for a month's supply of insulin.

Require additional transparency and reporting for prescription drug supply chain entities to better understand the drivers of high-cost prescription drugs and inform future policymaking.

Increase the number of Department of Justice consumer protection and anti-trust attorneys focused on improper pharmaceutical industry practices.

Increase the annual appropriation for free and charitable clinics, dedicating a portion of the funding to pharmacy, to expand access.

Develop a statewide, medication repository with a centralized prescription drug inventory in Wisconsin, or collaborate with an existing medication repository program in another state.

Support efforts by the Wisconsin Association of Free and Charitable Clinics and other stakeholders to remove barriers that unnecessarily prohibit the Wisconsin Drug Repository Program from accepting prescription drug donations from other states.

Allow one-third of continuing education requirements for pharmacists to be dedicated towards volunteerism.

Ensure that Federally Qualified Health Centers, Critical Access Hospitals, and Ryan White HIV/AIDS programs participating in the 340B drug discount program are able to reinvest savings from drug purchases into patient care and support activities.

Create a public sector prescription drug purchasing entity, initially for government purchasers as a means to leverage purchasing power and other cost-saving opportunities that may be available.

Executive Summary

Tier 1: Task Force Recommendations; Majority Task Force Member Support (continued)

Require Pharmacy Services Administration Organizations (PSAO) executing agreements with pharmacists in Wisconsin to be registered or hold a state license.

Explore and support efforts to improve physician access to real-time patient pharmacy benefit information in electronic medical records (EMRs) to allow physicians to consider out-of-pocket costs when prescribing medications. Also, explore access to the total drug cost so that decisions can be made that may save costs at a system level.

Advocate for federal regulatory changes to address practices that delay the market entry of affordable generic equivalents and other market practices identified as drivers of prescription drug unaffordability.

Tier 2: Policy Options for Consideration

The following are policy proposals that have been raised and discussed, to some extent, throughout the work of the Task Force since the first meeting in November 2019. These proposals are not necessarily Task Force recommendations; however, these proposals may merit further discussion and consideration outside of the work of the Task Force. Also, of note, at least one Task Force member expressed support for each of these proposals, while others have expressed concern or opposition. Including these proposals is important for meeting the requirement to summarize the work of the Task Force, as directed by Executive Order #39.

Require insurers to apply manufacturer prescription discounts utilized by consumers to deductibles and annual maximum out-of-pocket costs, if no generic exists or where a generic exists but the beneficiary obtained access to the prescribed drug after undergoing prior authorization, step therapy, or the insurer's exceptions and appeals process.

Create a prescription drug affordability/accountability review board to establish prescription drug spending targets for public sector entities and explore establishing price limits.

Allow wholesale importation of prescription medication from Canada.

Encourage providers and insurers to adopt, as a best business practice, the administration of specialty drugs at the lowest-cost setting available, taking into account specific patient needs, the drug, and clinical appropriateness to ensure patient safety.

Develop best practice guidelines for PBM business practices.

Enhance public awareness of pharmaceutical manufacturer patient assistance programs.

Executive Summary

Tier 3: Issues Raised but Not Thoroughly Discussed/Recent Additions

The following are policy proposals that were raised by Task Force members for potential consideration. However, the Task Force did not have time to extensively discuss these items, therefore they are being included with the acknowledgment that more analysis would be needed to determine if they merit favorable consideration.

Licensure and regulation of pharmaceutical sales representatives.

Additional regulatory oversight (licensure or regulation) of PBM brokers and consultants.

Require PBMs to act as a fiduciary on behalf of their plan sponsors.

At free and charitable clinics, consider expanding pharmacist responsibilities, implementing telepharmacy services, and making it easier to allow remote dispensing sites, in particular, for onsite inspections.

Allow the state Department of Justice (DOJ) to have direct Civil Investigative Demand (CID) authority for anti-trust cases without seeking court authority each time.

Additional restrictions on improper prescription drug marketing and advertising practices.

Create an insulin safety net program.

Create a value-based pilot project for diabetes medications.

1. Background

1.1 Defining the Problem: High Prescription Drug Costs

The high cost of prescription drugs continues to impose a financial burden on American families. According to a Kaiser Family Foundation poll, one in four Americans taking prescription drugs say it is difficult to afford their medications.¹ On a per capita basis, inflation-adjusted retail prescription drug spending in the U.S. increased from \$90 in 1960 to \$1,025 in 2017.² In Wisconsin, prescription drugs were estimated to cost residents over \$1.3 billion in 2019.³

The high cost of prescription drugs is not a problem isolated to any one specific payer type. Government programs assisting the most vulnerable populations are paying millions of dollars to ensure access to medications. The Wisconsin Medicaid program spends over \$400 million on prescription drugs each year.⁴ Free and charitable clinics are consistently faced with challenges to remain a reliable safety net for those who cannot afford prescription medications on their own; for example, helping consumers access manufacturer offered coupons, collecting unused prescription drugs through donations, leveraging state funding, and relying on volunteers and other community support. Many insured individuals, despite having coverage, experience high out-of-pocket expenses that strain family budgets. Cost increases to employers and other plan sponsors over the past several decades have resulted in increased cost sharing, increased member contributions to premiums, and even elimination of some employer or other sponsored health plans.⁵

An AARP 2019 RxPrice Watch Report found that the average annual increase in retail prices for a combined set of drugs widely used by older adults exceeded the corresponding rate of general inflation every year from 2006 through 2017.⁶ Older adults now take an average of 4.5 medications each month, which can add up to a total retail cost of more than \$30,000 a year for brand-name drugs.⁷

Due to the high cost of prescription drugs, some individuals are forced to make difficult decisions to ensure access to their medication. In some cases, it is a decision to cut back on other household expenses, while in others, individuals are choosing to ration their medication, potentially putting their health at risk. A Kaiser Family Foundation Health Tracking Poll issued in 2019 indicates for those individuals reporting difficulty affording prescription medication, six in ten are not taking their medication as prescribed.⁸ This includes not filling a prescription, taking an over-the-counter medication instead, and cutting pills in half or skipping a dose.⁹ A 2018 survey indicated that, of those experiencing a rate increase in the past year, 32% reported spending less on groceries, 32% spent less on family, 21% postponed paying for other bills, 31% used credit more often, 12% postponed retirement to maintain coverage, and 8% reported taking on a second job.¹⁰

1. Background

1.2 Task Force Membership and Approach

Recognizing the hardship prescription drug costs have on Wisconsin consumers, Governor Tony Evers issued [Executive Order #39](#), creating the Governor's Task Force on Reducing Prescription Drug Prices (Task Force). The Executive Order requires the Task Force to, "...advise and assist the Governor in addressing the excessive prescription drug prices and the financial burden that prescription drug prices place on Wisconsin residents."

Chaired by the Office of the Commissioner of Insurance Deputy Commissioner, Nathan Houdek, the Task Force convened eight times between November 2019 and August 2020. The Task Force heard presentations from each entity of the prescription drug supply chain to gain an understanding of each entity's role and the impact their practices have on the prices consumers ultimately pay for their medications. Recognizing that manufacturers set the initial sales price of their drugs and there are few state levers to impact that "list price," Mr. Houdek focused the Task Force on identifying practices within the supply chain where the state could effectuate change after the list price is set. In doing so, discussions sought to (a) identify unfavorable business practices that may be increasing costs; (b) understand a means towards reducing the opaque nature of prescription drug pricing; (c) determine a means for directly impacting consumer out-of-pocket costs, while understanding any implications to the larger system (i.e. taking one action that may lower costs for a subset of the population while increasing costs for consumers overall); and (d) ensure recommended actions maintain the ability for businesses to be flexible and innovative in their approach to maximizing consumer cost savings.

Recordings of the meetings, slide decks from the presentations, and meeting minutes are available on the [Task Force website](#). [This publication](#) also includes the meeting agendas, minutes, and presentations.



Governor's Task Force on Reducing Prescription Drug Prices | Meeting Materials

1. Background

1.2 Task Force Membership and Approach

The Task Force is comprised of the following members.



Nathan Houdek, Chair
Deputy Commissioner of Insurance
for the State of Wisconsin



Anna Benton
Deputy Director at the
Division of Medicaid Services



Alan Lukazewski
Director of Clinical Pharmacy
at NeuGen LLC



Josh Bindl
CEO of National CooperativeRx



Laura McFarlane
Assistant Attorney General



Tim Carpenter
State Senator, representing
Milwaukee's 3rd Senate District



Robyn Schumacher
Vice President of
Consultant Relations for OptumRx



Brent Eberle
Senior Vice President,
Health Strategies & Chief Pharmacy
Officer of Navitus Health Solutions
and General Manager of
Lumicera Health Services



Brian Stamm
Deputy Director
of the Office of Strategic Health
Policy at Wisconsin's Department
of Employee Trust Funds



Tony Fields
Vice President and
Chief Pharmacy Officer at the
AIDS Resource Center of Wisconsin



Brian Stephens
Chief Executive Officer and
Director for the Door County
Medical Center



Peter Fotos
Senior Regional Director, State
Advocacy for the Pharmaceutical
Research and Manufacturers of
America (PhRMA)

1. Background

1.2 Task Force Membership and Approach (continued)



Lisa Subeck
State Representative,
78th Assembly District



Janet Fritsch
Pharmacist and owner of
Corner Drug Hometown Pharmacy
in Baraboo, Wisconsin



Lara Sutherlin
Administrator of the Division
of Trade and Consumer Protection



Michael Goldrosen
Doctor of Internal Medicine
at Associated Physicians



Yolanda Tolson-Eveans
Pharmacist in Charge at St. Vincent
de Paul Charitable Pharmacy



Ian Hedges
Chief Executive Officer at
HealthNet of Rock County



Tyler Vorpapel
State Representative,
27th Assembly District



Lisa Lamkins
Advocacy Director for
Federal Issues for AARP Wisconsin



Sue Wilhelm
Interim Clinical Officer and
Director of Pharmacy Services
for Security Health Plan

Background

1.2 Task Force Membership and Approach (continued)

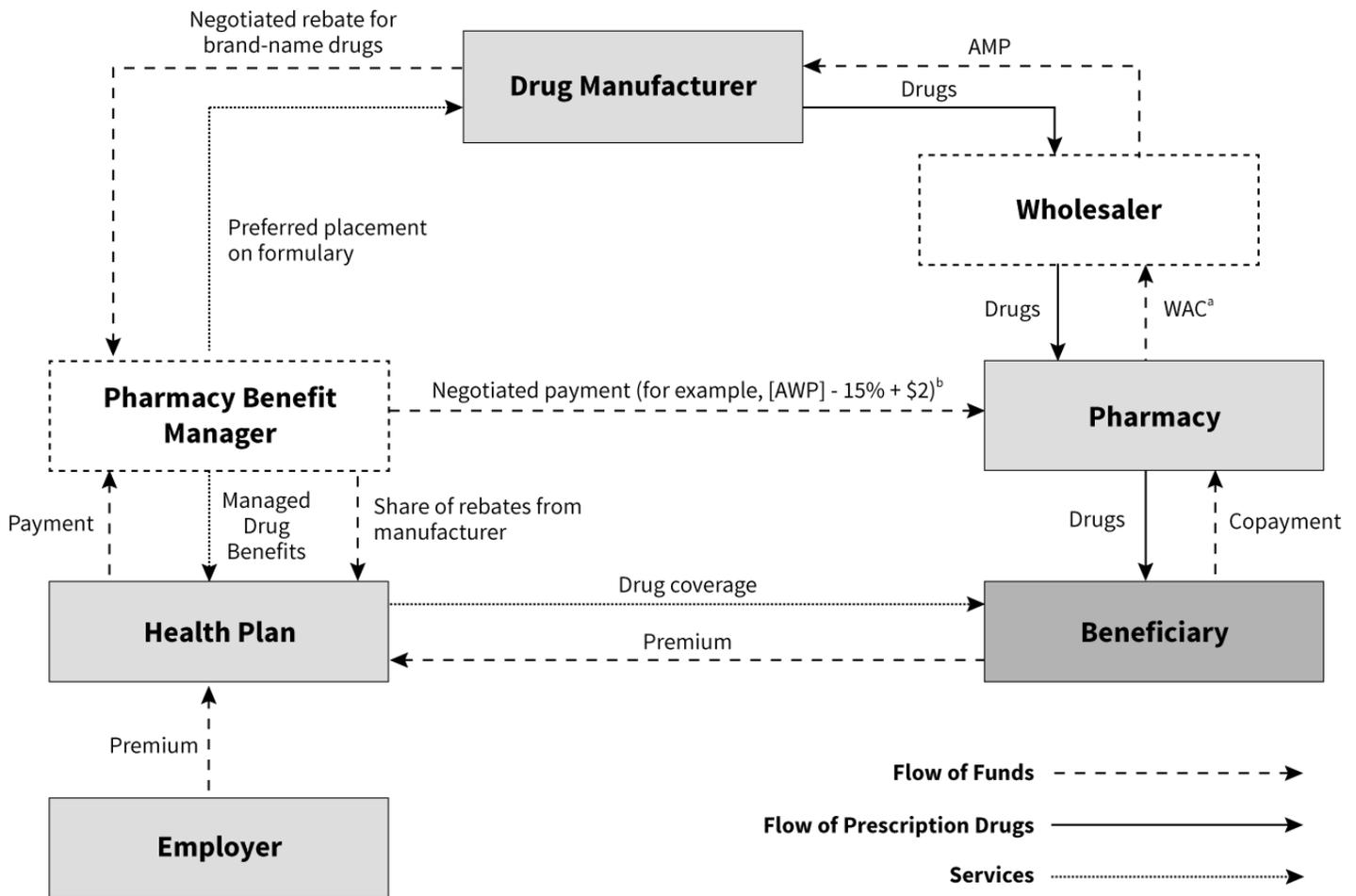
Meeting #	Date	Presenters
Meeting #1	November 20, 2019	<ul style="list-style-type: none"> • Wisconsin Department of Justice Update on Prescription Drug Lawsuits • National Governors Association and Horvath Health Policy
Meeting #2	January 22, 2020	<ul style="list-style-type: none"> • Neeraj Sood, PhD, Professor and Vice Dean for Faculty Affairs & Research, USC Price School of Public Policy & USC Schaeffer Center • IngenioRx • Navitus Health Solutions
Meeting #3	February 19, 2020	<ul style="list-style-type: none"> • America's Health Insurance Plans • Pharmaceutical Care Management Association • Magellan Rx • The Alliance and self-funded employers
Meeting #4	March 18, 2020	<ul style="list-style-type: none"> • Canceled Due to the COVID-19 Public Health Emergency
Meeting #5	April 15, 2020	<ul style="list-style-type: none"> • Canceled Due to the COVID-19 Public Health Emergency
Meeting #6	May 20, 2020	<ul style="list-style-type: none"> • Pharmacy Society of Wisconsin • Hometown Pharmacy • HealthNet of Rock County and St. Vincent De Paul Charitable Pharmacy
Meeting #7	June 18, 2020	<ul style="list-style-type: none"> • Department of Justice Litigation Update • Healthcare Distribution Alliance • Pharmacy Services Administrative Organization Coalition • American Hospital Association • Door County Medical Center • National Governor's Association and Horvath Health Policy
Meeting #8	July 21, 2020	<ul style="list-style-type: none"> • Pfizer • Pharmaceutical Research and Manufacturers of America • Civica Rx
Meeting #9	July 22, 2020	<ul style="list-style-type: none"> • OptumRx • Wisconsin Pharmacy Cost Study Committee • Northwest Prescription Drug Consortium • American Association of Retired Persons • American Diabetes Association • Vivent Health/ 340B Issues
Meeting #10	August 25, 2020	<ul style="list-style-type: none"> • Policy Discussion

2. Prescription Drug Supply Chain

2.1 Supply Chain Diagram

The prescription drug supply chain is complex. There are detailed and often opaque agreements between entities throughout the supply chain, making it difficult to fully understand profit margins and where potential savings could be realized. Manufacturers, who are largely regulated by the federal government, set the list price, kicking off the start of the process for pricing and distributing medications. Overall, while there does not appear to be large profit margins throughout the supply chain after the list price is set, the areas for cost savings may remain unclear until greater transparency is infused throughout the supply chain.

Below - *Flow of Funds for Single-source Brand-name Drugs Purchased at a Retail Pharmacy and Managed by a Pharmacy Benefit Manager for an Employer's Health Plan*¹¹



According to a USC Schaeffer Center for Health Policy and Economics study, "Of a \$100 expenditure on pharmaceuticals by consumers (composed of both out-of-pocket and insurer payment), roughly \$17 goes to drug production costs, \$41 accrues to the manufacturers (a third of which is net profit), and \$19 accrues to insurers (\$3 of which is net profit). PBMs keep about \$5 (\$2 net profit), pharmacies keep \$15 (\$3 net profit), and wholesalers keep about \$2 (30 cents net profit). Total net profit on a \$100 expenditure is \$23, of which \$15 is captured by manufacturers and the remaining \$8 by intermediaries."¹²

2. Prescription Drug Supply Chain

2.1.1 Drug Manufacturers

Drug manufacturers invest in the research and development of prescription drugs and produce the prescription drugs purchased by consumers. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), on average, it takes over 10 years and \$2.6 billion to research and develop a new medicine.¹³ Manufacturers set the price of the drugs, often referred to as the list price. From there, costs are both added and removed from the cost of drugs throughout the supply chain process. Manufacturers offer rebates and discounts as part of their negotiations with PBMs, insurers, and employers.

The average lifespan of brand name medication before generic competition enters the market is 12.5 years.¹⁴ As described by the Food and Drug Administration's (FDA) Center of Drug Evaluation and Research, "Generic drugs are copies of innovator or brand-name prescription drugs and make up about 88 percent of prescriptions filled in the United States. Brand-name drugs must demonstrate their safety and effectiveness through expensive and time-consuming research and development programs, including clinical studies. In contrast, generic drug developers can use data from their brand-name counterparts, resulting in much less expensive development programs and affordable access to treatments for many patients and consumers."¹⁵

FDA approval, federal patent laws, and federal exclusivity laws regulate drug manufacturer business practices, including how long drug manufacturers are protected from competition (impacting consumer access to lower cost generic medication). While state levers available to impact list price and the speed by which generic medications can be sold are limited, the state can require manufacturers to report price increases and other information as a means to increase transparency around drug prices (refer to Task Force [recommendation 3.2.2](#)). The Wisconsin Department of Justice (DOJ) has consumer protection and anti-trust attorneys who are involved with cases related to improper pharmaceutical industry practices. View [additional background on DOJ action here](#).

2. Prescription Drug Supply Chain

2.1.2 Wholesale Drug Distributors

Distributors provide a one-stop-shop for dispensing locations to acquire product from any licensed manufacturer.¹⁶ Wholesalers operating in Wisconsin are required to obtain a license from the Department of Safety and Professional Services (DSPS). According to the DSPS website, “A distributor’s license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. A distributor’s license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber’s prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.”¹⁷

The Healthcare Distribution Alliance, representing wholesaler distributors, including Cardinal Health and McKesson located in Wisconsin, describe the activities of wholesalers as follows:¹⁸

- Purchase pharmaceuticals from manufacturers based on the wholesale acquisition cost (WAC), a publicly available figure.
- Manufacturers set WAC, distributors are not privy to how WAC is set.
- Charge manufacturers distribution fees related to their services, these fees are not passed on to the customer or impact drug cost.
- Typically sell branded drugs based on WACs or WAC minus a percentage.
- May purchase generic drugs at a manufacturer’s list price but often are able to use market power to negotiate discounted prices on generic drugs.
- Market power allows wholesalers to offer discounted pricing on generic drugs.

The [Healthcare Distribution Alliance submitted comments](#) about the wholesale distributors industry to the Task Force.

2.1.3 Pharmacy Services Administrative Organizations

Pharmacy Services Administrative Organizations (PSAOs) are voluntary service organizations that independent pharmacies and small chains use to execute contracts with payers and PBMs.¹⁹ PSAOs are often owned by the wholesaler, but that is not always the case. According to the [PSAO Coalition presentation](#) to the Task Force, the coalition was started in 2020 by the three largest PSAOs that are owned by pharmaceutical wholesalers: AmerisourceBergen – Elevate, Cardinal Health – LeaderNET, and McKesson – Health Mart Atlas.

Core PSAO responsibilities include the evaluation and execution of PBM contracts and claims processing. PSAOs do not touch prescription drugs or dollars affiliated with them. They do not dictate reimbursement rates, set maximum allowable cost (MAC) rates for generic drugs, or retain pharmacy reimbursement.²⁰ While PSAOs are not typically highlighted in the prescription drug cost discussions,

2. Prescription Drug Supply Chain

2.1.4 Pharmacists and Pharmacies

there has been greater attention to their role and interest in the data they can provide. Pharmacists and pharmacies dispense medication to patients. Types of pharmacies include brick and mortar retailers such as Walgreens and CVS, mail-order firms, and inpatient pharmacies in facilities such as hospitals and nursing homes.²¹

Free and charitable clinics also have pharmacies that play a critical role in ensuring underserved populations are able to access needed medications. In 2019, more than 150,000 Wisconsinites used more than 99 free and charitable clinics.²² Examples of individuals who utilize these services are those who cannot afford insurance premiums or pay for their deductibles, do not qualify for Medicaid, missed the individual market open enrollment period, or are waiting for their employer-sponsored coverage to become effective.²³

Community pharmacies, also known as independent pharmacies, are the most well-known type of pharmacy, providing the community with access to the medications they need, as well as advice to promote the safe and effective use of the medicines they provide.²⁴ Unlike chain pharmacies, community pharmacies are owned by a sole proprietor or a small group of people rather than being franchised.²⁵ These pharmacists have expressed concerns over the reimbursement rates and contract terms available in working with PBMs and insurers. Payers, including PBMs, establish a maximum allowable cost (MAC) list, which is a list of products that includes the upper limit or maximum amount that a plan will pay for generic drugs and brand name drugs that have generic versions available.²⁶ Community pharmacists are vocal in their concerns about their ability to remain in-network providers and continue to serve their customers. 2019 Assembly Bill 114 (AB 114)/Senate Bill 100 (SB 100), explained in more detail under [section 3.1](#) are a starting point for addressing their concerns.

2.1.5 Pharmacy Benefit Managers

Generally, pharmacy benefit managers (PBMs) are third party administrators that contract with insurers and self-insured employers to manage prescription drug formularies and claims. This entails leveraging their volume (client base) in negotiating with manufacturers to determine which prescription drugs will be included on plan formularies. PBMs also pay pharmacy claims after plan enrollees purchase their medication. Insurers and self-insured employers pay an administrative fee to the PBM for taking on those services. Such agreements between the PBMs and insurers/employers may include terms specifying whether all manufacturer rebates must be passed through to the insurer/ employer, whether a portion may be retained to cover administrative fees, and to what extent additional financial incentives are included to further incent PBMs to negotiate the lowest price possible on their client's behalf.

Three PBMs account for roughly 75% of covered lives: CVSHealth; Express Scripts; and OptumRx.²⁷ Health insurers in Wisconsin covering a majority of insured lives in the state utilize a PBM. All PBMs under contract with Wisconsin insurers are licensed as Employee Benefit Plan Administrators (EBPAs). [Section 3.1.2 of this paper](#) further explains this licensure and the Task Force recommendation related to PBM licensure.

2. Prescription Drug Supply Chain

2.1.5 Pharmacy Benefit Managers (continued)

PBMs and their role in the supply chain have received increased attention over the past few years, with increased efforts by states to enact regulatory requirements around their business practices. At a high level, recognizing that not all PBMs operate in the same manner, issues raised during Task Force meetings were similar to those raised nationally.

Some of those include:

- The extent PBMs develop formularies based on rebates and whether more expensive drugs are included over less expensive options as a result;
- Uncertainty around rebate dollars generally and who ultimately benefits financially from them; i.e., the PBMs, insurers, consumers, some combination thereof;
- PBM contract terms when entering into agreements with independent/community pharmacies and how those pharmacies fit into an evolving delivery system;
- The value of ensuring new regulatory measures are balanced and do not unintentionally stifle innovation or flexibility that allows PBMs to achieve goals specific to individual insurers/employers, and;
- PBM networks and the overall evolving landscape as more PBM/insurer business affiliations occur (e.g., OptumRx and United Healthcare, CVS Health and Aetna, Express Scripts and Cigna, and IngenioRx and Anthem). There is a recognition that when PBMs own pharmacies, they might favor their own pharmacies, even if other pharmacies have lower costs, or where there is an ownership interest in the insurer, the PBM might try to increase drug costs of rival health plans.²⁸

Many of the issues listed above were vetted in the state legislature for several months as lawmakers debated and amended companion bills AB 114 and SB 100; discussed in more detail under [section 3.1](#) of this paper.

2.1.6 Insurers

Insurers offer health insurance coverage to individuals directly and through employer sponsored health plans. Enrollees pay a monthly premium and insurers pay for a portion of their medical and pharmaceutical expenses. The portion not covered by health insurance is the responsibility of the enrollee and is referred to as the enrollee's out-of-pocket expenses or cost sharing (i.e., deductible, copay, coinsurance).

Insurers often enter into agreements with PBMs to process pharmacy claims, negotiate discounts with drug manufacturers, and manage their prescription drug formularies. Insurers generally value the role PBMs take on in negotiating pricing, as they could not bring the level of covered lives to the table in negotiations with manufacturers that PBMs can. Issues raised during Task Force discussions related to insurers include transparency around their top drug spend and utilization of rebates. Specifically, to that latter point, there are PBMs that utilize a business model where they pass 100% of the rebates through to the insurers. There is interest in understanding the degree to which those rebates offset expenses for enrollees.

2. Prescription Drug Supply Chain

2.1.7 Consumers

Individual consumers purchase their prescription drugs from pharmacies. Task Force members heard consumers explain their challenges in accessing needed medications and the hardship high cost prescription medications have imposed on their families. Summaries of those stories are detailed below, along with links to videos of the consumers sharing their stories with the Task Force.



Consumer Story 1

Kyle Kemp
Small Business Owner
Oshkosh, Wisconsin

[View the Video](#)

- Kyle had insurance coverage at the time of his type 1 diabetes diagnosis, which occurred after an emergency room visit at the age of 24.
- Left the hospital with two boxes of insulin which was a one month's supply. One type of insulin was to be used right before meals and the other taken daily to keep blood sugar regulated. The cost for the two boxes was \$1,000. He later received a \$10,000 bill for the emergency room visit.
- Given the nature of his work, Kyle's income varies throughout the year and he determined it was not worthwhile to pay monthly insurance premiums on a high deductible health plan when the cost of insulin was about the same under insurance coverage as when he purchased it using manufacturer coupons. Kyle acknowledged he is at risk should other health issues arise given he does not have insurance coverage.
- Kyle has rationed insulin at times to make his supply go further, due to the high cost.
- Family and friends have helped ensure he has the insulin and test strips he needs at times.

2. Prescription Drug Supply Chain

2.1.7 Consumers (continued)



Consumer Story 2

Kimberly Goffard

(sharing on behalf of her 19 year old, diabetic son)

Communicable Disease Nursing Supervisor Wisconsin

[View the Video](#)

As the communicable disease nursing supervisor at the Winnebago County Health Department, she is also well versed in the medical system and the struggle that people with diabetes face in affording their medications.

- At the age of 18, her son was recruited to play football at a Division 2 school in Minnesota. As the school year went on, he was losing more and more weight. He eventually came home and started school at UW Oshkosh. In April 2019, he went to the doctor and called Kimberly to tell her that he was diagnosed with type 1 diabetes and needed to be hospitalized. His blood sugar was 800 and he was in diabetic ketoacidosis.
- Her family has insurance and is very aware that they are fortunate in that respect. With insurance, putting the maximum amount they can into flex spending, and budgeting to cover expenses with cash flow, they are able to ensure their son has the insulin and supplies he needs.
- They are not rich but cover their expenses. Kimberly wanted to make the point that if a family like hers is using all their flex account funds and supporting the rest through cash flow for one child, individuals without those resources are in trouble.
- Kimberly emphasized the importance of proper nutrition for a person with diabetes. She has seen that living on a fixed income while trying to afford insulin and supplies can lead to poor dietary choices as often quick, unhealthy food is less expensive than healthier alternatives. Unhealthy food choices can then lead to increased blood sugar which requires people to use more insulin, which is expensive – creating a negative, unhealthy cycle.
- Her son is worried about aging out of his parent's insurance at the age of 26. He has commented that he tries not to eat carbohydrates because that increases his blood sugar, causing the need for more insulin, and insulin is expensive. Kimberly used this as an example of the thought process a person with diabetes goes through to save money and her son is only 19. She indicated others think about reusing needles or rationing supplies.

2. Prescription Drug Supply Chain

2.1.7 Consumers (continued)



Consumer Story 3

Mark Miller
Retired
North Freedom, Wisconsin

[View the Video](#)

- Diagnosed with chronic obstructive pulmonary disease (COPD)
- Mark had a kidney transplant eight years ago and was on disability for several years after that. He eventually lost that benefit due to his 401K earnings. His wife is on disability. They are on a very fixed income and the cost of his COPD inhaler further strains their financial situation as it costs approximately \$400 a month until the deductible on his drug plan is met.
- Mark indicated he was supposed to use his previous inhaler four times a day and had rationed that down to once a day to make his supply last longer. He was charged \$385 for that inhaler. His doctor changed him to one where only one dose a day is needed, however the cost is now over \$400 a month (before his plan deductible is met).

2. Prescription Drug Supply Chain

2.1.7 Consumers (continued)



Consumer Story 4

Herrick Family Living with Diabetes Cushing, Wisconsin

[Video 1](#)

[Video 2](#)

- Ted Herrick has type 2 diabetes and his teenage daughter, Carly, has type 1 diabetes.
- The family highlighted the financial strain the cost of diabetes drugs and supplies put on their family and the level of navigating necessary on the part of the family to figure out the lowest cost option for accessing medication and supplies.
- At the time of Carly's diagnosis, the initial cost for a three-month supply of all her insulin and testing strip needs cost the family their entire \$2,600 deductible.
- A local pharmacist connected the family with the local hospital that has an agreement with the government that now allows them to access insulin for less than their insurance plan.
- Both the father and daughter have had to change medications due to formulary changes. In some cases, when the formulary changed, the family doctor was able to indicate there was a need to stay on the current medication and their insurance allowed it. To the mother who navigates much of the care, it is a frustrating step to reach out to the doctor and ask for the note.
- Every time the formulary changes, a different meter seems to be covered. The family has a box of 15 meters that all do the same thing. They see this as waste and are frustrated by that.
- The family highlighted ketone strips to demonstrate mark-up. The strips are used to test levels in the blood. Their insurer charged \$140 for two boxes, which is 40 strips. The manufacturer charges \$40 for two boxes.

2. Prescription Drug Supply Chain

2.1.7 Consumers (continued)



Consumer Story 5

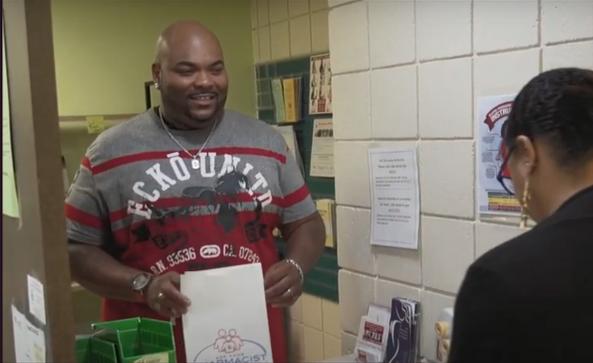
Dr. Barbara Horner-Ibler
Physician at Bread of Healing Clinic
Milwaukee, Wisconsin

[View the Video](#)

- The Bread of Healing Clinic serves uninsured adults with chronic illness.
- Individuals they serve have incomes that are too high to qualify for BadgerCare.
- Many of the people the clinic treats can afford to purchase an individual market health insurance plan but cannot afford to use the policy. One example, although there are many:
 - The patient earned \$15,000 a year in the foodservice industry and received a raise. She was excited to purchase a health insurance plan. She then saw Dr. Horner-Ibler as a private pay patient and was prescribed two inhalers to treat her asthma.
 - The patient went to the pharmacy and was told she would have to pay the full price of over \$500 for the inhalers until her \$1,500 deductible was met.
 - The patient had to let her health insurance policy lapse so that she could qualify for the clinic's services for individuals without coverage because she could not afford to meet the plan's deductible.

2. Prescription Drug Supply Chain

2.1.7 Consumers (continued)



Consumer Story 6

Isaac
Local musician and chef
Dane County, Wisconsin

[View the Video](#)

- Isaac is uninsured and has type 2 diabetes.
- He does not have insurance and uses St. Vincent de Paul as a means for accessing his medications and foods that align with a diabetic's needs.



Consumer Story 7

Annette Huston
Registered Nurse
Stevens Point, Wisconsin

[View the Video](#)

- Diagnosed with Multiple Sclerosis (MS).
- Annette has insurance through her husband's employer; she pays \$500 out-of-pocket each month for the medication that treats conditions many people suffer from, such as bladder issues. Her MS-specific medications used to slow the progression of the disease cost approximately \$100,000 a year, of which she pays \$700-\$800 a year.
- None of the MS medications she is taking are on the Medicare formulary.
- Annette is 61 years old and she is fearful she will need to stop taking her MS-specific medications in a few years, once she is Medicare eligible.

2. Prescription Drug Supply Chain

2.1.8 Hospitals

While hospitals are not listed in the supply chain diagram in [section 2.1](#), hospitals both purchase and administer prescription medication to individuals in inpatient and outpatient settings. Cost increases experienced by other entities in the supply chain have impacted hospital expenses. In January 2019, the American Hospital Association, the Federation of American Hospitals (FAH), and the American Society of HealthSystem Pharmacists (ASHP) released a report finding that continued rising drug prices, as well as shortages for many critical medications, are impacting patient care and putting strains on hospital budgets and operations.²⁹

The Task Force learned that drug availability is as critical an issue as cost and something hospitals dedicate staff to monitoring daily. Hospitals work with partner facilities and third-party buyers to ensure accessibility for their patients.³⁰ This landscape has also led to collaboration and innovation in purchasing drugs in this space. In 2018 leading health systems founded CivicaRx, a nonprofit corporation that works with health systems and manufacturers to reduce shortages of generic medications in hospitals.

Below - *How Civica Works*³¹



3. Task Force Recommendations & Policy Options

3.1 Task Force Support for Provisions included in Assembly Bill 114 and Senate Bill 100

Background

During the 2019-2020 legislative session, a bipartisan group of legislators introduced companion bills Assembly Bill 114 (AB 114) and Senate Bill 100 (SB 100), related to the regulation of PBMs. Working with interested parties, the bills were amended to include provisions that were amendable as a first step in imposing additional state regulation over PBMs. AB 114 passed the Assembly as amended with a vote of 96-0 and was approved by the Senate Committee on Health and Human Services on March 10, 2020. It was anticipated that AB 114 would be scheduled for a vote before the full Senate, however, the COVID-19 pandemic interrupted the legislative session, shifting state priorities to the immediate health and safety needs of residents during that time. AB 114 was not able to advance before the session ended at the end of March.

The Task Force recommends that the provisions in AB 114/SB 100, as amended, move forward in the next legislative session. Below is a list of the issues addressed in the bills and the specific recommendations. For a detailed summary of the differences between the bills as introduced and the amended version, the Legislative Council Amendment Memo is available here: <https://docs.legis.wisconsin.gov/2019/related/lcamendmemo/ab114.pdf>

The Task Force received written comments from the following organizations related to AB 114/SB 100: [Common Ground Healthcare Cooperative](#), [The Alliance](#), [NeuGen LLC](#), [Coalition of State Rheumatology Organizations](#), [Pharmacy Society of Wisconsin](#), [American Association of Retired Persons](#), [Greater Wisconsin Agency on Aging Resources](#), [National Association of Chain Drug Stores](#), [Wisconsin Counties Association](#).

3.1.1 PBM Rebate Transparency

Recommendation

Require PBMs to submit a report to OCI annually with (1) aggregate rebate amounts from the previous year received from all manufacturers but retained and not passed through to insurers; and (2) the percentage of the aggregate rebate amount that is retained in rebates. Reports from PBMs to OCI are considered a trade secret under s. 134.90, Wis. Stat.

Rationale

Today, there is a lack of publicly available PBM rebate data. This recommendation is a first step in collecting rebate data from PBMs that may lead to a better understanding of the current practices and help to inform future discussions that seek to address high prescription drug costs.

3. Task Force Recommendations & Policy Options

3.1.2 PBM Licensure

Recommendation

Require PBMs to either hold an Employee Benefit Plan Administrator license or a newly created PBM license. The requirements for obtaining these licenses would be the same.

Rationale

Currently, there is no PBM specific licensure requirement or statutory language directly citing PBMs as required to obtain an Employee Benefit Plan Administrator license. However, the business conducted by PBMs aligns with the business practices that require an Employee Benefit Plan Administrator license. Therefore, PBMs contracted with insurers offering comprehensive health insurance coverage in Wisconsin are licensed as Employer Benefit Plan Administrators through OCI; governed by [Chapter 633](#), Wisconsin statutes. The following must be submitted to OCI for Employee Benefit Plan Administrator licensure: a surety bond; a financial statement that includes assets, liabilities, and net worth; and a \$100 annual fee.

A specific PBM licensure requirement ensures OCI is aware of the entities operating as PBMs in Wisconsin and provides state authority to suspend or revoke a license.

3.1.3 Gag Clauses

Recommendation

Require insurers to ensure the PBMs they contract with do not restrict a pharmacy from or penalize a pharmacy for informing an enrollee of any differential between the out-of-pocket cost to the enrollee with insurance and the amount an individual would pay for the acquisition of the drug without using health insurance.

Rationale

“Gag clauses” in contracts between pharmacies and PBMs are designed to prevent pharmacists from disclosing to a patient whether a drug’s cash price would be lower than the patient’s cost sharing burden under their insurance plan.

Prohibiting gag clauses allows pharmacists to be open with consumers regarding drug prices available to them, without fear of retaliation. This allows consumers to understand all their options at the point of sale.

The federal [Patient Right to Know Drug Prices Act](#) prohibits gag clauses in PBM contracts. This law was enacted in October 2018. Despite federal law addressing gag clauses, enacting a similar prohibition at the state level will provide new state regulatory authority to enforce the law. Additional state oversight can help ensure gag clauses are not being used and enforce penalties against entities found to be using them.

3. Task Force Recommendations & Policy Options

3.1.4 Lowest Cost at Point of Sale

Recommendation

Prohibit PBMs from requiring an enrollee to pay, at the point of sale, an amount that is more than the lowest of the following:

- The cost sharing amount for the prescription drug under the enrollee’s health insurance plan; or
- The amount an enrollee would pay for the prescription drug if they purchased the drug without health insurance coverage.

Rationale

Imposing the “lower of” logic ensures consumers are receiving the lowest price available.

3.1.5 Retroactive Claim Reduction

Recommendation

Prohibit PBMs from retroactively denying or reducing a pharmacist’s claim after adjudication unless one of the following is true:

- The original claim was submitted fraudulently.
- The payment for the claim was incorrect.
- The pharmacy services were not rendered by the pharmacist.
- The pharmacist violated state or federal law.
- The reduction is permitted in a contract between a pharmacy and a PBM and is related to a quality program.

Rationale

Retroactively charged fees are imposed by PBMs on pharmacies, sometimes based on performance, after adjudication of a claim. These fees are not known at the point of sale and are billed to the pharmacy at a later date.

Establishing parameters defining when retroactive claim reductions are permitted provides a new level of transparency not in place today. The new structure, if implemented, provides both pharmacists and PBMs with a common understanding, upfront, as to when retroactive claim reductions are permitted. It also establishes a framework for holding PBMs accountable concerning claim reductions.

3.1.6 PBM Auditing Requirements

Recommendation

Establish requirements PBMs must adhere to when conducting audits of pharmacists and pharmacies. To view a full list of requirements, review [2019 AB 114](#), starting on page 13 of the bill.

3. Task Force Recommendations & Policy Options

3.1.6 PBM Auditing Requirements (continued)

Rationale

The new requirements would add transparency to the auditing process that does not exist today. Pharmacists and PBMs would understand the parameters under which audits must be conducted upfront, preventing surprises on the side of pharmacists and creating a new level of accountability for PBMs.

3. Task Force Recommendations & Policy Options

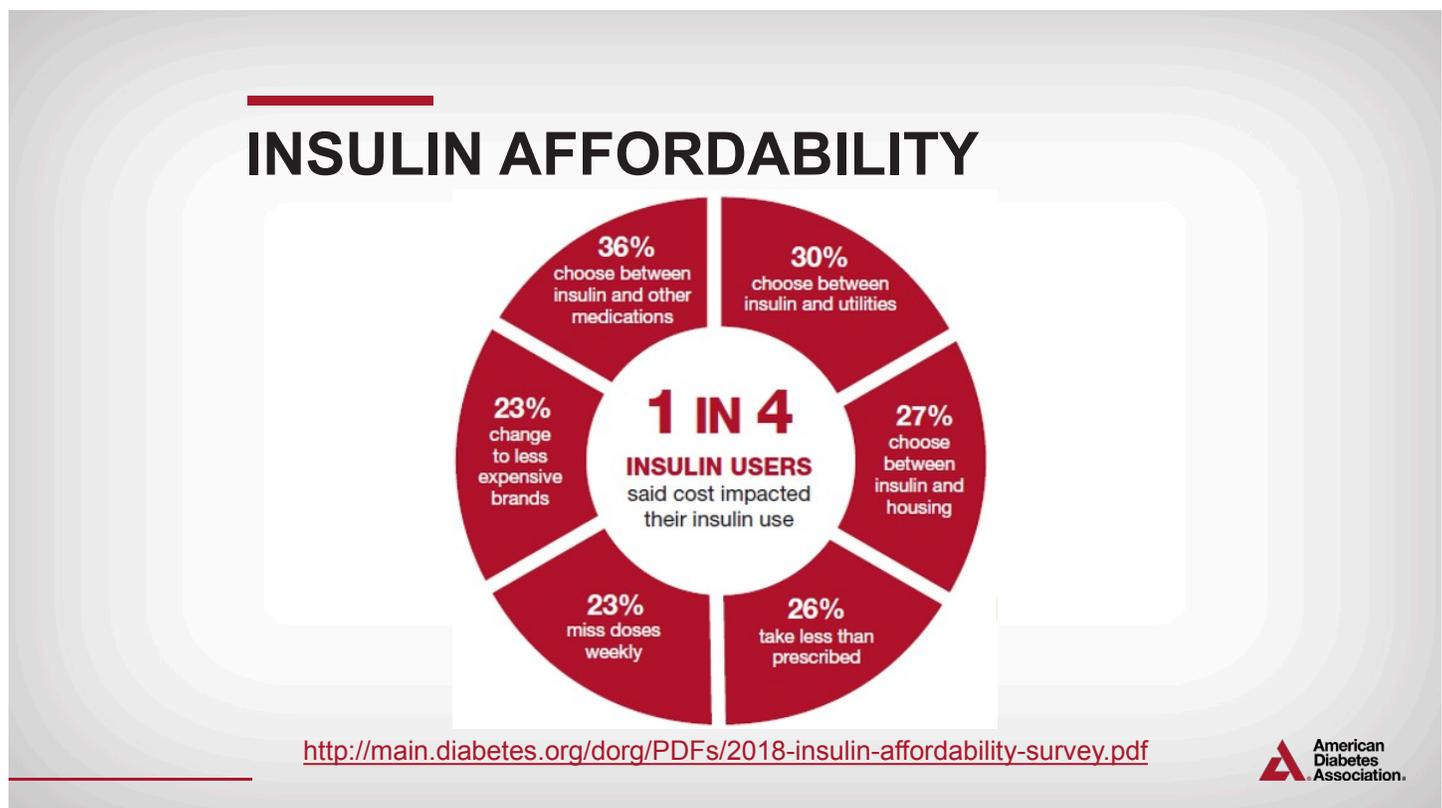
3.2 Tier 1: Task Force Recommendations; Majority Task Force Member Support

There were several recommendations where a majority of the Task Force, after weighing the pros and cons of each, determined the recommended action to be a positive step toward reducing prescription drug prices. In some cases, the recommendation has a more direct impact on pricing and in others, it creates a greater level of transparency that will help inform future discussions. Those recommendations are detailed below.

MEDICATION USED TO TREAT DIABETES

Background

According to the American Diabetes Association, 439,000 adults in Wisconsin have diagnosed diabetes, an additional 135,000 have it but do not know it, and 1.6 million have prediabetes.³²



The consumer stories that Task Force members heard at their meetings are highlighted under [section 2.1.7](#) of this report. The recommended proposals seek to offer an immediate means for relief for individuals struggling to pay for their insulin and compromising their health by forgoing or rationing their medication or other critical health needs to access insulin.

3. Task Force Recommendations & Policy Options

MEDICATION USED TO TREAT DIABETES

3.2.1 Insulin Copay Cap

Recommendation

Statutorily limit the copay an insurer can charge for a month's supply of insulin.

Rationale

A copay cap offers immediate relief to people with diabetes who require insulin. More affordable medication should result in more individuals accessing their medications and adhering to their treatment plans, which could lead to additional savings within the health care system.

Several states have passed laws capping insulin copays; caps range from \$25 to \$100. In Wisconsin, companion bills Senate Bill 340 and Assembly Bill 411, introduced during the 2019-20 legislative session, proposed limiting cost sharing for insulin to \$100 for a one-month supply. Both bills failed to pass before the end of the legislative session.

There was a lot of discussion throughout various Task Force meetings related to the perceived savings a particular proposal may have on the surface but that may lead to increased costs in other areas. Imposing cost sharing caps is an example. The point was made that placing government-imposed limits on enrollee out-of-pocket expenses would result in increased costs in other areas, such as increased health insurance premiums for all enrollees. While there is merit to the discussion and agreement that squeezing the balloon on one end shifts the problem of increased costs to the other end, it may be possible to work with insurers to determine a cost sharing cap amount where there is benefit to consumers without putting insurers in a position of having to increase costs in other areas. Efforts in Colorado seem to reflect this.

In 2019, Colorado became the first state to pass legislation to cap insulin costs.³³ The National Academy for State Health Policy (NASHP) interviewed the bill's author, Representative Dylan Roberts, in January 2020 and asked the following, "Does the legislation have a mechanism for preventing cost-shifting to premiums? Was this a concern?" He responded, "This was a concern when I drafted the bill, so we worked closely with the insurance companies and arrived at \$100 for the cap as the point where we could save money for people who need insulin without raising costs for everybody else on the same insurance plan. The insurance companies have said publicly that insurance prices won't go up because of the cap."

Comments expressing support were submitted by the following organizations: [Greater Wisconsin Agency on Aging Resources, Inc.](#), [American Diabetes Association](#), [American Association of Retired Persons](#), [Common Ground Healthcare Cooperative](#) (supported SB 340 but concern regarding caps as the answer to high insulin costs)

Comments expressing concern were submitted by the following organizations: [The Alliance](#), [Common Ground Healthcare Cooperative](#) (supported SB 340 but concern regarding caps as the answer to high insulin costs), [America's Health Insurance Plans](#), [Wisconsin Association of Health Plans](#), [Alliance of Health Insurers](#), [NeuGen, LLC](#)

3. Task Force Recommendations & Policy Options

TRANSPARENCY AND REPORTING

Note: PBM reporting is not detailed in this section as a recommendation due to Task Force support for the PBM reporting included in AB 114/SB 100 referenced in [section 3.1.1](#) of this paper. The rationale provided for transparency below applies to PBMs.

Background

While data collection in and of itself will not lower the cost of prescription drugs, it is a first step in understanding prescription drug costs across the supply chain and a means for gaining greater insight into which drugs are high cost drivers and why. States that design reporting templates using consistent and compatible concepts and measures, and report those measures publicly, can foster mutual understanding of facts among policymakers and stakeholders in a complex system.

3.2.2 Transparency and Reporting

Recommendation

Require additional transparency and reporting for prescription drug supply chain entities to better understand the drivers of high-cost prescription drugs and inform future policymaking.

While the Task Force did not put forth specific recommendations for additional transparency and reporting, below are policy options for specific supply chain entities.

The [American Diabetes Association submitted comments](#) to the Task Force in support of transparency for entities in the supply chain.

TRANSPARENCY POLICY OPTION: INSURERS

Require insurers to report a list of the prescription drugs costing them the most and the prescription drugs with the highest price increases. For example, included in Governor Evers' 2019-21 budget recommendation, but ultimately removed by the legislature, was a requirement for insurers to report the top 25 drugs that are the highest cost to the insurer and the 25 with the highest cost increases over the 12 months before submission of the report. Other states require similar reporting, for example, Oregon requires insurers to report the 25 most prescribed drugs, the 25 most costly drugs, and the 25 drugs which caused the largest increases in yearly health plan spending. The Oregon Department of Consumer and Business Services publishes an annual report summarizing the information: [2019 Insurer Reports on Prescription Drugs Drug Price Transparency Program](#).

The Maine Health Data Organization, the state's all-payer claims database, is annually required to report similar data. Wisconsin also has an all-payer claims database: the [Wisconsin Health Information Organization \(WHIO\)](#). It is possible that the Wisconsin Health Information Organization could be leveraged to collect and publicly report prescription drug data.

Additional data required by the state of Washington in [House Bill 1224](#), effective July 2019, includes

3. Task Force Recommendations & Policy Options

TRANSPARENCY AND REPORTING

the portion of the premium, after rebates, attributable to brand, generic, and specialty drugs. It also requires the year-over-year increase, calculated on a per member, per month basis, in the total annual cost of each category of covered drugs, after accounting for all rebates and discounts.

TRANSPARENCY POLICY OPTION: MANUFACTURERS

Require manufacturers to report prescription drug costs when the wholesale acquisition cost of a drug increases by a certain percentage. Governor Evers' 2019-21 budget recommendations included the following reporting requirements, which were not included in the final version of the budget: Require a prescription drug manufacturer to notify the Office of the Commissioner of Insurance (OCI) if it is increasing the wholesale acquisition cost of a brand-name drug on the market in Wisconsin by more than ten percent or by more than \$10,000 during any 12-month period or if it intends to introduce to market in Wisconsin a brand-name drug that has an annual wholesale acquisition cost of \$30,000 or more. In addition, require a manufacturer to notify OCI if it is increasing the wholesale acquisition cost of a generic drug by more than 25 percent or by more than \$300 during any 12-month period or if it intends to introduce to market a generic drug that has an annual wholesale acquisition cost of \$3,000 or more.³⁴

Comments in support were submitted to the Task Force by the following organizations: [The Alliance](#), [Greater Wisconsin Agency on Aging Resources, Inc.](#), [Common Ground Healthcare Cooperative](#), [Wisconsin Association of Health Plans](#), [Wisconsin Counties Association](#), [America's Health Insurance Plans](#), [American Association of Retired Persons](#)

Comments in opposition were submitted to the Task Force by the following organizations: [Pharmaceutical Research and Manufacturers of America](#)

TRANSPARENCY POLICY OPTION: PSAOS

Require PSAOs to report the negotiated reimbursement rate of the 25 prescription drugs with the highest reimbursement rate, the 25 drugs with the largest year to year change in reimbursement rate, and the schedule of fees charged to pharmacies. Washington enacted this requirement, HB 1224, however, it excludes PSAOs whose revenue is generated from flat service fees not connected to drug prices or volume, and paid by the pharmacy.

It was suggested by the [Wisconsin Association of Health Plans in their comment letter](#) to the Task Force that PSAOs publicly disclose any arrangements with pharmaceutical manufacturers, switch operators, and pharmacies that incentivize increased utilization of brand name drugs.³⁵

The [PSAO Coalition submitted comments](#) about their industry to the Task Force.

Rationale for Transparency Policy Options

The opaqueness of the prescription drug supply chain and a need for greater transparency,

3. Task Force Recommendations & Policy Options

TRANSPARENCY AND REPORTING

while protecting proprietary information, was a theme that kept surfacing within the Task Force discussions. A clear starting point is the collection of aggregate data across the supply chain. Aggregate data can serve a purpose in highlighting where more information and focus is needed and can help identify trends.

The National Academy for State Health Policy published a paper in August 2019 entitled, [What Are We Learning from State Reporting on Drug Pricing?](#) The report summarizes what California, Nevada, Maine, Oregon, and Vermont are learning from the reports they collect in their respective states from PBMs, insurers, and manufacturers. There is data in the report specific to the costliest drugs in the states, the impact on health insurance premiums, manufacturer costs/profit (Nevada), and PBM rebates.

The executive summary of the National Academy of State Health Policy report reflects the following; shared here as an example of the type of information available from reporting.

*Costliest Drugs across States*³⁶

Five states — California, Nevada, Maine, Oregon, and Vermont — have published reports identifying specific drugs that are high cost, for which costs are rising fastest, and/or that are most frequently prescribed. In Nevada, these drugs include only those related to the treatment of diabetes. California, Maine, Oregon, and Vermont reported up to 126 prescription drugs across therapeutic uses. These states reported many of the same drugs—including five drugs used for the treatment of diabetes and four drugs used for the treatment of psoriasis, psoriatic arthritis, or rheumatoid arthritis.

*Impact on Premiums*³⁷

California, Vermont, and Oregon have reported impacts of retail prescription drug costs on insurance premiums, averaging 13 percent in California (before accounting for manufacturer rebates, which averaged 10.1 percent of insurers' retail drug costs) in 2017, 15.67 percent of premiums in Vermont in 2018 (before accounting for rebates), and up to 18 percent of premiums in Oregon (after accounting for rebates) in 2018.

*Manufacturer and PBM Reporting*³⁸

Requiring both manufacturers and PBMs to report allows states to track drug pricing along the supply chain. As of August 2019, only Nevada had publicly reported information about manufacturer and PBM costs, focused on essential diabetes drugs. Nevada's report indicates that:

- Production costs accounted for 29 percent of manufacturers' estimated average revenue in 2018 for essential diabetes drugs after rebates. Administrative costs and profit each accounted for 25 percent. On average, manufacturers earned \$42 in profits for every \$100 spent on production and administrative cost for these drugs.
- Financial assistance to consumers accounted for 14 percent of the manufacturers' estimated total revenues after rebates, although most manufacturers reported offering no financial assistance.

3. Task Force Recommendations & Policy Options

TRANSPARENCY AND REPORTING

- Most of the rebates that PBMs in Nevada negotiated nationally for essential diabetes drugs were on behalf of private insurers and self-insured employer plans. PBMs retained 6.6 percent of all rebates, whether negotiated on behalf of private third parties or Medicaid.

After the collection of aggregate data, if there are specific areas of interest related to a drug or therapeutic class, a state may want to consider the collection of more granular data. PBM reporting by manufacturer/product code (if not by National Drug Code) is critical to understanding the supply chain for the specific drugs of interest to the states.³⁹ Nevada's PBM reporting requirement for a list of specified National Drug Codes demonstrates that PBMs are able to report on specific drugs, not only on their aggregate business.⁴⁰ In 2019, Maine enacted [LD 1162](#), requiring manufacturers and PBMs to report cost data to the Maine Health Data Organization. Maine goes beyond other states' transparency bills because it requires reporting from each entity in the supply chain about past and projected costs and revenues at the individual drug level.⁴¹ Should Wisconsin pursue more detailed, comparative cost data, as mentioned above, the Wisconsin Health Information Organization may be an entity to consider for collection, analysis, and reporting.

National Academy for State Health Policy provides a summary of state transparency laws enacted in other states from 2017-2020, available here: <https://www.nashp.org/rx-laws/>

3. Task Force Recommendations & Policy Options

WISCONSIN DEPARTMENT OF JUSTICE CONSUMER PROTECTION AND ANTI-TRUST ATTORNEYS

Background

The Wisconsin Department of Justice (DOJ) has consumer protection and anti-trust attorneys who are involved with cases related to improper pharmaceutical industry practices.

As in any other sector of business, there are good and bad actors. As such, DOJ plays a critical role in challenging manufacturers that appear to be engaging in anti-trust activities. For example, Wisconsin is leading a lawsuit against the manufacturer of Suboxone, an opioid replacement therapy for the treatment of opioid dependency. Wisconsin and 42 other states allege that the manufacturer engaged in an overarching conspiracy to prevent and delay generics to maintain their monopoly profits.⁴² DOJ is involved in additional lawsuits alleging generic drug manufacturers fixed prices, rigged bids, allocated drug markets, and engaged in other anti-competitive conduct.⁴³

DOJ has successfully settled with multiple manufacturers admitting to engaging in anti-trust activities: (a) Apotex Corp. admitted to fixing prices of Pravastatin, a popular cholesterol drug, and agreed to pay \$24.1 million; (b) Sandoz Inc. pled guilty to four counts of bid rigging and price fixing as part of a deferred prosecution agreement and agreed to pay \$195 million; (c) Rising Pharmaceuticals admitted to fixing prices and allocating customers for Benazepril HCTZ and agreed to pay more than \$3 million in criminal penalties, restitution, and civil damages – subject to bankruptcy court approval; and (d) Heritage Pharmaceuticals admitted that it conspired to fix prices, rig bids, and allocated customers for glyburide and agreed to pay more than \$7 million.⁴⁴

3.2.3 Enhance Consumer Protection Oversight and Hire Additional Anti-Trust Attorneys to Focus on Pharmaceutical Industry Practices

Recommendation

Increase the number of DOJ consumer protection and anti-trust attorneys to focus on improper pharmaceutical industry practices.

Rationale

Creating a more robust team of attorneys focused on consumer protection and anti-trust cases related to health care fraud and pharmaceutical issues will allow DOJ to take a more aggressive approach to ensuring Wisconsin residents are not harmed by illegal business practices in this area.

3. Task Force Recommendations & Policy Options

WISCONSIN FREE AND CHARITABLE CLINICS

Background

According to the [Wisconsin Association of Free & Charitable Clinics \(WAFCC\) website](#), free and charitable clinics serve as a critical safety net provider to over 150,000 Wisconsinites. The state budget appropriates \$500,000 annually to free and charitable clinics. They provide medications to patients in a variety of ways, including provider dispensing and in-house and stand-alone pharmacies; St. Vincent de Paul is the only stand-alone pharmacy in the state.⁴⁵ Seven free and charitable clinics/pharmacies are listed as drug repositories in Wisconsin.⁴⁶ Drug repositories are entities where pharmacies or medical facilities collect unused or discontinued medications and supplies from patients to pass them onto other consumers who may need them.⁴⁷ The Wisconsin Drug Repository Program was enacted in 2005 and is regulated by the Department of Health Services (DHS).

3.2.4 Free and Charitable Clinic Funding

Recommendation

Increase the annual appropriation for free and charitable clinics, dedicating a portion of the funding to pharmacy services, to expand access.

Rationale

Current funding is not sufficient to meet the demands placed on free and charitable clinics and their pharmacies in providing services to Wisconsin's most vulnerable residents. According to the Wisconsin Association of Free & Charitable Clinics, there is a strong return on investment in their work, as \$1 of funding translates into \$5 to \$10 worth of care.

Comments in support were submitted to the Task Force by the following organization: [NeuGen LLC](#)

3.2.5 Modification to the Wisconsin Drug Repository Program: Real-Time Inventory of Prescription Drugs

Recommendation

Develop a statewide, medication repository with a centralized prescription drug inventory in Wisconsin or collaborate with an existing medication repository program in another state.

Rationale

The current repository program is underutilized and cumbersome, as it does not include a centralized means for obtaining real-time drug inventory information. A [written statement](#) provided to the Task Force from the Medical College of Wisconsin School of Pharmacy, SafeNetRx, Wisconsin Association of Free & Charitable Clinics, and Foley & Larder indicates the following:

In order to participate in the Wisconsin Drug Repository Program, a Wisconsin-licensed pharmacy must first complete and submit form F-62643, Drug Repository Program Notice of Participation or Withdrawal.

3. Task Force Recommendations & Policy Options

WISCONSIN FREE AND CHARITABLE CLINICS

Participating pharmacies are added to a master List of Drug Repository Participants that is publicly available on the WDHS website, however, it is unclear when the list was last updated or how often it is updated. When a patient is in need of a medication that he or she cannot afford, a pharmacist can call each participating pharmacy on the list to see if they have the donated medication in their repository at their location. This is a time-intensive process that often yields no results. Consequently, many pharmacists and pharmacies seldom use the program.

When properly implemented, medication repository programs can redistribute unused, unexpired medications to patients in need that would otherwise be incinerated or disposed of in our landfills and sewers. There are clear benefits to creating a centralized collection location and perpetual inventory that is easily accessible to participating pharmacies. Expanding the existing Wisconsin Drug Repository Program to closely mirror successful state-wide programs or collaborating with an existing program would have tremendous benefits for Wisconsin residents, including improving access to life-saving medications, reducing medication waste, preventing diversion and abuse of unused medications left in the home, and preventing pharmaceutical waste from contaminating our environment, including the landfills and water supply.

Comments in support were submitted to the Task Force by the following organizations: [Wisconsin Hospital Association](#), [NeuGen LLC](#)

3.2.6 Accepting Prescription Drug Donations from other States

Recommendation

Support efforts by the Wisconsin Association of Free & Charitable Clinics and other stakeholders to remove barriers that unnecessarily prohibit the Wisconsin Drug Repository Program from accepting prescription drug donations from other states.

Rationale

Allowing the Wisconsin Drug Repository Program to accept out-of-state prescription drugs will help increase Wisconsin free and charitable clinic drug inventory and further ensure they can meet the needs of the population they serve.

Comments in support were submitted to the Task Force by the following organization: [NeuGen LLC](#)

3.2.7 Pharmacist Continuing Education/Volunteerism

Recommendation

Allow one-third of continuing education requirements for pharmacists to be dedicated towards volunteerism.

3. Task Force Recommendations & Policy Options

WISCONSIN FREE AND CHARITABLE CLINICS

3.2.7 Pharmacist Continuing Education/Volunteerism (continued)

Rationale

Allowing the satisfaction of continuing education units (CEUs) through volunteerism creates increased pathways and incentives to volunteer at free and charitable clinic pharmacies; creating more opportunities to build capacity in serving uninsured patients.

Ohio has a law in place allowing pharmacists to satisfy one-third of their continuing education units through volunteerism. Their law also establishes criteria for entities to become approved as in-state providers of volunteer health care services.

Excerpt from Ohio Code [4729: 1-5-02 \(G\)](#)

A pharmacist may satisfy up to one-third of the pharmacist's continuing education requirements by providing health care services as a volunteer in accordance with section [4745.04](#) of the Revised Code. The location where health care services are provided shall be an approved in-state provider of volunteer health care services in accordance with rule [4729-6-03](#) of the Administrative Code.

Comments in support were submitted to the Task Force by the following organizations: [NeuGen LLC](#)

3. Task Force Recommendations & Policy Options

FEDERAL 340B DRUG PRICING PROGRAM

Background

The federal 340B program was established to provide relief to safety net providers from high drug prices and allow these providers to (a) stretch scarce federal resources as far as possible, (b) reach more vulnerable patients, and (c) deliver more comprehensive services.⁴⁸ Regulated by the federal Health Resources & Services Administration (HRSA), the program requires manufacturers participating in Medicaid to provide outpatient drugs to covered entities at significantly reduced prices.⁴⁹ Eligible health care organizations/covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. [See the full list of eligible organizations/covered entities.](#)⁵⁰

Savings to the covered entities as a result of reduced prescription drug prices under the 340B program are to be reinvested into the populations they serve. For example, Vivent Health, an HIV Medical Home with locations in Wisconsin uses 340B savings to keep dental clinics in Madison and Green Bay open; keep mental and behavioral health services operating in smaller communities throughout Wisconsin; and increase the amount of food their pantries provide to clients.⁵¹

3.2.8 340B Program Reimbursement to Federally Qualified Health Centers, Critical Access Hospitals, and Ryan White HIV/AIDS Programs

Recommendation

Ensure that Federally Qualified Health Centers, Critical Access Hospitals, and Ryan White HIV/AIDS programs participating in the 340B drug discount program are able to reinvest savings from drug purchases into patient care and support activities.

Rationale

As it is referred to by some stakeholders, the practice of “discriminatory reimbursement” refers to the practice among some PBMs and other third-party payers who offer 340B safety net providers and their in-house or contracted pharmacies lower reimbursement rates than those offered to non-340B entities. As explained by entities claiming to receive low reimbursement for those medications, low reimbursement reduces covered entity savings, resulting in fewer funds available for reinvestment into underserved populations. Prohibiting reimbursement that is less than a defined state rate may help ensure covered entities serving vulnerable populations, such as Vivent Health, realize savings through their participation in the 340B program and continue to reinvest those savings into their patients. It is important to note that prescription drugs purchased through 340B are not eligible for rebates.

3. Task Force Recommendations & Policy Options

FEDERAL 340B DRUG PRICING PROGRAM

3.2.8 340B Program Reimbursement to Federally Qualified Health Centers, Critical Access Hospitals, and Ryan White HIV/AIDS Programs (continued)

Several states have laws addressing “discriminatory reimbursement.”

STATE LAWS PROHIBITING DISCRIMINATORY REIMBURSEMENT							
	West Virginia SB 489	Minnesota SF278	Montana SB 335	Oregon HB 2185	South Dakota HB 1137	Utah SB 138	Georgia HB 946
Enacted into law	Feb. 26, 2019	July 26, 2019	April 30, 2019	July 15, 2019	March 7, 2019	March 28, 2020	July 2, 2020
General 340B nondiscrimination provision	✓	✓	✓	✓	✓	✓	✓
Protects all types of 340B safety net providers from discriminatory arrangements	✓	✓	✓	✓	✓	✓	✓
Prohibits discriminatory arrangements by PBMs and third party payors	✓	X (Exempts managed care contracts)	✓	X (Prohibits only PBMs from such practices)	X (Prohibits only PBMs from such practices)	X	X (Prohibits only PBMs from such practices)
Specifically prohibits chargebacks or other adjustments based on 340B eligibility	✓	X	X	X	X	✓	✓
Prohibits discrimination that interferes with the patient's choice to receive drugs from a 340B entity	✓	X	X	X	X	✓	X

Comments expressing concern were submitted to the Task Force by the following organization:

[Wisconsin Association of Health Plans](#)

3. Task Force Recommendations & Policy Options

PUBLIC SECTOR PRESCRIPTION DRUG PURCHASING ENTITY

Background

Coordinating the purchase of prescription drugs across state and local government purchasing entities, in some manner, increases volume and may offer new opportunities to reduce the cost of prescription drugs to those programs and their enrollees.

Currently, state agencies responsible for offering prescription drug coverage to the populations they serve do so through their own agreements with PBMs, group purchasing pools, manufacturers, etc. In 2019, after receiving a grant from the National Governor's Association, the Department of Corrections (DOC), Department of Employee Trust Funds (ETF), Department of Health Services (DHS) and the Office of the Commissioner of Insurance (OCI) began meeting on a regular basis to explore possible areas for cost savings and collaboration in purchasing prescription drugs. This group, formally referred to as the Wisconsin Pharmacy Cost Study Committee (WPCSC), was able to identify an opportunity for the DOC to leverage 340B pricing through a subgrantee relationship with the state Division of Public Health.⁵² However, determining a strong course of action related to multi-agency collaboration in purchasing prescription drugs was stifled by an inability to collect apples to apples cost data across agencies. Access to comparative data is critical to identifying opportunities for cost savings. Due to various confidentiality rules tied to contracting and program requirements, in particular under the Medicaid program, the WPCSC could not determine what each agency is paying for specific prescription drugs by delivery and dose after manufacturer rebates are applied.

The WPCSC was able to gather pre-rebate cost information by therapeutic class for the top 50 drugs for each agency. That data indicated there were seven common drugs across DOC, ETF, and DHS.⁵³ The [WPCSC final report](#) includes analysis results for the top three drugs prescribed, with an emphasis on DOC and ETF pricing and possible savings to each agency, if the agency paying more could leverage the lower-paying agency's price. However, it was determined out of scope for WPCSC to drill down into the potential cost savings further and determine, for example, how removing one drug from an agency's current purchasing contracts might impact pricing on other drugs covered under the agreement.

3.2.9 Development of an Executive Level State Prescription Drug Purchasing Entity

Recommendation

Create a public sector prescription drug purchasing entity, initially for government purchasers, as a means to leverage purchasing power and other cost saving opportunities. Government purchasers include state and local government purchasers. Charge the purchasing entity with determining whether agreements and concepts they utilize in government purchasing may benefit private sector prescription drug purchasers.

3. Task Force Recommendations & Policy Options

PUBLIC SECTOR PRESCRIPTION DRUG PURCHASING ENTITY

3.2.9 Development of an Executive Level State Prescription Drug Purchasing Entity (continued)

Rationale

Coordinating the purchase of prescription drugs across state and local government purchasing entities, in some manner, increases volume and may offer new opportunities to reduce the cost of prescription drugs to those programs and their enrollees.

Given the data transparency challenges that surfaced through the WPCSC work, it was suggested in the WPCSC report that a means for collecting the data and ensuring subject matter expertise for analyzing it, could be to create a single purchasing entity for the State of Wisconsin.⁵⁴

The scope of a state prescription drug purchasing entity can be determined by policymakers, using examples from other states and considering Wisconsin's specific needs and goals. The purchasing entity could take on a range of responsibilities, from data collection and analysis to contracting for prescription drugs which could mean exploring opportunities to partner with CivicaRx⁵⁵ or pursuing new pooled purchasing opportunities. The Northwest Prescription Drug Consortium (Consortium) is an example of a purchasing pool created at the state level. The Consortium leverages the purchasing power of over 1 million people in Oregon and Washington to obtain the best price on medications, including specialty medications.⁵⁶ Members served are with public employers, commercial employers, Managed Medicaid, the discount card, and facility programs.⁵⁷ The discount card is a free card for under or un-insured individuals offering consumers pricing comparable to participating groups under the Consortium.⁵⁸

It may be within the scope of a purchasing entity to identify an area of public health concern, such as diabetes, and, as suggested in the [WPCSC final report](#), the state may take on negotiating the bulk purchase of insulin or other drugs through public health entities who could then provide the drugs to all state residents at either no or very low costs.⁵⁹

Comments expressing support were submitted to the Task Force by the following organizations: [Greater Wisconsin Agency on Aging Resources, Inc.](#), [NeuGen LLC](#)

3. Task Force Recommendations & Policy Options

REGULATORY OVERSIGHT OF PSAOS

Background

As stated earlier in this paper, PSAOs are voluntary service organizations that independent pharmacies and small chains use to execute contracts with payers and PBMs.⁶⁰

PSAOs are not regulated by the state; however, many are affiliated with wholesalers, which are regulated by the state Department of Safety and Professional Services.

3.2.10 PSAO Registration/Licensure

Recommendation

Require PSAOs executing agreements with pharmacists in Wisconsin to be registered or hold a state license.

Rationale

As another entity involved in the prescription drug supply chain, additional regulatory oversight could ensure fair business practices are established and adhered to, especially as the role of PSAOs evolves.

PHYSICIAN ACCESS TO PATIENT INSURANCE PLAN INFORMATION

Background

Some insurers and PBMs offer tools to providers that allow them to view lower cost alternatives and patient insurance information; however, access is not consistent across providers and not all PBMs/insurers offer these tools.

3.2.11 Improve Physician Access to Patient Insurance Plan Information

Recommendation

Explore and support efforts to improve physician access to real-time patient pharmacy benefit information in electronic medical records (EMRs) to allow physicians to consider out-of-pocket costs when prescribing medications. Also, explore access to total drug cost so that decisions can be made that may save costs at a system level. For example, if two drugs cost the consumer their \$10 copay, allowing the provider to access information to determine whether one drug costs the provider less, may help reduce costs to the health system (and eventually impact consumers through premium rates).

Rationale

Through Task Force discussions it was raised that greater price transparency at the point of prescribing would be a helpful tool in reducing the cost of prescription drugs for individual consumers at the pharmacy counter. It was also expressed that access to the total cost of the drug to the system

3. Task Force Recommendations & Policy Options

PHYSICIAN ACCESS TO PATIENT INSURANCE PLAN INFORMATION

3.2.11 Improve Physician Access to Patient Insurance Plan Information (continued)

would be helpful in prescribing the lowest cost medications. Providers seem to have varying degrees of access to a patient's health insurance information, meaning: the formulary (whether a drug is covered under their plan), how much of a patient's deductible is met, and any other cost sharing that might apply. Additionally, general practice physicians, in particular, who prescribe many different classes of medications may not know offhand whether a lower cost alternative exists. Combining access to that information with the consumer's health insurance information can empower the physicians to prescribe the lowest cost medication available to patients to treat their conditions.

Greater attention to this issue and continued efforts across providers, insurers, PBMs and EMR companies can empower providers to help consumers meet their medication needs for the least cost possible.

FEDERAL REGULATORY CHANGES

Background

State government leaders are always in a position of being able to work with federal leaders to effectuate change at the federal level. There are areas of federal oversight with respect to manufacturer business practices that warrant continued attention and action, namely, in the areas of patent laws and orphan drug exclusivity. Both of which lead to the delay in the market entry of more affordable generic equivalents.

3.2.12 Advocate for Federal Regulatory Changes

Recommendation

Advocate for federal regulatory changes to address practices that delay the market entry of affordable generic equivalents and other market practices identified as drivers of prescription drug unaffordability.

While the Task Force did not put forth specific recommendations related to advocacy, patent laws and orphan drug issues were raised. Potential options for advocacy in those areas are referenced below.

Option for Advocacy: Patent Law Changes

Advocate that federal leaders review current patent laws and address any loopholes currently allowing for potential abuses in the area of extended patent protections.

3. Task Force Recommendations & Policy Options

FEDERAL REGULATORY CHANGES

3.2.12 Advocate for Federal Regulatory Changes (continued)

Rationale

As explained in the [Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Drug Prices report](#), “Some drug makers will file successive patents on a drug with the same active chemical ingredient, a practice sometimes referred to as ‘evergreening’ or ‘patent layering.’ For example, AbbVie filed 247 patent applications for Humira, which is used to treat arthritis and is the top-selling drug in the world. A total of 132 of those patents were issued, resulting in 39 years of patent protection.” The price on the brand-name drug protected by a patent thicket or evergreening stays high because there is no competition.⁶¹

Comments expressing support were submitted to the Task Force by the following organization: [America’s Health Insurance Plan](#)

Option for Advocacy: Orphan Drug Exclusivity Changes

Advocate that federal leaders review orphan drug exclusivity laws and address any loopholes currently allowing for potential abuses that delay the entry of more affordable generic equivalents into the market.

Rationale

The laws for orphan drug exclusivity originally were designed to allow drug manufactures to have several years of exclusivity to recoup investments on research and development for new drugs likely to have reduced sales due to small patient populations.⁶² By 2017, the world’s 10 most expensive drugs were all orphan drugs.⁶³ Manufacturers have used orphan drug exclusivity as a vehicle to insulate themselves from competition for even well-established drugs that treat large patient populations.⁶⁴ Drug companies can achieve this by so-called “salami slicing” of a drug’s approved treatment indication into ever narrower indications for disease subtypes until they can qualify for orphan drug status.⁶⁵ Humira is an example: Approved in 2002 to treat rheumatoid arthritis and then three years later AbbVie sought orphan drug status for the drug to treat juvenile rheumatoid arthritis.⁶⁶ Since that approval, AbbVie has obtained approval for Humira to treat four more rare diseases; one approved uses for an eye disease extends the drug’s exclusivity for that disease until 2023.⁶⁷

3. Task Force Recommendations & Policy Options

3.3 Tier 2: Policy Options for Consideration

The following are policy proposals that have been raised and discussed, to some extent, throughout the work of the Task Force since the first meeting in November 2019. These proposals are not necessarily Task Force recommendations; however, these proposals may merit further discussion and consideration outside of the work of the Task Force. Also, of note, at least one Task Force member has expressed support for each of these proposals, while others have expressed concern or opposition. Including these proposals is also important for meeting the requirement to summarize the work of the Task Force, as directed by [Executive Order #39](#). The pros and cons listed reflect issues raised throughout Task Force member discussions. Links to specific comments submitted by Task Force members and interested parties are provided where applicable.

MANUFACTURER COPAY ASSISTANCE PROGRAMS/APPLICABILITY TO HEALTH PLAN OUT-OF-POCKET LIMITS

Background

It is common for prescription drug companies to offer consumers discount assistance for the brand name drugs they develop and manufacturer. This assistance may be referred to as copay assistance, copay cards, discount coupons, and drug coupons. In response to this assistance, some insurers and PBMs have adopted [accumulator adjustment programs](#).⁶⁸ This means the insurer or PBM will not apply a copay card or other manufacturer coupon to an enrollee's deductible or out-of-pocket maximum, meaning the enrollee cannot count any of the coupon's amount towards their annual limit on out-of-pocket costs.⁶⁹

Example: *How Copay Assistance Works with Copay Accumulator Adjustment Programs*⁷⁰

- Patient has a \$1,000 deductible
- Patient has \$500 in copay assistance

No Copay Accumulator Program

The \$500 copay assistance **will** count toward the patient's deductible.

$\$1,000 - \$500 = \$500$.

The patient **only has to pay the \$500 remaining** to reach their deductible.

Copay Accumulator Program

The \$500 copay assistance **will not** count toward the patient's deductible.

$\$1,000 - \$0 = \$1,000$. The patient **has to pay the full \$1,000** to reach their deductible.

Wisconsin [2019 Senate Bill 907](#) proposed requiring insurers to apply amounts paid for prescription drugs on behalf of a plan enrollee to any calculation of an out-of-pocket maximum or to any cost-sharing requirement of the plan. The bill was referred to the Senate Committee on Health and Human Services but did not pass prior to the end of legislative session.

3. Task Force Recommendations & Policy Options

MANUFACTURER COPAY ASSISTANCE PROGRAMS/APPLICABILITY TO HEALTH PLAN OUT-OF-POCKET LIMITS

3.3.1 Policy Proposal: Manufacturer Copay Assistance/Health Plan Out-of-Pocket Limits

Require insurers to apply manufacturer prescription discounts utilized by consumers to deductibles and annual maximum out-of-pocket costs, if no generic exists or where a generic exists but the beneficiary obtained access to the prescribed drug after undergoing prior authorization, step therapy, or the insurer's exceptions and appeals process. Also, require insurers to include a consumer disclosure with plan information making it clear the circumstances under which a manufacturer coupon applies to plan deductibles and maximum out-of-pocket costs.

Pros/Cons

Pros

- Consumers would not have to choose between using a manufacturer coupon to reduce the cost of their prescription medication or utilizing their insurance coverage. If insurers are required to apply manufacturer coupons to deductibles, consumers receive a discount at the point of sale and get a larger portion of their deductible met.
- Limiting the requirement to circumstances where there is no generic equivalent available or medically appropriate alternative, makes it less likely the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market.⁷¹

Comments expressing support were submitted to the Task Force by the following organizations: [Coalition of State Rheumatology Organizations](#); [Greater Wisconsin Agency on Aging Resources, Inc.](#); [Pharmaceutical Research and Manufacturers of America](#)

Cons

- The effort does not lower the cost of prescription drugs, rather it shifts who pays for them.
- The requirement circumvents health plan designs from being used as intended.
- Creates an issue of unfairness across health plan members. If a coupon is treated as money out of a patient's pocket, two patients, one with a coupon and one without, are both treated as if they had money come out of their pocket in accessing plan coverage. The patient with the coupon did not.
- IRS rules may require that a member must experience out-of-pocket costs and only those can be applied to a deductible in a high deductible health plan.

Comments expressing concerns were submitted to the Task Force by the following organizations: [The Alliance](#), [Common Ground Healthcare Cooperative](#), [America's Health Insurance Plans](#), [Wisconsin Association of Health Plans](#), [Alliance of Health Insurers](#), [NeuGen LLC](#), [Wisconsin Counties Association](#)

3. Task Force Recommendations & Policy Options

STATE ACCOUNTABILITY/AFFORDABILITY REVIEW BOARD

Background

Affordability boards are typically modeled after public utilities where the board monitors and establishes price limits. A National Academy for State Health Policy comparison of state affordability board models can be found here: <https://www.nashp.org/comparison-of-bills-creating-state-prescription-drug-affordability-review-boards/>

3.3.2 Policy Proposal: State Accountability/Affordability Review Board

Create a prescription drug affordability/accountability review board to establish prescription drug spending targets for public sector entities and explore establishing price limits.

Pros/Cons

Pros

- Establishing limits on the amount an entity will pay for prescription drugs puts the entity in direct control of their drug spend and can result in significant cost savings.
- An affordability board combined with a centralized purchasing entity would have significantly stronger negotiation power than smaller, individual entities, and would therefore be able to lower prescription prices.
- An accountability board is a means to get at the root cause of high prescription drug prices (i.e., the manufacturer set list prices).
- Setting upper payment limits may aid in controlling excessive price increases by manufacturers and aid in bringing pharmaceutical companies to the table for discussions.
- Affordability boards can bring awareness and greater transparency to pharmaceutical pricing.

Comments expressing support were submitted to the Task Force by the following organizations: [The Alliance](#), [Wisconsin Counties Association](#), [American Association of Retired Persons](#), [NeuGen LLC](#), [Common Ground Healthcare Cooperative](#)

Cons

- Access issues could result if drug manufacturers refuse to meet price limits set by the affordability board.
- A challenge could be applying the affordability board model to independent health plans across the state; probably more readily applied to state-run programs.

Comments expressing opposition were submitted to the Task Force by the following organizations: [Pharmaceutical Research and Manufacturers of America](#)

3. Task Force Recommendations & Policy Options

PRESCRIPTION DRUG IMPORTATION

Background

Federal law allows for wholesale importation of certain drugs from Canada if certain conditions are met. Those include, but are not limited to, no additional risk to health and safety, significant reduction in costs to the consumer, and certification by the Secretary of the U.S. Department of Health and Human Services (HHS).⁷² Biologics, including insulin and vaccines, are excluded from importation.⁷³

3.3.3 Policy Proposal: Prescription Drug Importation

Allow wholesale importation of prescription medication from Canada.

Pros/Cons

Pros

- Importation may serve as a means for pharmacies to obtain prescription drugs for a lesser amount than they can in the United States, allowing for that cost savings to be passed along to consumers.

Comments expressing support were submitted to the Task Force from the following organization:

[American Association of Retired Persons](#)

Cons

- Only a few states have enacted laws and submitted proposals to the federal government for approval. No proposals have received federal approval to date. Therefore, no lessons learned or cost savings analysis is available.
- Federal regulations are in proposed form; the finalized version could look different, resulting in a different set of rules.
- If interest in importation increases and becomes a more viable option, Canada may seek to limit the drugs and quantities they are willing to export.

Comments expressing concern were submitted to the Task Force from the following organizations:

[The National Association of Chain Drug Stores](#)

3. Task Force Recommendations & Policy Options

ADMINISTRATION OF SPECIALTY DRUGS

Background

As explained in a CVS Health article:⁷⁴ *There is no standard definition for a specialty medication, but drugs in this category typically share one or more of the following characteristics. First, they are expensive — the average monthly cost to payers and patients for a specialty medication is \$3,000, ten times the cost for non-specialty medications. Second, they can be difficult to administer. They are often given by injection or infusion to treat complex, chronic conditions such as rheumatoid arthritis, multiple sclerosis and psoriasis. Third, the drugs may require special handling, including temperature control. And finally, patients taking these medications may need ongoing clinical assessment to manage challenging side effects.*

Depending on the patient and the drug, administration of specialty medication may be performed in a hospital, physician's office, or at the patient's home. The location of administering these drugs impacts cost but must also take into account a patient's specific medical needs and personal situation.

According to a [UnitedHealth Group publication](#), "Administering specialty drugs in physician offices and patients' homes instead of hospital outpatient settings reduces the cost of the drugs and their administration by \$16,000 to \$37,000 per privately insured patient per year for five conditions that account for over 75 percent of spending on administered drugs."

3.3.4 Policy Proposal: Administration of Specialty Drugs

Encourage providers and insurers to adopt, as a best business practice, the administration of specialty drugs at the lowest-cost setting available, taking into account specific patient needs, the drug, and clinical appropriateness to ensure patient safety.

Pros/Cons

Pros

- Allows insurers and providers to work together in determining the best course of administration, with the lower cost sites of care as a priority, along with individual patient needs and safety.
- For certain administered specialty drugs, treatment at home can help reduce costs while also improving patient's physical and mental wellbeing and reducing disruption of work schedules and family responsibilities, all without increasing the likelihood of adverse drug events or side effects.
- The option to receive infused medications at home provides patients at higher risk of contracting/experiencing complications from COVID-19 a safe and effective alternative to visiting the hospital or clinic to receive infusions necessary for managing chronic conditions.

Cons

- In-home administration of specialty medication may make it difficult to manage adverse reactions to the medication.

3. Task Force Recommendations & Policy Options

3.3.4 Policy Proposal: Administration of Specialty Drugs (continued)

Comments expressing concern were submitted to the Task Force by the following organizations: [Coalition of State Rheumatology Organizations](#), [Wisconsin Association of Health Plans](#) (opposed to mandating site of care), [Wisconsin Hospital Association](#) (opposed to requiring the administration of certain specialty drugs outside of the hospital setting)

PBM BUSINESS PRACTICES

Background

See [section 2.1.5](#) of this paper.

3.3.5 Policy Proposal: PBM Business Practices

Develop best practice guidelines for PBM business practice.

Pros/Cons

Pros

- Establishes a core set of business practices focused on transparency and cost savings that may lead to an industry-wide shift away from business practices most often criticized, such as spread pricing and rebate arrangements that do not pass 100% of rebate dollars through to PBM clients.
 - The [Pharmaceutical Care Management Association submitted comments](#) to the Task Force speaking to rebates and spread pricing.
- Guidelines do not limit flexibility in business models. Clients seeking flexibility to allow PBMs to retain rebate dollars to cover administrative expenses, as opposed to making a separate payment to the PBM for those services, are not limited in doing so.
- A set of best practices may serve as a tool for entities comparing services offered by PBMs before contracting with one.

Cons

- While there is acknowledgment that a set of best practices could be beneficial, it is unclear what entity would be best poised to create and promote industry best practices.

Comments expressing concern were submitted to the Task Force by the following organization: [The Alliance](#), [Wisconsin Counties Association](#), [Alliance of Health Insurers](#), [America's Health Insurance Plans](#)

3. Task Force Recommendations & Policy Options

MANUFACTURER PATIENT ASSISTANCE PROGRAMS

Background

Prescription drug manufacturers often offer discount programs to help consumers reduce their out-of-pocket costs for brand name drugs. Given the number of pharmaceutical companies offering these programs, as well as the various means for accessing and qualifying for them, it can be confusing and cumbersome for consumers to seek out assistance. The Task Force heard through its discussion that numerous volunteer hours at free and charitable clinics are spent assisting consumers in applying for these programs. The Task Force also heard comments from the pharmaceutical manufacturers indicating that work is underway to pull information about the various assistance programs together. [Mat.org](#) was offered as an example of that effort. A public affairs campaign to increase awareness about that website is underway.

3.3.6 Policy Proposal: Manufacturer Patient Assistance Programs

Enhance public awareness of pharmaceutical manufacturer patient assistance programs.

Pros/Cons

Pros

- Increasing public awareness around existing resources may help consumers more easily navigate what is available.
- DHS has a website that lists various drug assistance resources: <https://www.dhs.wisconsin.gov/guide/freeprescr.htm>
- The Minnesota Board of Pharmacy has a webpage with information about prescription drug resources: <https://mn.gov/boards/pharmacy/public/savingonprescriptiondrugs.jsp>

Cons

- It is unclear which entity is in the best position to dedicate resources for leading this effort.

3. Task Force Recommendations & Policy Options

3.4 Tier 3: Issues Raised but Not Thoroughly Discussed/Recent Additions

The following are policy proposals that were raised by Task Force members for potential consideration. However, the Task Force did not have time to extensively discuss these items, therefore they are being included with an acknowledgment that more analysis would be needed to determine if they merit favorable consideration.

3.4.1 Licensure and regulation of pharmaceutical sales representatives

The National Academy for State Health Policy released model legislation in July 2020 to license pharmaceutical sales representatives. The model act also incorporates requirements enacted in Colorado in 2019 that mandate sales representatives to disclose the wholesale acquisition cost of the drugs they market and to share the names of generic options in the same therapeutic class when available.⁷⁵

Comments in support were submitted to the Task Force by the following organizations: [Wisconsin Association of Health Plans](#), [America's Health Insurance Plans](#), [Alliance of Health Insurers](#)

3.4.2 Additional regulatory oversight (licensure or regulation) of PBM brokers and consultants

PBM brokers and consultants work with clients to procure the services of a PBM. Depending on the current level of regulatory oversight, more may be needed to ensure their conduct is free of conflict of interests and full disclosure is provided if any conflicts exist. This includes situations where the broker/consultant keeps an undisclosed amount of rebates from the PBM or client (insurer/employer).

3.4.3 Require PBMs to act as a fiduciary on behalf of their plan sponsors

PBMs could be required to act as a fiduciary when using their discretion to spend plan assets. The PBM should consider the benefit plan's best interests instead of their own.

PBMs could be required to disclose to the benefit plan any conflicts of interests, such as:

- (a) Indirect profit that PBMs receive from owning pharmacies or service providers;
- (b) Payments to consultants and brokers who are working on behalf of the benefit plan;
- (c) Any amount retained from manufacturers related to the client's claims or bona fide service fees; and
- (d) Any amount received or retained from network pharmacies including pharmacy access fees, audit recovery fees, and spread (net margin retained)

3. Task Force Recommendations & Policy Options

3.4.4 Consider the expansion of responsibilities pharmacists working for free & charitable clinics can take on.

At free and charitable clinics consider expanding pharmacist responsibilities, implementing telepharmacy services, and making it easier to allow remote dispensing sites, in particular, for onsite inspections.

3.4.5 Allow the state Department of Justice to have direct Civil Investigative Demand authority for anti-trust cases without seeking court authority each time

Nearly all states have less restrictive Civil Investigative Demand/subpoena authority than Wisconsin. Florida law is an example of Civil Investigative Demand authority that could be emulated in Wisconsin; § 542.28, Fla. Stat.

3.4.6 Additional restrictions on improper prescription drug marketing and advertising practices

As explained in the [joint comment letter submitted to the Task Force from the Department of Agriculture Trade and Consumer Protection \(DATCP\) and the Department of Justice \(DOJ\)](#):

Direct to consumer advertising of prescription drugs is an extensively utilized tool by the U.S. drug manufacturers to increase the prescription and consumption of their drugs. A widely cited study in the Journal of the American Medical Association found that the marketing of drugs directly to U.S. consumers grew exponentially after the loosening of marketing restrictions by the FDA in 1997.

The letter also indicates that Wisconsin has a Fraudulent Drug Advertising law in place, enforced by DATCP; however, the agency does not have rulemaking authority specific to the law.⁷⁶

3.4.7 Create an insulin safety net program

Develop a state safety net program, working with manufacturers, to ensure individuals with diabetes in need of insulin have access to it.

In 2020, Minnesota enacted the Alec Smith Insulin Affordability Act. The Act creates an Insulin Safety Net Program that will aid individuals who cannot afford insulin.⁷⁷ The program is made up of two parts: 1) the urgent need program, and 2) the continuing need program.

The urgent need program allows eligible individuals who are in urgent need of insulin to get a one-time, 30-day supply of insulin from their pharmacy, for a \$35 copay. An urgent need for insulin

3. Task Force Recommendations & Policy Options

means an individual has less than a 7-day supply of insulin and will likely have significant health consequences if they run out.⁷⁸

The continuing need program requires insulin manufacturers to provide insulin to eligible individuals for up to one year, with the option to renew annually. Throughout the year, manufacturers will provide eligible individuals with prescribed insulin for a copay of no more than \$50 for each 90-day supply. Some individuals with insurance may be referred to a manufacturer's copay program, which waives all or part of the copay that the patient normally has to pay, if the copay program provides a better value.⁷⁹

On June 30, 2020, PhRMA filed a [complaint](#) challenging the law.

3.4.8 Create a value-based pilot project for diabetes medications

Explore value based contracting models focused on reducing prescription drug costs and improving patient outcomes.

4. Conclusion

The Task Force worked diligently to understand the complexity of the prescription drug supply chain while offering feedback and perspectives on the various recommendations and policy proposals that surfaced. This report seeks to capture the issues and perspectives discussed while compiling ideas that can serve as the start of a pathway toward reducing prescription drug prices in Wisconsin.

5. Letters

5.1 Alliance of Health Insurers



Providing quality coverage to nearly 3 million Medicaid and private sector enrollees in Wisconsin.

From: The Alliance of Health Insurers
To: Governor's Task Force on Reducing Prescription Drug Prices
Re: Comments to Governor's Task Force on Reducing Prescription Drug Prices
Date: August 13, 2020

The Alliance of Health Insurers (AHI) is a nonprofit state advocacy organization created to preserve and improve upon consumer access to affordable health insurance in Wisconsin, both via the private sector and public programs. Thank you for allowing us the opportunity to submit comments to this task force.

Prescription medications are an important part of medical treatment and under the Affordable Care Act (ACA), every health insurance policy must include a comprehensive "essential health benefits" package covering ten categories of services, including prescription drug coverage. In 2018, \$335 billion was spent on prescription drugs. The Centers for Medicare and Medicaid Services (CMS) estimates that, over the next decade, spending for retail prescription drugs will be the fastest growth health category and will consistently outpace that of other health spending.

According to the Campaign for Sustainable Rx Pricing, one out of four Americans cannot afford their medication. To manage high drug prices, our plans work closely with pharmacy benefit management companies (PBMs) as an efficient and effective way to administer prescription drug benefits. PBMs are the primary lever available to health plans to ensure that their customers can obtain the medications they need at the lowest possible cost; and that providers and pharmacies are providing quality care.

Our members and employers work with PBMs because PBMs mitigate increasing drug costs by using expertise and technology solutions to administer certain essential functions of a prescription drug benefit. They do this by:

- Using clinically based services to reduce medication errors, achieve higher rates of medication adherence, and improve health outcomes.
- Negotiating directly with manufacturers and pharmacists to obtain discounts for their customers in the form of lower out-of-pocket costs. The level of comparable volume and cost reductions PBMs can generate cannot be achieved by many health plans, most employers, or individuals.
- Implementing of cost-cutting strategies that include discount pharmacy networks, incentives to use therapeutic alternatives, formulary management (including manufacturer rebates), mail-order pharmacies, drug-use reviews, and disease management.
- Educating their consumers about safe, effective, and lower cost generic drugs.

AHI members have reviewed the policy options you are considering and are concerned that many of the ideas will disrupt how our member plans develop, in conjunction with PBMs, affordable options for employers and their enrollees. We understand that this

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5. Letters

5.1 Alliance of Health Insurers

task force cannot overhaul the prescription drug supply chain, but we ask that you fully appreciate the value proposition our plans bring to the table.

If you limit the use of spread pricing, alter how PBMs and insurers use rebates, change how we establish our network of pharmacies, and mandate how insurers apply copay coupons to deductibles, you will make it nearly impossible for plans to create affordable prescription drug coverage options. AHI member cost-management tools are constantly in the crosshairs of policymakers across the country while drug price hikes have been observed but untouched.

We heard during the task force meetings that a vial of insulin, the best treatment for diabetes, costs between \$3.00 and \$6.00 to manufacture. Yet between 2009 and 2019, Humalog, went from \$93 to almost \$300. At the same time, Levemir, Novolog, and Lantus saw similar price hikes.

Instead of addressing the tripling in price, policymakers are requiring a cap on the insurance copayment for patients. The price remains unchanged; manufacturers continue to reap the benefit of the increased price. As legislators and regulators restrict the pharmacy benefit managers, the high costs of prescription drugs are shifted to the health insurance plans, who are forced to increase premiums for beneficiaries and their employers. This creates an unending vicious cycle of rising health insurance costs and increasing numbers of uninsured families due to unaffordable health coverage. Capping copayments does not address the root cause of prescription drug cost or price.

In closing, AHI plans are concerned that many of the policies the task force is deliberating are simply shifting the inflated price of drugs to other players while doing nothing to address cost.

AHI appreciates your review of these comments and welcomes further discussion as you move toward the conclusion of your work.

5. Letters

5.2 America's Health Insurance Plans

America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South Building, Suite Five Hundred
Washington, DC 20004



July 20, 2020

Nathan Houdek
Deputy Commissioner of Insurance
Wisconsin Office of the Commissioner of Insurance
125 South Webster Street
Madison, WI 53703-3474

Re: Governor's Task Force on Reducing Prescription Drug Prices Recommendations

Dear Mr. Houdek:

I write today on behalf of America's Health Insurance Plans¹ concerning the Governor's Task Force on Prescription Drug Pricing. AHIP appreciates the opportunity to comment on elements the Task Force is considering. At the end of this letter we offer a set of ideas that Wisconsin could consider that will make a true impact on the price of drugs.

Out-of-control prices of prescription drugs have been an ongoing concern for all payers, including large and small employers, public employee health programs, and individuals and families who purchase coverage on their own. Our members appreciate the Task Force's efforts to understand and address the many factors that are contributing to this problem in Wisconsin.

Health insurance providers and pharmacy benefit managers (PBMs) aggressively negotiate with drug manufacturers to reduce the impact of out-of-control drug prices, which are a consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain. The lack of competition, transparency, and accountability in the prescription drug market has created price-dictating monopolies that exist nowhere else in the U.S. economy. These are the factors that must be addressed in order to rein in prices. Unfortunately, many of the ideas being considered by the Task Force merely address symptoms of the problem, not the problem itself; they paper over structural issues, and they will ultimately prevent health insurance providers and PBMs from negotiating lower prices to benefit consumers. This is the wrong direction.

Spread Pricing and Rebate Pass Through

Spread pricing offers certainty in an incredibly unpredictable market. As health insurance providers, employers, and public programs look for predictability, many choose this option because of how large their pharmacy spend is and the inability to predict and control drug costs. States, employers, and health insurance providers are sophisticated purchasers; they demand audit provisions and they require substantial reporting and data to justify the fees and charges made for PBM services. If purchasers believe spread pricing is a valuable tool in keeping drug costs down it should not be taken away from them.

¹ America's Health Insurance Plans (AHIP) is the national association whose members provide insurance coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

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5.2 America's Health Insurance Plans

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Reducing options takes away flexibility in contracting for health insurance providers and can have dire consequences. The Congressional Budget Office analyzed a federal bill proposal that would mandate 100% pass-through of rebates and prohibit spread pricing in all PBM contracts. The report notes, "**CBO estimates that the bill would reduce average premiums charged in the private health insurance market by nearly 0.2 percent in the first full year of implementation, although plan savings would probably erode quickly.**"² These types of arbitrary government restrictions simply shift more costs to consumers instead of attacking head on the price of the drugs, which is the root cause of drug price increases.

Network Adequacy

We appreciate the desire to aid consumers by providing greater access to prescription drugs, however, requirements restricting PBMs from incentivizing how their networks are used limits the effectiveness of the networks, thereby removing a cost-saving tool and harming consumers. Removing market forces to artificially broaden pharmacy networks will diminish the role of price negotiation and reduce competition.

PBM Reimbursement to Out-of-Network Pharmacies

Networks are created to drive quality and affordability of health and pharmacy care for consumers. They are intended to protect consumers. Government intervention that erodes those protections – by treating out of network providers more like in-network providers – increases costs to consumers and harms the ability of PBMs and health insurance providers to negotiate lower prices, which goes counter to the Task Force's goals.

Coupons and Cost Sharing Limitations

Drug makers offer copay coupons for brand name drugs under the guise of helping patients afford their medications. Instead, they mask the true cost of brand-name medications from the patient and cause everyone else in the system to pay more.

Coupons are not freely available – they are intentionally time limited. Drug makers only offer coupons to specific patients with certain plans for a narrow choice of drugs, and only until those patients' deductibles are met. When patients reach their out-of-pocket maximums, employers and health insurance providers pay all future costs.

The federal government considers copay coupons to be an illegal kickback if used by an enrollee in Medicare or Medicaid since copay coupons induce a patient to use a specific drug, with the rest of the cost picked up by taxpayers. Additionally, the federal government authorized exchange plans to utilize accumulator programs to ensure that taxpayer dollars are appropriately spent.

Copay accumulator programs hold drug companies accountable and allow consumers to see the true price and price increases of their medications. Drug makers raise prices on existing medications – sometimes multiple times a year and sometimes by double or triple digits – without patients ever knowing the cost has gone up. Copay accumulator programs would also help promote generic drug competition which could exert downward pressures on drug spending, helping to stabilize health care costs for all consumers.

² Congressional Budget Office Cost Estimate of S. 1895. July 16, 2019. Accessed at: https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.

5. Letters

5.2 America's Health Insurance Plans

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Co-payment Cap on Insulin

For many diabetes patients, the rising cost of insulin products has created an affordability crisis that threatens their health and well-being. Out-of-control prices for insulin products – and other prescription drugs – are a direct consequence of drug makers taking advantage of a broken market that lacks competition, transparency, and accountability and has created extended, price-dictating monopolies. The result is that everyone pays more. Something has to be done.

Since 2006, while the number and supply of insulin products has grown, the list price of insulin products has increased exponentially – in direct violation of the economic laws of supply and demand. One study shows that the price of insulin has increased more than 240% over the past decade.³ The Health Care Cost Institute (HCCI) found that prices for insulin nearly doubled from 2012 to 2016.⁴ Even when accounting for rebates, patient assistance, and/or manufacturer-sponsored coupons, HCCI still found that the average price of insulin would have doubled over the same time period.

Capping insulin copays allows drug manufacturers to not only hide the real prices of their drugs from consumers but actually encourages them to raise the cost for everyone. Our members support market-based solutions that hold drug makers accountable for high list prices and put downward pressure on prescription drug prices through competition, consumer choice, and open and honest drug pricing.

On May 11, the Centers for Medicare & Medicaid Services launched a groundbreaking voluntary model to lower out-of-pocket insulin expenses for seniors. Under this new innovative program for seniors, drug companies will reduce the underlying cost, by increasing discounts for insulin, allowing health insurance providers to use those savings to reduce the out-of-pocket costs for seniors when they pick up their insulin prescription at the pharmacy counter. This approach – holding down health insurance costs by holding down the price of the drug – is critically important and informative as states consider how to hold down insulin costs for patients.

Recently, Minnesota took another approach to providing access to insulin by creating an emergency insulin safety net program, adopted in [HF 3100](#) (2020), for individuals not eligible for Medicaid or Medicare who have private insurance that does not meet a copay limit. The program requires insulin manufacturers to make insulin available to eligible individuals who are in urgent need of insulin or who are in need of access to an affordable insulin supply.

Placing arbitrary caps on consumer cost sharing is the wrong direction and will not achieve lower costs for consumers. Attempts to limit copayments on insulin will likely exacerbate cost issues because a blanket cost for all insulin products reduces health insurance providers' ability to negotiate with drug manufacturers to develop innovative benefit designs to lower out-of-pocket costs.

Recommendations

³ *Several Probes Target Insulin Drug Pricing*. Kaiser Health News. October 28, 2017. Available at <https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141>.

⁴ *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*. Health Care Cost Institute. January 2019 Available at <https://www.healthcostinstitute.org/research/publications/entry/spending-onindividuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>.

5. Letters

5.2 America's Health Insurance Plans

September 3, 2020
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- **Advance notification by manufacturers of drug cost increases and launch prices**
- **Address Patent Abuses**
- **Involve and Support Attorney General on Price Anomalies**
- **Ensure Drug Reps Include Prices When Marketing to Physicians**

We appreciate you taking our views into consideration and look forward to working with you on these important issues. Please do not hesitate to contact me at mhaffenbredl@ahip.org (202-413-9817) should you have any questions.

Sincerely,



Mary Haffenbredl
Regional Director, State Affairs, AHIP

Cc: Members of the Governor's Task Force on Reducing Prescription Drug Prices

5. Letters

5.3 American Association of Retired Persons



Wisconsin

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September 2, 2020

Mr. Nathan Houdek
Deputy Commissioner, Wisconsin Office of the Commission of Insurance
Chair, Governor's Task Force on Reducing Prescription Drug Prices
125 South Webster Street
Madison, WI 53703

Dear Deputy Commissioner Houdek and Members of the Governor's Task Force:

AARP Wisconsin is pleased to be a participant on the Governor's Task Force on Reducing Prescription Drug Prices and we appreciate the hard work that all stakeholders have contributed towards the goal of lowering prescription drug prices for Wisconsinites.

With over 830,000 AARP members across the state, AARP Wisconsin has identified the skyrocketing cost of prescription drugs as one of our top priority issues. It's unfair that Americans pay the highest prescription drug prices in the world, and increasing drug prices are hitting older Americans particularly hard. For example, the median annual income for Medicare beneficiaries is a modest \$26,000. At the same time, older people tend to use more prescription drugs with the average Medicare Part D enrollee taking 4.5 drugs per month. Too many older Wisconsinites are having to choose between buying groceries and paying for their medicine.

As a non-profit, non-partisan organization that advocates for people 50+ and their families, AARP has heard heartbreaking stories from Wisconsin residents struggling with the cost of prescription drugs. Here in Wisconsin, the average annual cost of brand name prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for Wisconsin residents increased only 12.9%. In fact, in 2017, 22% of Wisconsinites stopped taking medication as prescribed due to cost.

We believe the following policy options under consideration by the Task Force could play a role in bringing down drug prices.

Policy options providing immediate relief for consumers



5. Letters

5.3 American Association of Retired Persons

The following policy options being considered by the Task Force will be part of AARP Wisconsin's legislative priority list for the next legislative session.

Licensure of Pharmacy Benefit Managers: AARP supports the major provisions included in 2019's AB114/SB100 (as amended) as it improves transparency throughout the prescription drug supply chain. We support state licensure, certification and registration laws for PBMs as long as they are not so restrictive or burdensome so that PBMs are effectively prevented from doing business in the state.

Prohibiting Gag Clauses: AARP is supportive of legislation that prohibits the use of gag clauses. These provisions prevent pharmacists from telling consumers that the list price of a medication may be cheaper than their insurance copay, or from discussing potential lower cost options.

Co-Pay Cap for Insulin: Over 462,000 Wisconsinites are living with diabetes or pre-diabetes. From 2012 to 2017, the average annual cost of one common diabetes drug, Lantus, increased from \$2,907 to \$4,702. Medications do not work if people cannot afford them. A co-pay cap on insulin will help Wisconsinites living with diabetes better afford the exorbitant prices that are being charged for lifesaving insulin medication.

Policy options for longer-term consideration

Price Gouging: AARP supports efforts to prohibit drug manufacturer price gouging and believes that federal, state and local governments should ensure that prescription drug launch prices and subsequent pricing decisions are reasonable, justified, and support improved consumer access and affordability. Anti-price gouging policies protect consumers from sudden and unreasonable spikes in prescription drug prices. They also ensure prices do not make essential medications out of reach, which is especially important during times of disaster or crisis, when the market could see a spike in cost.

Manufacturer Reporting: AARP strongly supports increased transparency in the drug development and pricing process, particularly in cases of drug manufacturers that benefit from taxpayer-funded research. Legislation that appropriately increases disclosure around pricing practices will result in more meaningful and actionable information for states and accountability for manufacturers and will help payers determine whether a drug price or price increase is justified.

Affordability boards: Transparency bills, while by themselves do not reduce prescription drug prices, are important building blocks for other legislative efforts such as cost review commissions and drug affordability boards that can more directly address costs. AARP supports the development of a state drug affordability review board and believes that such an effort could help ensure that prescription drug launch prices and subsequent pricing decisions are reasonable, justified, and support improved consumer access and affordability.

Importation: AARP Wisconsin supports state importation legislation that would authorize Wisconsin to seek federal approval to import prescription medication on a

5. Letters

5.3 American Association of Retired Persons

wholesale basis from Canada or other countries with similar safety and quality standards.

AARP Wisconsin looks forward to building on the good work of the Governor's Task Force on Reducing Prescription Drug Prices and working with Wisconsin's elected officials to pass common-sense legislation to bring relief to Wisconsinites struggling with high prescription drug prices. Wisconsin seniors can't afford to wait.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sam Wilson', written in a cursive style.

Sam Wilson
AARP Wisconsin State Director

5. Letters

5.4 American Diabetes Association



August 13, 2020

Mr. Nathan Houdek
Deputy Commissioner of Insurance
Chair, Governor's Task Force on Reducing Prescription Drug Prices
P.O. Box 7873
Madison, WI 53707-7873

via email – OCIRXDrugTaskForce@wisconsin.gov

Dear Mr. Houdek and Members of the Governor's Task Force on Reducing Prescription Drug Prices:

People with diabetes are facing a crisis.

Of the 34.2 million Americans with diabetes,¹ about 6.8 million use insulin.² Right here in Wisconsin, more than two million people have or are at risk for diabetes.³ Many people with diabetes need insulin to live and to avoid devastating complications that include blindness, kidney failure, lower limb amputation, heart attack, stroke, and even death. For them, the cost has spiraled out of control and is beyond the reach of many.

Insulin prices have tripled between 2002 and 2013⁴ and have doubled since then⁵ - for a medicine that is nearly 100 years old. There have been incredible advances in research and development and technology that have improved the lifespan and quality of life for those with diabetes, but the formula for insulin has not changed significantly since the 1990s.

Without insulin, people with diabetes die and scaling back on insulin can lead to costly and sometimes deadly complications. People with diabetes can require as much as two to four vials of insulin per month. So, when deductibles are high, even people with insurance end up paying upwards of \$1,200 per month simply to live or they're rationing their insulin, either taking less than the dose they have been prescribed or skipping doses altogether, which may lead to deadly complications and high costs to the state. Research conducted for the American Diabetes Association (ADA) has shown that, for one in four insulin users, cost has impacted their use, causing them to ration their insulin.⁶

As the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic, we consistently hear from people with diabetes who struggle to afford their life-sustaining insulin.

As I shared during my July 22 presentation to the Task Force, the American Diabetes Association has been and continues to be a leader in the insulin affordability discussion.


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5. Letters

5.4 American Diabetes Association



ADA, through the work of its Insulin Access and Affordability Working Group, reached a number of conclusions that have been published in the journal *Diabetes Care*⁷:

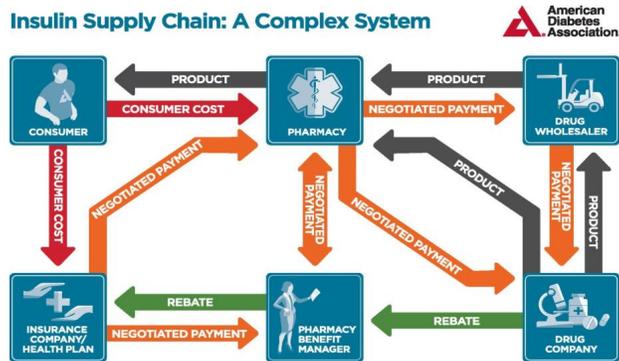
- The current pricing and rebate system encourages high list prices.
- There is a lack of transparency throughout the insulin supply chain.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs.
- Patient medical care can be adversely affected by formulary decisions.
- The regulatory framework for development and approval of biosimilar insulins is burdensome for manufacturers.

After further study, ADA released a public policy statement⁸ that included key recommendations such as:

- Increasing pricing transparency throughout the insulin supply chain,
- Lowering or removing patient cost-sharing for insulin, and
- Increasing access to health care coverage for all people with diabetes.

Recommendation #1 - Increasing pricing transparency throughout the insulin supply chain.

Transparency is at the forefront of any recommendations to address the high cost of insulin. This representation of the complexities of the insulin supply chain shows the numerous stakeholders involved in the delivery of insulin as well as the multiple opaque transactions between and among these stakeholders.



It is unclear precisely how the dollars flow and how much each intermediary in the insulin supply chain profits. This lack of transparency clouds the true cause of higher prices. In order to better understand the role of each link in the supply chain, there must be full transparency.

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5. Letters

5.4 American Diabetes Association



To accomplish this, ADA recommends:

- requiring all entities in the insulin supply chain to report certain pricing, sales, and profit data to a designated state agency,
- compiling the information in an aggregated report and providing it to the state legislature and insurance commissioner's office, and
- publishing the report on the agency's website.

Recommendation #2 - Lowering or removing patient cost-sharing for insulin.

The American Diabetes Association has joined with other diabetes stakeholders to support state legislation to cap the amount a patient with diabetes pays each month for their insulin. This would apply to all state-regulated commercial health insurance plans.

In May of last year, Colorado became the first state in the nation to enact an insulin co-pay cap bill. The law:

- caps co-pays for insulin at \$100/month, regardless of the type of insulin or the number of vials a patient requires and
- calls on the Colorado Attorney General to investigate the rising prices of insulin in the state and make recommendations to the General Assembly for further action.

Soon after Governor Polis signed the bill in Colorado, other state's legislators began exploring the possibility of replicating the bill in their own states.

Insulin co-pay cap laws have now been enacted this year in Illinois, New Mexico, Maine, West Virginia, Utah, Washington, New York, Virginia, New Hampshire, Delaware, and Connecticut.

In Wisconsin, Sen. Dave Hansen and Rep. Jimmy Anderson introduced SB 340 and AB 411, respectively, last Fall. Similar to the Colorado law, each bill sought to establish a monthly co-pay cap on insulin and require the Commissioner of Insurance to investigate and report on the pricing of insulin.

Although neither bill gained traction during this session, ADA will continue to work with the legislature to enact an insulin co-pay cap bill next session.

Some states have also taken action to exempt insulin from the deductible, an action ADA also supports.

A related recommendation is to include the value of drug manufacturer coupons toward a patient's out-of-pocket cost obligation. Whereas ADA recognizes that cost-sharing coupons are not a long-term solution to prescription drug affordability issues, they can be essential to ensuring individuals with high


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5. Letters

5.4 American Diabetes Association



Connected **for Life**

cost-sharing requirements are able to afford medications their providers deem necessary, including insulin, for which there is no generic available.

This type of legislation has already been enacted in Arizona, Illinois, Virginia and West Virginia. Senate Bill 907, introduced at the end of this past session by Sen. Andre Jacque, is an example of legislation supported by ADA.

Finally, Medicare coverage can be a guide for states as they consider coverage decisions. With the announcement earlier this year that the Part D Senior Savings Model will limit the cost of insulin for participating seniors to a maximum of \$35 for a 30-day supply,⁹ we urge Wisconsin and insurance plans doing business in the state to follow suit.

Recommendation #3 - Increasing access to health care coverage for all people with diabetes.

An analysis by the Robert Wood Johnson Foundation estimates that 120,000 Wisconsinites would gain access to Medicaid if the state were to accept federal funding to fully expand coverage, and that the state's uninsured rate would drop by 16 percent.¹⁰

Expanding Medicaid coverage would have a tremendous impact on their lives, particularly those living with or at risk of developing diabetes. The need is only intensified by the COVID-19 pandemic.

Access to affordable, adequate health coverage is critically important for all people with, and at risk for, diabetes. Low-income populations experience great disparities in access to care and health status. For these individuals, access to Medicaid coverage is essential to managing their health.

On average, people with diagnosed diabetes have medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes.¹¹ In 2017, diagnosed diabetes cost an estimated \$5.5 billion in Wisconsin.¹² This included \$4.1 billion in direct medical costs and \$1.4 billion in indirect costs such as absenteeism, unemployment due to disability, and premature mortality.

In Medicaid expansion states, more individuals are being screened for and diagnosed with diabetes than states that have not expanded.¹³ Additionally, a recent study found expansion states have a higher rate of prescription fills for diabetes medications than non-expansion states.¹⁴ Regular medication use with no gap in health insurance coverage leads to fewer hospitalizations and less use of acute care facilities.^{15,16}

Wisconsin is now one of 12 states not to have expanded Medicaid. With the recent voter approvals in Oklahoma (June 30) and Missouri (August 4), we urge the Wisconsin legislature to continue this momentum and extend Medicaid coverage to tens of thousands of Wisconsinites, many of whom are living with diabetes and other chronic health conditions.


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5. Letters

5.4 American Diabetes Association



Conclusion

It's time to reduce the financial burden on the state and on Wisconsin diabetes patients who need insulin. People with diabetes - Wisconsinites with diabetes - are sometimes forced to choose between insulin and rent or between insulin and food to survive.

The American Diabetes Association believes that no individual in need of life-saving medications should ever go without due to prohibitive costs or accessibility issues.

On behalf of the more than two million people with or are at risk for diabetes, we urge this Task Force to issue a report urging the General Assembly to:

- Increase access to health care coverage for all people with diabetes.
- Increase pricing transparency throughout the insulin supply chain.
- Lower or remove patient cost-sharing for insulin.

Thank you very much for the opportunity to present to the Task Force last month and to submit these written comments.

Sincerely,

Gary Dougherty
Director, State Government Affairs

¹ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States," <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>

² American Diabetes Association, "Fast Facts: Data and Statistics about Diabetes," February 2020, https://professional.diabetes.org/sites/professional.diabetes.org/files/media/sci_2020_diabetes_fast_facts_sheet_final.pdf

³ Diabetes Care 2019;42:1661-1668 | <https://doi.org/10.2337/dc18-1226>

⁴ Diabetes Care 2018;41:1299-1311 | <https://doi.org/10.2337/dc18-0019>

⁵ "Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices," Health Care Cost Institute, January 2019 - <https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>

⁶ American Diabetes Association, Insulin Affordability Survey, 2018, available at <http://main.diabetes.org/dorg/PDFs/2018-insulin-affordability-survey.pdf>

⁷ <https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf>

⁸ <https://www.diabetes.org/sites/default/files/2019-10/insulin-affordability-one.pdf>

⁹ Centers for Medicare and Medicaid Services, March 11, 2020 press release. Available at <https://www.cms.gov/newsroom/press-releases/cms-launches-groundbreaking-model-lower-out-pocket-expenses-insulin#:~:text=The%20Part%20%20Senior%20Savings%20Model%20allows%20Medicare,a%20maximum%20%2435%20copay%20per%20thirty-day%20supply%20>

¹⁰ Simpson, Michael, "The Implications of Medicaid Expansion in the Remaining States: 2020 Update," Robert Wood Johnson Foundation. June 2020. Available at https://www.rwjf.org/en/library/research/2020/06/the-implications-of-medicaid-expansion-in-the-remaining-states--2020-update.html?cid=xem_other_unpd_ini:quickstrike_dte:20200608_des:medicaid%20exp

¹¹ <https://www.diabetes.org/resources/statistics/cost-diabetes>

¹² http://main.diabetes.org/dorg/docs/state-fact-sheets/ADV_2020_State_Fact_sheets_WI.pdf

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5. Letters

5.4 American Diabetes Association



²³ Kaufman H., Chen Z., Fonseca V. and McPhaul M., Diabetes Care, "Surge in Newly Identified Diabetes Among Medicaid Patients in 2014 Within Medicaid Expansion States Under the Affordable Care Act," March 2015. Available at: <http://care.diabetesjournals.org/content/early/2015/03/19/dc14-2334>

²⁴ Myerson R., Tianyi L., Tonnu-Mihara I., and Huang E.S., Health Affairs, Medicaid Eligibility Expansions May Address Gaps in Access to Diabetes Medications, August 2018. Available at: <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.0154>

²⁵ Id.

²⁶ Rogers M, Lee J, Tipirneni R, Banerjee T, and Kim C, Health Affairs, Interruptions in Private Health Insurance and Outcomes In Adults with Type 1 Diabetes: A Longitudinal Study. July 2018. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0204>

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5. Letters

5.5 Coalition of State Rheumatology Organizations



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August 14, 2020
Governor's Prescription Drug Task Force
2 E Main St, Madison, WI 53703

Re: Wisconsin Task Force on Reducing Prescription Drug Prices Policy Considerations

Task force members,

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of state and regional professional rheumatology societies, including our member society in Wisconsin. CSRO was formed by physicians to ensure excellence and access to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease. It is with this in mind that we write to you in response to the task force's policy considerations for reducing prescription drug costs in the state of Wisconsin. We appreciate your consideration of our comments.

Rebate and Fee Transparency & Rebate Pass Through

CSRO strongly supports improved rebate and fee transparency, and rebate pass through. Pharmacy Benefit Managers (PBMs) are not the sole cause of burdensome drug prices, however, any solution that does not examine their hand in creating a system that incentivizes list price inflation would be incomplete. Improved transparency would serve as a starting point for better understanding the extent to which the rebate system is shouldering sick patients in Wisconsin with burdensome prescription drug costs.

The out-of-pocket cost for certain prescription drugs has become increasingly untenable for many patients. This is especially true for patients who pay a percentage of a drug's list price (coinsurance) rather than a fixed copay. For many specialty drugs, a patient may pay between 20% and 40% of a drug's list price. Increasing enrollment in high-deductible health plans has exacerbated patients' exposure to untenable coinsurance costs.

Coinsurance rates are often based on the list price of a drug although the net price of the drug after rebates is substantially cheaper. The patients, who themselves generate rebate dollars, do not sufficiently

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5.5 Coalition of State Rheumatology Organizations

benefit from them. In 2019, Texas began to require reporting of rebate data annually to the Texas Department of Insurance. Their inaugural report of this data was [recently released](#).¹ The data unambiguously shows that roughly 12% (\$356,578,864) of rebates were retained by a PBM as revenue, and carriers passed only .54% of total rebates to their enrollees that generated them. This functions as a system of reverse insurance, where the sickest patients who require expensive specialty medications are subsidizing the cost of care for healthier and other individuals.

This is especially troublesome because the rebate system incentivizes higher list prices, further exposing patients who face coinsurance based on list prices. Five large manufacturers have released transparency reports that detail the divergence between net and list pricing for their products.^{2,3,4,5,6} These reports are succinctly summarized by the [Drug Channels Institute](#).⁷ This data shows that although list prices have increased, net prices have either fallen or increased at a smaller rate. Further, the average rebate generated from a drug's list price was 51%. Unfortunately, sick patients are the ones who bear the cost of this system.

Improving transparency of the rebate system would allow a clearer picture for policymakers as they debate how to proceed on drug pricing. In addition, requiring that patient cost-sharing obligations be based off the net price of a drug, rather than the list price would immediately deliver savings to patients in Wisconsin.

Coupons and Cost Sharing Limitations

Insurers and pharmacy benefit managers are currently implementing alternative cost-sharing structures known as “accumulator adjustment programs.” These programs prevent the value of co-pay assistance from being applied towards a patient's deductible as an out-of-pocket expense. In the past, once the value of a patient's copay assistance was depleted, a patient's deductible had been met, ensuring they could afford otherwise financially inaccessible drugs. Under these programs insurers will pocket the value of the co-pay card in addition to extracting the full deductible value from the patient. Due to the move towards high deductible health plans, and the inherent costliness of the drugs used to treat complex chronic conditions, most patients will not be able to afford their medication once the co-pay card benefit is exhausted, and they are forced to start paying off their deductible. This will result in otherwise stable patients discontinuing their treatments, allowing for adverse health effects.

¹ <https://www.tdi.texas.gov/reports/documents/drug-price-transparency-PBMs.pdf>

² [Eli Lilly and Company: 2019 Integrated Summary Report](#) - Page 22

³ [2019 Janssen U.S. Transparency Report](#) – Page 12

⁴ [Merck & Co., Inc.: 2019 US Pricing Transparency Report](#)

⁵ [Novartis: Novartis in Society 2019 US Report](#) – Page 9

⁶ [Sanofi: 2020 Pricing Principles Report](#) – Page 6

⁷ <https://www.drugchannels.net/2020/08/five-top-drugmakers-reveal-list-vs-net.html>

5. Letters

5.5 Coalition of State Rheumatology Organizations

Although many drugs have less expensive alternatives that are in the same therapeutic class, in many cases these alternatives are not suitable due to unique characteristics of each patient's medical history and disease state. Where these alternatives are appropriate, physicians should be trusted to prescribe them. In some cases, patients are prescribed an innovator product that has no competing generic; accumulator adjustment programs leave them without recourse in properly treating their disease.

Although we acknowledge the task force members' concern that certain copay assistance programs and coupons may crowd out less expensive competition, accumulator programs are indiscriminate in their exclusion of copay assistance. As noted by the task force, states such as Arizona and Georgia have recognized this nuance in their recent passage of laws addressing accumulator programs.

Specialty Drugs Home & Outpatient Administration

CSRO is strongly opposed to the utilization of patients' homes as a site of care for infusion of specialty drugs. The drugs infused by rheumatologists are highly complex and many of the medications require advanced clinical skills to prepare and administer. Potential adverse reactions to the infusion are difficult to properly manage in a patient's home. In turn this may also increase liability to the physician's practice. As a result CSRO believes that expansion of infusions in the home setting present is inappropriate.

We appreciate the task force's time and consideration, and should you like to discuss our comments in further detail you may contact brian@wjweiser.com.

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5.6 Common Ground Healthcare Cooperative



August 11, 2020

Nathan Houdek, Deputy Commissioner
Wisconsin Office of the Commissioner of Insurance
125 South Webster Street
Madison, Wisconsin 53703

Submitted electronically via OCIRXDrugTaskForce@wisconsin.gov

Dear Deputy Commissioner Houdek,

Thank you for the invitation to provide recommendations to the Governor's Task Force on Reducing Prescription Drug Prices. We have been closely following the work of the task force from our perspective as a consumer-governed health insurance cooperative advocating for our consumer members.

Common Ground Healthcare Cooperative is one of the state's largest individual market insurers. Many of our members would not be able to afford their health coverage without advanced tax credits available to lower monthly premiums and out-of-pocket costs. Our members are often early retirees or individuals working in jobs that do not have access to employer sponsored health benefits.

Focus on Consumers and Cost

We encourage the task force to keep the needs of consumers top of mind when considering its recommendations to the governor and narrow its scope only to actionable initiatives that will truly lower the cost of medications for consumers or, in the alternative, initiatives that otherwise support consumers with information to make well-informed decisions. Consumers are the ones bearing the greatest burden for the cost of medications in the United States – either paying directly out of pocket or indirectly through the premiums they pay to insurers. We would encourage the task force to focus on ideas that remove dollars from the calculus instead of shifting costs to the premium side of the equation which does not help consumers.

For example, though it appears on the surface to signal value to the individual health plan member, the idea presented by PhRMA to require insurers to count the value of drug coupons toward consumers' out of pocket costs is a "solution" that actually brings *more* costs into the equation, not less. We believe that pay-for-performance is the true exemplar of a value-based health care system, leading to improved access, quality, and affordability for our members – but only when decisions are based upon evidence

5. Letters

5.6 Common Ground Healthcare Cooperative

and best practices. Rendering consumers insensitive to drug prices through couponing is, in reality, an enabling paradigm that leads to market distortion by allowing drug manufacturers to raise prices, while inoculating themselves against losing market share. This, in turn, encourages drug manufacturers and pharmacy benefits managers (PBMs) to engage in perverse contracting schemes and formulary tiering practices that are not only uncoupled from natural market forces, but often uncoupled from real-world patient health outcomes. When PhRMA helps consumers meet their out of pocket responsibilities by paying them to take expensive medications, it increases utilization not only on the drug side but also on the medical side, and benefits relatively few at the expense of many.

A good first step for the task force would be remove any recommendation from consideration that fails the litmus test of realistically having a good chance to lower medication costs for consumers. A good second step would be for the task force to design a platform to effectively measure resulting cost savings from any task force recommendation that is implemented. This may be something that could be tasked to an “affordability board” should that become an idea the task force agrees upon. Without having much detail, we would generally support the creation of an affordability board if its purpose were aligned to the best interest of health care consumers.

Provisions Included in SB 100/AB 114

Common Ground Healthcare Cooperative is on record supporting provisions in SB 100/AB 114 that we believe will bring down the cost of medications and that are in consumers’ best interests. That includes state-level protections for pharmacists that discuss alternative medications with their customers and ensuring that consumers pay the lowest cost at the pharmacy counter. We believe both ideas can have a positive impact on cost.

There are other recommendations that were also part of SB 100/AB 114 that we would support as legislation, such as increasing OCI’s oversight authority when it comes to PBMs and addressing network adequacy. However, we are struggling to see how some of these ideas are in scope for a task force focusing on the cost of prescription medications. We also believe that policy ideas like this should not be included in the budget bill but pursued as separate legislation to ensure they are properly vetted.

Recommendations on Transparency and Rebates

Common Ground Healthcare Cooperative is strongly supportive of open and transparent disclosures of drug costs and rebates by key pharmacy supply chain stakeholders including health insurers. It is possible such disclosures may engender more trust in our industry and spur important public conversations about the cost of certain medications.

That said, while we would not oppose the transparency provisions that have been proposed (assuming they would be written to minimize costs related to regulatory burden), we are hoping the task force will concentrate efforts around the ideas that would have the most significant impact on the price of medications. In our view, the recommendation that rises to the top is the one that would place reporting requirements on drug manufacturers so they would have to notify OCI and provide a justification when increasing the wholesale acquisition cost of brand and generic drugs.

In regard to rebate pass through requirements and the elimination of spread pricing, we would only provide our feedback inasmuch that, as an insurer, we believe we have the ability to address these issues in contracts with PBMs if we feel that doing so would result in lower costs for our members. We do not believe it is necessary to see these provisions legislatively mandated.

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5.6 Common Ground Healthcare Cooperative

Addressing Price Gouging and Specifically, Insulin

Common Ground Healthcare Cooperative was the only health insurance company to register support for Senate Bill 340 last session that would have placed limits on insulin copayments. Our position is aligned with our philosophy of putting people first, and right now people are suffering because they cannot afford insulin.

The fact affordable insulin continues to be inaccessible for many with diabetes is a national disgrace. And, as a member-centered cooperative we will always take the side of consumers over the insurance industry when it comes to life-saving treatment. We deemed the legislation as the most immediately expedient way to help consumers who are struggling. These are the reasons we supported SB 340.

That said, we do not believe caps on copayments are the answer to high insulin costs because they do not address the root cause of the problem. Addressing pricing gouging with caps on insurer copays only shifts costs around instead of removing them altogether. Limits on consumer cost-sharing could also have the unintended effect of encouraging manufacturers to increase insulin prices instead of decreasing them. We need solutions that lead to lower manufacturer costs and, therefore, the federal government must act. States that have attempted to hold manufacturers accountable for insulin costs, such as Minnesota, are now being sued by manufacturers.

We would recommend that the task force look for alternatives to copay caps on insulin that might be more effective. Please consider Minnesota's [Alec Smith Insulin Affordability Act](#) and the National Academy of State Health Policy's [Anti-Price Gouging Model Act](#). We believe these solutions appropriately attempt to address costs at the manufacturer level where it will have the most impact for consumers.

Conclusion

We encourage the task force, as it contemplates the value of various recommendations brought forward from stakeholders with divergent perspectives, to set aside their own industry interests and focus instead on putting consumers first. The conversations we have with our members reveal that most consumers feel isolated and unsupported when trying to navigate the health care industry's often perverse incentives with regard to medication affordability and the cost of health care overall. It is important that the task force remain true to its charge and stand up for consumers, advancing recommendations that will truly take costs out of the equation instead of protecting a particular industry or interest group.

We are happy to be a resource to the task force as it weighs their important decisions ahead. Please do not hesitate to contact Melissa Duffy at (608) 334-0624 if we can answer any questions or provide pertinent data or information that may be helpful to you.

Sincerely,



Cathy Mahaffey, CEO
Common Ground Healthcare Cooperative

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5.7 Department of Agriculture, Trade and Consumer Protection and the Wisconsin Department Justice



State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection
Secretary-designee Randy Romanski

Dear Deputy Commissioner Houdek and Members of Governor Evers' Task Force on Reducing Prescription Drug Prices:

The Department of Agriculture, Trade and Consumer Protection and the Wisconsin Department Justice very much appreciate the opportunity to be part of the important discussion on how best to bring down the cost of prescription drugs. As the agencies charged with enforcing the State's Fraudulent Drug Advertising's law, Wis. Stat. § 100.182, DATCP and DOJ would like to comment on the expanding landscape of prescription drug marketing and limited regulatory oversight to stem the tide of deceptive and misleading drug advertising.

Direct-to-consumer advertising of prescription drugs is an extensively utilized tool by the U.S. drug manufactures to increase the prescription and consumption of their drugs. A widely cited study in the Journal of the American Medical Association (JAMA) found that the marketing of drugs directly to U.S. consumers grew exponentially after the loosening of marketing restrictions by the FDA in 1997.¹ The study found that from 1997 through 2016, direct-to-consumer advertising ballooned "from \$1.3 billion (79,000 ads) in 1997 to \$6 billion (4.6 million ads, including 663,000 TV commercials)" in 2016.² JAMA's study also found that direct-to-consumer advertising has been linked with increased demand for specific pharmaceuticals despite often the existence of cost-effective alternatives.³

Concerned with the effects this type of advertising was having on the provision and cost of medical care, in 2015 the American Medical Association (AMA) called for a ban on direct-to-consumer advertising, explaining that "a growing proliferation of ads is driving demand for expensive treatments despite the clinical effectiveness of less costly alternatives." The AMA went on to state that "direct-to-consumer advertising also inflates demand for new and more expensive drugs, even when these drugs may not be appropriate."⁴

Significantly, the Journal of the American Medical Association's study also found that despite the dramatic increase in direct-to-consumer marketing, regulatory oversight had decreased. Researchers found the Federal Drug Administration issued 156 violation letters to manufacturers in 1997. That number dropped to 11 violation letters in 2016.⁵ The United States Department of Justice and States Attorneys General continued to pursue the off-label and deceptive marketing practices of drug

¹ Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States: 1997-2016*, The Journal of the American Medical Association, Vol. 321, No. 1, at 80 (January 8, 2019), <https://jamanetwork.com/journals/jama/fullarticle/2720029> (last visited September 2, 2020).

² *Id.* at 82.

³ *Id.* at 88-89.

⁴ American Medical Association, Press Release: AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices (November 17, 2015), <https://www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices> (last visited September 2, 2020).

⁵ *Medical Marketing in the United States*, at 80.

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5. Letters

5.7 Department of Agriculture, Trade and Consumer Protection and the Wisconsin Department Justice



State of Wisconsin
Governor Tony Evers

Department of Agriculture, Trade and Consumer Protection
Secretary-designee Randy Romanski

companies during that time, resolving allegations of wrongdoing that resulted in nearly \$11 billion in financial penalties and 103 settlements with drug companies.⁶

Wisconsin has a law directly addressing Fraudulent Drug Advertising. It prohibits “untrue, deceptive or misleading representations material to the effects of the drug.”⁷ Unlike some other consumer protection laws enforced by DATCP, the Fraudulent Drug Advertising law does not provide the agency with specific rule making authority. Consideration should be given to providing DATCP direct rulemaking authority, specifically on the issue on prescription drug marketing. This could allow the promulgation of rules that address some of the more common deceptive and misleading practices as they relate to prescription drugs and their unfair pricing.

In addition, consideration should be given to including an unfairness prong to the Fraudulent Drug Advertising statute.⁸ Many states regulate deceptive and *unfair* conduct in the marketplace. An unfairness prong could give DATCP and DOJ the latitude to better address the conduct in the drug market, particularly as it relates to pricing, which can have an unfair impact on some of our most vulnerable citizens.

DATCP and DOJ appreciate the opportunity to have been part of this very rich discussion and would be pleased to serve in whatever future capacity to address the pressing issue of lowering prescription drug prices.

A handwritten signature in cursive script that reads "Lara Sutherlin".

Lara Sutherlin, Administrator
Division of Trade and Consumer Protection

Wisconsin Department of Agriculture,
Trade and Consumer Protection

JOSHUA L. KAUL
Attorney General of Wisconsin
Electronically signed by:

s/ Laura E. McFarlane
LAURA E. MCFARLANE
Assistant Attorney General
State Bar #1089358

⁶ *Id.* at 80.

⁷ Wis. Stat. § 100.182.

⁸ Wis. Stat. § 100.18.

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5. Letters

5.8 Greater Wisconsin Agency on Aging Resources, Inc.



Date: August 14, 2020

Re: Comments on Proposals of the Governor's Task Force on Reducing Prescription Drug Prices

Dear Deputy Commissioner Houdek, Task Force Chair and members of the Governor's Task Force on Reducing Prescription Drug Prices,

The Greater Wisconsin Agency on Aging Resources, Inc. (GWAAR) is a nonprofit agency committed to supporting the successful delivery of aging programs and services in our service area consisting of 70 counties (all but Dane and Milwaukee) and 11 tribes in Wisconsin. We are one of three Area Agencies on Aging in Wisconsin. We provide lead aging agencies in our service area with training, technical assistance, and advocacy to ensure the availability and quality of programs and services to meet the changing needs of older people in Wisconsin. GWAAR is also a member of the Wisconsin Aging Advocacy Network (WAAN) a collaborative group of individuals and associations working with and for Wisconsin's older adults to shape public policy to improve their quality of life.

Thank you for this opportunity to provide comments on the proposals currently being discussed by the Task Force. Reducing the cost of prescription drugs is an important issue for many older adults. The prevalence of multiple chronic diseases and healthcare utilization (including utilization of prescription drugs) increase with age. According to the Kaiser Family Foundation, nearly 90% of adults 65 and older report they are currently taking any prescription medicine, with more than half of them reporting taking four or more prescription drugs. Nearly 1 in 4 older adults report difficulty paying for prescription drugs.¹ According to the Wisconsin Poverty Report, "For elders, medical cost increases outpaced the sum of all noncash benefits and led to a higher WPM (Wisconsin Poverty Measure) rate than that found in the official measure by 2.4 percentage points. This suggests that public policies designed to increase the coverage of medical expenses for the low-income elderly can do more to help to alleviate the economic hardship felt by this group than almost any other public policy."²

While most older adults have prescription drug coverage through Medicare Part D or Wisconsin's SeniorCare program, older adults are still very much affected by the list price of

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5. Letters

5.8 Greater Wisconsin Agency on Aging Resources, Inc.

J. L. Zander – Comments and recommendations to the Governor’s Task Force on Reducing Prescription Drug Prices_8/14/20

drugs as they are often subject to deductibles, coinsurance (calculated as a share of list price), and/or paying the full list price for medications not on their insurance formulary.

GWAAR supports proposals identified by the Task Force that reduce prescription drug costs for consumers, as well as those that improve drug price transparency. Specifically, GWAAR supports the following proposals found on the Task Force’s Issue Summary Table:

Issue:

7. Amount Consumer Charged at Point of Sale - Insured consumers should never be asked to pay more out of pocket at the point of sale than they would without their prescription drug coverage or more than the contracted price for a prescription.

12. Coupons and Cost Sharing Limitations – While not a permanent solution to lowering prescription drug costs, requiring insurers to apply manufacturer coupons/discounts to deductibles and annual limitations on cost sharing would reduce out-of-pocket expenses for consumers.

13. Co-payment Cap on Insulin – While limiting the co-pay for a month's supply of insulin to \$100 would not address the cost of prescription drugs as a whole, it would offer much needed support to individuals with diabetes struggling to cover the cost of needed insulin. Capping insulin costs would likely reduce the likelihood that individuals would skip insulin doses or use less than prescribed doses to stretch their supply of insulin (practices which can result in increased ambulance and Emergency Room costs).

14. Affordability Boards – Creation of a central entity to coordinate the prescription drug purchasing needs of state agencies, monitor the prescription drug purchasing process in the commercial market, and recommend changes to create efficiencies would ultimately result in consumer savings. This entity could be used to monitor and respond to the manufacturer reported price increases (see #18).

18. Manufacturer Reporting - Requiring manufacturers to submit information to the Office of the Commissioner of Insurance (OCI) when increasing the wholesale acquisition cost of brand and generic drugs would bring additional transparency to prescription drug pricing. Enhancing drug price transparency will improve agencies/providers ability to negotiate prices with prescription drug manufacturers and help to better inform consumer decision making.

Prescription medications do not work if they are not taken or are not taken as prescribed.

5. Letters

5.8 Greater Wisconsin Agency on Aging Resources, Inc.

J. L. Zander – Comments and recommendations to the Governor’s Task Force on Reducing Prescription Drug Prices_8/14/20

Skipping doses of needed medicine to save money is an expensive strategy in the long run, resulting in unnecessary complications, bad health outcomes, and increased medical costs from hospitalization or other medical interventions. The Greater Wisconsin Agency on Aging Resources extends sincere appreciation to all members of the Governor’s Task Force on Reducing Prescription Drug Prices for your efforts to develop safe ways to reduce prescription drug costs.

Thank you for your consideration of these comments on this important health care and economic security issue.

Contact: Janet Zander, Advocacy & Public Policy Coordinator
Greater Wisconsin Agency on Aging Resources, Inc.
janet.zander@gwaar.org
(715) 677-6723 or (608) 228-7253 (cell)

¹ <https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/>

² <https://www.irp.wisc.edu/wp/wp-content/uploads/2019/06/WI-PovertyReport2019.pdf>

GWAAR’s Mission:

Delivering innovative support to lead aging agencies as we work together to promote, protect, and enhance the well-being of older people in Wisconsin.

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5. Letters

5.9 Healthcare Distribution Alliance



September 4, 2020

Deputy Commissioner Nathan Houdek
Chair, Wisconsin Governor's Task Force on Reducing Prescription Drug Prices
125 South Webster Street
Madison, WI 53703

Re: HDA Comments for September Task Force Report to the Governor

Dear Chairman Houdek & Members of the Wisconsin Drug Pricing Task Force,

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing primary pharmaceutical wholesale distributors, we would like to thank you for the opportunity to present during the June Task Force meeting. We look forward to continued collaboration with the state and policymakers as it relates to the pharmaceutical wholesale distribution industry. As the taskforce prepares its final policy recommendations for the Governor, we want to provide this letter as a resource explaining the role wholesale distributors play within the healthcare supply chain and their impact on drug pricing.

To that end, attached to this document is a recent letter HDA sent to the National Academy for State Health Policy (NASHP) regarding their recent model acts targeting drug pricing. While NASHP has provided states with an impressive array of materials for policymakers to consider, these proposals do not always reflect how the pharmaceutical supply chain operates. It is essential for policy proposals to accurately reflect the various components of the supply chain to develop sound policy proposals. HDA would like to ensure any model considered by Wisconsin and other states accurately reflects the role and responsibility of the primary pharmaceutical wholesale distribution industry.

Role of Wholesale Distributors:

HDA represents the nation's pharmaceutical wholesale distributors who work around-the-clock to safely and efficiently ship pharmaceutical and medical products to pharmacies, hospitals and other healthcare providers nationwide. In their role as distributors wholesalers do not conduct research, manufacture, promote or prescribe medications, nor do they influence prescribing patterns, the demand for specific products or patient-benefit designs. Their primary role is to ensure that medicines travel from manufacturers to dispensing locations safely, securely and efficiently.

Without pharmaceutical distributors, pharmacies and providers would be forced to have large warehouses, carry weeks of inventory and undertake the time-consuming process of placing daily orders with each manufacturer for the products patients need. This would essentially become an impossible task for most dispensing locations, as there are thousands of manufacturers serving the marketplace. By working with primary wholesale distributors, who provide logistical, inventory, and other service support, providers can maintain a one-stop-shop for all medical products, which creates efficiency, reliability and security within our healthcare supply chain. Additionally, it allows dispensers to get the medicines they need in a timely fashion, saving our healthcare system approximately \$33 billion each year.

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5. Letters

5.9 Healthcare Distribution Alliance

Role in Drug Pricing:

It is critical for members of the task force to understand the role wholesalers play in pricing pharmaceuticals. The primary pharmaceutical distribution industry has a very high-volume, low-profit margin model – like most wholesale industries. In fact, overall industry profitability for the primary distribution sector shows little notable change over the past several years, even during recent market volatility.

Wholesale distributors purchase brand pharmaceuticals based on a manufacturer's list price, or Wholesale Acquisition Cost (WAC). Wholesale distributors may purchase generic drugs at a manufacturer's list price, but they are often able to use their market power to negotiate discounted prices on generic drugs with pharmaceutical manufacturers. In 2019, nine out of every ten prescriptions in the U.S. were dispensed using generic medicines. However, generics account for only 22% of prescription drug spending.¹ Wholesale distributors are uniquely positioned to continue negotiating discount arrangements on generic drugs with pharmaceutical manufacturers further lowering the cost of generic drugs. This, and the other non-medication related services wholesalers provide, result in some medications being sold at discounted rates and lower-than-list price to dispensing locations.

Since wholesalers purchase and subsequently sell pharmaceuticals from manufacturers based on their list price, or a discounted negotiated price in the case of generic drugs, wholesale distributors will charge manufacturers distribution fees related to their services. These fees, which are not passed on to the customer, represent a fair market value for a bona fide service - an itemized service performed on behalf of the manufacturer that the manufacturer would otherwise need to perform (or contract for) in the absence of a distributor.

As reported by numerous industry studies, wholesale distributors retain approximately 1 percent of total drug expenditures on brand name medications². You can look at a wholesaler's role like this: once a drug reaches the dispensing location, a wholesaler's job is done in the supply chain and the provider and insurance benefit market takes over.

HDA supports the state's efforts to better understand the prices that consumers pay at the pharmacy counter. However, as noted previously, wholesale distributors do not have insight into the pricing of dispensable units, pharmacy benefit design or the ultimate price that consumers pay to fill their specific prescriptions. Distributors are not a part of negotiations on the "pay side" of the supply chain. Rather, this is the role of health insurers and pharmacy benefit managers (PBMs). Wholesale distributors simply purchase medical products in bulk, not per pill or per dose, and sell to hundreds of thousands of points of care across the country.

Certain Prescription Drug Pricing Data is Publicly Available:

The state already has full access to publicly available pricing information reported to the Centers for Medicare and Medicaid Services (CMS) that would obviate much of the need for wholesale distributors to report pricing data. The [National Average Drug Acquisition Cost \(NADAC\)](#) data is determined for virtually every drug in the marketplace through a nationwide, pharmacy survey process and is the

¹ Tracking Who Makes Money on Brand-Name Drug, Kaiser Health News, October 2016.
<https://khn.org/news/little-known-middlemen-save-money-on-medicines-but-maybe-not-for-you/>

² Revisiting the Pharmaceutical Supply Chain: 2013-2018, BRG, January 9, 2020.
<https://www.thinkbrg.com/pp/publication-1090.pdf>

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invoice price pharmacies pay wholesalers for their medication products. This information is updated weekly and is not proprietary. It is available immediately to benchmark pharmaceutical prices in Wisconsin against national drug pricing trends while at the same time creating a certain level of pricing transparency with little concern for building out and managing data systems and contending with numerous confidentiality concerns.

In addition to NADAC, each pharmaceutical manufacturer also reports a list price for all products sold in the U.S. The WAC, set by the manufacturer of a drug product, is the “list price” that wholesalers are charged for the purchase of all drugs. WAC is reported in various published compendia, such as First DataBank and Medi-Span, that the state likely already has access to invoice manufacturers under the Medicaid Drug Rebate Program (MDRP) and any supplemental rebate programs. Each WAC is specific to the drug, strength, dosage form, package size and manufacturer. A manufacturer choosing to increase the published WAC drives marketplace price increases for brand and generic drugs alike. When the WAC of a product is increased by a manufacturer, the pharmaceutical wholesale distributor will likely pay more to purchase the product. In turn downstream customers may pay more to the pharmaceutical wholesale distributor for that product.

Both of these indexes are readily available and searchable by National Drug Code (NDC). As such, officials have the manufacturer pricing (WAC), wholesale distributor pricing and pharmacy acquisition costs (NADAC) by a simple process of deduction, the margin between the two.

Conclusion:

On behalf of HDA’s members, we ask that the task force consider these factors when developing the final report of policy recommendations for consideration by Governor Evers. Additionally, we have also provided the HDA letter to NASHP for your review below. This letter helps illustrate how several model acts place erroneous requirements and penalties on the industry due to a fundamental mischaracterization of the role wholesale distributors play within the supply chain as well as their minimal impact on the ultimate price of prescription medication. Again, thank you for your time during the June meeting, and we hope this letter serves as a resource as the task force determines policy recommendations and seeks to address drug pricing in Wisconsin during the next legislative session.

Sincerely,



Roxolana Kozyckj
Director, State Government Affairs
Healthcare Distribution Alliance

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HDA
Healthcare Distribution Alliance

August 25, 2020

PATIENTS MOVE US.

National Academy for State Health Policy (NASHP)
Attn: Executive Director, Trish Riley
2 Monument Square, Suite 910
Portland, Maine 04101

Re: Healthcare Distribution Alliance (HDA) Letter on NASHP Model Legislation

Executive Director Trish Riley:

The Healthcare Distribution Alliance (HDA) respectfully offers this letter to thank NASHP for its recent collaboration that ultimately resulted in clarifying amendments to “A Model Act to License Pharmaceutical Representatives.” HDA is hopeful that our organizations can continue to have an open line of communication to discuss additional concerns that the wholesale distributor industry has involving NASHP model Acts. We are confident that we can provide beneficial insights into the role of wholesale distributors within our nation’s healthcare supply chain. This letter incorporates our general perspectives on several NASHP model acts, specifically involving how they would impact pharmaceutical distribution in the United States. We appreciate your consideration and hope to continue a productive dialogue.

Background:

HDA is the national trade association representing primary pharmaceutical wholesale distributors, the vital logistics focused link between the nation’s pharmaceutical manufacturers and roughly 180,000 pharmacies, hospitals, long-term care facilities, and other healthcare settings nationwide. HDA’s membership includes 35 national, regional, and specialty primary distribution companies. HDA members are not just distributors, these companies are technology innovators, information management experts, security specialists, and efficiency professionals. Their expertise streamlines the supply chain to ensure safety and efficiency while also achieving cost savings for our nation’s healthcare system. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time.

Wholesale Distributors’ Role in the Supply Chain

The U.S. healthcare supply chain is highly complex. Each day, hundreds of thousands of healthcare provider locations must receive vital medicines and healthcare products produced by thousands of manufacturers worldwide. These manufacturers and providers are served predominantly by HDA’s primary distributor members who operate out of approximately 176 warehouses nationwide. Distributors purchase directly from authorized manufacturers, facilitating this highly effective network. In fact, most pharmaceutical sales in the U.S. flow through primary distributors (93.79 percent).

HDA members work around the clock to ship nearly 15 million healthcare products (medicines, medical supplies, durable medical equipment, etc.) to pharmacies, hospitals, and other healthcare providers daily to

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keep them stocked with the medications and products they need to treat and serve patients. Distributors are unlike any other supply chain participants. Their core business is **not manufacturing**, and **they do not prescribe medicines, influence healthcare professionals prescribing patterns, dispense medications to patients, influence patient benefit designs, or set the Wholesale Acquisition Cost (WAC) of medications**. Their key role is to serve as a conduit for medicines to travel from manufacturer to patient while ensuring the supply chain is fully secure and operating efficiently.

Pharmaceutical distributors also provide a wide array of supporting services, including critical logistics and inventory, that enable the pharmaceutical supply chain to function efficiently, reliably, and safely, delivering significant value to manufacturers and healthcare providers — and therefore ultimately to patients. Most importantly, distributors ensure healthcare providers can get the medicines they need in a timely manner, saving our healthcare system between \$33\$53 billion each year³.

The primary pharmaceutical wholesale distribution industry is a very high volume, yet very low-profit margin industry, with annually reported profit margins just over one percent (1.3 percent in 2019)⁴. In fact, overall profitability for the primary distribution sector shows little notable change over the past several years, even during recent market volatility. Moreover, in a 2017 study, the Berkeley Research Group concluded that the pharmaceutical wholesale distributor profit on overall branded drug costs was just *under* one percent.⁵

Primary wholesale distributors operate on a fee-for-service business model where wholesalers purchase pharmaceutical products from manufacturers based on the WAC, a publicly available figure that represents the *manufacturer's list price* for a product. **Wholesale distributors are not privy to WAC pricing decisions**. Each WAC is specific to the drug, strength, dosage form, package size, and manufacturer. Wholesalers then typically sell branded drugs to downstream customers based on the WAC or often the WAC minus a percentage.

Distributors charge the manufacturer a “bona fide service fee” in exchange for a variety of distribution and logistics services provided. These fees, **which are not passed on to the subsequent purchaser**, represent a fair market value for a bona fide service as required by federal law 42 CFR § 414.802. This model reduces demand volatility and allows for the supply chain to operate smoothly and predictably. Under rulemaking from the Centers for Medicare & Medicaid Services (CMS) following the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), and further upheld in 2006 and 2007, bona fide service fees are excluded from drug pricing metrics as they are not passed on to the subsequent purchaser in part or in full.

Similarly, wholesalers may purchase generic drugs at a manufacturer's list price but are often able to use their market power to negotiate discounted prices on generic drugs. Due to negotiations and overall volume, wholesalers are then uniquely positioned to assist in lowering the cost of generic drugs to downstream customers (i.e. dispensing locations).

Price increases can happen when a manufacturer chooses to increase the published WAC of a drug. When a manufacturer increases the WAC of a product, the pharmaceutical wholesale distributor will naturally pay

³ The role of distributors in the US health care industry (2019) <https://www2.deloitte.com/us/en/pages/life-sciences-and-healthcare/articles/the-role-of-distributors-in-the-us-health-care-industry.html>

⁴ Data obtained from Annual HDMA/HDA Factbook, compiled and compared across multiple years.

⁵ The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized By Stakeholders: <https://www.phrma.org/-/media/Project/PhRMA/PhRMA->

[Org/PhRMA-Org/PDF/S-U/The-Pharmaceutical-Supply-Chain-BRG-Report.pdf](https://www.phrma.org/-/media/Project/PhRMA/PhRMA-)

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more to purchase the product and, in turn, downstream customers may pay more as well. However, the above process remains consistent with wholesalers operating on a high volume, low profit margin model.

Below, please find our specific feedback on several NASHP model act proposals and the potential impact on the pharmaceutical wholesale distribution industry.

An Act to Protect Consumers from Unsupported Price Increases on Prescription Drugs

As noted within the Q&A document on this model act, the intent behind the proposal is to “identify and penalize manufacturers that are significantly increasing drug prices without adequate justification for those price hikes.” However, Section 5(c) of the model act specifically includes enforcement powers involving wholesale distributors based on the actions of other supply chain entities.

An Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs

HDA and our member companies are opposed to price gouging activities in the healthcare system. However, HDA opposed the Maryland legislation and subsequent law due to its clear mischaracterization of wholesale distributors’ role within the supply chain and ultimately its clear violation of the U.S. Constitution. As NASHP references in its Q&A on this new model act, the federal courts ruled that the Maryland drug price-gouging law was unconstitutional due to its violation of the Dormant Commerce Clause. Specifically, the law sought to regulate interstate commerce by preventing excessive price gouging in the state using a national drug pricing measure, WAC.

This model act intends to circumvent the violation of the Dormant Commerce Clause by *requiring* wholesale distributors to maintain a registered agent in the state to establish nexus. However, this is already a requirement wholesale distributors comply with in most states. In the case of the Maryland law, wholesale distributors had an established presence in the state through registered agents, and this was still not sufficient legal ground for the courts.

While HDA believes there are additional constitutional challenges, we remain opposed to the inclusion of wholesale distributors in the model act. Specifically, HDA members should not be held liable under Section 6 for the manufacturer choosing to remove a product from the market in a certain state. Distributors must not be penalized for actions dictated by another supply chain entity. As a distribution agent of a manufacturer, a wholesale distributor must abide by a manufacturer’s contractual restrictions related to distribution of its drug products, including a manufacturer’s instructions not to sell a drug product in a certain state or only to certain classes of customers or otherwise. Furthermore, as noted in the above overview, in their role as wholesale distributors, HDA members do not set or increase the WAC of a product. Therefore, distributors should not be penalized for actions solely dictated by the manufacturer.

An Act to Reduce Prescription Drug Costs Using International Pricing

As noted in the Q&A related to this model act, the language will “not dictate what a manufacturer can charge for a drug – but it does limit how much payers in a state pay.” However, given the role and position of a wholesale distributor in the supply chain, this model act would unintentionally impact the pharmaceutical wholesale distribution industry.

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Wholesale distributors generally purchase products from the manufacturer at the WAC and then sell the product to a licensed customer. This means the wholesaler is the entity making the sale into the state as opposed to the actual manufacturer. Wholesale distributors also contract with state entities, like the Department of Corrections, to supply products for administration within those programs. However, the wholesale distributor is not responsible for the WAC of the product, and therefore, is unintentionally placed in the middle of this model act's target and enforcement powers.

Similar to previous comments, Section 9 attempts to penalize a wholesale distributor for actions determined and directed by other supply chain entities.

An Act to Promote Prescription Drug Price Transparency and Cost Control: Wholesale Drug Distributor Report

Simply put, wholesale distributors purchase medicine and healthcare products from manufacturers in bulk and store, pack, and ship those products to over 180,000 points of care across the country based on orders to supply the provider community. Wholesale distributors have no insight into patient-level data, nor are they privy to how products are dispensed at the patient level. These quantities vary significantly, not just by the kind of payor but also the type of healthcare setting to which the distributor is shipping. The quantities sold by a wholesale distributor to a pharmacy customer do not align with how other supply chain entities calculate and negotiate drug prices. Comparing these two data sets provides misleading and inaccurate information. Numerous studies, both industry specific and those crafted by third-parties, have reported the limited impact wholesalers have on drug prices.

Ultimately, unlike any other supply chain entities, wholesale distributor operations do not influence the price a patient pays for their medication. If anything, the efficiency and streamlined distribution and the storage, security, and financial services offered by wholesale distributors reduces cost for the providers and patients in their care.

Conclusion

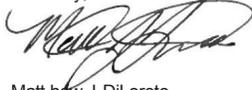
The pharmaceutical supply chain is extremely complex. HDA believes it is essential for policymakers to have an accurate and clear understanding of the pharmaceutical supply chain in order to identify sound policy solutions. While HDA understands NASHP's intent to address the cost of prescription drugs, the four model acts described above include provisions that inaccurately convey wholesale distributors' role, which will ultimately lead to the implementation of flawed policy.

We hope this overview and information on the wholesale distribution industry provides NASHP with a greater understanding of our industry and the limited impact we have on the costs of prescription drugs at the pharmacy counter.

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Sincerely,



Matthew J. DiLoreto
Vice President, State Government Relations
Healthcare Distribution Alliance (HDA)

CC: Jennifer Reck, Project Director, National Academy For State Health Policy (NASHP)

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Developing a State-Wide, Centralized Medication Repository in Wisconsin

Project Proposal

Prepared for The Governor's Task Force on Reducing Prescription Drug Prices

Authors:

Brianne Bakken, PharmD, MHA, Assistant Professor, Medical College of Wisconsin School of Pharmacy
Jon Rosman, Chief Executive Officer, SafeNetRx
Dennis Skrajewski, PA, MBA, FACHE, WAFCC Executive Director
Jennifer Malcore, Director of Public Affairs, Foley & Lardner

Background:

The cost of medications and the number of medication shortages continue to rise at an exponential rate, leaving patients without access to life-saving medications. Despite progress made, millions of Americans lack access to affordable care, a number that continues to grow. Twenty percent of the US population is medically underserved. This figure includes roughly 28 million medically uninsured persons¹ and 41 million underinsured persons with employer-provided, marketplace or Medicare plans.² Further, over 40 percent of adults in the US delayed or did not get a needed prescription drug due to cost.³ COVID-19 has led to unprecedented job loss, giving way to a significant rise in the number of uninsured and underinsured households. At the same time, hospitals and clinics are facing catastrophic financial challenges, many of which are limiting support for uninsured and low-income patients. These mounting challenges further underscore the need for affordable prescriptions.

Meanwhile, millions of pounds of unused prescription medications are being wasted each year. An estimated \$5 billion worth of unexpired prescription drugs in unopened, tamper-proof packaging are wasted annually in the United States.⁴ In 2015, the Environmental Protection Agency (EPA) estimated that approximately 740 tons of medications are wasted by nursing homes each year alone.⁵

Medication Disposal & Environmental Concerns

Medication waste is also a growing issue in our homes. The US Food and Drug Administration advises consumers to dispose of unused medications in the household trash, and in other instances flushing the medications down the toilet.⁶ Research studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water as a result of flushing medications down the sink and/or toilet. In the first large-scale assessment of US ground water pumped for drinking water supply, 60% of the water sources contained hormones and pharmaceuticals.⁷ Research studies have also shown active pharmaceutical ingredients are present in landfills as a result of disposing of medications in municipal solid waste.^{8,9} The EPA issued a new proposal for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors on September 25, 2015 ([80 FR 58014](#)). As a result, hospitals, pharmacies and other healthcare facilities must incinerate unused and expired medications considered to be classified as "hazardous waste". The EPA encourages the public to utilize take-back collection programs in order to safely dispose of their unused and expired medications. The EPA recommends these unused medications collected via take-back programs also be incinerated in order to prevent diversion and environmental concerns.¹⁰

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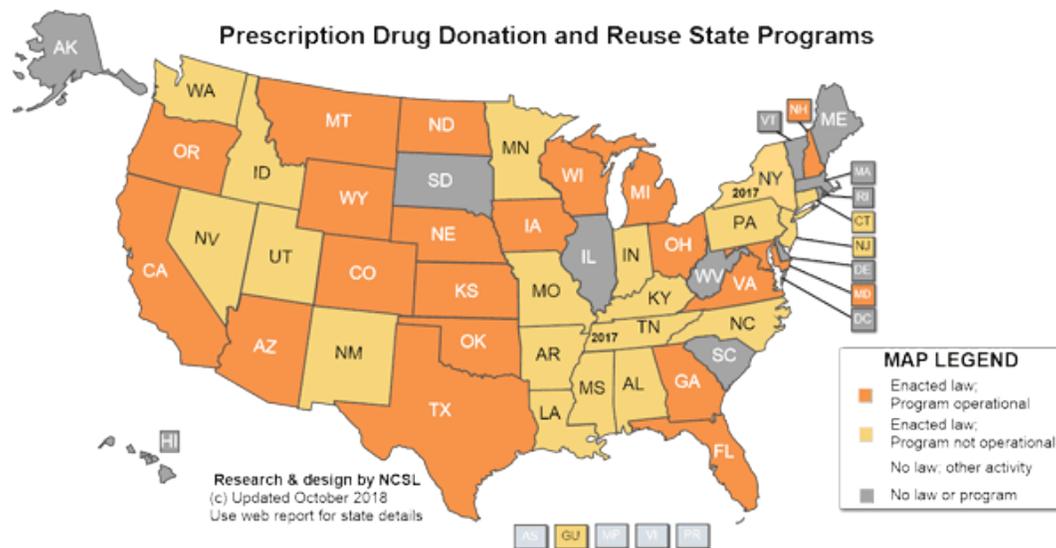
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Medication Donation & Repository Programs

There is another alternative to flushing, disposing, and incinerating unused, unexpired medications and over-the-counter products. Across the country and beyond, drug donation or reclamation programs have quietly emerged as a practical channel to connect patients in need of assistance with unused prescription medications. The World Health Organization has developed international guidelines for humanitarian relief as a basis for national and institutional guidelines. That National Conference of State Legislatures reports that 38 states and Guam have passed legislation to allow drug donation programs to operate.⁶



Several states have gone on further to develop state-wide programs with a centralized repository or collection site where medications are inventoried and redistributed either to pharmacies or directly to patients. Some of those notable and successful state-wide programs include Iowa, Wyoming, and Oklahoma. The Oklahoma Medication Recycling Program was implemented in 2004.^{6,11} Between 2004 and July 2020, the Oklahoma program filled 255,802 prescriptions, totaling \$26,056,771 in medications redistributed to patients (based on Average Wholesale Price).¹¹ The Wyoming Medication Donation Program was implemented in 2005.^{6,12} In 2017, the Wyoming program collected 15,000 pounds of donated medications, filled 26,000 prescriptions, served 3,000 patients and distributed \$4 million usable medications to patients in need.¹² Between 2005 and 2019, the Wyoming program filled more than 150,000 prescriptions, worth more than \$25 million that were provided to qualified patients.¹² The SafeNetRx Drug Donation Repository in Iowa was implemented in 2007.^{6,13-14} As of July 2020, it had served 105,610 patients and redistributed more than \$42 million in free medication and supplies to people in need.¹⁴ For every \$1 used to administer the program generates over \$9 in free medications and supplies.¹⁴

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Wisconsin Drug Repository Program

The State of Wisconsin passed legislation permitting medication donation and the formation of a medication repository program in 2005 ([Wis. Admin. Code § DHS 148](#)). The Wisconsin Department of Health Services (WDHS) created the rules and operations required to implement the program. The initial program implemented by the WDHS did not include the creation of a state-wide, centralized repository or perpetual inventory.

In order to participate in the Wisconsin Drug Repository Program, a Wisconsin-licensed pharmacy must first complete and submit form [F-62643, Drug Repository Program Notice of Participation of Withdrawal](#). Participating pharmacies are added to a master [List of Drug Repository Participants](#) that is publicly available on the [WDHS website](#), however, it is unclear when the list was last updated or how often it is updated. When a patient is in need of a medication that he or she cannot afford, a pharmacist can call each participating pharmacy on the list to see if they have the donated medication in their repository at their location. This is a time-intensive process that often yields no results. Consequently, many pharmacists and pharmacies seldom use the program.

Many pharmacies have also decided that they will no longer accept donated medications, as they often expire before being used by one of their patients or by another participating pharmacy. This leaves the pharmacy responsible for paying for the cost of incinerating the expired, donated medications. Some larger health-systems with multiple pharmacy locations, such as health-system pharmacies (e.g. Ascension, Froedtert, UW Health) have developed internal processes that support collecting unused, unexpired medications that are later redistributed to patients within their health-system.

Opportunities For Improvement or Expansion:

When properly implemented, medication repository programs can redistribute unused, unexpired medications to patients in need that would otherwise be incinerated or disposed of in our landfills and sewers. There are clear benefits to creating a centralized collection location and perpetual inventory that is easily accessible to participating pharmacies. Expanding the existing Wisconsin Drug Repository Program to closely mirror successful state-wide programs or collaborating with an existing program would have tremendous benefits for Wisconsin residents, including improving access to life-saving medications, reducing medication waste, preventing diversion and abuse of unused medications left in the home, and preventing pharmaceutical waste from contaminating our environment, including the landfills and water supply.

Develop a State-Wide, Medication Repository with a Centralized Inventory in Wisconsin

Other states have successfully implemented state-wide programs that collect unused and unexpired medications that are redistributed to underserved patients. These state-wide programs have demonstrated positive outcomes in terms of patients served, prescriptions written, dollars of medications provided and pounds of medication properly incinerated. Expanding the existing Wisconsin Drug Repository Program to closely mirror successful state-wide programs would require the following:

- Expansion of drug donation and collection locations and procedures for sending collected medications to a centralized location.

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- Creation of a centralized medication repository where all medications are collected, inspected, and inventoried.
- Development of a real-time inventory management system where participating pharmacies can order medications for underserved patients.
- Development of a process for sending medications to pharmacies that can be dispensed to qualifying patients.
- Start-up and ongoing investment to establish and sustain a statewide drug repository.

Iowa's Drug Donation Repository was established in 2007 through a partnership between the Iowa Department of Public Health and a non-profit 501c3, SafeNetRx. The program currently redirects approximately \$8 million in donated medicines (AWP) annually and is funded through an annual state appropriation of \$600,000 plus approximately \$250,000 in annual grants, gifts and revenue generating services. Iowa's program is currently the largest state drug donation program and serves 8,000 – 9,000 patients annually. Although the program currently enjoys a return on investment of over \$9 in donated medicine for every \$1 invested in the program, the program has taken well over a decade to achieve this rate and receives donated medicines from over 180 donors across the United States.

The Wyoming program was implemented in 2007. The estimated start-up costs were between \$160,000-\$300,000 with initial funding come from the state of Wyoming and grant funding from United Way, the Hospital Foundation and a Community Development Block Grant. The program continues to be funded and maintained by the Wyoming Department of Health. The Wyoming Legislature ([SF 0105](#)) appropriated \$400,000 to expand the program in 2018.

Collaborate with Existing Medication Repository Programs to Form a National Drug Donation Program

Resolving our nation's patient need and medication waste crises requires a national drug donation program where institutions, clinics and pharmacies can easily donate medicines – and know that the medicines will be inspected, safely redistributed, and provided to underserved patients. The status and capacity of drug donation in each state varies greatly, largely determined by existing legislative statutes, administrative rules and the coalition of pharmacy stakeholders that have worked to advance drug donation locally. Wisconsin is fortunate to have enacted state drug donation legislation in 2005. With guidance from state pharmacy leaders including state agencies, the state pharmacy association, colleges of pharmacy, safety net providers and regulators, the administrative rules governing the program could be adapted to allow widespread participation throughout the state of Wisconsin. SafeNetRx can provide flexibility to support a state-administered network for donated medicines or work with clinics and pharmacies in Wisconsin directly as dispensing sites. Opportunities also exist to integrate colleges of pharmacy and health systems as collection and distribution points for donated medicine, creating unique opportunities for pharmacy students, medical students, and providers serving vulnerable populations in the state.

Collaborating with an existing state drug donation program yields multiple benefits for vulnerable patients, health providers, and taxpayers. Firsthand, collaborating with another program allows patients in need of prescription assistance to be served immediately. The start-up investment and significant time to develop a free-

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standing program in Wisconsin could be avoided. Millions of dollars have been invested to develop a robust program in Iowa. Access to Iowa's existing inventories of donated medicine could be opened to Wisconsin patients and providers with some changes to Wisconsin's current drug donation rules. In addition to the immediate access to donated inventories, the formulary of available medicines is greatly enhanced by partnering with a drug donation program that is national in scope. Although smaller, independent donation programs can address a percentage of the safety net patients need, often donated medicines expire before they can be connected to patient in need. A multi-state drug donation program allows medicines to be collected and distributed across the country to clinics and pharmacies that immediately need the donated product for dispensing. For example, a high cost cancer medication donated in Des Moines could be dispensed to a patient in Madison as opposed to being stored and eventually incinerated after expiration.

Lastly, partnering with Iowa's drug donation program eliminates the need for ongoing financial support from the state of Wisconsin. The multi-state drug donation program utilizes a subscription-based revenue model where participating clinics and pharmacies pay an annual fee to access donated medicines. The annual subscription is based on a small percentage (2-5%) of the value of donated medicines a participating clinic or pharmacy dispenses annually. A subscription-based drug donation program removes the burden for state governments or other funding partners to financially sustain the operations and growth of a state's drug donation program. The subscription model is currently utilized by other charitable medication distribution programs across the country and is a proven model of sustainability. Further, clinics and pharmacies that pay a small fee to be part of a charitable medication distribution program are not only financially invested in the program, but historically participate at a higher level than partners that access similar programs for free.

Legislative Assessment:

Legislative revisions would be required in order to improve the existing program and allow for collaboration with existing state-wide medication repository programs, such as those in Iowa, Wyoming, and Oklahoma.

[Wisconsin Administrative Code Department of Health Services \(DHS\) Chapter 148 – Drug Repository Program \[Wis. Admin. Code § DHS 148\]](#)

Participating Entities:

- [DHS 148.03](#) defines a drug repository as, “a medical facility (i.e. hospital) or pharmacy that has notified the department of its election to participate in the drug repository program.”
 - A new definition for “out-of-state repository program” should be added
- [DHS 148.04](#) states that only pharmacies and medical facilities may elect to participate in the Wisconsin drug repository. This current verbiage precludes other state-wide repository programs from participating in collecting donated medications and/or distributing donated medications in Wisconsin.
 - “Out-of-state repository programs” should be added throughout DHS 148.04 as an entity that may elect to participate in the Wisconsin Drug Repository program.
 - Consider the creation of a new subsection (c) specifically for out-of-state repository programs.

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Donation of Drugs & Supplies:

- Consider incorporating language similar to what is used in the [Iowa Admin. Code § 109.4\(4\)](#) and [Iowa Admin. Code § 109.4\(5\)](#) to ensure the quality and integrity of donated medications necessary to promote patient safety.
- Donation forms should be updated to be more user friendly and less time intensive. Such changes would include allowing the donor to list all medications being donated on a single form or addendum rather than one medication per form.
- A new section should be created for the transfer of medications and supplies between out-of-state repository programs and participating repositories in Wisconsin.
 - This section should have a provision for accepting donated and/or repackaged medications that have been previously inspected and validated by a repository program in another state.

Wisconsin Residents:

- [DHS 148.01](#) and [DHS 148.05](#) allow any Wisconsin resident to receive drugs or supplies following the dispensing priority established in [DHS 148.07\(4\)](#).
 - Consider removing the priority system from DHS 148.07(4) in favor of creating a list of qualifications that promote using donated medications and supplies for our most vulnerable patients without insurance or other financial resources.
 - Consider revising DHS 148.07(4) to include any one of the following as qualifications for receiving donated medications and supplies from the repository:
 - Individuals who are uninsured
 - Individuals who receive or are eligible to receive Medicaid, Medicare, or other government-based health care
 - Individuals who are underinsured or who have no active third-party prescription drug benefit coverage for the prescribed drug
 - Individuals with an income that does not exceed 300% of the Federal Poverty Line (FPL)
- Consider incorporating language similar to what is used in [Iowa Admin. Code § 109.7](#)

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Updated 8/21/20

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5.11 National Association of Chain Drug Stores



August 14, 2020

Nathan Houdek
Deputy Commissioner of Insurance for the State of Wisconsin
Chair, Governor's Task Force on Reducing Prescription Drug Prices
125 South Webster Street
Madison, Wisconsin 53703-3474

Via Email: OCIRXDrugTaskForce@wisconsin.gov

Dear Deputy Commissioner Houdek and Members of the Governor's Task Force:

Re: Recommendations on Prescription Drug Pricing

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide input to the Wisconsin Governor's Task Force on Reducing Prescription Drug Prices ("Task Force") as the Task Force deliberates prescription drug pricing and develops recommendations to Governor Evers.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Background on Retail Community Pharmacies

Retail pharmacies are the most accessible patient point of contact along the prescription drug supply chain. In a 2018 survey of registered voters conducted by *Morning Consult* and commissioned by NACDS, eight-in-ten respondents said that pharmacists are credible sources of information about how to save money on prescription drugs – the highest rating of healthcare professionals tested. NACDS shares the goal of reducing the cost of prescription drugs and believes retail community pharmacies are ideally situated to help by improving medication adherence and promoting utilization of generic drugs as safe, cost-effective alternatives. In many cases, pharmacists are not paid for these and other services.

1776 Wilson Blvd., Suite 200, Arlington, VA 22209 • P: 703.549.3001 • F: 703.836.4869 • NACDS.org

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The following facts should be considered in dissecting the cost of a prescription drug:

- About 80 percent of the average retail prescription price represents the pharmacy's costs of purchasing the product from a manufacturer or wholesaler.
- About 14 percent of the average retail prescription price is consumed by pharmacy operational costs, including salaries, rent, utilities, the costs of maintaining and transferring inventory, and computer systems infrastructure.
- One to two percent of the average retail prescription price goes to pay state and federal taxes.
- After all expenses, the remaining net pharmacy profit on the average retail prescription price is about 2 percent or less.

Retail pharmacies cannot control the purchase price and have little to no control over the price at which prescriptions are sold. Manufacturers determine the product cost, and third-party payers (Medicare, Medicaid, TRICARE, etc.) or pharmacy benefit management companies (PBMs) set the reimbursement to the pharmacy and the price to the patient.

To keep prescription drug prices to a minimum while maintaining patient safety, NACDS recommends beneficial policies such as:

- **Reforming Pharmacy Reimbursement Claw Backs and Post-Adjudications Fees:** Payers often exploit loopholes to claw back reimbursement paid to pharmacies for prescriptions. Post-adjudication fees and payment claw backs lead to higher cost-sharing for patients' prescription medications.
- **Rejecting Unworkable Prescription Drug Importation:** In an attempt to lower prescription drug costs, a number of state and federal policymakers are supporting regulation and legislation to allow the importation of prescription drugs from foreign sources, most commonly Canada. However, proposals allowing importation would undermine decades of drug safety policy.

II. Reform Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees

As mentioned above, payers impose on pharmacies various fees after a prescription drug claim has already been adjudicated. These post-adjudication fees and reimbursement claw backs go directly to payers' bottom lines and lead to increased patient costs at the pharmacy counter. In fact, the federal Centers for Medicare and Medicaid Services (CMS) has recognized the impact and costs of pharmacy reimbursement claw backs and post-adjudication fees on beneficiaries, pharmacies, and on overall government costs. The impacts range from increased beneficiary cost-sharing to less transparency and competition.

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A. Impact of Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees on Patients

CMS has extensively analyzed the impact of pharmacy reimbursement claw backs and post-adjudication fees on patients' out-of-pocket costs. As CMS has recognized, pharmacy reimbursement claw backs and post-adjudication fees raise patients' out-of-pocket costs and obfuscate patients' abilities to engage in meaningful comparisons of their available prescription drug plan choices. Patients are paying a greater share of the prescription drug cost while at the same time being blocked from recognizing the cause and being denied tools to remedy their concerns.

In a recent proposed Medicare Part D drug pricing rule, CMS recognized that “when pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, [however] beneficiaries do not benefit from pharmacy price concessions through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug.”¹ CMS estimated in a proposed rule that restructuring pharmacy price concessions would lead to overall beneficiary savings of \$7.1 to \$9.2 billion over 10 years.² CMS further stated that “[g]iven the significant growth in pharmacy price concessions in recent years, when such amounts are not reflected in the negotiated price, it has become increasingly difficult for consumers to know at the point of sale what share, or approximate share, they are paying of the costs of their prescription drugs to the plan....”³ CMS noted that “[v]ariation in the treatment of these price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program.”⁴ CMS added:

Consequently, consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations. The quality of information available to consumers is even less conducive to producing efficient choices when pharmacy price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy.”⁵

¹ CMS, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62154, 62190 (Nov. 30, 2018), available at <https://www.govinfo.gov/content/pkg/FR-2018-11-30/pdf/2018-25945.pdf>. While this evidence is derived from CMS' experience in the Medicare Part D program, the impact on patient costs is similar for any pharmacy benefit design that claws back pharmacy reimbursement and/or imposes on pharmacies post-adjudication fees. Here, CMS used the term “pharmacy price concessions,” which has the same meaning as pharmacy claw backs and post-adjudication fees.

² Id. at 62192-93.

³ Id. at 62176.

⁴ Id. at 62190.

⁵ Id. At 62176.

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B. Unsustainable Growth of Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees

Pharmacy reimbursement claw backs and post-adjudication fees are a growing problem that must be addressed at both the state and federal level. In the same proposed Medicare Part D drug pricing rule mentioned above, CMS highlighted the growth of the use of pharmacy reimbursement claw backs and post-adjudication fees. CMS noted the exponential increase in the use of pharmacy reimbursement claw backs and post-adjudication fees in recent years, and stated it expects the growth to continue in the future:

- “The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017. The data also show that much of this growth occurred after 2012.”⁶
- “Actual pharmacy price concessions have increased from \$229 million in 2013 to \$4 billion in 2017.”⁷

In a January 2017 publication, CMS highlighted that the growth in pharmacy reimbursement claw backs and post-adjudication fees has led to several concerns, including higher point of sale prices and higher cost sharing obligations for patients when fees are retroactively applied after the point of sale.

C. Current Payer Marketplace

Prescriptions filled by patients who are paying cash without any form of insurance account for 5-8% of the total volume of prescriptions.⁸ While 92-95% of the prescriptions filled have a payment component coming from Medicare Part D, Medicaid, or a commercial insurance plan, these plans are ordinarily administered by PBMs. The top three PBMs manage about 75% of the volume.⁹ The top six PBMs and plans manage about 95% of the volume.¹⁰ Five of those six PBMs are owned by large national health insurers.¹¹ This business environment makes it very difficult for pharmacies to negotiate equitable business practices and transparency because the PBMs and health insurers have more commercial market power and leverage in the relationship due to their size and scale.

⁶ Id. at 62175.

⁷ Id. at 62191.

⁸ PHAST® *Prescription Monthly*, data drawn August 6, 2019.

⁹ Fein, Adam J.; “The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” March 2020; p. 131.

¹⁰ Id.

¹¹ Id. at 131, 136.

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D. Impact of Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees on Pharmacies

The impact of pharmacy reimbursement claw backs and post-adjudication fees on pharmacy entities has been substantial. If all fees were calculated during the claim adjudication process at the point-of-sale, the pharmacy would know exactly what price they are selling the product for and how much it cost them. When fees are applied after point-of-sale and claw backs occur, pharmacies lose control over their own revenues and profitability, creating undue financial risk.

Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs. Dire financial pressures have caused an alarming number of pharmacies to shut their doors. Payers have increasingly reduced reimbursements; in many cases pharmacies dispense prescriptions below cost. Retroactive fees and claw backs often occur weeks or months after a transaction closes, when a payer decides to recoup a portion of the pharmacy's reimbursement. These fees have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines. Last year pharmacies paid over \$9 billion in reimbursement claw backs and post-adjudication fees. Nationwide, there are now approximately 2,000 fewer pharmacies than just two years ago.¹²

A study commissioned by the PBMs' own trade association, the Pharmaceutical Care Management Association (PCMA), recognizes that retail community pharmacies, and particularly chain pharmacies, are in trouble.¹³ PCMA concludes there are fewer chain pharmacies now than a decade ago, and a net loss of 1,583 chain pharmacies over the past three years.¹⁴ PCMA's chart from the study shows an accelerating decline in chain pharmacies since 2015.¹⁵ While PCMA does not suggest why chains are closing pharmacies, in a recent Supreme Court filing, PCMA agreed it is "undisputed" that "reimbursements below cost are approximately 10% of prescriptions filled."¹⁶

¹² Independent data sources confirm that the number of retail pharmacies in the United States dropped by almost 2,000 over the past two years. See IQVIA, DDD – Drug Distribution Data (showing the number of U.S. retail pharmacies dropped from 58,706 in December 2017 to 56,788 in December 2019); National Council for Prescription Drug Programs, dataQ (showing 995 pharmacy profiles closed in 2018 and 695 pharmacy profiles closed in 2019).

¹³ See https://www.pcmnet.org/wp-content/uploads/2020/03/FINAL_Independent-Pharmacies-in-the-U.S.-are-More-on-the-Rise-than-on-the-Dcline.pdf. Accessed August 10, 2020.

¹⁴ Id.

¹⁵ Id. at Figure 1.

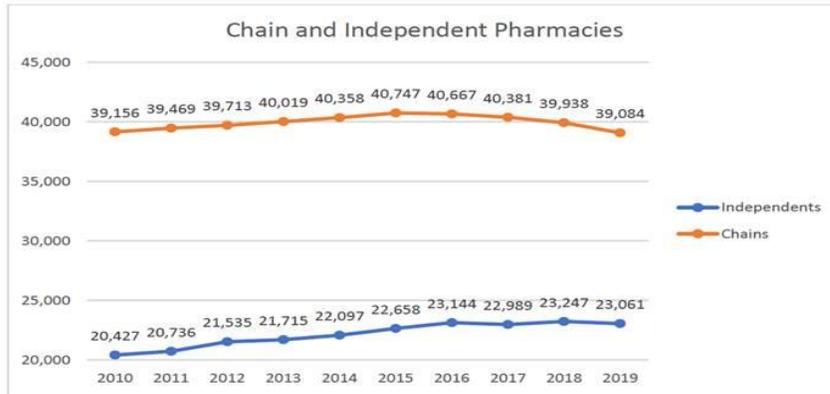
¹⁶ *Rutledge v. Pharmaceutical Care Management Association*, 18-540, 1 App. 341 (petition granted Jan. 10, 2020) (referring to the joint appendix in the case now pending before the Supreme Court of the United States).

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Figure 1. Growth Trend of Pharmacies from 2010-2019



The epidemic of pharmacy closures is reducing access to vital healthcare services, especially in rural areas where options are already limited. Recent polling by Morning Consult confirmed that pharmacies are considered the most accessible part of the healthcare delivery system. However, that accessibility is increasingly threatened as more pharmacies go out of business. A recent study published in the *Journal of the American Medical Association* found that pharmacy closures led to a significant drop in medication adherence for older adults taking cardiovascular medications.¹⁷

E. Solutions to the Problems of Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees

NACDS urges the Task Force to enact reforms to address pharmacy reimbursement claw backs and post-adjudication fees. Specifically, to lower patients' out-of-pocket costs at the pharmacy counter, as well as keep pharmacies in business to serve patients and protect their access to healthcare, we urge the enactment of legislation to prohibit pharmacy claw backs and post-adjudication fees. Pharmacies should not be subject to fees or price concessions applied retroactively after a prescription drug claim has been adjudicated at the point-of-sale. Reforming pharmacy post-adjudication fees by prohibiting claw backs will lower out-of-pocket costs for beneficiaries, lead to greater price transparency, and make medicine more accessible, leading to greater adherence, and better health outcomes.

¹⁷ Qato, Dima M., PharmD, MPH, PhD; Alexander, G. Caleb, MD, MS5; Chakraborty, Apurba, MBBS, MPH; et al.; *JAMA Network Open*. 2019;2(4):e192606. doi:10.1001/jamanetworkopen.2019.2606; April 19, 2019; Accessed August 12, 2020.

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III. Reject Unworkable Prescription Drug Importation

Federal and state policymakers have enacted laws and regulations to ensure that prescription drugs are manufactured, stored, shipped, dispensed, and used safely. Our infrastructure of safety is undermined when prescription drugs are imported from foreign suppliers.

The most recent comprehensive update to prescription drug safety nationwide occurred in 2013 when Congress enacted the Drug Supply Chain Security Act (DSCSA), which requires the creation of an electronic interoperable system to track and trace prescription drugs. The purpose of the DSCSA is to prevent the introduction of counterfeit and/or dangerous products into the supply chain at a nationwide level to replace a patchwork of state requirements. When drugs are purchased from foreign sources, it would be effectively impossible to apply the DSCSA safety standards.

There are a host of safety and operational concerns with allowing importation. First, most foreign internet sites selling prescription drugs cannot be presumed to be safe as it is impossible for the consumer to know if there is a licensed pharmacy supporting its operation and if it is a trustworthy business. Second, the potential for counterfeit drugs being mailed into the U.S. from foreign internet sites offering prescription drugs is very high. Third, no U.S. licensed pharmacist is available to consult with the patient about the imported drug. Fourth, if a foreign dispensed drug becomes subject to a recall or is withdrawn from the market, there is no way to inform patients. Finally, many customers of “Canadian pharmacies” report getting shipments straight from Pakistan, India, and Turkey. Canadian law does not prohibit the transshipment of drugs from any country, including from countries with low manufacturing standards, into Canada and then on to the U.S. In fact, Canadian law explicitly states that the Canadian equivalent to the FDA does not have to inspect drugs prior to exportation.^{18, 19}

It is common knowledge that the internet is replete with illegal online pharmacies posing as “Canadian” and claiming to be selling safe U.S. Food and Drug Administration (FDA)- or Health Canada-approved medicines. At any given time, there are up to 35,000 active online pharmacy websites operating on the open web, of which about 94.8% are operating out of compliance with U.S. state and federal law and relevant pharmacy practice standards.²⁰ U.S. consumers buying medications from alleged “Canadian online pharmacies” rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. Indeed, FDA has found that 85% of the drugs being promoted as “Canadian” came from 27 other countries around the globe.²¹

Moreover, mass quantities of counterfeit pills – many of which have been laced with deadly fentanyl and other synthetic opioids – from foreign sources commonly slip into the U.S. illegally through international mail. It is estimated that FDA is only able to inspect less than .018% of the

¹⁸ HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.

¹⁹ Letter to The Washington Post, Diane Gorman, Assistant Deputy Minister, Health Canada, May 9, 2003.

²⁰ Alliance for Safe Online Pharmacies; <https://buysaferx.pharmacy/>

²¹ Id.

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packages assumed to contain drug products that are shipped through the international mail. FDA estimates that of the packages that it does screen 87% contain illegal, unapproved, counterfeit and potentially dangerous drugs.²²

In light of the dangers and real patient harm that would likely result, NACDS has significant concerns about the importation of prescription drugs. We urge the Task Force to consider how an importation program could be implemented safely and, considering the patient safety challenges to be overcome, whether any such program could actually provide cost savings to consumers.

IV. Conclusion

NACDS appreciates the opportunity to share with the Task Force our perspectives for lowering prescription drug costs. We look forward to working with you to reform pharmacy reimbursement claw backs and post-adjudication fees as a workable mechanism to lower patient out-of-pocket costs. We also urge you to reject unworkable and unsafe proposals, such as importing prescription medications from Canada and other countries. For any follow up, please feel free to contact Joel Kurzman, NACDS State Director, at (847) 905-0555 or jkurzman@nacds.org.

Sincerely,



Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer

²² <https://www.fda.gov/media/111980/download>

5. Letters

5.12 NeuGen, LLC



To: Nathan Houdek and the OCI Drug Task Force Team

From: NeuGen LLC, Alan Lukazewski

Date: August 31 2020

Re: NeuGen comments regarding proposed efforts to lower prescription costs to consumers and affect lower spend in aggregate for all of Wisconsin's

Thank you for the opportunity to serve on the Governor's Task Force on Reducing Prescription Drug Prices. It was truly an honor to partake in this first phase with a group of stakeholders rendering their opinions on what need be considered in affecting the cost burden of prescription drug prices on Wisconsin citizens. Our comments on what was proposed in writing are listed below.

Preface

It is presumed that the goal of this endeavor is to authentically affect drug costs so that prescription drugs are more affordable, and less cost burdensome, for all people of Wisconsin. This task force was not charged with presenting options that either protect a particular stakeholders' area of business, nor with just slowing the rise in prescription drug prices. It is our position that we are charged with **making prescription drugs more affordable**, meaning if they are currently unaffordable for many that solutions must result in lower costs individually or in aggregate. That being said, many of the proposed elements brought forth for consideration do not meet that goal, hence our position is to support the following:

In support of

- 1) Create a drug affordability and review board that is charged with creating a multi-year plan to a) bring forth transparency in all areas of the supply chain so opportunities can be identified where costs can be lowered b) work collaboratively with all stakeholders to identify models that can lower prescription drug prices, yet support stakeholder costs in order to continue to deliver pharmaceuticals that deliver value to our population c) if the prior cannot be achieved, consider setting annual spending limits for all public entities, including state employees, school districts, counties, municipalities thereby delivering predictable, affordable budgets each year.
 - a. Consider a pilot that removes rebates in order to substantially lower net cost, over 50% in some instances, but is a free-market test in which pharma bids by therapeutic class to lowest net cost, and the board works with experts to manage utilization in order to support prescription drug use that is associated with value as measured by cost-savings and/or cost-effectiveness and appropriateness and safety
 - i. This can move us closer to a "cost plus" system getting us closer to realistic pricing models.
 - b. Consider reviewing the impact of "pricing parity" across all sites of care since the delivery of prescription drugs is strictly a commodity-based mechanism, and where prescription drugs can be delivered at a lower cost site of care there should be parity in unit pricing of these provider administered drugs.
- 2) We support the creation of a prescription drug purchasing entity to leverage buying power resulting in lower prescription drug prices. Use the state Pharmacy Cost Study Committee result as a framework to outline this work.

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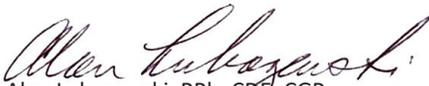
5.12 NeuGen, LLC



- 3) Identify where the use of 340b does NOT support our communities or citizens as we expect those who are low income or on high deductible health plans receive the benefits of the 340b program as intended. Although this is a Federal program, we ask for transparency to be made public as to the use of the program by provider system by dollars gained in order to at least better understand where the program is serving our communities, and where it is not. We recommend the use of independent consultants to work with the Task Force to model those projections and bring forth recommendations where safeguards against abuse or misuse of the program can be explored with provider systems in order to collaboratively develop solutions which are beneficial to our communities and don't lead to financial toxicity for its citizens.
- 4) We fully support enhancing access to Wisconsin's charitable clinics and pharmacies, as some of these pricing practices make poverty not access. All aspects of what is proposed in the final document from the Task Force we support without reservation.
- 5) We support all advocacy that increases awareness so best policy decision making can come forth, such as increasing awareness of the issue of slowing generic drugs to market.

Opposition

- 1) We do not support the PBM bill in the context of it making prescription drugs more affordable as it does NOT. Components we can support are "lower of" logic to deliver the lowest cost at point-of-sale and prohibition of gag clauses. Since lower of logic applies to multisource MAC list generics, the savings is modest at best since the largest affordability challenges are in other areas, such as brand diabetes medications and specialty drugs.
- 2) We do not support that the copay assistance amount from manufacturer's be applied to deductibles for two reasons a) compliance with various statutes and regulations b) use of plan design integrity in order to manage unnecessary and wasteful spend. To remain compliant with IRS rule and ERISA rules regarding HDHPs and HSAs, only true out of pocket costs can be applied to deductibles. Also, it is our measured experience supported by behavioral economics that when plan design is thwarted by any measure that utilization increases substantially and is not necessarily correlated with improved outcomes or better health.
- 3) We do NOT support copay caps for insulin for several reasons.
 - a. Most insurance plans already have low copays for preferred insulin products and free markets will drive to proper copay structures and plan designs.
 - b. It does NOT assist those most in need, those with high deductibles that are not in plan designs with copays, and those without insurance who do not qualify for Medicaid or other low-income assistance.
 - c. Insurance plans can offer insulin at no cost to groups with high-deductible plans who chose to add a rider to cover drugs at no cost under safe harbor protections.
 - d. Since the cost of making a vial of analog insulin is estimated to be between \$4.50 and \$6.00 (Six dollars, or 600 pennies), we suggest that the list price of insulin be properly set in order to make insulin more affordable for all.


Alan Lukazewski, RPh, CDE, CGP
Director of Clinical Pharmacy

5. Letters

5.13 Patricia Koepke

Health Insurance Drug Coverage vs Personal Experience Using the Benefits

Patricia Koepke
3927 Charleston Dr
Eau Claire, WI 54703
Cell: (715) 829-0195

These past five months working with my husband's insurance have been trying and frustrating at many times. His employer is Intel, the insurance is through Anthem Blue Cross and uses Express-Scripts for drug coverage. The plan we had in 2019 was discontinued and the new drug coverage is different. The 2020 requirement Express Scripts uses when I can't use a generic due to an allergy or it is not effective is that an exception be written by my primary physician.

To further complicate the situation, I found out on March 15th of 2020 the pharmacy I had been using for years closed – without warning and without any guidance on how to get my prescriptions filled. When I called Value Center Pharmacy, the answering service forwarded my call to Walgreens Pharmacy. I asked the tech at Walgreens why Value Center was forwarding calls to them and how am I going to get my prescriptions filled. She had no idea what was happening. I asked to talk to the pharmacist who informed me that Walgreens would be taking over the Value Center customers. Walgreens had purchased Value Center and all my information was forwarded to them.

I started calling other pharmacies in the area to find who could fill my prescriptions, including the ones I was allergic to and needed the “name brand” prescribed by my physician. I called CVS to see if they could fill my pain management prescriptions since they were the ones needed ASAP. They told me the one(s) I needed weren't available through their supplier. In addition, CVS is not in network for Express-Scripts.

Walgreen's is in network for my primary, so I had to use them. After several more phone calls, I found out that one of the Walgreens in town was able to order the drugs I needed. My primary physician needed to rewrite my prescriptions and also rewrite the exception explaining why a generic needed to be replaced by a drug from a specific supplier or that it be a name brand drug. Additionally, the information they got from Value Center did not specify if the exception was for that month or the full year. Express-Scripts also required the prescriptions and exceptions be faxed directly to them and not to Walgreens.

I called my doctor and let him know that the pharmacy (Value Center) that I had been using has been closed and what that meant for my medications. I informed him which four I need refills for ASAP because I was nearly out. Two of these drugs were “controlled substances” and therefore had additional requirements. One of the two had limited availability and was out of stock at the Accord warehouse that Express-Scripts uses. The prescription needed to be rewritten to use a “name brand” and as a result, both my primary and secondary insurers refused to cover the prescription. The second of the two controlled substance prescriptions was a pain medication. I was allergic to the generic that was commonly used so the physician also needed to write an exception for the name brand.

5. Letters

5.13 Patricia Koepke

On May 13, 2020 I saw my primary physician to (try to) get my prescriptions and exceptions rewritten to satisfy Express-Scripts requirements. I tried to explain as best I could that the closing of Value Center Pharmacy and Walgreens taking over required new procedures to handle the exceptions. (It should be noted that much of this churn is the result of Walgreens being unwilling to submit claims to my secondary provider – Wellcare, and that Value Center was more accommodating).

As a result of all this back-and-forth, a week had passed, and I still haven't gotten my prescriptions refilled. Express-Scripts wouldn't fill one of them because the exception was not written to their satisfaction. I called my physician to tell him the generic brand I needed was now available and instead of trying to correct the exception, he could rewrite the prescription (again) and replace the name brand with the now available generic. As a result of this prescription writing, insurance denial and my physicians rewriting of it, the pill dosage and number of pills needed for a one-month supply (controlled substance prescriptions can only be filled for a 30-day supply) was now incorrect. So, both the primary and secondary insurers rejected the prescription and it wasn't refilled.

I had to physically return the prescription to my primary physician, explain what was happening and wait for them to correct the prescription. I then had to deliver the written prescription to Walgreens in person because it was a controlled drug and (hopefully) get it refilled.

In addition to Express-Scripts specific requirements for exceptions, they were also aggressively pressing me to use their mail-order refill service. (They wanted the pharmacy business instead of having to pay Walgreen's Pharmacy). I am not comfortable receiving my prescriptions by mail. Because of the additional time needed to fill and mail a prescription, if an error is made or an exception missed and the prescription needs to be re-issued, I have to waste that additional time to get my meds.

I called Express-Scripts again and informed them I didn't want to use their mail service and wanted the prescriptions filled at the local Walgreens. Also, since Express-Scripts is through my husband's High Deductible policy, I would be required to pay full price for each prescription until the \$3900 annual deductible was met. I also requested that Walgreens bill my secondary Medicare Wellcare provider. The initial deductible is \$200 so I can meet the deductible within the first month given the cost of my meds.

I had back surgery in 2005. In Jan 2006 I slipped and fell at work. I worked for two more years with restrictions prescribed by my doctor and then was laid off. Once my unemployment benefits were used up, I applied for disability. In 2010 I was put on disability and now I am enrolled in Medicare and a Part-D program and have been paying monthly premiums for both. I should be allowed to make use of their coverage. Since I am eligible for a secondary prescription insurance and I pay a monthly premium for it so I should be able to use it. Walgreens told me they do not work with secondary insurers!

I called the Eau Claire Aging & Disability Resource Center representative to see if she could get things straightened out with Walgreens. I explained what I had experienced to date, that Walgreens wasn't willing to process claims with my secondary carrier and as a result I was paying full price for all of my prescriptions until the \$3900 annual deductible was met.

5. Letters

5.13 Patricia Koepke

I went to Walgreens for a third time to get my pain medication (controlled substance) and several other prescriptions refilled, I specifically requested they bill my secondary insurer. They did, I was back to making the same co-pays that Value Center was charging.

When I got home, I noticed one of the prescriptions was only partially filled when the physician had written it for a month. I called Walgreens and they said I would have to talk to Express-Scripts to find out why the prescription was short. I called Express-Scripts and they informed me that the prescription had been fully filled. I called Walgreens again, spent a long time on hold, and they were able to get an “over-ride” for this prescription and I could pick up the rest of the prescription.

Hoping that after all of this hassle, my prescription status was finally straightened out, I got another call from Express-Scripts. They informed me that they saw the prescriptions written with exceptions were on a month-by-month basis and the physician needed to rewrite them for the full year! This was news to me (and my physician) since when the 2020 coverage started in January the exceptions written for Value Center were for the full year. So now I am back on the phone to my physician asking him to make changes and resubmit my prescriptions that required exceptions AGAIN. Needless to say, along with my frustration, the physician is getting fed up with the changing requirement – and me.

I feel like things have gotten out of control. The drug companies hold all the power. They set the drug prices, how much co-pays will be (when you qualify) and what name brands and generics they will allow you to use. Express-Scripts was strongly suggestion I use their mail order service (instead of another pharmacy) because it was more convenient – for them. They even went as far as contacting my physicians, without my permission, in an attempt to get the prescriptions transferred to them. I am not comfortable using an online service and prefer to have my prescriptions filled locally.

We all know that drug costs have gotten out of control. Each year plans and coverage change, premiums and co-pays get higher and the end user (me) gets squeezed. Who can keep up with the constant changes in coverage and requirements? The insured seems to have fewer rights and less to say about their coverage from year to year. Customer support is in short supply as shown by the long wait times I had trying to talk to someone when I called. Even physicians are being asked to do more each year. “The cure is worse than the disease”!

Sincerely,



Pat Koepke

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5.14 Pharmaceutical Care Management Association



July 21, 2020

VIA EMAIL

Mr. Nathan Houdek
Deputy Commissioner of Insurance
Wisconsin Office of the Commissioner of Insurance
125 South Webster Street
Madison, WI 53703-3474

Re: Recommendations of the Wisconsin Drug Pricing Task Force

Dear Mr. Houdek:

I am writing to provide the Pharmaceutical Care Management Association's (PCMA) comments on the draft recommendations of the Governor's Task Force on Prescription Drug Prices. As you know, PCMA is the national trade association for pharmacy benefit managers (PBMs), which manage prescription drug benefits on behalf of health plans, large and small employers, labor unions and government programs. I remain grateful for the opportunity earlier this year to address the Task Force members about the rising cost of drugs, and how PBMs provide high quality, cost effective prescription drug management programs.

Rebates

Price concessions, in the form of rebates, that are negotiated by PBMs significantly lower the cost of drugs. According to researchers, PBMs, who are hired by plan sponsors to maximize the value of prescription drug benefits, help patients and payers save \$94.1ⁱ per enrollee per year in prescription drug costs, equaling \$654 billion over the next 10 years.ⁱⁱ Plan sponsors use these savings to benefit patients by lowering premiums, deductibles, and cost sharing.

Drug manufacturers alone set the prices for the drugs they make. PBMs can negotiate price rebates but only when there is competition among drug manufacturers for products that treat the same medical condition. Where there is no competition within the drug class, very rarely, if ever, are manufacturers incented to provide rebates to PBMs and payers. On average, more than 90% of rebates collected by PBMs are passed on to plan sponsor clients, and the value of these rebates helps to lower out-of-pocket costs and premiums for plan members. To the extent that any rebate amounts are retained by the PBM, it is a form of compensation for the PBM services being performed. As a result of the role of PBMs in negotiating discounts from manufacturers, PBMs have been able to consistently put downward pressure on net cost.

Spread Pricing

The concept of "spread" is not unique to PBMs; every business has "spread." It is simply the difference between a product acquisition cost and the price that the end user pays to purchase the product. Plan sponsors contract with PBMs to administer the prescription drug portion of the health care benefit for their enrollees. In doing so, they each negotiate contract terms and

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conditions, and the plan sponsor retains full audit rights. Purchasers of PBM services are sophisticated, and compensation terms are clearly defined and discussed in advance of any contract being signed.

Plan sponsors can choose between two basic pricing approaches to compensate their PBM for the services it performs: spread pricing or pass-through pricing. In a spread pricing model, PBMs are compensated by handling the flow of rebate payments from manufacturers to plan sponsors and the flow of drug payments from plan sponsors to network pharmacies. Plan sponsors permit the PBM to earn revenues from the difference between the amount charged by a PBM to a plan sponsor and the amount paid by the PBM to the retail network pharmacy. These revenues must cover the expenses the PBM incurs for the services it provides such as formulary development, drug utilization review, clinical management, and claims processing. Under this model, plan sponsors will usually require PBMs to guarantee rates—putting the onus on the PBM to negotiate well with drug manufacturers and network pharmacies.

In a pass-through pricing model, plan sponsors require the PBM to forward all discounts and rebates to the plan and the PBM is compensated through an administrative fee. Under this model, it is the plan sponsor who bears the risk of price fluctuations resulting in cost predictability because the PBM is simply passing through the actual price.

It is important to reiterate that the plan, as the purchaser of the PBM services, always has the final say on the type of compensation terms. PBMs believe that is critical for plan sponsors to retain flexibility in choosing which compensation model meets their own unique needs, and not be mandated to only contract one particular way.

I'd like to remind the Task Force that clients of PBMs are not required to hire them, but do so because PBMs, through aggregating the power of millions of enrollees, are uniquely capable and successful at lowering the cost of providing prescription drug benefits.

Network Adequacy

Mail-service and specialty pharmacies offer safe and cost-effective home delivery of medication. Mail-service pharmacy channels typically give plan sponsors deeper discounts than retail pharmacies, which are passed onto members in the form of lower copayments. Because of computer-controlled quality processes, robotic dispensing machinery, and advanced workflow practices, mail-service pharmacies can fill large quantities of prescriptions—improving quality and reducing costs. Patients also benefit from mail-service by way of increased adherence, which contributes to better health outcomes. As a result, plan sponsors often use lower copays as incentives for patients to use mail-service pharmacies. Restrictions on the use of mail-service pharmacies take choices away from patients, force one-size-fits-all copayments, and may have the unintended consequence of actually increasing patient costs.

Pharmacy Reimbursements

A PBM's primary mission is to deliver a high-quality pharmacy benefit to patients at the lowest net cost to the client. It would be inappropriate for PBMs to focus on enriching pharmacies, as policies that favor subsidizing pharmacies would threaten access to pharmacy services for Wisconsin patients. We believe that all stakeholders in the health care system have a

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responsibility to help lower health care costs and drug makers and pharmacy providers should not be an exception.

PSAOs & Transparency

PCMA appreciates the Task Force's attention to the issue of PSAOs and their role in the drug supply chain. PBMs also believe that meaningful transparency reform should also contain tangible information that patients can use to make more informed choices, such as the usage of real-time benefit check capabilities, and electronic prescribing and electronic utilization review.

Again, I appreciate the willingness of Task Force to accept feedback from stakeholders and to continue an open dialogue. If you have any questions, please feel free to reach me at 202-756-5729.

Respectfully,



Heather R. Cascone
Senior Director, State Affairs

ⁱ Visante, Inc. "The Return on Investment (ROI) on PBM Services," Prepared by Visante on behalf of PCMA, November 2016. <https://www.pcmnet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf>

ⁱⁱ Visante Inc., "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," Prepared for PCMA, February 2016. <https://www.pcmnet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf>

5. Letters

5.15 Pharmacy Services Administrative Organization (PSAO) Coalition

Pharmacy Services Administrative Organization (PSAO) Coalition
425 W. Capitol Ave, Suite 3525
Little Rock, AR. 72201

September 4, 2020

Governor's Task Force on Reducing Prescription Drug Prices
Office of the Commissioner on Insurance
c/o Ms. Jennifer Stegall
125 S. Webster Street
Madison, WI. 53703

Dear Task Force Members and Staff:

I am writing on behalf of the Pharmacy Services Administrative Organization (PSAO) Coalition to thank you for the opportunity to present to the Task Force earlier this summer and to provide a brief recap of the important facets of the PSAOs that you should keep in mind as you are formulating any policy recommendations.

First, the PSAOs are voluntary organizations that pharmacies choose to use to ease the administrative burden of reading, analyzing and executing contracts with the Pharmacy Benefits Managers (PBMs). The PSAO stands in the shoes of the pharmacies and executes contracts on their behalf. Additionally, once the contracts are signed, the PSAOs perform the very valuable service of helping the pharmacies reconcile the payments that they receive from the PBMs to ensure that every penny that is owed to the pharmacy from the PBM is paid and accounted for.

Second, PSAOs charge a transparent, flat fee for the services they provide to the pharmacy. There are no hidden fees or "spread" profits that exist among the PSAOs, this only exists with the PBMs.

Third, PSAOs **do not** process claims, set reimbursement rates or maximum allowable costs (MACs), or determine patient drug coverage or network design -- these functions are done exclusively by the PBMs and the health plans. Further, PSAOs **do not** create pooled purchasing power for the pharmacies, sell or distribute drugs, help with inventory management or negotiate with pharmaceutical manufacturers.

Fourth, it is important to understand that while the PSAOs represent thousands of independent and small chain pharmacies, they do not have an improved negotiation position with the much larger PBMs for the purpose of leveraging better reimbursement rates. And while the PSAO Coalition members have parent organizations that are large companies in healthcare, the size of the parent companies does not extend any contracting advantage when dealing with the PBMs.

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5.15 Pharmacy Services Administrative Organization (PSAO) Coalition

Finally, I will close by saying please do not confuse the functions that the PSAOs perform with the functions that the PBMs perform. They are nowhere near the same functions. The PSAOs do not influence drug cost in any manner. They are simply a voluntary service that the pharmacy may choose to use to assist with managing their back off of their business, much like they could hire an accountant, personal assistant, or any other voluntary business service.

The PSAO Coalition stands ready to address any further questions that you may have about our businesses and the role that we play in assisting independent and small chain pharmacies.

Thank you for the opportunity to submit comments.

Respectfully,

A handwritten signature in black ink that reads "Scott Pace". The signature is fluid and cursive, with the first name "Scott" and last name "Pace" clearly legible.

Scott Pace, Pharm.D., J.D.
Chair

5. Letters

5.16 Pharmacy Society of Wisconsin



TO: Governor's Task Force on Reducing Prescription Drug Prices

FROM: Danielle Womack, MPH
Vice President, Public Affairs
Pharmacy Society of Wisconsin

DATE: August 14, 2020

SUBJECT: Task Force Recommendations

On behalf of the Pharmacy Society of Wisconsin and our 4,000 members representing a variety of pharmacy practice settings, I would like to commend the Governor's Task Force on Reducing Prescription Drug Prices for their diligent work in exploring the prescription drug supply chain and factors that influence the cost of prescription drugs.

As the Task Force looks to adopt recommendations, the Pharmacy Society of Wisconsin respectfully submits the following comments for your consideration:

Pharmacy benefit managers, or PBMs, play a crucial role in prescription drug benefits. In fact, PBMs manage plans for nearly 95% of Americans with prescription drug coverage¹. As you know, PBMs serve as an intermediary between health plans and pharmacies to create formularies of preferred medication lists, negotiate with drug manufacturers for discounts and rebates, negotiate with pharmacies to establish networks for dispensing drugs, and process prescription claims at the point of sale for more than 200 million Americans. In addition, many PBMs own and operate mail order pharmacies.

Even though PBMs manage numerous prescription plans funded by taxpayer dollars and despite the fact that all other aspects of health care are closely regulated, there are almost no regulations at the state level in Wisconsin specific to pharmacy benefit managers. Over the past decade, more than thirty states have passed legislation to regulate specific PBM practices.

PBMs were created to bring savings to health plans and their members by reducing administrative costs, validating patient eligibility, and negotiating costs between pharmacies and health plans; however recent studies have demonstrated that many PBMs operate with a lack of transparency and have taken advantage of their middleman position between the health plan and pharmacy provider; additionally, some PBMs have implemented business practices that are unfair to pharmacies and patients.

Due to this lack of transparency and accountability, patients are often forced to pay higher out-of-pocket costs for their prescription drugs, while pharmacies are reimbursed using complicated methodologies that often result in below-cost reimbursement. This model is not sustainable for patients or pharmacies.

In order to address these issues, we encourage the Task Force to adopt the following recommendations:

¹ AIS Market Data, Pharmacy Benefit Management, PBM Market Share, Top 25 Pharmacy Benefit Management Companies and Market Share by Membership. 2000-2011 Survey Results: Pharmacy Benefits Trends & Data.

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5. Letters

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1. **Pharmacy Benefit Manager Licensure:** Despite existing state laws relating to MAC transparency, efforts to ask PBM for reconsideration of MAC pricing have been returned with a statement from PBM of “Pricing per contract.” While Wisconsin has a MAC transparency law on the books, it is not currently being enforced. **OCI must have the authority to enforce the existing MAC transparency law and any other laws relating to PBMs.** In order to enforce PBM-centric regulations, a regulatory framework must be created. While PBMs in Wisconsin are licensed as Employee Benefit Plan Administrators, countless pharmacies report an inability to have existing statutes specific to PBMs enforced upon these entities. Clearer regulatory oversight must exist to ensure compliance with the law.
2. **Fair Audit Practices:** PBM audits of pharmacies often focus on finding the largest recoupments, versus looking for legitimate fraud, waste, and abuse. We suggest adopting fair audit practice regulations that are uniform for all PBMs conducting audits. Adopting these uniform regulations will add transparency to pharmacies and allow both pharmacies and PBMs to be held accountable for their actions during an audit. Fewer than ten states, including Wisconsin, do not have fair pharmacy audit practice language in place.
3. **Pharmacy Networks:** Many patients are required to obtain their prescription drugs from mail order pharmacies, or are financially penalized for not using a mail order pharmacy through higher out-of-pocket costs. Patients must have a choice in the pharmacy they use; in-network pharmacies, whether brick-and-mortar or mail order, should require the same cost sharing to patients.
4. **Gag Clauses & Clawbacks:** When PBMs charge patients co-pays that are more expensive than the pharmacy’s price for the same medication, pharmacists have been banned by contract from informing the patient of the lower cost option. Practice such as these force patients to spend more money out-of-pocket when using insurance than they would spend without using insurance. **PBMs must not ban or penalize pharmacists from informing patients of a lower-cost option to purchase medications - for example, if paying with cash is less expensive than the patient’s copay. Additionally, PBMs should never require a patient to pay an amount that is greater than the cost of the drug or the amount the patient would pay if using cash as this artificially inflates the out-of-pocket costs to consumers.**
5. **Retroactive Claim Reduction:** Retroactively charged fees can total in the tens of thousands of dollars or more annually for pharmacies. These fees are not known at the point of sale and are impossible to accurately predict, leaving pharmacies little ability to prepare. The lack of transparency regarding how these fees are calculated and imposed unfairly targets pharmacies and requires pharmacies to inflate their prices in order to account for estimated fees they will be charged at a later date. While the most common retroactive claim reduction is the Direct and Indirect Remuneration Fee (DIR Fee) through the Medicare Part D program, PBMs regulated at the state level must also be prohibited from retroactively reducing or denying valid claims.

Thank you again for the opportunity to provide feedback to the Task Force. Please do not hesitate to reach out with any questions.

Sincerely,



Danielle M. Womack, MPH
Vice President, Public Affairs
Pharmacy Society of Wisconsin
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5. Letters

5.17 Pharmaceutical Research and Manufacturers of America



950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

August 26, 2020

VIA EMAIL

Nathan Houdek
Deputy Commissioner of Insurance, Wisconsin Office of the Commissioner of Insurance
Chair, Governor's Task Force on Reducing Prescription Drug Prices
125 South Webster Street
Madison, WI 53703-3474

Re: Task Force Policy Proposals

Dear Mr. Houdek and Task Force Members:

On behalf of our 34 member companies and the patients we serve, thank you for allowing us to provide a high level briefing about our industry in July and discuss the role that we play in the complex supply chain. We hope that the information we provided was both informative and helpful. The mission of the Task Force on Reducing Prescription Drug Prices, to examine prescription drug spending and drug affordability, is important. We feel strongly that no patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false and ignores cost savings that medicines provide to the health care system overall.

Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances, changing the direction of health care as we know it. With more than 4,500 medicines in the pipeline (74% which have the potential to be first in class medicines and 42% of which could be personalized medicines), patients have greater hope than ever before.

In this letter, we are providing our specific opposition to two of the proposals that are identified in the Task Force's proposal grid:

- 1) **The creation of an Affordability Board as described in Proposal #14, and**
- 2) **Mandating manufacturer reporting as described in Proposal #18.**

Both proposals would require significant reporting mandates, which will not help patients, could threaten access to needed prescription medications, and potentially chill the innovation of future treatments.

The establishment of an Affordability Board (Proposal #14) could arbitrarily cap prices and limit access to medicines.

Discussions about the creation of an Affordability Board to review prescription drugs are important. However, the intention of such proposals is often to cap drug prices. Arbitrarily capping drug prices could lead to a shortage of or limit access to medicines for patients who may need a medicine and raises constitutional concerns. In the long-term, capping prices can harm the innovation of new therapies. Further, proposals like this often attribute sole responsibility to the biopharmaceutical industry when there are a variety of stakeholders involved in determining what consumers ultimately pay for a medicine at the counter, such as health plans, pharmacy benefit managers (PBMs), and others. Finally, this strategy could undermine the competitive market, as well as the positive impact of the biopharmaceutical industry

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5.17 Pharmaceutical Research and Manufacturers of America

on Wisconsin's economy. The industry supports over 51,000 jobs and includes an average annual compensation of \$89,007 per year (as compared to the average job salary in Wisconsin of \$53,806) and provides more than \$697M in revenue, generated in both state and federal taxes.¹ Our industry is committed to continuing our work in Wisconsin, but we rely on policies that promote manufacturing, research and development, and innovation, not harm these important endeavors. We believe that the establishment of an Affordability Board would hurt the industry and the patients we serve.

In addition, brand and generic biopharmaceutical companies, unlike other sectors of health care, pay rebates in the amount of \$782 million to the State of Wisconsin and federal government in 2018, which is 60% of the total Medicaid spend on prescription drugs in the state.²

Mandating Manufacturer Reporting (Proposal #18) does nothing to help the patient.

Mandating manufacturer reporting is likely to skew important discussions of policy issues in ways that are systematically biased against innovation and ignores the value of medicines to patients, the overall health care system, and the economy of Wisconsin. The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies currently report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures in 10-K filings. Proposals to mandate public disclosure of additional confidential and proprietary information by biopharmaceutical companies ignore the large amount of information already publicly reported on an annual basis by companies and are based on the faulty assumption that prescription drug spending is the major cost driver in health care.

The reporting requirements for manufacturers do not reflect the total investment of industry because of the long-term nature of research and development. Manufacturers pursue research efforts that include many failures and iterations on the path to development of a single approved drug. In fact, according to Tufts's Center for Study of Drug Development (CSDD), only 12% of medicines in the pipeline make it through the approval process by the Food and Drug Administration (FDA).³ An 88% failure rate underscores how expensive and risky drug development is.

It is important to note that medicines are the *only* part of the health care system where costs decrease over time. When brand name medicines face brand competition, or when they lose their patent protection and generic drugs become available, prices drop, often significantly. In fact, it is projected that from 2019-2023, there will be approximately \$105B in savings due to competition from generic and biosimilar products as patents for brand medicines expire.⁴ In addition, nearly 90% of all medicines dispensed in the United States are generic and cost pennies on the dollar.⁵ One component of health spend that is not decreasing, however, is health care insurance, which is seeing significant increases instead. Out-of-pockets expenses, including deductibles and coinsurance have more than doubled for many patients over 2007-2017.⁶ The Kaiser Family Foundation has shown patient costs are increasing faster than insurers' cost.⁷ Health insurance and plan administration costs are rising at more than twice the rate of drug spending.⁸

¹ "Biopharmaceutical Sector Impact on Wisconsin's Economy," (http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_GB_StateFactSheet/PhRMA_GB_StateFactSheet_2019_Wisconsin.pdf).

² "The Facts About Medicaid in Wisconsin," (http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/WI-One-Pager_19.pdf).

³ Tufts Center for the Study of Drug Development (CSDD), "Briefing: Cost of Developing a New Drug," Nov 2014.

⁴ QuintilesIMS Institute, "Medicines Use and Spending in the U.S." May 2017.

⁵ IQVIA Institute Drug Channels Institute

⁶ "2018 Employer Health Benefits Survey," Kaiser Family Foundation. (<http://www.kff.org/report-section/2018-employer-health-benefits-survey-section-7-employee-cost-sharing/>)

⁷ "Increases in Cost-Sharing Payments Continue to Outpace Wage Growth," Kaiser Family Foundation. (<http://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start>)

⁸ "National Health Expenditures 2018 Highlights," Centers for Medicare and Medicaid Services (CMS). (<http://www.cms.gov/files/document/nhighlight.pdf>).

5. Letters

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According to new research from the **Berkeley Research Group (BRG)**, rebates, discounts, and fees paid by manufacturers are on the increase while the share received by manufacturers has decreased over time.⁹ In fact, nearly half (46%) of total spending on brand medicines went to the supply chain and other entities in 2018. This is a 13%-point increase from 2013, when other stakeholders retained 33% of brand medicine spending. This data reaffirms that we need to look at the entire supply chain in order to solve patient affordability challenges. Misaligned incentives must be fixed in the supply chain, including the broken rebate system, to ensure patients benefit at the pharmacy counter from the significant discounts and rebates.

Proposals #14 and #18 will not improve access and affordability to needed medicines.

It would do nothing to address how much consumers ultimately pay for a medicine, an amount determined by insurers, not biopharmaceutical companies. These proposals should do something to help patients afford their prescription medicines, such as passing on the rebates directly to the patients at the point of sale at the pharmacy counter. Instead, these rebates are going to the plans and other supply chain stakeholders. Recent data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan.

Today, a patient pays only about 3% for out-of-pocket hospital costs, but 13% or more for their medicines.¹⁰ Additionally, insurers are increasing utilization management techniques to aggressively restrict a patient's use of medicine. Currently, three major pharmacy benefit managers (PBMs) negotiate steep discounts on prescription drugs for more than 70% of all prescriptions filled in the United States—Express Scripts alone covers nearly 50 million Americans.¹¹

Prescription medicines have transformed the trajectory of many debilitating diseases and conditions, including HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Better use of medicines could eliminate up to \$213 billion in U.S. health care costs annually, which represents 8% of the nation's health care spending.¹² Therefore, instead of focusing on reporting of information that does nothing to help the patient, perhaps the conversation should focus on issues such as adherence, care coordination and better use of medicines, which yields significant health gains by avoiding the need for other, more costly, medical services.

What we can do at PhRMA

At PhRMA, we will continue to research and develop therapies that save lives and improve quality of living for patients and their families. Our researchers are working around the clock to bring new treatments and cures to market. Now, especially during the time of this pandemic, our industry is working tirelessly to develop COVID-19 vaccines and treatments to preserve the health and wellness of the residents of Wisconsin and those around the world. We will continue to work with the Task Force to develop solutions and look for ways to lower costs and offer affordability tools for the uninsured and underinsured. For more specifics on the types of policies we are proposing, please see four enclosed policy issue briefs.

Thank you again for allowing us to present in July and provide follow-up. Please don't hesitate to contact us if you have further questions or inquiries.

⁹ Berkeley Research Group (BRG). Revisiting the Pharmaceutical Supply Chain: 2013-2018. <http://www.thinkbrg.com/newsroom-publications-revisit-pharma-supply-chain.html>

¹⁰ Avalere Health analysis of the US Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, 2015. (<http://meps.ahrq.gov/mepsweb>. Accessed February 2018). Analysis includes individuals with any source of health care coverage, public or private; this includes individuals who had health coverage without coverage for prescription drugs, which can be expected to account for less than 2% of those with health coverage.

¹¹ 2019 Drug Trend Report," (<http://www.express-scripts.com/corporate/drug-trend-report#2019-in-review>).

¹² Su W, Lockwood C, IHS Markit. Comparing health outcome differences due to drug access: a model in non-small cell lung cancer. (http://cdn.ihs.com/www/prot/pdf/0119/HSM_NSCLC%20HTA%20model%20white%20paper_18Jan2019r.pdf). Published December 13, 2018.

5. Letters

5.17 Pharmaceutical Research and Manufacturers of America

Sincerely,

Peter Fotos
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pfotos@phrma.org

Peter Fjelstad
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CC: Members of the Governor's Task Force on Reducing Prescription Drug Prices

Enclosures (4)

5. Letters

5.17 Pharmaceutical Research and Manufacturers of America

Policies to Help *Patients Pay Less* for their Medicines: *Cover Medicines from Day One*



For many patients with commercial health insurance, the amount they pay for their medicines continues to increase, even as the amount insurance companies pay continues to grow more slowly, if at all. Unfortunately, when patients must pay more out of pocket for their medicines, they often fail to fill the medicines their doctors prescribe or ration medicines to make them last longer. This can lead to serious complications and worse health for patients, which could ultimately lead to higher overall health care costs.



The Problem

Historically, more patients paid a fixed-dollar copay for their medicines or had coinsurance for their medicines, which requires patients to pay a percentage of the medicine's price.

In recent years, however, **the use of deductibles for prescription drug coverage has risen dramatically**. Deductibles require patients to pay in full for their medicines before insurance coverage kicks in, which can cost thousands of dollars. Between 2012 and 2017, the percentage of health insurance plans that employed deductibles for prescription drugs almost doubled from 23% to 52%.

Compounding the challenge, these deductibles are usually structured to reset at the beginning of each calendar year, when Americans face post-holiday financial stress, tax bills and winter utility costs. This burden is further exacerbated by the fact that, while health insurance companies receive substantial discounts from prescription drug manufacturers, **the amount patients subject to a deductible must pay is often based on a drug's list price, not the discounted price being paid by their health insurance company**. For example, for a drug with a \$100 list price, the health insurance company may negotiate a discount or rebate of \$40, for a net cost to them of \$60. But a patient with a deductible pays the full \$100. That \$40 rebate may go to the health insurance company, which has paid nothing on the claim. It does not go to the manufacturer of the medicine.

The Solution: *Cover Medicines from Day One*



States can help patients immediately by simply requiring that certain medicines be covered by insurers from day one – without subjecting patients to deductibles. The Internal Revenue Service recently issued guidance allowing high-deductible health plans to exclude certain drugs, such as those for the treatment of some chronic conditions, from requirements that deductibles be met before those medicines are covered. Because of the federal guidance, states can now require plans to exclude those medicines from the deductible in high-deductible health plans.

States may also choose to require other state-regulated plans to eliminate deductibles for all drugs. While health insurance companies would still have flexibility to offer different plan designs, limiting or eliminating deductibles in this way could help to smooth out patients' expenditures over the calendar year and could provide immediate relief to patients at the pharmacy counter.



5. Letters

5.17 Pharmaceutical Research and Manufacturers of America

Policies to Help *Patients Pay Less* for their Medicines: *Make Coupons Count*



For patients with commercial health insurance, the amount they pay for their medicines is determined by health insurance companies and pharmacy benefit managers (PBMs). **New tactics by these companies to block manufacturer cost-sharing assistance, as also known as copay coupons, threaten to make it harder for patients to get important treatments** for chronic illnesses such as asthma, diabetes, HIV, arthritis, hemophilia and others.



The Problem

In the commercial health insurance market, **patients are being forced to pay more out-of-pocket for their medicines due to an increase in deductibles and the use of coinsurance instead of copays.**

Deductibles require patients to pay in full for their medicines before insurance coverage kicks in. And unlike copays, which are a fixed dollar amount charged per prescription, coinsurance requires patients to pay a percentage of the medicine's price. When patients are facing their deductible or paying high coinsurance, they will often have higher out-of-pocket costs than when their plan requires a copay because **deductibles and coinsurance are often based on the list price of the medicine and not the discounted amount the insurance company and PBM have negotiated to pay.** This higher cost sharing can impact patients' ability to adhere to their prescribed treatment, which can be devastating for patients with chronic conditions who rely on medicines to keep their symptoms in check.

To help patients better afford their medicine and stay adherent, many third-party entities, including pharmaceutical manufacturers, offer cost-sharing assistance such as copay coupons. Historically, commercial health insurance plans have counted these coupons towards a patient's deductible and maximum out-of-pocket limit, providing relief from high cost sharing and making it easier for patients to get their medicines.

Unfortunately, health insurance carriers and PBMs have adopted policies, often referred to as "accumulator adjustment programs," that block manufacturer coupons from counting towards deductibles and maximum out-of-pocket limits. This means **patients could be paying thousands more at the pharmacy than they should be.**

Many patients who have relied on this assistance to afford their medicines have no idea that health insurers and PBMs are no longer counting coupons toward their out-of-pocket limits. This can result in unpleasant surprises at the pharmacy counter, where patients may face thousands of dollars in charges because manufacturer coupons don't count towards their deductible and maximum out-of-pocket limit.

The Solution: *Make Coupons Count*



States should enact laws that protect third-party cost-sharing assistance, including copay coupons, to help protect patients and enable them to better afford their medicines. Specifically, it will decrease patient out-of-pocket costs and reduce the risk of patients going without needed medicines. Four states -- Illinois, Virginia, West Virginia and Arizona -- have already enacted legislation to address this issue, and we encourage other states to follow their lead to help patients pay less.



5. Letters

5.17 Pharmaceutical Research and Manufacturers of America

Policies to Help *Patients Pay Less* for their Medicines: *Offer Lower, More Predictable Cost Sharing Options*



For many patients with commercial health insurance, the amount they pay for medicines continues to increase, even as the amount insurance companies pay continues to grow more slowly, if at all. Unfortunately, when patients must pay more out of pocket for their medicines, they often fail to fill the medicines their doctors prescribe or ration medicines to make them last longer. This can lead to serious complications and worse health for patients, which could ultimately lead to higher overall health care costs.



The Problem

Historically, more patients paid fixed-dollar copays for their medicines – one price for a generic and another for a brand medicine. **In recent years, however, the use of deductibles and coinsurance for prescription drug coverage has risen dramatically.**

First, let's take deductibles. Deductibles require patients to pay in full for their medicine, sometimes up to thousands of dollars, before their insurance coverage kicks in. **Between 2012 and 2017, the percentage of health insurance plans that employed deductibles for prescription drugs almost doubled from 23% to 52%.**

In addition to employing deductibles for prescription drug coverage, insurers have increasingly replaced fixed-dollar copays with percentage-based coinsurance, which requires patients to pay a percentage of the medicine's price.

For prescription drugs, **these increasing out-of-pocket costs are further exacerbated by the fact that, while health insurance companies often receive substantial rebates and discounts from prescription drug manufacturers, the amount patients subject to a deductible or coinsurance must pay is typically based on a drug's list price, not the discounted price being paid by their health insurance company.** For example, for a drug with a \$100 list price, the health insurance company may negotiate a discount or rebate of \$40, for a net cost to them of \$60. But a patient still in their deductible pays the full \$100. That \$40 rebate may go to the health insurance company, which has paid nothing on that patient's claim. It does not go to the manufacturer of the medicine.

The same is true for coinsurance. A patient with a 25% coinsurance pays \$25 for a medicine with a \$100 list price (.25X100), rather than \$15 (.25X60). The additional \$10, paid by the patient, does not go to the manufacturer of the medicine and instead may go to the health insurance company or others in the supply chain.

5. Letters

5.17 Pharmaceutical Research and Manufacturers of America

Policies to Help *Patients Pay Less* for their Medicines:
Offer Lower, More Predictable Cost Sharing Options



The Solution: Offer Lower, More Predictable Cost Sharing Options

Patients should have more choices when it comes to their medicine coverage. States can help patients immediately by requiring each insurer to have at least 50% of its health insurance plans offered in a given market to include the following cost sharing options for patients:

1. **No deductible:** Medicines must be covered by insurers from day one – without subjecting patients to deductibles;
2. **Copayment-only cost sharing:** patients pay only a flat-dollar copay per prescription, not percentage-based coinsurance; and
3. **Limited copayments:** the highest-allowable copayment may not exceed 1/12 of the patient's annual out-of-pocket spending maximum.

While health insurance companies would still have flexibility to offer different plan designs to meet various patient preferences, requiring each insurer to offer at least 50% of its plans to include these three features would provide patients with lower, fairer and more predictable prescription drug coverage options.

5. Letters

5.17 Pharmaceutical Research and Manufacturers of America

Policies to Help *Patients Pay Less* for their Medicines: *Share the Savings*



Many patients with commercial health insurance are required to share in the cost of their prescription medicines. **The cost to patients is often much higher than the cost to their insurance company – for the same medicine on the same prescription.** That's because health insurance companies and pharmacy benefit managers (PBMs) negotiate significant rebates and discounts on the cost of the medicine and do not share these savings with patients.

The Problem

Health insurance companies and PBMs often receive sizeable rebates from brand pharmaceutical manufacturers. **On average, manufacturers rebate 40 percent of a medicine's list price back to health insurers, PBMs, the government and other entities in the pharmaceutical supply chain.** In 2018, these rebates and discounts totaled \$166 billion.

At the same time, patients are being forced to pay more out of pocket for their medicines due to an increase in deductibles and the use of coinsurance. Deductibles require patients to pay in full for their medicines before insurance coverage kicks in. And unlike copays, which are a fixed dollar amount charged per prescription, coinsurance requires patients to pay a percentage of the medicine's price.

Here's what unfair: **When patients are facing their deductible or paying coinsurance, the amount they must pay is often based on the full list price of the medicine** – even if their insurance company and PBM are only paying the discounted amount they negotiated with the manufacturer.

For example, for a drug with a \$100 list price, a health insurance company or PBM may negotiate a discount or rebate of \$40, for a net cost to them of \$60. But a patient still in her deductible pays the full \$100. A patient with a 25% coinsurance pays \$25 for a medicine with a \$100 list price (.25X100), rather than the \$15 (.25X60) she would pay if the coinsurance was based off the discounted amount being paid by her insurance company. That extra money collected from the patient may go to the health insurance company or the PBM. It does not go to the manufacturer of the medicine.

What's worse is that **this situation is unique to health insurance coverage of prescription medicines, and it penalizes patients who need medicines the most.** Right now, patients receive the benefit of negotiated discounts when sharing in costs for doctor or hospital visits, but they do not always receive the same benefits for prescription drugs.

The Solution: *Share the Savings*



States can enact laws that would require health insurance companies and PBMs to share at least part of their negotiated savings with patients at the pharmacy counter. Despite what health insurance companies claim, this will not drastically increase premiums. One study demonstrated that, even if health insurance companies were required to share all the negotiated rebates with patients, premiums would increase at most 1%, while patients could save up to \$800 each year on their medicine costs. Fixing this broken part of the system and sharing these savings will give patients immediate relief and help them better afford the medicines they desperately need.

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5. Letters

5.18 The Alliance



August 19, 2020

Dear Deputy Commissioner Houdek and Members of Governor Evers' Task Force on Reducing Prescription Drug Prices:

Thank you for your work over the past several months to consider potential remedies to the problem of high prescription drug prices. We appreciated the opportunity to provide the perspective of self-funded employers, who are members of The Alliance, at the meeting of the committee on February 19, 2020.

As you may recall, The Alliance is a not-for-profit health care purchasing cooperative which is owned by 275 employers who provide health benefits to over 105,000 employees and their family members. Employers are well-positioned to offer guidance on policy efforts to curb drug prices as we balance the important priorities of ensuring a healthy workforce while also controlling health care costs that threaten to make health care unaffordable.

Our overarching guidance to the committee is to focus on policy measures that lower the *total cost* of prescription drug prices, versus mechanisms that simply shift costs from one party to another. Prescription drug affordability is a concern for our employees and their family members, as well as for the self-funded employers who are paying the majority of the cost. Unless the *total cost* and the rate of increase are addressed for everyone, the goal of affordability will not be achieved.

As it pertains to some of the specific measures under consideration by the Committee:

We support the following proposals:

- Establishing a Prescription Drug Affordability Board – This mechanism can improve public accountability and cost control. We believe the Board can play an important role in making our current market-based approach more efficient and effective.
- The proposed Manufacturer Reporting Requirement – This can be another important step to provide needed industry oversight.
- Passage of AB114/SB100 – This bill includes provisions that bring greater accountability and transparency and provide important protections for consumers.

We have some concerns about the following ideas, many of which sound good in theory, but have the net effect of driving costs up:

- Co-pay cap on insulin – While we believe this is a well-intended idea to make this life-saving drug more affordable for consumers, we caution against this form of benefit mandate, which does nothing to control the *total cost* of the product. Instead, we would encourage that steps be taken to put downward pressure on the list price of insulin. Doing so would control costs for both employers and their employees instead of simply shifting the burden.
 - As an aside, many employers have value-based benefit plan designs where high-value medications and treatments, like insulin, are 100% covered by the plan with no cost share for the employee. We want to ensure that employers retain the flexibility to implement progressive strategies such as this.

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The Alliance moves health care forward by controlling costs, improving quality, and engaging individuals in their health.

5. Letters

5.18 The Alliance

- Coupon programs – These programs ostensibly provide relief for patients by covering their out of pocket costs; however, they do nothing to impact the total cost of the drug. Moreover, coupons often drive up plan costs by undermining efforts to encourage consumers to use the most cost-effective pharmaceutical options for their conditions.
 - While we oppose coupons, we support the use of accumulator programs, as these maintain the integrity of our benefit plan design.
- Network adequacy provisions – While convenient access to prescription drugs is an important goal, so too is affordability, which poses the greatest threat to prescription drug access. Unlike hands-on forms of clinical care, location of pharmacy services is not a significant consideration, particularly for maintenance medications. Employers need the latitude to encourage consumers to use the highest value options, including mail order services and specialty pharmacy providers.
- Promotion of one PBM purchasing model over another – There is debate about the merits of “pass-through” vs “spread-pricing” models for PBM purchasing. We think this debate misses the point. At the end of the day, what matters to employers and our employees is the total price we pay for pharmaceuticals, and our ability to fully understand and compare those prices. We believe that having multiple, competing options in the market can create healthy competition that serves to control PBM prices.
- Sharing rebates with consumers – This idea sounds good in theory. However, as a practical matter, this requirement actually benefits very few consumers while raising the cost for other plan participants. We don’t believe this is the intention of the Task Force.

We appreciate your efforts and the time and expertise of the Task Force members to develop options to make prescription drugs more affordable for Wisconsinites. This is an issue of great importance for the businesses and Wisconsin families who are increasingly burdened by high and rising prescription drug costs. Please contact me if we can be of any further assistance.

Kind regards,



Cheryl A. DeMars
President and CEO

5. Letters

5.18 The Alliance



PLANK 1 - COST AND QUALITY TRANSPARENCY

RESOLUTION 1.02:

PROMOTE FAIR MARKET PRICES FOR PRESCRIPTION DRUGS TO ENSURE APPROPRIATE CARE AND PREDICTABLE HEALTH CARE EXPENSES

Insurers, employers and patients all depend upon an affordable health care system in order to cover the cost of the care needed to maintain a healthy workforce. It is common knowledge that America's health care costs are on the rise, with prescription drugs being one of the major contributing factors to annual increases in health care expenditures. The rising cost of drugs affects a company's bottom line, and the unpredictability of drug pricing makes it difficult for employers, particularly those who self-insure, to plan for their health care costs.

Employers are limited in their options to manage rising drug prices, as they want to ensure their employees and dependents have access to crucial medications and don't want to put employees in the position of pricing essential medications out of reach. Additionally, for some conditions, appropriate pharmacotherapy may help avoid more expensive or risky medical interventions.

There are many contributing factors to the increases in drug prices:

- » Demand inelasticity. Because drugs can be life-altering or lifesaving, consumers don't have the option to walk away from high prices. Furthermore, Americans are living longer, with more chronic illness, requiring more use of medicine to treat seniors, driving up demand.
- » Negotiating power. The federal government, which purchases one third of all prescription drugs sold in the United States through the Medicare and Medicaid programs, does not use this high-volume purchasing power to negotiate lower rates, nor do these programs consistently require members to use generic drugs when they are available.
- » Supply chain. Prescription drug supply chains are complex and include the pharmaceutical manufacturer, wholesale distributors, retail stores, mail order distributors and specialty pharmacies. All of these entities take a cut of the drug price, which is passed on to the consumer.
- » Extended patents. United States patent law allows manufacturers to block competition for an extended period. The Food and Drug Administration (FDA) typically approves patents on medications for up to seven years for chemical-based medications and even longer for more complex biologic drugs. Once patents expire, manufacturers are able to use litigation or minor changes to a drug's composition to delay competitors' entry into the market. A recent study revealed that exclusive brand name drugs account for 72 percent of drug spending, but only 10 percent of the prescription drugs dispensed.

The Alliance supports the Five Rights framework adopted by the National Alliance of Health Care Purchasing Organizations. Although this framework was designed specifically to address rising specialty drug costs, The Alliance supports these principles across the board in efforts to address rising pharmaceutical costs:

1. Right Drug - prescribing decisions should be guided by the best available evidence on drug safety and efficacy, and testing to assess the best drug for a patient should be covered.
2. Right Price - costs along the pharmacy supply chain should be transparent to purchasers and patients alike.
3. Right Place - there should be parity in charges across settings of care.
4. Right Data - purchasers should be engaged with providers, regulators and drug manufacturers to ensure that purchasing decisions are informed by meaningful data analysis.
5. Right Support - patients should be supported to ensure follow-through with prescription drug therapies.

more >>>

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Guided by the Five Rights, The Alliance encourages state and federal policymakers to adopt the recommendations of the National Academy of Sciences report, “Making Medicine Affordable: A National Imperative.” The report identifies several policies that policymakers can adopt to directly impact this national dilemma, including:

- » Use the clout and purchasing power of the government to negotiate lower prices with manufacturers.
- » Require greater transparency regarding how drug prices are set.
- » Incorporate value-based principles into drug formularies.
- » Limit direct marketing of prescription drugs to consumers.
- » Limit the total annual out-of-pocket costs paid by Medicare enrollees.
- » Evaluate opportunities along the pharmacy supply chain to increase value.
- » Share information with consumers regarding pharmaceutical effectiveness and value.
- » The Federal Trade Commission (FTC) should use the drug pricing formulas to “identify and act upon any anti-competitive practices.”
- » Federal and state governments should work to control rising drug prices while at the same time ensuring that any cost savings realized as a result of these actions are not shifted to employers and other private sector health care purchasers.

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5. Letters

5.19 Wisconsin Association of Health Plans

From: Tim Lundquist, Director of Government & Public Affairs
Wisconsin Association of Health Plans
To: Governor's Task Force on Reducing Prescription Drug Prices
Re: Task Force Policy Recommendations
Date: July 16, 2020

The Wisconsin Association of Health Plans appreciates the time and energy members of the Governor's Task Force on Reducing Prescription Drug Prices are committing to understanding the prescription drug supply chain and evaluating potential solutions to the high cost of prescription drugs. Association members and staff are following the work of the Task Force and appreciate the opportunity to share the health plan industry's perspective.

The Wisconsin Association of Health Plans is the voice of twelve community-based health plans that provide employers, individuals, and government programs across Wisconsin access to high-quality health care, including prescription drug benefits. The Association works on behalf of its member plans on policy matters that can impact health insurance costs and consumer access to affordable health insurance coverage.

Association members encourage the Task Force to focus its recommendations on state public policy solutions that lower the cost of prescription drugs for all patients and will not simply shift costs from one group of patients to another. The Association also encourages Task Force members to consider what evaluation tools should be employed to determine whether enacted policies are successful in achieving the goal of reducing prescription drug prices.

The Wisconsin Association of Health Plans respectfully submits the following preliminary recommendations for Task Force consideration.

Topic 16 – Pharmacy Service Administration Organizations (PSAO) Reporting

PSAOs play an increasingly important role in the drug supply chain. Because health plans support transparency measures that lead to disclosure of activities that increase drug costs, health plans believe the Task Force should recommend PSAOs publicly disclose any arrangements with pharmaceutical manufacturers, switch operators, and pharmacies that incentivize increased utilization of brand name drugs. This includes arrangements to process pharmaceutical manufacturer electronic coupons.

Manufacturer coupons often encourage consumers to use higher cost products where less expensive alternatives are available. When these electronic coupons are processed by a PSAO, they can be applied without the patient's knowledge. If a coupon expires or a manufacturer simply discontinues the program, patients can be confused by why their cost-sharing appears to have changed – even though their insurance benefit hasn't changed at all. Health plans, consumers, and policymakers should know how and where these manufacturer coupons are being applied.

For these reasons, health plans are also not opposed to disclosing to consumers how coupons are being applied to out-of-pocket costs (Topic 15). These disclosures should occur via a member's certificate of coverage.

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Topic 17 – Insurer Rx Drug Rebate Reporting

Drug rebates are already included in medical loss ratio (MLR) calculations and the Affordable Care Act's MLR rules ensure consumers benefit from these rebates. Given the consumer protections that already exist, additional rebate disclosure in rate filings adds limited value, while creating additional administrative effort for health plans. Finally, health plans are concerned that public disclosure of proprietary information could negatively impact Wisconsin's competitive health insurance market. Because insurer drug rebate reporting will not reduce the price of prescription drugs, it should be rejected by the Task Force.

Topic 18 – Manufacturer Reporting

High prescription drug prices are set by pharmaceutical manufacturers. The Task Force should support reporting measures to ensure Wisconsin consumers better understand the factors that lead pharmaceutical manufacturers to continuously increase their prices and establish high annual costs for certain drugs.

Topic 19 – Specialty Drug Administration

For prescription drugs and health care services at-large, health plans believe managing the site of care delivery is an important means of controlling cost, promoting quality, and managing patient safety. However, where and how a drug is administered is specific to each drug, provider, and payer. While care should be delivered at lower cost sites whenever possible and medically appropriate, the Task Force should not recommend new mandates on health plans that would reduce insurers' ability to apply appropriate utilization management tools to specialty drug administration.

Topic 24 – Discriminatory Reimbursement

Because drugs are purchased at a steep discount under the 340B program, claims for those drugs do not qualify for additional price concessions that would otherwise be provided by a pharmaceutical manufacturer. This means that health plans and pharmacy benefit managers sometimes pay more than the usual contracted price for drugs purchased through the 340B program. Health plans should not be required to pay higher than usual rates, especially when the drugs are being purchased at a discount. Health plans should be able to continue to manage networks and reimbursement models to reduce the overall cost of prescription drugs. Because this proposal will not reduce the price of prescription drugs in Wisconsin, it should be rejected by the Task Force.

Association member plans appreciate the Task Force's consideration of these initial comments. Please do not hesitate to e-mail me at tim@wihealthplans.org with any questions. As Task Force discussions evolve, the Association may submit additional comments on policy issues.

5. Letters

5.20 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans August 14, 2020

From: Tim Lundquist, Wisconsin Association of Health Plans
Mary Haffenbredl, America's Health Insurance Plans
R.J. Pirlot, Alliance of Health Insurers
To: Governor's Task Force on Reducing Prescription Drug Prices
Re: Task Force Policy Recommendations
Date: August 14, 2020

The Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Insurers appreciate the continued dedication of the members of the Governor's Task Force on Reducing Prescription Drug Prices to finding state-level solutions to the high cost of prescription drugs. Our organizations previously submitted comment under separate cover, and appreciate the opportunity to submit an additional recommendation here.

Licensing and Regulation of Pharmaceutical Representatives – The Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Insurers encourage the Task Force to recommend legislation to license pharmaceutical sales representatives to increase transparency surrounding their activities and to require training on ethical standards. The National Academy on State Health Policy, a nonpartisan forum of state policymakers, has developed a model act to accomplish these purposes. A copy of the model act is attached to this memo.

Recommended legislation requires sales representatives to disclose to health care providers the wholesale acquisition cost of the drugs they market and to share the names of generic drugs in the same therapeutic class when available. Additionally, recommended legislation requires pharmaceutical representatives to annually disclose to the state certain information about marketing activities aimed at health care providers. A regulatory body, likely the Department of Safety and Professional Services, would in turn annually provide a deidentified report to the Legislature and to the public, summarizing the disclosures and identifying trends.

Why License Pharmaceutical Representatives? The marketing of prescription drugs significantly impacts total drug spending. Pharmaceutical sales representatives play a significant role in marketing high-cost drugs to providers. In 2016, pharmaceutical companies spent \$6 billion on direct-to-consumer advertising, and over \$20 billion to market brand-name drugs to health care providers.

A sales force focused on influencing prescribing decisions should be subject to licensure, as are the health care professionals they seek to influence. Sales representatives provide useful information to health care professionals, but also have an incentive to encourage prescriptions for more costly brand-name drugs when equally effective, less-costly options are available.

State-level licensure provides an opportunity to establish and enforce professional and ethical standards for pharmaceutical representatives. Required disclosure of the wholesale acquisition cost and of available generic alternatives also ensures prescribers have more complete information about prescription options. Finally, state-level disclosure of marketing activity allows Wisconsin to consider further, informed action, based on that information.

5. Letters

5.20 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans August 14, 2020

Our member health plans appreciate the Task Force's consideration of this recommendation. Please do not hesitate to email us at tim@wihealthplans.org, mhaffenbredl@ahip.org, or pirlot@hamilton-consulting.com with any questions.

5. Letters

5.20 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans August 14, 2020

A Model Act to License Pharmaceutical Representatives

Section 1. Statement of Legislative Intent; Purpose

Whereas pharmaceutical marketing impacts clinical decision-making, outcomes, and resource utilization;

Whereas marketing strategies may keep prescription drug prices high by aggressively marketing patented products to limit generic competition;

Whereas aggressive marketing of opioids fueled the opioid epidemic;

Whereas evidence-based prescribing can reduce health care costs and save lives;

Therefore, be it resolved that [State] will require Pharmaceutical Representatives to obtain a license to conduct business in [State]. Pharmaceutical Representatives must participate in professional education, including training on ethical standards, and Pharmaceutical Representatives must disclose information about the extent and nature of their interactions with health professionals as conditions of licensure.

Section 2. Definitions

For the purposes of this section, the following terms will have the following meanings:

(a) "Health care professional" shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical or biologic products.

(b) "Pharmaceutical" means a medication that may legally be dispensed only with a valid prescription from a health care professional.

(c) "Pharmaceutical Representative" means a person who markets or promotes pharmaceuticals to health care professionals on behalf of a pharmaceutical manufacturer or a distributor for a fee. Pharmaceutical representatives include pharmaceutical sales representatives and medical science liaisons.

Section 3. Licensure of Pharmaceutical Representatives

(a) License – Required.

(1) No person shall act as a pharmaceutical representative in [State] without first having obtained a pharmaceutical representative license.

(2) In order to become initially licensed, a pharmaceutical representative shall complete a professional education course as determined by the [State Agency responsible for professional regulation] prior to application for the license and affirm that this training was completed on the application for the license.

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5.20 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans August 14, 2020

(3) To maintain a license, a pharmaceutical representative must complete minimum continuing education in accordance with subsection (e).

(b) License – Non-transferability. No transfer of ownership shall be allowed on any license issued under this section.

(c) License – Application. An application for a pharmaceutical representative license shall be made to the [State Agency responsible for professional regulation] on a form accessible at the [State Agency responsible for professional regulation] website, and shall include the following:

(1) The applicant's full name, residence address, residence telephone number, business address and business telephone number;

(2) A description of the type of work in which the applicant will engage;

(3) The license fee;

(4) An attestation of professional education:

(A) In the case of an initial license, attest that the applicant has completed a professional education course in compliance with subsection (e); or

(B) In the case of a renewal, attest that the applicant has completed at least five hours of continuing professional education in the previous year in compliance with subsection (e);

(5) Proof that the applicant has paid any assessed penalties and fees; and

(6) Any other information that the [State Agency responsible for professional regulation] may reasonably require.

(7) Any changes made to the information submitted on the application or any material changes made to the licensee's personal or businesses operations or to any information provided under this section must be reported, in writing, to the [State Agency responsible for professional regulation] within four business days of the change.

(d) License – Fee. The annual fee for a pharmaceutical representative license shall be \$750.00.

(e) Professional education.

(1) The [State Agency responsible for professional regulation] shall establish by rule education requirements as a condition for an initial or a renewal pharmaceutical representative license. All pharmaceutical representatives shall complete a minimum of five hours of continuing professional education prior to renewing their license. The initial and continuing professional education must include training in ethical standards, whistleblower protections, laws and regulations applicable to pharmaceutical marketing, and other areas that the [State Agency responsible for professional regulation] shall designate by rule.

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(2) Upon request, pharmaceutical representatives shall provide proof of completion of the professional education requirements to the [State Agency responsible for professional regulation].

(3) The [State Agency responsible for professional regulation] shall designate and publish a list of institutions that provide courses that meet the education requirements. The [State Agency responsible for professional regulation] shall also designate the courses that satisfy the education requirements. A professional education provider shall not be a pharmaceutical representative's employer. Education providers must disclose conflicts of interests. Funding for education courses shall not be provided by the pharmaceutical industry or by a third-party funded by the pharmaceutical industry.

Section 4. Disclosure to State

- (a) No later than June 1 of each calendar year, pharmaceutical representatives shall provide the following information from the previous calendar year, to the [State Agency responsible for professional regulation]:
- (1) The aggregate number of times health care professionals in [State] were contacted;
 - (2) The specialties of the health care professionals contacted;
 - (3) The location and duration of contact, including telephone, in-person, and on-line contact;
 - (4) The pharmaceuticals promoted;
 - (5) Whether product samples, materials, or gifts of any value were provided to the health care professional;
 - (6) The value of any products, materials, gifts, or compensation provided;
- (b) The [State Agency responsible for professional regulation] shall make this information publicly available on the [State Agency responsible for professional regulation] website in a manner in which individual health care professionals are not identifiable by name or other identifiers such as National Provider Identifiers.
- (c) The [State Agency responsible for professional regulation] shall produce a public annual report to the legislature summarizing the disclosures and identifying trends. The report is due November 1 each calendar year.
- (d) A model disclosure form may be issued to facilitate compliance with the disclosure requirements of this section.

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5.20 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans August 14, 2020

Section 5. Disclosure to Health Care Professionals

- (a) Pharmaceutical representatives must disclose the following information during each visit with a health care professional:
 - (1) The wholesale acquisition cost of a prescription drug when the pharmaceutical representative provides information concerning the drug to the prescriber.
 - (2) The names of at least three generic prescription drugs from the same therapeutic class, or if three are not available, as many are available for prescriptive use.

Section 6. Ethical Standards

- (a) The [State Agency responsible for professional regulation] shall produce a list of ethical standards for pharmaceutical representatives that shall be incorporated into the rules and published on the [State Agency responsible for professional regulation] website. In addition to those rules, a pharmaceutical representative shall not:
 - (1) Engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact;
 - (2) Use a title or designation that could reasonably lead a licensed health professional, or an employee or representative of a licensed health professional, to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation, in [State], unless the pharmaceutical detailer currently holds such a license; or
 - (3) Attend patient examinations without the consent of the patient.

Section 7. Enforcement

- (a) Pharmaceutical representatives must display their license during each visit with a health care professional. Health care professionals that meet with a pharmaceutical representative not displaying a license may report the unlicensed pharmaceutical representative to the [State Agency responsible for professional regulation] for further action.
- (b) Health care professionals who meet with a pharmaceutical representative not sharing the information required in Section 5(a) may report the pharmaceutical representative to the [State Agency responsible for professional regulation] for further action.

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5.20 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans August 14, 2020

- (c) Fine: Any person violating any of the provisions of this chapter shall be fined not less than \$1,000 nor more than \$3,000 for each offense. Every day such violation continues shall constitute a separate and distinct offense.
- (d) License Suspension and Revocation: A violation of any of the provisions of this chapter may result in license suspension or revocation in accordance with [cite relevant State Statute]. No license suspended or revoked pursuant to this section shall be reinstated until all code violations related to the suspension or revocation have been remedied and all assessed penalties and fees have been paid. No person whose pharmaceutical license under this chapter is revoked for any cause shall be granted a license under this section for a period of two years from the date of revocation.
- (e) Rules - The [State Agency responsible for professional regulation] shall have the authority to promulgate rules necessary to implement their respective powers and duties under this Article.

July 2020

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5.21 Wisconsin Association of Health Plans, America's Health Insurance Plans, and Alliance of Health Plans September 3, 2020

To: Deputy Insurance Commissioner Nathan Houdek
Members of the Governor's Task Force on Reducing Prescription Drug Prices

From: Wisconsin Association of Health Plans
Alliance of Health Insurers
America's Health Insurance Plans

Date: September 3, 2020

Re: Task Force Policy Options

The Wisconsin Association of Health Plans, the Alliance of Health Insurers, and America's Health Insurance Plans appreciate the opportunity to provide further feedback on policies considered by the Governor's Task Force on Reducing Prescription Drug Prices. Collectively, Wisconsin health insurance providers have serious concerns with two insurance mandate proposals reviewed by the Task Force: establishing a copayment cap on insulin and requiring the application of drug manufacturer coupons to deductibles and out-of-pocket maximums.

Our primary concerns with these two proposals are the same:

- 1) Imposing mandates on health plan benefit design does not address the root problem of pharmaceutical manufacturers' high list prices.
- 2) By creating a divide between a drug's true cost and a consumer's out-of-pocket cost, these proposals hide the real cost of prescription drugs.
- 3) Because these proposals hide the real cost of a drug, they may also have the **perverse and undesirable effect of undermining health plan and pharmacy benefit manager (PBM) efforts to negotiate lower prices for patients.**
- 4) Since these proposals do not reduce the actual price of a prescription drug, high prescription drug costs will simply be shifted from patients with a specific drug need to all patients across the board.
- 5) Finally, because **these proposals can only apply to state-regulated, fully-insured plans—which account for only about one-fifth of Wisconsin's coverage landscape**—the costs of these mandates would be disproportionately borne by small businesses and individuals that already struggle with health care costs.

Establishing a Copayment Cap on Insulin

The rising price of insulin has created an unconscionable affordability crisis for many diabetics. One study shows that the price of insulin has increased more than 240% over the past decade.¹ The Health Care Cost Institute (HCCI) found that prices for insulin nearly doubled from 2012 to 2016.² Even when accounting for rebates, patient assistance, and/or manufacturer-sponsored coupons, HCCI still found that the average price of insulin doubled over the same time period.

¹ *Several Probes Target Insulin Drug Pricing*. Kaiser Health News. October 28, 2017. Available at: <https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141>.

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Consumers, employers, and government programs bear the cost of pharmaceutical companies taking advantage of a broken insulin market for their own financial gain. Mandating a cap on insulin copayments without addressing the underlying price will merely shift more costs to all patients and employers through higher premiums.

Requiring the Application of Coupons to Deductibles & Out-of-Pocket Maximums

Drug manufacturers offer copay coupons for certain brand name drugs under the guise of helping patients afford their medications. **These copay coupons are considered to be an illegal kickback if used by an enrollee in Medicare or Medicaid**, and undermine health insurance providers' ability to encourage the use of high-value, cost-effective treatments. For example, one study found that copay coupons increase brand drug sales by more than 60%, entirely by reducing the sales of bioequivalent generic drugs. During the five years following the introduction of a new generic competitor, **copay coupons are estimated to increase total drug spending by \$30 million to \$120 million per drug.**³ This unnecessary spending is borne by consumers and employers in the form of higher premiums.

Copay coupons obscure a drug's true cost, incentivize the use of high-cost drugs, and make pharmaceutical manufacturers less accountable for both their prices and price increases.

Copay coupons deliberately circumvent health plan efforts to encourage equally effective, lower-cost treatments. State law should not legitimize the use of copay coupons.

Conclusion

Holding down out-of-pocket prescription drug costs for insured patients starts with holding down the price of prescription drugs. We look forward to working with all state policymakers on proposals that support the Task Force charge of reducing prescription drug prices **for all patients.**

Please contact Tim Lundquist (tim@wihealthplans.org), Rebecca Hogan (hogan@hamilton-consulting.com), and Mary Haffenbredl (mhaffenbredl@ahip.org) with any questions.

³ *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization.* Leemore Dafny, Christopher Ody & Matt Schmidt. October 4, 2016. Available at: https://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03be8cc4.pdf.

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5.22 Wisconsin Counties Association



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August 14, 2020

Nathan Houdek
Deputy Commissioner of Insurance
Wisconsin Office of the Commissioner of Insurance
125 South Webster Street
Madison, WI 53703-3474

DELIVERED VIA EMAIL

Re: County Positions on Topics of the Prescription Drug Task Force

Dear Deputy Commissioner Houdek,

The Wisconsin Counties Association (WCA) appreciates the opportunity to submit comments to the Governor's Task Force on Reducing Prescription Drug Prices. WCA represents all 72 counties—who serve as major employers throughout the state—as well as the interests of the WCA Group Health Trust (GHT). GHT was created in 1991 when a group of Wisconsin county officials concerned with the rising costs of providing local government employees with health benefits joined together to create a not-for-profit employee health benefit trust.

Over the past 28 years, GHT has saved local governments (counties, municipalities, and schools) millions of dollars in health benefit costs due to its strong public-private partnership and its unique ability to proactively manage both health benefit and prescription drug costs.

WCA has closely followed discussions of the task force as local governments, their employees, their health plans, and local taxpayers are directly impacted by any action the state implements as a result of the task force recommendations. WCA recognizes the prescription drug market is complex and in need of reform and appreciates the task force's review and consideration of the following items.

WCA Supports:

AB 114/SB 100

- Hundreds of hours went into crafting and modifying the provisions of AB 114/SB 100 among a diverse group of stakeholders. Although the legislation is not perfect, WCA considers the agreed upon bill one that was negotiated in good faith and that address several concerns raised about the current marketplace. WCA

MARK D. O'CONNELL, EXECUTIVE DIRECTOR

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supports passage of the amended legislation approved by the Wisconsin State Assembly and is awaiting action in the Wisconsin State Senate.

Affordability Board & Manufacturer Reporting

- Pharmaceutical companies often price medications based on what the market will bear and make multiple increases to the price of the medication each year.
- The current prescription drug market is not a perfect free market as the patient often does not pay the full cost of the medication and, bearing coinsurance, may not be aware of cost increases.
- Requirements to force pharmaceutical companies to justify their prices and price increases will help to balance this inefficient market.

WCA Opposes

Network Adequacy

- Limitations on a PBM's ability to narrow the network will jeopardize adherence, quality and add to the cost of prescription drugs.
- Mail-order and specialty pharmacies offer patients convenient access to drugs and save patients and their employers money.
- Several specialty medications are high cost, distributed by limited pharmacies and come with special handling and administration instructions. The safest method of distribution for these medications is through a pharmacy that regularly handles these medications and can appropriately advise the patient.

Rebate Pass-through

- As a local government health benefit trust, GHT uses any prescription drug savings generated through rebates or other price control tools directly to benefit local governments and plan participants through premium savings.
- Mandates to share rebates with patients or eliminate rebates will result in higher premiums for the entire group, as was seen in a study of the Trump administration's proposal to eliminate rebates in Medicare.

Spread Pricing

- Having multiple PBM models promotes the effectiveness of the free market.
- Spread pricing is preferred by GHT because it has shown lower costs when compared to pass-through PBMs.
- Forcing public sector employers to use a pass-through PBM model will increase costs and add to an already complex market

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Copay Caps

- Limits on copays for one class of medication will result in added cost to the plan that will need to be made up by higher cost share for others, higher premium for the plan, or both.
- Limits to copays on any one class of medication values that group of patients over a group of patients who do not receive a cap on the price of their medications.

Local government employers in GHT paid 90% of the cost of medications for patients covered under their plans in 2019. As all members of GHT are local government employers, the high cost of prescription drugs impacts taxpayers. As such, WCA would like to reiterate its opposition to any potential prescription drug changes that increase costs to consumers or the public at large. Thank you for your valuable work on this important topic and please contact WCA with any questions.

Sincerely,



Mark D. O'Connell, Executive Director
Wisconsin Counties Association

cc: Members of the Governor's Task on Reducing Prescription Drug Prices

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5.23 Wisconsin Hospital Association



ADVOCATE. ADVANCE. LEAD.

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August 14, 2020

Mr. Nathan Houdek
Ms. Jennifer Stegall
Office of Commissioner of Insurance
125 South Webster Street
Madison, WI 53703

Re: Governor's Task Force on Reducing Prescription Drug Prices: WHA Policy Recommendations

Dear Mr. Houdek and Ms. Stegall,

WHA has been closely following the progress of the Governor's Task Force on Reducing Prescription Drug Prices. We have been impressed with the adept facilitation and policy research that has supported the Task Force's work. We appreciate the opportunity to comment on some issues that have emerged during the Task Force deliberations that affect our members' abilities to provide optimal care to our patients, and to offer our own policy suggestions.

Specialty drugs: WHA opposes the recommendation which would require the administration of certain specialty drugs outside of the hospital setting. Costly specialty drugs are those which must be administered by a clinician to a patient through injection or infusion in the outpatient setting. Providers may purchase and store these drugs themselves for use in the outpatient setting. However, some payers contract with third-party specialty pharmacies to purchase the drugs, removing the provider from the drug acquisition process. This process may require the patient to pick up and transport the drug to the clinician for administration (brown bagging) or be dispensed and shipped by the specialty pharmacy to the clinic or hospital for administration (white bagging). Brown bagging and white bagging remove the provider from the drug acquisition process and may create problems for patient care.

The decision on where to best administer a specialty drug should be a clinical one, tailored for that specific patient by their treating provider on a case-by-case basis. Further, specialty drug administration outside of hospitals is not always less expensive, as proponents suggest. A study published in the American Journal of Managed Care found that risk-adjusted chemotherapy drug spending was lower for patients receiving chemotherapy in hospital outpatient departments than for patients using physician offices. White bagging and brown bagging may also result in waste of these expensive drugs. A drug obtained through white and brown bagging may only be administered to the patient for whom it was ordered. If there is any excess of the drug in the vial after the treatment, that excess must be discarded. Also, if the drug isn't available at the time of the patient's appointment, patient inconvenience and missed doses may result.

WHA urges the Task Force to oppose the recommendation to require the administration of certain specialty drugs outside of the hospital setting.

340B: WHA strongly supports the 340B Prescription Drug Discount Program which helps hospitals and other entities (including Federally Qualified Health Centers and Aids Drug Assistance Programs) that serve a disproportionately high volume of Medicaid patients obtain discounted access to certain outpatient prescription drugs. Created by Congress and signed into law by President George H.W. Bush in 1992, the 340B program was intended by Congress to help hospitals and other covered entities "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."¹ Over 600 drug manufacturers participate in the program in exchange for access to Medicaid's beneficiary market.

¹ H.R. Rep. No. 102-384(II), at 12 (1992)

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5.23 Wisconsin Hospital Association

Wisconsin hospitals have been using the 340B program for its intended purpose – to help them stretch scarce federal resources. For example, the program has helped Wisconsin hospitals:

- Provide free or low-cost dental care for patients they serve.
- Expand access to psychiatric and other behavioral health programs that would otherwise run on large deficits.
- Operate remote dispensing sites that help folks in rural communities get access to prescription drugs without driving long distances.
- Generally offset the significant losses hospitals face from the underfunding of state and federal Medicaid and Medicare programs – which pay hospitals on average 67 cents on the dollar and 73 cents on the dollar respectively compared to the cost to provide such services.

While some have attempted to shift blame for the increasing cost of prescription drug prices to the 340B program, those attempts are misguided at best and intentionally misleading at worst. It is rather ironic that some in this task force have suggested reforming 340B – a program that helps hospitals and other entities better serve vulnerable, low income populations – rather than focusing on policies that could have a measurable impact on reducing the cost of prescription drugs. The 340B program has been alleged to be responsible for everything from driving up the cost of prescription drugs to incentivizing hospitals to prescribe more expensive prescription drugs to their patients.

A recent inquiry from the U.S. House Energy and Commerce Committee requested the federal Medicare Payment Advisory Commission look at this second question, and it could find no conclusive evidence that 340B hospitals are incentivized to prescribe more expensive drugs after analyzing data from the Office of the Inspector General.² Instead, it concluded that any correlation is most likely due to the fact that 340B hospitals treat a sicker patient population with more complex medical needs that increase the cost of care. Additionally, MedPAC staff noted that the 340B hospitals typically care for patients with later stages of cancer and include a higher proportion of younger patients who select more aggressive treatments that are often costlier. For the types of cancer that did see a correlation with higher spending, the commissioners agreed it was more appropriately correlated to those higher-cost cancers rather than any incentive within the 340B Program.

As to the claim that 340B is driving up the cost of prescription drugs, the federal Health Resources & Services Administration (HRSA) estimates 340B accounts for 4.3% of the overall drug market – a small fraction. In fact, the discounts themselves are worth less than 2% of overall drug manufacturer revenue – a smaller fraction still. When considering that drug manufacturers continue to post by far the highest profits in health care, it is obvious they are trying to deflect attention from this fact when they bring up the idea of reforming 340B.

Efforts to add more regulations to the 340B program would only lead to hospitals devoting even more staff and resources toward compliance – when the average hospital already dedicates 59 FTE staff toward regulatory compliance, with nearly a quarter being physicians and nurses, according to the American Hospital Association (AHA). Hospitals devote significant resources toward compliance of the various requirements of the 340B program itself, including rigorous internal audits.

One policy related to 340B that has also been brought up at the task force is the policy of discriminatory reimbursement by some pharmacy benefit managers. In late 2018, WHA became aware of letters circulating from certain PBMs informing a number of rural 340B covered entities in Wisconsin that they would be reducing their reimbursements for 340B covered drugs since they were obtained at a discount. WHA partnered with the AHA and 340B Health to bring attention to this issue on a national scale. The 340B program was designed to help hospitals and other covered entities stretch scarce federal resources, but this discriminatory reimbursement policy proposed by certain PBMs would have allowed PBMs to pocket the savings Congress intended for 340B covered entities. Fortunately, the PBMs publicly announced they would no longer pursue this policy and WHA has not pursued any legislative remedies at this time since the issue appears to be resolved for now.

Additional policies for consideration: The Task Force has gathered testimony from a wide range of stakeholders. Many of the ideas proposed conflict with one other and are unlikely to gain consensus. However, some proposals are aimed increasing supply chain transparency or making some prescription drugs more affordable for certain populations, and could garner support from most Task Force members, including:

² MEDPAC. *Congressional request on health care provider consolidation: Does the 340B program create incentives for participating hospitals to use more expensive drugs?* (2020) Kim Neuman, Nancy Ray, Shinobu Suzuki. Retrieved from: http://www.medpac.gov/docs/default-source/default-document-library/consolidation_340b_public_jan_2020.pdf?sfvrsn=0

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- **Support DOC in pursuing 340B pricing:** The Prescription Cost Study Committee, which included the Departments of Health Services, Corrections and Employee Trust Funds and the Commissioner of Insurance, issued one recommendation, which is for DOC to apply with the federal Health Services Resources Administration to become a 340B subgrantee with DHS's Division of Public Health. This will allow DOC to fill client prescriptions for clients who are receiving STD or tuberculosis treatments. Drugs for treatment of these conditions, which may include Hepatitis C, can be very expensive. Obtaining these drugs at 340B pricing can result in large savings for the state.
- **Create a real-time; live inventory of donated drugs for sharing between repositories in the state of Wisconsin:** The State of Wisconsin's donated drug repository is authorized under s. 255.056, Stats. The program's purpose is to make drugs available for persons who are uninsured or participate in government-operated healthcare programs. Creation of a real-time, live inventory of donated drugs would provide a more streamlined and efficient way to link available drugs with patients in need.

The Task Force's work has deepened understanding of the drug supply chain's complexities and highlighted the concerns of patients who lack access to necessary drugs. WHA respects the work of the Task Force and appreciates the commitment of time and resources by Task Force members and staff. WHA, which supports in providing high-quality, affordable, accessible health care for Wisconsin families and communities, appreciates the opportunity to contribute to the Task Force's efforts.

Sincerely,



Eric Borgerding
WHA President & CEO

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