



STATE OF WISCONSIN

**GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES**

December 2019 Report

Background

On August 20, 2019, Governor Tony Evers signed Executive Order #39, creating the Governor’s Task Force on Reducing Prescription Drug Prices (Task Force). The Executive Order can be found at the end of this report as Appendix I.

Indicating prescription drugs are estimated to cost Wisconsin residents over \$1.3 billion in 2019, 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 (OCI) Deputy Commissioner, Nathan Houdek, the Task Force held its first meeting on November 20, 2019. This was the only meeting held in 2019, with monthly meetings planned starting in January 2020.

The 2020 meeting schedule is as follows:

Date	Location
January 22 nd	Milwaukee
February 19 th	Oshkosh
March 18 th	Wausau
April 15 th	Rhineland
May 20 th	La Crosse
June 17 th	Sturgeon Bay

Task Force information, including membership, meeting minutes, and presentations can be found on the Task Force website at www.Rxdrugtaskforce.wi.gov

November 20, 2019 Task Force Meeting

An overview of the November 20, 2019, Task Force meeting is provided below.

The meeting agenda/open meeting notice can be found as Appendix II to this report.

Welcome

Commissioner Mark Afable

Commissioner Afable welcomed and thanked members of the Task Force and introduced the Governor’s message.

Governor Tony Evers

Governor Evers, via video message, thanked Task Force members for their willingness to take on the challenge of reducing prescription drug prices. The Governor emphasized the need for everyone to have access to affordable prescription drugs and not be put in a position of choosing between paying for their medication and paying for other things, such as utility bills. As an example of the hardship unaffordable medication and supplies can present for residents, the Governor highlighted a woman's struggle in paying for insulin supplies and her decision to reuse needles as a result.

The Governor's message can be found on the Task Force website at: www.Rxdrugtaskforce.wi.gov

Video Presentation

U.S. Senator Tammy Baldwin

Senator Tammy Baldwin, via video message, thanked members for serving on the Task Force and acknowledge that their work will help Wisconsin residents who are struggling to pay for the prescription medication they need. She indicated she hears from residents about skyrocketing drug prices and that there is a need to hold drug corporations accountable. Senator Baldwin introduced the Fair Drug Pricing Act in May to address prescription drug costs.

To view Senator Baldwin's message, visit the Task Force website at: www.Rxdrugtaskforce.wi.gov

Opening Remarks

Nathan Houdek, Deputy Commissioner and Task Force Chair

Chairman Houdek welcomed and thanked members for their time and commitment to analyzing options for reducing prescription drug prices in Wisconsin. He emphasized the need to ultimately identify meaningful and workable solutions. He also indicated he was honored to lead a Task Force comprised of members with such a diverse set of experiences and professional backgrounds participating in the dialogue.

Member Introduction

Members introduced themselves and provided insight into their experiences and goals in addressing the rising cost of prescription drugs.

Member biographies can be found as Appendix III to this report.

WI Department of Justice Update on Prescription Drug Lawsuits

R. Duane Harlow, Assistant Attorney General

Mr. Harlow highlighted the antitrust lawsuit filed in 2016 by 42 states and led by Wisconsin related to the development, manufacture, and sale of Suboxone (an opioid replacement therapy for the treatment of opioid dependency). As stated on slide 12 of the presentation, "Defendants engaged in an overarching conspiracy to prevent and delay generics to maintain their monopoly profits."

Mr. Harlow also highlighted two cases addressing sudden price spikes in a number of generic drugs from 2013-14. As reflected on slide 17 of the presentation, "Both lawsuits allege the defendants engaged in

conspiracies to: fix prices, rig bids, allocate drug markets, and engage in other anticompetitive conduct.” The slide also indicates that, “Defendants claim the increased prices are the result of market forces and drug shortages.”

The presentation is available as Appendix IV to this report.

Understanding the Prescription Drug and Financing Chain/State & Federal Action Addressing Prescription Drug Access and Affordability

Hemi Tewarson, National Governors Association

Sandra Wilkniss, National Governors Association

Jane Horvath, Horvath Health Policy

In an effort to level set the Task Force with common knowledge related to the prescription drug landscape, the National Governors Association provided an overview of several key areas of activity. Namely, the prescription drug supply and financing chain (slides 6-18); key issues in the pharmaceutical market; including policy issues (slide 22); state action related to regulation of insurers, pharmacy benefit manager regulation, price transparency, affordability boards and importation (slides 25-33); legal challenges (pages 35-38); federal challenges (slides 39-43); and industry action (slides 44-46).

The presentation is included as Appendix V to this report.

Task Force Member Discussion

Following the presentations, the Task Force members discussed areas of interest, their concerns, and considerations for the Task Force in moving forward with its work.

Below is a compilation of Task Force member comments and considerations shared at the meeting.

- Consider how the cost of drugs impacts the employer, as well as the price the patient is paying at the point of sale at the pharmacy (for an insured person).
- Be mindful that some of the solutions may have a balloon effect, i.e. lowering the price in one area or for one population, with the result of increasing the cost in another area or for another population.
- Important to look beyond the pharmacy benefit and include consideration of medical management as a factor impacting the cost of prescription drugs.
- The application process for pharmaceutical company patient assistance programs is not streamlined and is difficult for consumers to navigate. Application standardization across pharmaceutical companies would help to ease the challenges consumers face in seeking assistance.
- There are efforts occurring by pharmaceutical manufacturers with respect to patient assistance application processes. Companies have been looking at ways to re-tool and address the process. Disease state interest groups also have put effort into compiling information on those programs; assistance available from the top three insulin drug companies is an example.
- A question is whether pharmaceutical drug sample programs are a means to get individuals hooked on brand name medications. If the Task Force is looking at standardizing these programs (drug assistance programs), members need to go in eyes wide open to make sure these are not a hook to stay on brand name prescriptions and prevent consumers from pursuing low-cost drug options.



- Without pharmaceutical company discounts, people could not afford care and that would increase uncompensated care.
- Physicians do not always know how much drugs are costing patients, especially general practice physicians. Specialty doctors are able to have a better handle on that. Physicians need to see at point of care how much prescriptions cost; price transparency at the point of prescribing.
- There are some pharmacy benefit managers developing information for the electronic medical record that displays alternative drug options; the low and high-cost drug options for a particular medication.
- It seems doable to increase transparency between the provider, pharmacy benefit manager, and consumer.
- Regarding transparency, it is important that it be meaningful and applicable to the whole supply chain. The flow of savings/rebates passed down to the consumer is one example of where transparency is important.
- Reimbursements to pharmacies for drugs are continuing to go down while patient prices are going up. Also, though, people stay out of hospitals and have an improved quality of life due to their medications.
- Pharmacy reimbursements and pricing does not seem very transparent. A patient gets charged forty dollars and twenty of it goes to the pharmacy benefit manager. More transparency over the flow of dollars is needed, as well as a focus on the consumer at the counter, who does not qualify for low-income assistance. The everyday consumer must be helped; they are the majority impacted by high-cost medications.
- Medicaid covers 1.2 million WI residents and when high-priced drugs come to market, it costs taxpayers millions of dollars, even with Medicaid pricing.
- Hepatitis C medication has come down in price some due to competition. The Task Force also needs to think about the high cost to treat Hepatitis C and the long-term cost savings captured with the availability of that medication. Medicaid is paying less management and hospital visit costs as a result of drugs used to treat Hepatitis C.
- From an insurer standpoint, another consideration, with respect to paying for high-cost medications upfront to avoid longer-term medical expenses, is that consumers change health insurers. One insurer may bear the upfront medication expense and then a different insurer benefits from the improved condition of the enrollee, without having had to pay for the initial treatment.
- The Task Force is going to have to look at several different solutions. Transparency does not save money for the consumer. The burden of realizing savings should not be put on the consumer, i.e. shopping around, looking at different pharmacies, filling out company rebate forms, etc. There should be a focus on high manufacturer cost, rather than shifting costs around.
- Consumers do need to be aware of the resources that are available.
- Regarding an interest in understanding the 340b program, it was explained that there is a Department of Employee Trust Funds pharmacy committee charged with reviewing and recommending options for the state to pursue as a purchaser that may lower the state's prescription drug expense. The 340b program is a top consideration for the Department of Corrections.
- The Task Force should be mindful that just because an option may not be the end solution, it may still be worth pursuing.
- Interest in understanding opportunities related to importation.

2020 Workplan

The Task Force work plan details meeting locations, dates, and the anticipated area of focus for each meeting. It serves as a high-level path for the Task Force in discussing the many issues that fall under the category of, and impact, prescription drug costs.

The Workplan is labeled as a draft and will remain that way, as it is a living document; meaning it is likely to change somewhat as the Task Force continues to meet and further define areas of interest and focus.

The work plan is attached as Appendix VI to this report.

Appendix I



EXECUTIVE ORDER #39

Relating to the Creation of the Governor's Task Force on Reducing Prescription Drug Prices

WHEREAS, prescription drugs account for 10 percent of overall health spending in the United States;

WHEREAS, prescription drugs are estimated to cost Wisconsin residents over \$1.3 billion in the year 2019;

WHEREAS, Medicaid expenditures on prescription drugs reach well over \$400 million each year in Wisconsin;

WHEREAS, the cost of prescription drugs continues to skyrocket, and studies show that Americans spend at least three times more for the same drugs than citizens of other high-income countries;

WHEREAS, the high cost of prescription drugs continues to be a burden on Wisconsin residents, with many reporting that they either skip doses or cut pills in half due to the difficulty of affording their medications;

WHEREAS, skipping needed medication due to the unaffordability of prescription drug prices imposes an even greater cost on the health care system as a whole, due to unnecessary physician visits, hospitalization, and use of emergency services;

WHEREAS, the prescription drug supply chain lacks transparency and assurances that savings are passed through to consumers;

WHEREAS, transparency and accountability are critical elements to controlling and reducing the cost of prescription drugs and improving affordability for all Wisconsinites; and

WHEREAS, Wisconsinites should be able to afford the prescription medicine they need to lead a healthy life.

NOW THEREFORE, I, TONY EVERS, Governor of the State of Wisconsin, by the authority vested in me by the Constitution and Laws of this State, including section 14.019 of the Wisconsin Statutes, do hereby create the Governor's Task Force on Reducing Prescription Drug Prices ("Task Force"), and order the following:

1. The Task Force shall be chaired by the Commissioner of the Office of the Commissioner of Insurance or a designee. Task Force membership shall consist of:

- a. The Lieutenant Governor or a designee;
 - b. The Attorney General of the State of Wisconsin or a designee;
 - c. The Secretary of the Department of Health Services or a designee, who shall serve as vice-chair;
 - d. The Secretary of the Department of Agriculture, Trade, and Consumer Protection or a designee;
 - e. The Secretary of the Department of Employee Trust Funds or a designee;
 - f. Four members of the Wisconsin Legislature, two representing each caucus;
 - g. Other individuals appointed by the Governor to serve at the pleasure of the Governor, including consumer advocates, and individuals representing industries involved with the development, pricing, distribution, and purchasing of prescription drugs including pharmacy benefit managers, pharmacies, pharmaceutical manufacturers, health insurance carriers, hospitals, the business community, and organized labor.
2. At the request of the Task Force, all executive branch agencies shall provide technical assistance and expertise as needed.
 3. 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.
 4. The Task Force shall issue a report to the Governor on or before December 31 of each year summarizing the work completed by the Task Force and recommending potential action items to reduce the price of prescription drugs in Wisconsin.

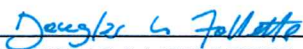


IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great seal of the State of Wisconsin to be affixed. Done at the Capitol in the City of Madison this 20th day of August in the year of two thousand nineteen.



TONY EVERS
Governor

By the Governor:



DOUGLAS LA FOLLETTE
Secretary of State

Appendix II

**WEEKLY OPEN MEETING NOTICE
OFFICE OF THE COMMISSIONER OF INSURANCE**

125 South Webster Street
Madison, Wisconsin 53703-3474

**MEETING NOTICE FOR THE WEEK OF
NOVEMBER 17, 2019**

DATE AND TIME, AGENCY, LOCATION, CONTACT PERSON	SUBJECT
<p>DATE AND TIME: Wednesday, November 20, 2019 10:00 a.m. to 2:00 p.m.</p> <p>AGENCY: Office of the Commissioner of Insurance</p> <p>LOCATION: Hill Farms 4822 Madison Yards Way, Rm N108 Madison, WI 53705</p> <p>This location is accessible for people with disabilities. If you need special accommodations due to a disability, please call the OCI contact person on this notice. For the hearing impaired, call 711 and give them the OCI contact person's number as listed in this notice.</p> <p>CONTACT PERSON: Olivia Hwang 608-267-9460</p>	<p>Governor's Task Force on Reducing Prescription Drug Prices</p> <ol style="list-style-type: none"> I. Welcome (15 minutes) <ul style="list-style-type: none"> • <i>Tony Evers, Governor</i> II. Video Presentation (5 minutes) <ul style="list-style-type: none"> • <i>Tammy Baldwin, U.S. Senator</i> III. Opening Remarks (10 minutes) <ul style="list-style-type: none"> • <i>Nathan Houdek, OCI Deputy Commissioner and Task Force Chair</i> IV. Member Introduction (20 minutes) V. WI Department of Justice Update on Prescription Drug Lawsuits (20 minutes) <ul style="list-style-type: none"> • <i>R. Duane Harlow, Assistant Attorney General</i> VI. Understanding the Prescription Drug Supply and Financing Chain (40 minutes) <ul style="list-style-type: none"> • <i>Hemi Tewarson, National Governors Association</i> • <i>Jane Horvath, Horvath Health Policy</i> <ol style="list-style-type: none"> a. Overview of Drug Supply and Financing Chain b. Stakeholder Issues and Concerns VII. Lunch (25 minutes) VIII. State and Federal Action Addressing Prescription Drug Access and Affordability (50 minutes) <ul style="list-style-type: none"> • <i>Sandra Wilkniss, National Governors Association</i> • <i>Jane Horvath, Horvath Health Policy</i> <ol style="list-style-type: none"> a. Overview of Federal and Industry Action b. Overview of State Action c. Overview of Legal Challenges to State Action IX. Task Force Member Discussion (40 minutes) X. Future Meetings (10 minutes) XI. Adjourn

Appendix III

Anna Benton

Anna Benton is Deputy Director at the Division of Medicaid Services, which provides healthcare coverage and services to 1.2 million Wisconsinites. In this role she is responsible for facilitating the development of executive-level strategy and goals, and for providing oversight of the senior management team. Anna has 20 years of experience in organizational management and operations. She has held leadership roles in the nonprofit and government sectors in Milwaukee and administered large international public health programs while based in Washington DC. Anna has expertise in organizational leadership, strategic planning and execution, and data-driven process improvement.

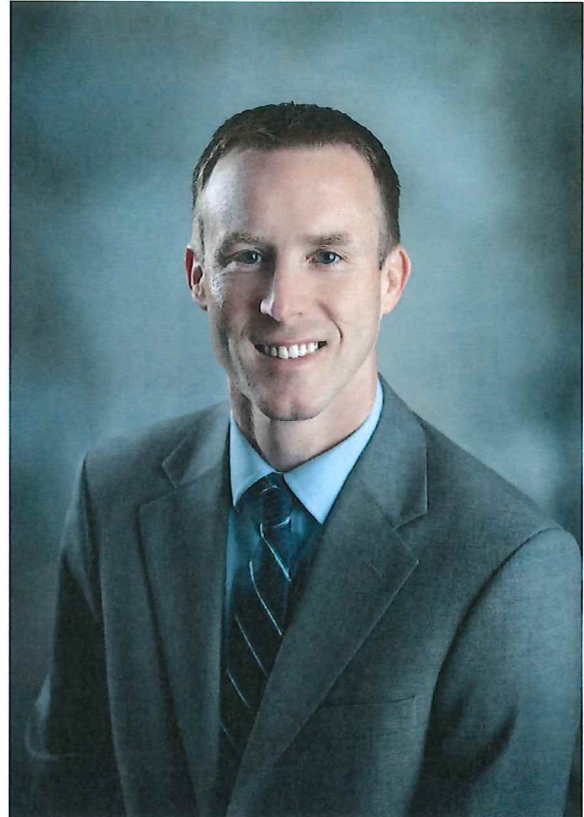


Josh Bindl

Josh Bindl is the CEO of National CooperativeRx, a national not-for-profit pharmacy benefits purchasing cooperative representing employer groups, unions, and coalitions who sponsor a health plan. Collectively they are responsible for the health and well-being of over 365,000 participants. Mr. Bindl strives to continue the Cooperative's trend of keeping costs low and adding value for members through joint purchasing and strategic clinical oversight programs.

Prior to his arrival at National CooperativeRx, Mr. Bindl served as the Director of Programs and Services for the Wisconsin Counties Association. There he led the WCA Group Health Trust, a self-funded employee health benefits trust. During his tenure the trust grew from 8,000 to 50,000 participants.

Mr. Bindl received his undergraduate degree from UW-La Crosse and his master's degree from UW-Madison.



Sen. Tim Carpenter

Senator Tim Carpenter serves in the Wisconsin State Senate representing the 3rd Senate District on Milwaukee's south side. Sen. Carpenter is a graduate of Pulaski High School and he earned his B.A. in Political Science from the University of Wisconsin-Milwaukee and his M.A. in Public Policy and Public Administration from the La Follette School of Public Affairs at the University of Wisconsin-Madison. He completed the Milwaukee Police Department Citizen Academy in 2018.

Sen. Carpenter served in the Wisconsin State Assembly from 1984-2000 before being elected to the State Senate. He served as Assembly Speaker Pro Tempore from 1993-1994 and as Senate President Pro Tempore from 2011-2013. He serves on the Council on Domestic Abuse, the State Fair Park Board, the Transportation Projects Commission, and the Wisconsin Economic Development Corporation Board of Directors.

During his time in office, Sen. Carpenter has been a recipient of the following awards: Mothers Against Drunk Driving *Legislator of the Year*; Wisconsin Professional Police Association *Law Enforcement Honor Roll*; Wisconsin League of Conservation Voters *Conservation Champion*; several Wisconsin Environmental Decade Clean 16 awards; Shepherd Express *Best State Legislator*; Wisconsin Public Health Association's *Champion of Public Health*;



Coalition of Wisconsin Aging Groups Award for Service to Seniors; Wisconsin Professional Fire Fighters *Legislator of the Year*.

Sen. Carpenter is also a member of the Sierra Club, Jackson Park Neighborhood Association, Story Hill Neighborhood Association, Milwaukee VA Soldiers Home Advisory Council, Milwaukee LGBT Community Center, Wisconsin Humane Society, Polish Center of Wisconsin, and the Democratic Party.

Brent Eberle

Brent Eberle is Senior Vice President and Chief Pharmacy Officer at Navitus Health Solutions. At Navitus, Brent oversees the Health Strategies Division, which is responsible for clinical and population health initiatives; drug utilization review programs; formulary and drug rebate management; and outcomes management initiatives. He also monitors industry trends and leads strategic product development opportunities designed to meet the changing needs of clients and their members.

Brent is also General Manager of Lumicera Health Services, a wholly-owned Navitus subsidiary and full service national specialty pharmacy accredited by both URAC and ACHC. He provides strategic direction and oversight at Lumicera, supporting its business model, its growth and regulatory needs, and the alignment of health management strategies between Navitus and Lumicera.

Brent began his tenure with Navitus in 2004 and has served in multiple capacities, including Clinical Pharmacist, Formulary Program Manager, Director of Industry Relations and Contracting, and VP of Health Strategies. Prior to joining Navitus, Brent worked as a Drug Information Pharmacist at Dean Health System.



Brent holds Bachelor of Science degrees in pharmacy and chemistry from the University of Wisconsin-Madison and the University of Wisconsin-La Crosse, and a Master of Business Administration degree from Edgewood College. He is a licensed pharmacist in Wisconsin and a member of the Academy of Managed Care Pharmacy and the Pharmacy Society of Wisconsin.

Tony Fields

My name is Tony Fields. I am the Chief Pharmacy Officer at the AIDS Resource Center of Wisconsin (ARCW). Previous to my time at ARCW I held multiple leadership roles with Walgreens over a 20 year career in the retail sector. I am a Wisconsin native with strong ties to my community and my profession. I served on multiple taskforces for Pharmacy Society of Wisconsin and also on their Board of Directors.

I have coached hockey, football, and baseball for my son and enjoy watching my three daughters as they progress through gymnastics and dance. My wife Dana and I are both healthcare professionals (Dana is a PA-C) and we see everyday the challenges access to care can have on our community. I am excited and humbled to be working on this taskforce with such great leaders in our profession.



Peter Fotos

Peter Fotos is Senior Director of State Advocacy for the Pharmaceutical Researchers and Manufacturers of America (PhRMA) with primary responsibility for outreach to state and local elected officials in the Midwest Region, which includes Illinois, Michigan, Missouri, and Wisconsin.

Prior to joining the State Advocacy team, Peter served four years on the Federal Advocacy team at PhRMA where he conducted outreach to the United States Senate on pharmaceutical issues related to Medicare, Medicaid, the Food and Drug Administration, and intellectual property rights.

Peter worked for eleven years on Capitol Hill in Washington, D.C. advising Members of Congress on health care policy in both the U.S. House of Representatives and the U.S. Senate. In his last position on Capitol Hill, Peter served as the Staff Director for the Subcommittee on Primary Health at the U.S. Senate Committee on Health, Education, Labor, and Pensions where he developed and collaborated on legislation related to prescription drugs, health care disparities, and long-term care.

A native of Atlanta, Georgia, Peter has a B.A. in Political Science from Presbyterian College in Clinton, South Carolina. He resides in Oak Park, Illinois with his wife and three children.



Janet Fritsch

Janet Fritsch graduated from the UW-Madison School of Pharmacy in 1987. She purchased Corner Drug Store in 1993, and has since purchased three other pharmacies in Baraboo, including a Dean Pharmacy in 2013. She partnered with Hometown in 2016 and currently manages 20 employees at two locations.

She has served 3 terms on PSW's Board of Directors. During those years, she was involved with the re-branding project, was on the PSW Technician Taskforce and was liaison with the PSW Technician Board. She has testified at 4 bill hearings in Madison and was privileged to be at 2 bill signings with the Governor.

She was awarded the Citation of Merit by the UW School of Pharmacy in 2016 and received the PSW Good Government Award in 2018. She enjoys being a clinical instructor for UWSOP and showing students the importance of community pharmacy.

She serves on the Sauk County Overdose Death Review Team and the St. Clare Hospital Diabetes Advisory Board. She and her staff participate in community events for medication reviews and fall prevention.

Janet has also owned and managed commercial properties in Downtown Baraboo with 16 commercial tenants since 1999.



She has been honored with the Baraboo Chamber of Commerce President's Award, Sauk County Historical Society Historic Preservation Award, Small Business Leadership Award and Sauk County's Small Business of the Year.

Janet is passionate about helping patients with their healthcare needs. She especially enjoys developing relationships with her patients and with her community.

Janet also enjoys her role as treasurer at her church in Baraboo. Janet has 3 daughters and 3 grandchildren. Her favorite activity is spending time with her grandchildren.

Michael Goldrosen

Dr. Goldrosen is a board-certified specialist in Internal Medicine, and he values building doctor-patient relationships in his practice. "It is important to me that I get to know patients and respect their preferences," he explains. "Everybody is unique, and I enjoy finding the best ways to work with a variety of personalities to accomplish the best and most satisfying result for each patient. Longer-term relationships bring many benefits to the doctor and the patient."

At Associated Physicians, Dr. Goldrosen provides expert primary health care services for patients throughout adulthood. He diagnoses and treats conditions ranging from minor upper-respiratory infections to chronic illnesses and serious health complications. In addition to office visits, Dr. Goldrosen also manages inpatient care, nursing home care, and end-of-life care for his patients. "I enjoy seeing a variety of patients from adolescence through senior years," he says. "I enjoy being able to work with patients to prevent illness as well as being able to diagnose and treat illnesses if they, unfortunately, occur."

Dr. Goldrosen received his medical degree from Loyola University in Chicago and completed his residency training in internal medicine at the University of Wisconsin. He serves on the Board of Directors for Meriter Hospital.



Ian Hedges

Ian Hedges has served as CEO of HealthNet of Rock County since August 2015. In 2014 & 2015, Ian served as the Associate Director of HIV Psychiatry and Psychosomatic Medicine for the American Psychiatric Association. In this role, Ian expanded a national education network on HIV and mental health, advocated for more mental health inclusions in the National HIV/AIDS Strategy, and help broadened the association's strategy around integrating primary care and mental health care.

Before he served in this role, Ian was the Special Assistant to the CEO and Medical Director, in which he advised the CEO on issues relating to mental health parity, minority health, and integrated care. Before coming to the APA, Ian served as the DC Healthy People Coordinator for the District of Columbia government, where he organized efforts around policy and planning health care services and delivery in the District of Columbia. Ian currently serves as a member of the Board of Directors for Nutrition & Health Associates/Rock County WIC Program.

Ian is a Beloit College graduate and resides in Beloit. Ian has been known to cheer on the Wisconsin Badgers and the West Virginia Mountaineers.



Nathan Houdek

Commissioner Afable appointed Nathan Houdek as Deputy Commissioner of Insurance for the State of Wisconsin in January 2019.

Deputy Commissioner Houdek serves as the chief operating officer for the Office of the Commissioner of Insurance. In that role, he is responsible for managing the office's regulatory, communications, legal, legislative relations, and administrative functions.

Mr. Houdek brings over 15 years of experience working in and around Wisconsin state government. He has worked on health insurance policy and regulatory issues in a variety of roles in the public and private sectors. He has also served as chief of staff for the current minority leader in the Wisconsin State Senate and as a principal at one of Wisconsin's largest public affairs consulting firms.

Deputy Commissioner Houdek grew up in northern Wisconsin and earned his BA and MBA degrees from the University of Wisconsin-Madison.



Lisa Lamkins

Lisa is the Advocacy Director – Federal Issues for AARP Wisconsin and has over 25 years of professional experience in non-profit membership organizations. Lisa has worked extensively on advocacy campaigns, legislative advocacy, grassroots organizing, community education, and program development and implementation. Prior to AARP, Lisa worked with the American Association of Colleges of Nursing and the American Apparel Manufacturer's Association.

Lisa current responsibilities at AARP focus on leading advocacy campaigns within Wisconsin, coordinating grassroots and key contact activity in support of AARP's legislative agenda, and providing in-depth substantive issue training to AARP volunteers, staff and partners on AARP priority issues with an emphasis in health care and financial security areas.

Lisa also provides leadership and coordination on public policy development and advancement of the AARP's public policy agenda.

Lisa received her Master's of Public Administration from the University of Missouri-Kansas City and Bachelor's in Political Science from Grinnell College.



Alan Lukazewski

Alan is the Director of Clinical Pharmacy at NeuGen, a shared service organization housing its not-for-profit health insurance plan WEA Trust, and its for-profit HMO Health Tradition, purchased from Mayo Health Systems in 2018. Since joining NeuGen he worked with his internal staff and PBM account team to implement several programs to manage pharmacy trend and the safe use of medications. His knowledge in adverse drug events has led to NeuGen applying analytics to identify value in pharmaceuticals by avoiding drugs with higher downstream medical costs. NeuGen has also matured efforts in medication non-adherence using analytics, enhanced utilization criteria, and member outreach, to manage specialty medication costs.

Prior to joining NeuGen, Alan worked at Oakwood Village Continuing Care Retirement Communities for 13+ years (2001-2015) as Director of Pharmacy Services where he collaborated with United Way and the Pharmacy Society of Wisconsin to implement a community-based comprehensive medication review program to help older adults avoid adverse drug events and falls. He received the Leadership Award from Dane County Public Health in 2012 for this effort. He has been preceptor for the University of Wisconsin School of Pharmacy since 2001.

Other professional experience includes working in long term care as a consultant with Weber Medical in Chicago (1984-1988), in retail pharmacy with Shopko Stores, Inc. (1989-1995) and PharMerica as Pharmacy Manager (1995-2001).



Alan graduated from the University of Illinois College of Pharmacy in 1984 and maintains certification in diabetes health education (1993) and geriatric pharmacy practice (2009). He has been Chair of the Pharmacy Society- Long Term Care Section, and has participated in the United Way Safe and Health Aging Delegation (2009- 2014).

Laura McFarlane

Laura E. McFarlane is the Chief of the Consumer Protection Section and Deputy Unit Director for the Public Protection Unit at the Wisconsin Department of Justice. Before joining the Department of Justice, Laura worked in private practice. In 2015, Laura was honored by the Wisconsin Law Journal as an Up and Coming Lawyer.

She received her J.D. from the University of Wisconsin Law School (cum laude) and her B.A. from Boston University (magna cum laude, phi beta kappa, with distinction).



Robyn Schumacher

Robyn Schumacher is Vice President, Broker and Consultant Relations for OptumRx, responsible for developing and managing key relationships with national, mid-market and boutique pharmacy consultant and broker firms across the United States. As part of this responsibility, Robyn works to ensure that OptumRx is delivering a consistent and differentiated value proposition in the market, in addition to understanding key industry trends and emerging customer requirements so this message is delivered deep within the organizations product and business develop areas. As an important liaison to the consultants that Robyn works with, she acts as their voice and plays a pivotal role in sharing that message with OptumRx's senior and executive leadership teams across the enterprise.

Robyn has over 15 years in the health care and pharmacy benefit management related space with a strong customer centric background having held leadership positions across network administration, sales, client and call center management areas. Prior to OptumRx, Robyn worked in physician recruitment and was a business office manager for a dental practice.

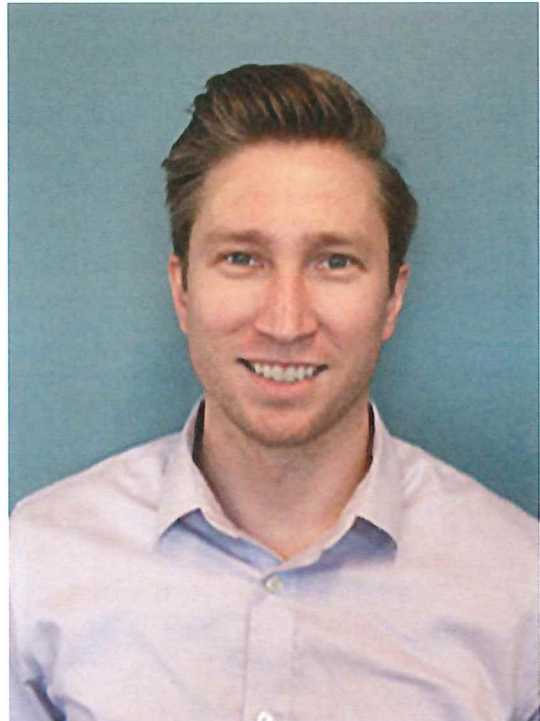
Robyn received her Bachelor of Arts degree from the University of Wisconsin – Stevens Point with a degree in Political Science.



Brian Stamm

My name is Brian Stamm and I am the Deputy Director of the Office of Strategic Health Policy at Wisconsin's Department of Employee Trust Funds. This role involves the oversight of all health, dental, wellness and pharmacy benefits in addition to HSA/FSA, Life, and Supplemental insurance for all participating State and Local government employees across the State of Wisconsin, which equates to roughly 240,000 members. We interact with health plans, a pharmacy benefit manager, all healthcare providers across the state, and other insurance administrators to ensure the best possible health outcomes for our membership. My team operates under the guiding principles of the IHI's Healthcare Triple Aim; focusing on patient experience, population health, and reducing the cost of care.

I am originally from Appleton and moved to Madison where I completed my undergraduate degree at UW-Madison focusing in Consumer Science. I then moved to Boston where I completed a dual degree MBA focusing in Health Sector Management and Leadership & Organizational Transformation at Boston University's Questrom School of Management. I am currently enrolled at Johns Hopkins Bloomberg School of Public Health working towards an MPH focusing on Infectious Disease and Epidemiology.



My entire career has been dedicated to the healthcare industry having spent eight years in pharmacy retail, four years on the provider side, four years on the payer side, and most recently joining health policy.

I look forward to working with the task force, learning from experts in the field, and sharing what knowledge I have on the subject.

Brian Stephens

Brian Stephens is the CEO of Door County Medical Center (DCMC) in Sturgeon Bay, WI. Originally from Abilene, TX, he is a graduate of Vanderbilt University and received his MBA from Marquette University. With over 20 years in healthcare, Brian has served as a revenue cycle consultant for Stockamp and Associates, and as a Director, Chief Financial Officer, and more recently in Administration roles with DCMC.

Along with his wife Amy of Greenwood, WI, and his two children, Maggie (15) and Ben (13), Brian enjoys running, hiking, boating, skiing, and generally following the kids in their activities.



Rep. Lisa Subeck

Lisa Subeck currently serves in the Wisconsin State Assembly, representing the 78th Assembly District encompassing the far west side of Madison. Prior to her election to the State Assembly, Lisa served two terms as an Alderwoman on the City of Madison Common Council. She has been active in state and local politics, both personally and professionally, for nearly 20 years.

Lisa is a graduate of University of Wisconsin-Madison, and her past work includes serving as the Executive Director of United Wisconsin and as the Executive Director of NARAL Pro-Choice Wisconsin. Before that, Lisa worked in the social services field focusing on issues of poverty, homelessness, and affordable housing at YWCA Madison. She began her career in childcare, working for several years with the Head Start and Early Head Start programs and also teaching technical college courses in early childhood education at Madison Area Technical College.

In the State Legislature, Lisa remains a staunch advocate for social and economic justice, as well as women's equality and reproductive choice.



In the State Legislature, Lisa serves on the Assembly Campaigns & Elections, Children & Families, Energy & Utilities, Health, Local Government, and Public Benefit Reform Committees, Vice Chair of the Adoption Task Force, and on the Joint Committee for the Review of Administrative Rules.

Lara Sutherlin

Lara Sutherlin is the Administrator of the Division of Trade and Consumer Protection at the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP). She is an attorney with extensive experience in complex litigation, having worked 13 years for the Wisconsin Department of Justice's (DOJ) Consumer Protection Unit. As an Assistant Attorney General, she was the lead Wisconsin attorney for numerous multistate investigations and cases against multinational pharmaceutical companies, regarding the off-label marketing of prescription drugs. She was also on the litigation team for the State of Wisconsin's Average Wholesale Pricing (AWP) cases against a number of multinational pharmaceutical companies. Prior to joining the DOJ, she practiced law in Boston, Massachusetts, where she specialized in wage-and-hour class actions, and she clerked in Iowa for then United States District Court Judge Michael Melloy. She is a frequent trainer and presenter on consumer protection matters both locally and nationally.

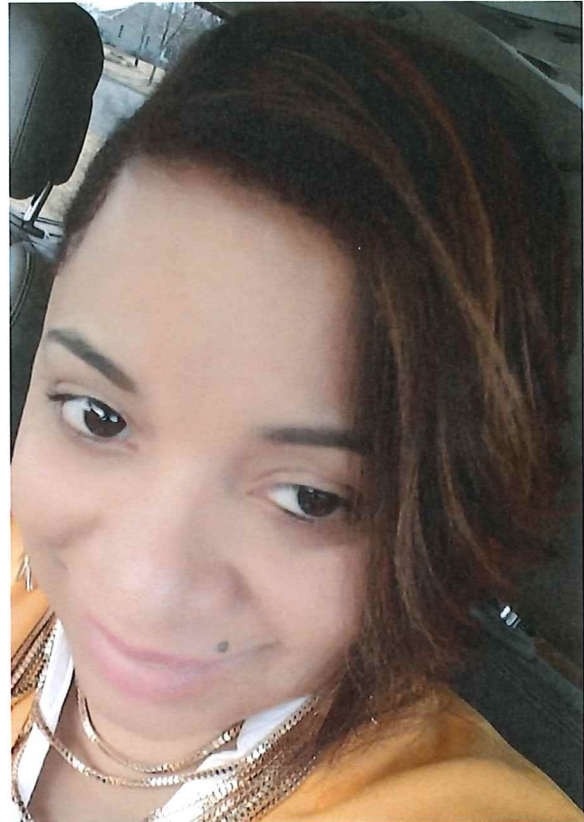
Among her other volunteer activities, she is the co-founder of the Wisconsin Coalition on Student Loan Debt, Inc., an organization designed to positively impact the student debt landscape in Wisconsin, and a trainer for the Anti-Human Trafficking Program with Lawyers Without Borders.



Yolanda Tolson

Yolanda Tolson, B.S. Pharm, is the Pharmacist in Charge at the St. Vincent de Paul Charitable Pharmacy (SVdPCP) in Madison, Wisconsin. She oversees day to day operations and manages drug inventory through a combination of wholesale purchases, donated drugs, and free medications through patient assistance programs. Her team is creating a progressive, interdisciplinary, environment utilizing the diverse skills of community-based and UW Madison affiliated volunteers to deliver direct patient care, and is working to obtain Wisconsin Pharmacy Quality Collaborative (WPQC) certification.

Yolanda received her B.S. in Pharmacy from the University of Wisconsin, Madison in 1995. In addition to St. Vincent de Paul Charitable Pharmacy Management, she serves as a faculty assistant and preceptor at the University of Wisconsin – Madison and is a relief pharmacist for local pharmacies in the Madison area.



Rep. Tyler Vorpapel

Tyler Vorpapel currently serves in the Wisconsin State Assembly, representing the 27th Assembly District. He graduated Plymouth High School, 2003; B.A. from the University of Wisconsin-Green Bay with bachelor's degrees in Political Science and Public Administration. In 2016, he completed the Emerging Leader Program at University of Virginia Darden School of Business.

Prior to his election to the State Assembly Tyler served as District Director for Congressman Tom Petri.

He is a member of the Sheboygan County Youth Apprenticeship Grant Advisory Committee, Sheboygan Elks #229, and the National Association of Parliamentarians. He also serves on the Republican Party of Sheboygan County (former member of executive committee); 6th District Republican Party of Wisconsin (former vice chair); and the Republican Party of Wisconsin (former member of executive committee).

Tyler is a major in the Wisconsin Wing, Civil Air Patrol Legislative Squadron (official Auxiliary of the U.S. Air Force).



Sue Wilhelm

Sue Wilhelm, BSPHarm, RPh, is Interim Clinical Officer and Director of Pharmacy Services for Security Health Plan. She has more than 20 years of experience as a health care leader and pharmacist, and a strong history for taking action to reduce pharmacy drug costs and improve quality of care for Security Health Plan members and Marshfield Clinic Health System patients. Over the course of her career, she has led and implemented programs aimed at reducing the cost of prescription medications, and improving the quality and efficiency of care for people taking those medications.

As Interim Clinical Officer and Director of Pharmacy Services at Security Health Plan, she led efforts to allow the health plan to sustain significantly reduced prescription drug costs for members. In addition, she has implemented programs that allow Security Health Plan to conduct evaluations of employee drug coverage for employer clients, and recommend strategies for reducing their drug spending. She also has oversight of the health plan's Quality Department managing NCQA, Star and HEDIS ratings, and accreditations.

Wilhelm received a Bachelor of Science pharmacy degree from the University of Wisconsin-Madison.



Appendix IV

PRESCRIPTION DRUG LITIGATION

WISCONSIN DEPARTMENT OF JUSTICE

1

PUBLIC PROTECTION UNIT

-
- Environmental Enforcement
 - Consumer Protection
 - Antitrust Litigation

2

ANTITRUST LAW

- Regulation of business conduct and organization.
- Purpose is to promote competition to protect the free market and benefit consumers.

3

ANTITRUST LAW – FEDERAL & STATE

- Sherman Act
- Clayton Act
- Federal Trade Commission Act
- Wisconsin's "Little Sherman Act" and "Little Clayton Act."
 - *Wis. Stats. Ch. 133.*

4

SUBOXONE

- Antitrust Lawsuit filed in 2016.
- Plaintiffs are 42 States and Commonwealths, led by the State of Wisconsin.
- Defendants are involved with the development, manufacture, and sale of Suboxone (buprenorphine/naloxone).

5

SUBOXONE

- Suboxone is a opioid replacement therapy for the treatment of opioid dependency.
- Until generic buprenorphine/naloxone was introduced to the market in 2013, Suboxone was the only replacement maintenance therapy that could be prescribed in an office setting and taken by patients at home.

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SUBOXONE

- 2002 Suboxone introduced as a sublingual tablet and granted "orphan drug" status by the FDA.
- The orphan drug designation provided the defendants with a seven year exclusivity period, expiring on October 8, 2009.
- Exclusivity = freedom to market as a brand-name drug, free from generic competition.
- After the exclusivity period expires, generic drugs may enter the market.

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HATCH-WAXMAN ACT

- Federal law passed with the intended purpose of pushing down prescription drug pricing by encouraging the manufacture of generic drugs by the pharmaceutical industry.
- Allows generic drugs to come onto the market more quickly through an Abbreviated New Drug Application. The ANDA process allows generic drug manufacturers to get drugs approved **without** replicating the costly and time-consuming clinical trials required of the original drug manufacturer.
- To be approved, an ANDA must demonstrate that the generic drug: (a) has the same active ingredients; (b) is pharmaceutically equivalent (same dosage form and strength); and (c) is bioequivalent (exhibiting the same drug absorption characteristics).

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GENERICS

- Oral drugs that are proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA.
- Oral drugs that carry the FDA's AB generic rating in a particular category may be substituted by pharmacists for a physician's prescription for a brand-name drug *without* the physician's approval.
- When generic drugs enter the market (typically at lower prices), it is not uncommon for the brand-name manufacturer to lose 80 percent or more of its brand-name sales.
- The entry of generics creates competition and genuine competition results in lower prices.

9

PRODUCT HOPPING - SUBOXONE TABLETS TO SUBOXONE FILM

- Defendants create Suboxone Film.
- Change to the dosage form (tablets to film) means generic tablets would not be pharmaceutically equivalent. **No AB rating.** Pharmacist may *not* substitute generic tablets if Film is prescribed.
- Film was patented and defendants enjoy a period of exclusivity (NO COMPETITION).

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MARKET CONVERSION – TABLETS TO FILM

- Campaign to drive the Film to market before the generic tablets could enter.
 - Promoting superiority of the Film over the Tablets to doctors, payors, and pharmacists.
 - Pricing the Tablets so that they were more expensive than the Film.
 - Hiring and compensating its sales force to incentivize them to sell the Film.
- September 2012, defendants publicly announce that they intended to discontinue Suboxone Tablets due to defendants' concerns regarding the safety of the Tablets. Defendants withdrew the Suboxone Tablets in March 2013.

11

DELAY OF GENERICS INTO THE MARKET

- Manufacturers of generic drugs filed ANDAs in 2009.
- Generic ANDAs were ultimately approved in February 2013.
- By the time generic tablets were introduced Suboxone Film constituted more than 85% of the market.

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DELAY OF GENERICS INTO THE MARKET

- Defendants failed to cooperate in good faith with the generic manufacturers in the submission of a joint Risk Evaluation and Mitigation Strategies (REMS) for the Tablets.
- Defendants filed a Citizen Petition asking the FDA to withhold approval.
- Due in part to the acts of the Defendants, the applications for generics were not approved until February 2013.

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SUBOXONE LAWSUIT

- Defendants engaged in an overarching conspiracy to prevent and delay generics to maintain their monopoly profits.
- The lawsuit seeks:
 - Injunctive Relief
 - Disgorgement
 - Penalties

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STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- 2013-14 sudden price spikes in a number of generic drugs.
- Congressional hearings.
- United States Department of Justice Criminal Investigation.
- State AGs' investigation and lawsuits.

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STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- 2016 State AGs' lawsuit:
 - 46 States.
 - 18 Corporate Defendants, and two corporate executives, all who were involved in the manufacture and sale of 15 generic drugs.
- 2018 State AGs' lawsuit:
 - 50 States and Territories.
 - 20 Corporate Defendants, and 15 corporate executives, all who were involved in the manufacture and sale of more than 100 generic drugs.

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STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- Both lawsuits allege the defendants engaged in conspiracies to:
 - Fix prices
 - Rig bids
 - Allocate drug markets
 - Other anticompetitive conduct
- Defendants claim the increased prices are the result of market forces and drug shortages.

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STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- Relief sought:
 - Injunctive remedies
 - Disgorgement
 - Civil Penalties

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CONSEQUENCES OF ANTICOMPETITIVE CONDUCT IN PHARMACEUTICAL SALES

- Anticompetitive conduct results in higher prices.
- Affects hospitals and pharmacists.
- Affects health insurance premiums and plans.
- Affects Medicare and Medicaid programs.
- Affects individual consumers.

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WISCONSIN DEPARTMENT OF JUSTICE

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Appendix V



Background on NGA Health

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
November 20, 2019

National Governors Association



Conference of Governors at the White House, 1908

Over 100 years of serving our nation's governors

Founded in 1908, the National Governors Association (NGA) is the nonpartisan organization of the nation's 55 governors. Through NGA, governors share best practices, address issues of national and state interest and share innovative solutions that improve state government and support the principles of federalism.

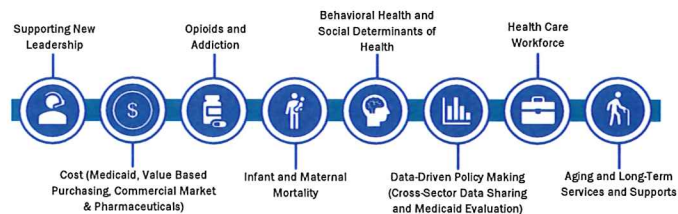


Organizational Structure

The NGA Center for Best Practices is a 501(c)(3) and part of our larger organization



NGA Health – 2019 Focus Areas



NGA Health – Recent Work on Pharmaceuticals

NGA Health

- **Pharmaceuticals and Public Health Crises** (2017 – 2018)
 - Identify strategies to address public health crises (e.g. opioids, hepatitis C) by increasing access to pharmaceuticals while ensuring fiscal sustainability of public programs
 - Collaborative work with 10 states (Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia and Washington)
 - Publication released August 2018: [Public Health Crises and Pharmaceutical Interventions: Improving Access While Ensuring Fiscal Sustainability](#)
- **Pharmaceuticals Learning Collaborative** (2019 – 2020)
 - Webinar series and multi-state meetings open to all states
 - Technical assistance with 6 states (Kentucky, Louisiana, Nevada, Ohio, Oregon, Wisconsin)

NGA Advocacy

- [2019 Principles For Federal Action To Address Health Care Costs](#)



Understanding the Prescription Drug Supply and Financing Chain

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

Jane Horvath Presentation
November 20, 2019

6

Pharmaceutical Market

BACKGROUND

Rx Industry Legal and Regulatory Framework

- **Food and Drug Administration, Health and Human Services Department**
 - Licenses prescription drug products
 - New Drug Application (small molecule)
 - Abbreviated New Drug Application (ANDA, generics small molecule)
 - Biologics License Application (large molecule, biologics and biosimilars)
 - Monitors Safety
 - Adverse Events Database
 - Sentinel System
 - Good Manufacturing Practices/physical plant inspections
 - Regulates Advertising
 - Wholesalers must also register
- **Centers for Medicaid and Medicare Services, HHS**
 - Drug Payment Amounts (Medicare Part B)
 - Anti kickback – Medicare and Medicaid (no drug-specific patient discounts or coupons...no inducement to use more services)
 - Coverage Policy (Medicare B and D)
 - Medicaid Drug Rebate Program
- **States license supply chain -- wholesaler to end purchasers**
 - Not all states regulate PBMs or Pharmacy admin service entities

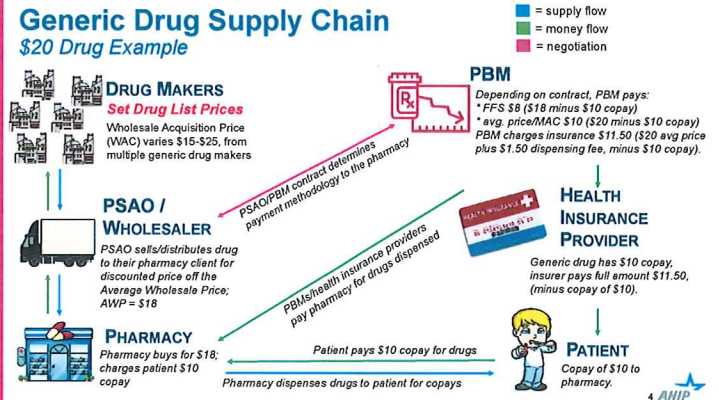
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Rx Purchase/Payment Terms

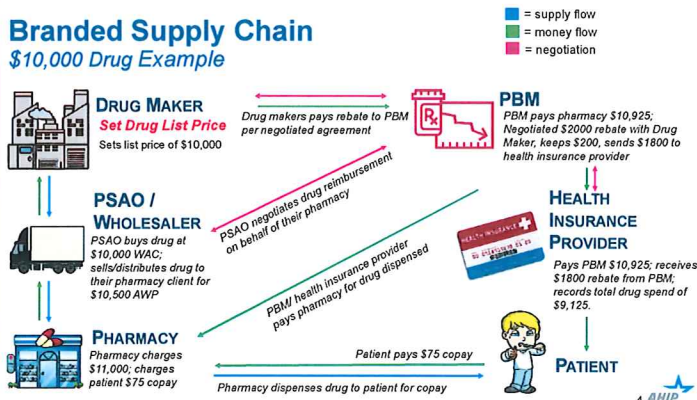
- **List Price – manufacturer catalogue price**
 - Often conflated with wholesale price
- **Wholesale Acquisition Price (WAC)**
 - Average of discounts provided to wholesalers purchasing the drug
- **Average Wholesale Price (AWP)**
 - Average of wholesaler prices to retail pharmacies and other direct purchasers
 - Sometimes used by payers to reimburse for drugs dispensed
 - Often thought to be overstated so payers reimburse @ AWP minus some %
- **Maximum Allowable Cost (MAC)**
 - Payer algorithm used to average prices for multi-source products used to reimburse pharmacies
 - MAC formula and Rx to which it applies varies by payer
- **Average Manufacturer Price (AMP)**
 - Average manufacturer sales price to wholesalers and retail pharmacies
 - Confidential
 - For Medicaid use only

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Generic Drug Supply Chain \$20 Drug Example



Branded Supply Chain \$10,000 Drug Example



Who Does What? Manufacturers

- **Bring Drugs to Market**
 - Buy promising molecules from research centers (Universities) that do the 'bench science'
 - Outright purchase price and/or contract for royalties if molecule is commercialized
 - Apply for patent (20 years),
 - or purchase patent from original developer, or lease rights from patent holder
 - Generally conduct R&D on molecules through Phase 1-3 clinical trials
 - Submit to FDA for approval
 - Manufacturer R&D can take 10 or 13 years, so 7-10 years left on patent at FDA approval
- **Set the price**
 - Often years before a drug reaches the market
- **Lease the drug license** to another company to market
- **Sales and marketing, life cycle management**
 - Price changes, price concessions, patient assistance
- **Regulated @ federal level**
 - States may license manufacturers whose drugs are sold in-state

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Who Does What? Wholesalers

- **Buy in large quantity** from manufacturers
 - Manufacturers can create 'tie-ins' buy all products direct from manufacturer
- **Store Rx**
- **Sell and Ship**
 - to very large purchasers
 - to regional distributors
 - to large pharmacies (local distributors)
- **A wholesaler can have several roles**
 - Specialty Pharmacy – on behalf of manufacturers or health plans for distribution of specialty drugs
 - Pharmacy Services Administration Organization (PSAO)
- **Regulated by States and Federal Food and Drug Administration (FDA)**

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Who Does What? PBMs (or Insurers without PBM)

- **Create pharmacy networks**
 - Negotiate pharmacy professional (or dispensing) fees
 - Set drug reimbursement amounts
 - Operate mail order pharmacy
- **Operate formulary**
 - Small plans take PBM national formularies, large plans may design their own
 - Negotiate manufacturer rebates based on formulary placement
 - Decide on pharmacy utilization management strategies
- **Claims payment**
 - Reimburse pharmacies and providers for drugs dispensed or administered
 - Bill insurer/client for Rx claims reimbursement
- **Collect manufacturer price concessions** based on paid Rx claims
- **Not all states license PBMs**

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Who Does What? Insurers

- **Contract with PBMs**
 - Scope of PBM role depends on insurer, usually size of insurer
 - Reimburse PBM for pharmacy 'claims paid'
- **Why contract with PBMs?**
 - Running pharmacy benefit has become complex
 - Response to rising prices (utilization management)
 - Negotiate and managing manufacturer rebates
 - Need to negotiate with pharmacies and create networks
- **Set overall premiums** based on expected medical and pharmacy costs
 - Rx costs are increasing share of premium (27% or so)
- **Run grievance and appeals** for pharmacy benefit
- **Are state licensed** (other than ERISA plans which are federally regulated)

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Who Does What? Pharmacies

- **Retail pharmacies** – open to public
 - Purchase drugs from wholesalers and distributors
 - May hire administrative services companies to handle claims wrangling and group purchase negotiations (PSAOs, see next slide)
 - Counsel patients
 - Can't drive brand name market share but can drive generic market share
- **Specialty pharmacies** – not open to public
 - May contract with manufacturers to handle specific 'specialty' drugs
 - May work with administering providers to get product to offices as needed
 - May provide case management for patients
 - May provide administrative assistance to administering providers (handling, billing etc.)
- **Licensed by States and somewhat by Federal programs** in which they participate

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Who Does What? PSOs

- **Pharmacy Services Administration Organization**
 - Target client is independent pharmacies
 - Independent pharmacies make ~90% of their revenue from dispensing
 - PSO market increasingly dominated by large wholesalers – McKesson, Amerisource Bergen, Cardinal (See next slide)
- **PSAO Services**
 - Network contracting with PBMs and health plans
 - Discount negotiations with Manufacturers and Suppliers for Rx purchase/acquisitions
 - Claims processing/dispute resolution and other administrative services
 - Performance monitoring in compliance with health plan/PBM contracts
 - Regulatory updates on pharmacy or durable medical equipment (DME) provider rules
- **Regulatory Framework**
 - State and federal regulation of pharmacies
 - State and federal regulation of wholesalers

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PSAO Ownership

Largest Pharmacy Services Administrative Organizations, by Members and Ownership, 2017

Pharmacy Services Administrative Organization (PSAO)	Participating Pharmacies	Ownership	Wholesaler Ownership?
Access Health	5,900	McKesson	Y
LeadorNET / MSInterNet / Managed Care Connection	5,600	Cardinal Health	Y
Elevate Provider Network ¹	4,500	AmerisourceBergen	Y
Arate Pharmacy Network	2,500	H.D. Smith/AAAP ²	Y
Third Party Station	2,100	Wholesale Alliance LLC ³	Y
EPIC Pharmacy Network, Inc.	1,700	Member-owned	N
Unify Rx	1,200	PSA Health/PPDK ⁴	N
American Pharmacy Network Solutions	700	American Pharmacy Cooperative	N

Sources: Drug Channels Institute research and estimates

¹ ABC's PSAO was previously called the GAP Provider Network

² In November 2017, AmerisourceBergen announced its acquisition of H.D. Smith's drug wholesaling business. Arate was not included in the transaction.

³ Arate was formed in 2014 by the merger of H.D. Smith's Third Party Network and United Drug's American Associated Pharmacies. The participating pharmacies figure includes the members of RxSide, which Arate acquired in December 2016.

⁴ Wholesale Alliance LLC is jointly owned by the following wholesalers: Burlington Drug, Dakota Drug, VIC Mutual Drug, Rochester Drug, Smith Drug, and Value Drug.

⁵ Unify Rx figures include the estimated PSAO members from TriNet Third Party Network (PSA Health) and Redefect Pharmacy Network (PPDK).

This table appears as Exhibit B7 in the 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. Available at <http://www.dciinstitute.org/2018-erom>



Potential Areas of Focus

Key Issues in Pharmaceutical Market

- **Definition**
 - Costly and/or
 - Requires special handling and/or
 - Requires provider training and/or
 - Requires patient case management or education
- **Startling Pricing**
 - Triage therapies become first line therapies
 - Rare disease treatment becomes chronic care treatment but pricing based on rare disease or salvage therapy (example: cystic fibrosis, HIV).

More Treatments Get Expedited Review/Less Data

- FDA fast track/reduced data approval paths 2018 ~56 NME Rx
 - 13 – Breakthrough – substantial treatment improvement
 - 42 – Priority Review – FDA decision within 6 months
 - 24 – Fast track – Rx treats serious conditions with unmet medical need
 - 4 – Accelerated Approval – serious medical condition with unmet medical need using surrogate clinical trial endpoints
 - 31 – Orphan Drug – treats patient populations of <200,000 people
- Expedited drug products may then be used for additional illnesses, but pricing remains the same

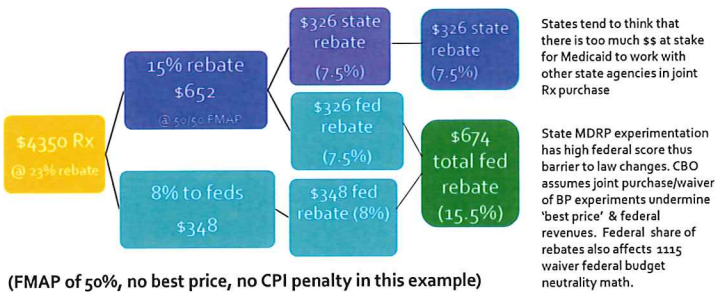
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Key Policy Issues in Rx Supply and Financing

Insurer	PBM	Manufacturer	Provider
<ul style="list-style-type: none"> • Insurer mergers • Insurer/PBM mergers • Rise of costly breakthrough/fast track drugs on patient costs and access • All the price-protected programs (Medicaid, CA, 340B, Medicare Part D) limit commercial insurer price negotiation ability 	<ul style="list-style-type: none"> • PBM/chain drugstore mergers • Treatment of independent pharmacies • How rebates are used • Lack of transparency/transparency laws 	<ul style="list-style-type: none"> • Corporate mergers • Focus on oncology and rare diseases (high-priced biologics) • Profits from price and price increases rather than sales • Gross to net bubble • Patent extensions 	<ul style="list-style-type: none"> • 340B program creates market inequities between eligible providers and ineligible providers • 340B program driving some provider consolidation

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Medicaid Rebates Complicate Policy



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Thank You!

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State and Federal Action Addressing Prescription Drug Access and Affordability

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
November 20, 2019

Agenda

- 01 Overview of State Action
- 02 Legal Challenges to State Action
- 03 Overview of Federal Action
- 04 Overview of Industry Action



Overview of State Action



Strategies Across Markets

States are pursuing a variety of strategies that have broad impact on pharmaceuticals access and costs across public, commercial, and self-insured markets:

-  Regulation of Pharmacy Benefit Managers (PBMs)
-  Importation
-  Regulation of Insurers
-  Public-Private Group Purchasing
-  Price Transparency
-  Pay for Delay
-  Affordability Boards
-  Price Gouging





Regulation of Pharmacy Benefit Managers (PBMs)

Regulation of PBMs has been the most prominent areas of action across states in recent years (40 bills addressing PBMs have been enacted in 2019 across 27 states):

- Prohibiting gag clauses in pharmacy contracts
- Imposing stronger disclosure and reporting requirements for PBMs
- Requiring PBMs to obtain licensure from the state
- Requiring PBMs to act as a fiduciary
- Regulating or prohibiting spread pricing
- Requiring that rebates and discounts received from manufacturers be fully passed on to the insurer
- Ensuring fair auditing of pharmacies by PBMs
- Prohibiting pharmacy copay clawbacks
- Regulating PBMs Maximum Allowable Cost (or MAC) lists
- Prohibiting PBMs from exclusively requiring mail-order pharmacies



Regulation of Insurers

States are pursuing a variety of approaches to regulate insurer benefit design and limit consumer cost sharing (32 bills addressing insurance design have been enacted in 2019 across 24 states):

- Restrict charging more than retail price at the point of sale
- Cap copayments for select drugs or drug classes
- Limit coinsurance percentage for specialty tier drugs
- Require prorated daily cost sharing rates for drugs dispensed by network pharmacies
- Limit the number of tiers on a formulary
- Establish step therapy protocol and override processes
- Restrict mid-year formulary changes, with certain exceptions



Price Transparency

Transparency has been a big focus in recent years regarding both drug prices (launch and increases) and PBM behavior (gag clauses and spread pricing):

- 2017 – 2019, 121 bills introduced across 33 states; 17 bills enacted across 11 states
- Transparency has also been implemented in conjunction with other strategies in some states (e.g., MA, NY)

Price transparency laws have typically included the following elements:

- Require manufacturers to report on and provide justification for drug launch prices and price increases over a certain threshold
- Require health plans to report on which drugs are driving plan spending
- Impose penalties for failure to report
- Publicize information ([California](#), [Nevada](#), [Vermont](#) have all released initial reports)



Affordability Boards

To address prices directly, several states have introduced and a few ([Maine](#), [Maryland](#) and [Ohio](#)) have enacted laws to establish authorities to review drug pricing and affordability:

- Boards or commissions tasked with reviewing and making recommendations regarding pricing, purchasing, and affordability challenges and opportunities in a state
- The charge and authority of affordability boards vary slightly across states
- In some states, these boards would have authority to set “allowable rates” for certain drugs



State Example: Massachusetts

Massachusetts recently introduced comprehensive health care legislation, which includes provisions related to pharmaceuticals:

- Creates a multi-pronged approach for increasing accountability for drug manufacturers
 - Subjects manufacturers of new, high-cost drugs to accountability reviews similar to existing processes for insurers and providers
 - Imposes a penalty on manufacturers that exponentially increase the cost of drugs which are sold or distributed in the Commonwealth
- Aims to increase state oversight of pharmacy benefit managers
 - Establishes a PBM certification requirement within the Division of Insurance
 - Requires PBMs to report financial data to increase transparency

Strategies for Public Programs

In addition to broader market strategies, states have been very active in advancing strategies to improve purchasing and manage access and costs for public programs:

Pharmacy Benefit Management	PBM Contracting	Reverse Auction Procurement	340B Oversight
340B for Corrections	Alternative Payment Approaches	Affordability Approaches	Multi-Agency Purchasing

Legal Challenges to State Action

Manufacturer Challenges

- Primarily related to state efforts to address price transparency and price gouging
- Alleged violations of trade secret laws, dormant commerce clause, due process, free speech laws, and federal patent laws
 - Alleged violations of trade secret laws are most compelling

State Examples



California

Lawsuit against California (PhRMA v Brown) is ongoing (lawsuit was dismissed in 2018 then amended and allowed to proceed in 2019)



Nevada

Lawsuit against Nevada (PhRMA and BIO v Sandoval) was dropped after state agreed to trade secret protection regulations



Maryland

Federal appeals court struck down Maryland's law ruling that it violates the dormant commerce (AAM v Frosh)

PBM Challenges

- Primarily related to state efforts to address transparency and disclosures, fiduciary duty, and MAC pricing
- Largely focused on alleged violations of ERISA preemption
 - Challenges have also included alleged violations to the dormant commerce clause, contract clause (Art 1, Sec. 10), Medicare Part D preemption, takings (5th amendment) and void for vagueness

State Examples

- The Pharmaceutical Care Management Association (PCMA) has challenged 5 state laws regulating PBMs and won three of those challenges (District of Columbia, Iowa, Arkansas)
- Thirty-three states filed an amicus brief with the Supreme Court, detailing that the Eighth Circuit rulings are not consistent with Supreme Court rulings on state authority to regulate payment rates and protect residents.



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How Legal Challenges Affect State Policy

PBMs

- Inconsistent rulings raise questions but have not limited activity
- States can mitigate risk by avoiding explicit reference to "ERISA" in legislation and clarifying that nothing is intended to conflict with existing law

Price Gouging

- Price gouging legislation limited to generics and off-patent brands in response to DC Circuit ruling on supremacy clause/patent law
- But then the 4th circuit found that limiting price gouging to generics was not fair

Affordability Boards

- New legislation has been more limited to state/local government purchasers and payers
- Such limitations protect a state from a dormant commerce clause lawsuit, but undermine the intent and effectiveness of the boards



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Overview of Federal Action



Federal Action – 116th Congress

- Over 20 hearings
 - Senate: Finance, Health Education Labor and Pensions (HELP), Judiciary, Aging
 - House: Energy and Commerce, Ways and Means, Oversight and Reform
- Over 130 bills have been introduced this Congress
 - At least 60 bills have bipartisan support and approximately 20 of those have support in both chambers
 - Bipartisan bills include those focused on:
 - Generic and biosimilar development (CREATES Act, FAST Act)
 - Pay-for-delay/anti-competitive behavior (Preserve Access to Affordable Generics and Biosimilars Act)
 - Patents and transparency (FAIR Drug Pricing Act, Biologic Patent Transparency Act, Prescription Drug Price Transparency Act, BLOCKING Act)
 - Importation (Safe and Affordable Drugs from Canada Act 2019)



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Federal Action – Bills to Watch

- **S.2543 - Prescription Drug Pricing Reduction Act of 2019**, sponsored by Sen. Chuck Grassley (R-IA)
 - Major **Medicare** provisions
 - Impose an inflationary rebate on Part B and Part D drugs
 - Establish a maximum add-on payment for Part B drugs
 - Establish a beneficiary out of pocket maximum for Part D drugs
 - Shift risk during the catastrophic phase to plans and manufacturers
 - Establish new reporting and transparency requirements
 - Major **Medicaid** provisions
 - Raise cap on rebates from 100 to 125 percent of the Average Manufacturer Price (AMP)
 - Exclude authorized generics from the calculation of AMP
 - Enable collection of rebates on certain drugs provided as part of outpatient hospital services
 - Prohibit spread pricing by pharmacy benefit managers
 - Permit value based purchasing arrangements for gene therapies
 - Create new standards related to reporting and conflicts of interest



Federal Action – Bills to Watch

- **S.1895 - Lower Health Care Costs Act**, sponsored by Sen. Lamar Alexander (R-TN) and Sen. Patty Murray (D-WA)
 - Broad package addressing health care costs that includes provisions on pharmaceuticals, such as:
 - Allowing certain generic or biosimilar drugs to enter the market earlier
 - Imposing new rules for insurers' contracts with pharmacy benefit managers and health care providers
 - Imposing new transparency requirements
- **S.1391 - Fair Accountability and Innovative Research Drug Pricing Act of 2019**, sponsored by Sen. Baldwin (D-WI)
 - Reporting and justification for certain drug price increases
- **H.R. 3 - Lower Drug Costs Now Act of 2019**, sponsored by Rep. Frank Pallone (D-NJ)
 - Would establish price negotiation for certain drugs in Medicare
 - Negotiated prices must also be offered under private health insurance unless insurers opt out
 - The negotiated maximum price may not exceed an international benchmark
 - Drug manufacturers that fail to comply would be subject to civil and tax penalties



Federal Action – Administration

? International Pricing Index: Advance notice of proposed rulemaking issued in October 2018 to set target sales prices for certain Medicare Part B drugs using an international benchmark based on prices in select foreign countries.

? Importation: Safe importation action plan was announced in July

- Pathway 1: HHS will outline a process for states, wholesalers, or pharmacists to submit plans for approval of demonstration projects to import drugs from Canada
- Pathway 2: Would allow manufacturers to import versions of their drugs sold in other countries if they can ensure it is the same version sold in the U.S. and meet other requirements.

X Pricing in Television Advertisements: A rule requiring drug price disclosure in television advertisements was blocked in federal court in July, the U.S. Department of Health and Human Services (HHS) filed a notice of appeal in August.

X Safe Harbor Proposed Rule: A proposed rule that would have eliminated safe harbor protection for drug rebates for Medicare Part D plans and Medicaid managed care organizations was withdrawn in July



Overview of Industry Action

Consolidation

Recent Mergers and Acquisitions

Insurers, PBMs, and Pharmacies

- Aetna/CVS
- Cigna/Express Scripts
- Anthem/IngenioRx

Manufacturers

- Takeda/Shire
- BMS/Celgene
- Eli Lilly/ Loxo Oncology



New and Existing High-Cost Drugs

- Price Increases
 - The costs of oral and injectable brand-name drugs increased annually by 9.2 percent and 15.1 percent, respectively, largely driven by existing drugs
- Pipeline/New Specialty
 - Late stage pipeline growth is mostly driven by specialty and niche therapies across a range of diseases
 - Oncology leads new launches
 - The prices of new drugs entering the market continue to rise, especially for oncology and orphan drugs
- Notable Products Highlight Challenges
 - Naloxone – opioid overdose reversal
 - Insulin - diabetes
 - Zolgensma – spinal muscular atrophy



Appendix VI



Tony Evers, Governor
Mark V. Afable, Commissioner

Wisconsin.gov

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Governor’s Task Force on Reducing Prescription Drug Prices Proposed 2020 Workplan

January 2020

Meeting Date/Location
January 22, 2020/Milwaukee
Subject Matter
Pharmacy Benefit Managers (PBMs)
Topics
<ul style="list-style-type: none"> • How PBMs function • Understanding different PBM business models • Review of other state’s PBM related laws • Overview of PBM efforts to increase prescription drug affordability • Concerns or support for additional transparency in the supply chain

February 2020

Meeting Date/Location
February 19, 2020/Oshkosh
Subject Matter
PBM con’t/Health Insurers/Self-Insured Employers
Topics
<ul style="list-style-type: none"> • Perspectives on offering affordable prescription drug coverage • Discussion on manufacturer coupons and enrollee cost sharing • Insurer/Employer interaction with PBMs • Overview of insurer/employer efforts to increase prescription drug affordability • Concerns or support for additional transparency in the supply chain • Discuss potential policy proposals

March 2020

Meeting Date/Location
March 18, 2020/Wausau
Subject Matter
Pharmacists & Pharmacies
Topics
<ul style="list-style-type: none"> • Review of different pharmacy models • Pharmacy interaction with PBMs • Understanding Maximum Allowable Cost (MAC) pricing • Overview of pharmacy efforts to increase prescription drug affordability

- Concerns or support for additional transparency in the supply chain
- Discuss potential policy proposals

April 2020

Meeting Date
April 15, 2020/Rhinelanders
Subject Matter
Wholesalers & Pharmacy Services Administration Organizations (PSAOs)
Topics
<ul style="list-style-type: none"> • Understanding wholesaler processes • Importation (role of US wholesalers, pros/cons) • Understanding other state importation laws • PSAOs: what are they, what is their role in the supply chain, how are they regulated • Overview of efforts to increase prescription drug affordability • Concerns or support for additional transparency in the supply chain • Discuss potential policy proposals

May 2020

Meeting Date/Location
May 20, 2020/La Crosse
Subject Matter
Pharmaceutical Manufacturers
Topics
<ul style="list-style-type: none"> • Understanding the drug manufacturing process (pricing, R&D, distribution, etc.) • Review of other state's laws impacting manufacturers • Overview of efforts to increase prescription drug affordability; including an explanation of manufacturer consumer incentive programs • Concerns or support for additional transparency in the supply chain • Discuss potential policy proposals

June 2020

Meeting Date/Location
June 17, 2020/Sturgeon Bay
Subject Matter
Efforts to Directly & Immediately Impact Prescription Drug Affordability
Topics
<ul style="list-style-type: none"> • Drugs used to treat specific disease states: <ul style="list-style-type: none"> ◦ Barriers to affordability/solutions? • Consumer access points for low cost/reduced cost prescription medication • Understand how affordability impacts populations differently (i.e. older adults, those with chronic conditions, low income populations) • Review other state solutions to improve consumer access to affordable prescription drugs • Discuss potential policy proposals

- **No Task Force meeting in July 2020.**
- **The Task Force will likely convene in August or September to review recommendations.**