National
Multiple Sclerosis
Society

Testimony Supporting House Bill 135
Senate Health Committee, The Ohio Senate
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The National Multiple Sclerosis Society
November 30, 2022

Chairman Huffman, Vice Chairman Antani, Ranking Member Antonio and members of the committee, The National Multiple Sclerosis Society appreciates the opportunity to submit comments in support of House Bill 135, crucial legislation for patients that passed the Ohio House without opposition. We thank Rep. Manchester and Rep. West for introducing legislation that if passed, will assist people living with multiple sclerosis (MS) access the medications they need to live their best lives.

As one of over 60 patient groups and professional health care organizations that support HB 135, we strongly believe HB 135 is a patient center bill that would bring relief and remove needless administrative barriers to consumers trying to access affordable medications.

Research shows that early and ongoing treatment with a disease-modifying therapy (DMT) is the best way to modify the course of MS, prevent the accumulation of disability, and protect the brain from damage. Yet, many people living with MS cannot access the medications they need to slow disease progression. Escalating costs within the entire pharmaceutical supply chain are creating significant barriers to treatment, including higher costs, increased stress, and a greater burden for those who already live with a chronic, rare and life-altering condition. Third-party assistance programs are at least one significant way to help our patients address these escalating challenges.

For people living with MS, copay accumulators make it more difficult to receive the disease modifying therapies (DMTs) they need. As many as 70% of people living with MS rely on some type of copay assistance to maintain access to their disease-modifying therapy. DMT's and symptom management medications are critical to slow the progression of MS. In 2021, the median price of these therapies was over $100,000 a year. The few generics currently available cost between approximately $25,000 and $75,000 per year.

I think it is very important to note a few things about HB 135. This legislation was carefully drafted to not interfere with the usage of potentially lower cost generic medications by a health plan or PBM. That language was included from the very start of this legislative process to ensure members of the legislature and the public that this bill would not cause the "steering" of patients to more expensive drugs. Still, I think it is important that you understand that people with MS are not choosing medications based on copay assistance programs or rather a medication is $70,000 a year versus $100,000. They will tell you they are working with their providers to find the treatment to slow their disease progression. They are choosing their medication based on which one may allow them to keep the use of their legs the longest or reduce their fatigue so that they may be employable. Additionally, patient organizations like ours worked with the bill sponsors and others to include language in the bill that will allow health plans and PBM's to continue to have great flexibility in managing their formularies. HB 135 does not mandate the coverage of any medication by insurers due to the use of third-party financial assistance.

As insurance companies and PBM's increasingly shift the cost of specialty medications to patients through extraordinary out-of-pocket maximums including deductibles, copayments, coinsurance and the

use of high-cost tiered formularies, specialty-pharmacies and formulary exclusions, it does not go unnoticed that the plans increase their bottom lines by either refusing to accept or just keeping both the third-party financial assistance provided for the patient and not apply that assistance to reducing these out-of-pocket mandates. Would any member of this committee find it acceptable if a family member or other party paid your mortgage payment for a month, but the financial institution told you they wouldn't apply that amount to reduce your debt simply because you were not the one making that payment and the funds came from someone other than you?

During her sponsor testimony to this Committee on November 16th, Rep. Manchester was asked to respond to a comment that copay accumulators are used solely to discourage patients and their doctors from choosing generics or less-costly prescription drug alternatives. To further address that original comment, I have attached a report from IQVIA, a global research firm of advanced analytics, technology solutions and clinical research services to the life sciences industry. Their report shows that 99.6% of manufacturer copay assistance exists solely for medications with no generic alternative.

I believe another finding that this committee should strongly consider regarding HB 135 was a recommendation from the Ohio Prescription Drug Transparency and Affordability Council, a body to whom Representative Manchester also referenced to during her sponsor testimony. I was appointed to and served on that Council, along with statewide business leaders including the Ohio Manufacturers' Association and the Ohio Business Roundtable labor unions, various state agencies, including AARP and other groups.

After extensive hearings and the discussions concerning the numerous presentations made by many groups that came before the Council, the Council, unanimously issued a report, which I have also attached, making several recommendations to the Governor and Ohio General Assembly on how to better assist purchasers and consumers of prescription drugs to address cost factors. One of those important recommendations was "Find Additional Ways to Benefit the Consumer." This recommendation, and I am quoting directly from this report, said Ohio should "expand options for the use of copayment programs produced by drug manufacturers to help defray the costs of expensive medications." The report further said, "Customers would benefit if these copayment programs could be applied to members' deductibles and out of pocket maximums." In the formulation of this recommendation, no party, including the business organizations on the Council, expressed any concern or objection that this practice would increase costs or premiums to purchasers. While I realize HB 135 is not just about manufacturer assistance programs, this important recommendation to assist consumers is the very heart of HB 135.

Until we find comprehensive, real solutions to the challenges in our overall healthcare system that prevent people from affordably accessing the care and treatments they need, we cannot allow needless administrative barriers to prevent use of real financial assistance programs to patients, such as copay assistance programs. We need to address challenges and barriers in our pharmaceutical supply chain that often make medications and other care unaffordable. There is no one party to blame for this ongoing problem. However, until those systematic overhauls are made, public policymakers must be willing to embrace and adopt measures that help patients, such as those contained in HB 135. House Bill 135 simply offers opportunities that allow consumers to receive assistance of any kind to pay for their medications and for that assistance to count towards their out-of-pocket costs.

This committee and Ohio lawmakers now have a chance to truly help patients and families by passing and enacting House Bill 135. In addition to my testimony, you have received the written testimony of three Ohioans living with MS who have been horribly burdened by the practice of copay accumulators. Additionally, over 60 patient advocacy groups and professional health care organizations strongly support this important legislation. Honestly, it's hard for me to understand why patients would be asked to give copay assistance when Health Plans and PBM's themselves are already accepting "assistance" in the form of rebates, from drug manufacturers. Still, those same health plans and PBM's

oppose assistance from those same manufacturers if that assistance is coming through a patient and they do not get to control the process and make money off that assistance? At least copay assistance is transparent, we can't say the same for the same thing for rebates.

I will close by thanking Reps. Manchester and West who have worked tirelessly, alongside advocates, to try to address many of the challenges brought by the opponents of the bill, and I think that is reflected by the unanimous passage of the bill by the Ohio House.

On behalf of the National Multiple Sclerosis Society and the patients we represent, thank you for your consideration of this legislation. I am happy to attempt to answer any questions that members of the committee may have at this time.

AN EVALUATION OF CO-PAY CARD UTILIZATION IN BRANDS AFTER GENERIC COMPETITOR LAUNCH

Introduction

Patient savings programs, in particular co-pay card programs, continue to bear scrutiny across the industry. Co-pay card programs are patient-based programs designed by manufacturers to assist commercially insured and cash paying patients in affording their medications. Industry stakeholders are especially critical of these programs, claiming they incentivize the use of high-cost therapies – including the purchase of branded drugs over their less expensive, generic equivalents. In an effort to quantify the use of patient savings programs among brands that have lost exclusivity on their patents (LOE) and have generic equivalents in the market, IQVIA identified post-LOE brands in pharmacy claims data and measured co-pay card use within them.

Approach

IQVIA analyzed retail, pharmaceutical, patient claims-level data from 2013 through 2017 to quantify the use of co-pay card programs in brands that have lost exclusivity. Brands with at least one generic equivalent were identified as "post-LOE" in the analysis. IQVIA further categorized the post-LOE brands by those with a manufacturer co-pay offset program (i.e, brands that demonstrated at least 1% of volume adjudicated with a co-pay card while a generic was available). Claims volumes were aggregated and compared across these different market cohorts (summarized in Figure 1).

Co-pay card use is captured in the IQVIA data at a claim level using the secondary payer information present on the claim. Among commercial claims, secondary payers predominantly are attributed to co-pay card programs provided by manufacturers.

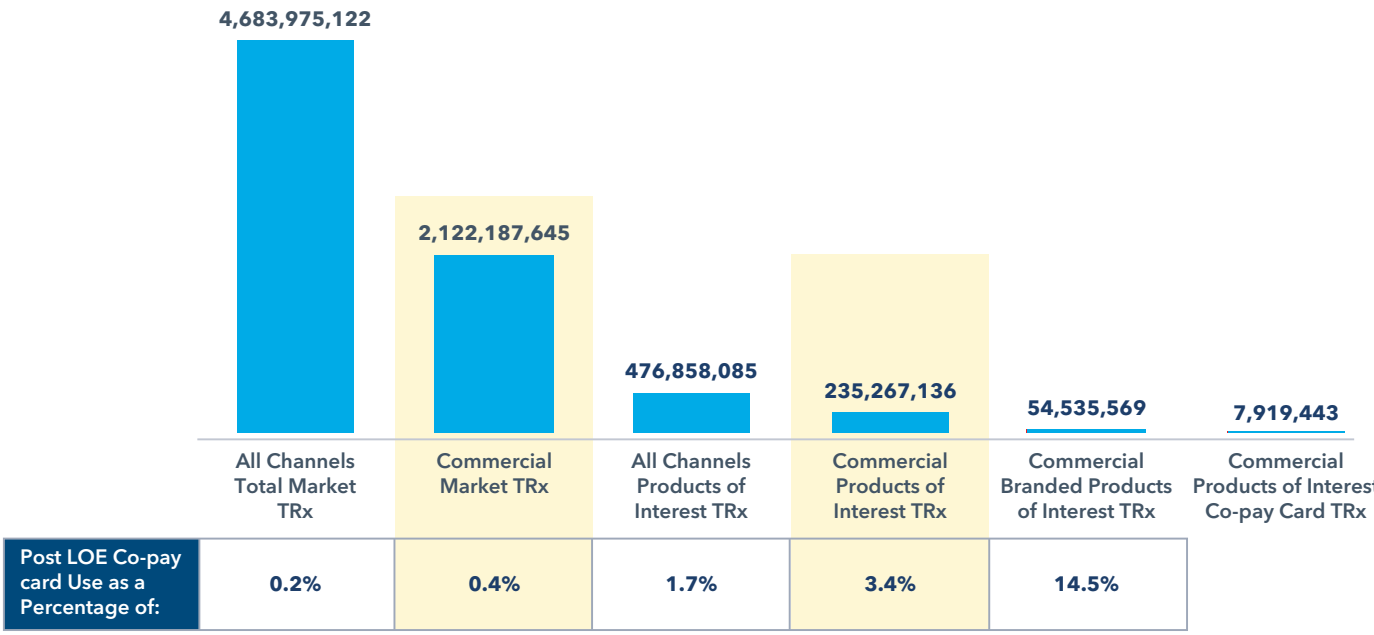
Figure 1: Market Cohort Definitions

MARKET COHORT	DESCRIPTION	B AND/OR G
All Channels Total Market TRx	Encompasses all volume across payer channels.	Brand & Generic
Commercial Market TRx	Limits to commercial volume only.	Brand & Generic
All Channels Products of Interest TRx	Flags brands with at least one generic entry and further refines by limiting to brands that had at least 1% of their volume adjudicated with a co-pay card post-LOE. The generic volume associated with these brands is also included to reflect the molecule's volume across payer channels.	Brand & Generic
Commercial Products of Interest TRx	Limits to the commercial volume for Products of Interest.	Brand & Generic
Commercial Branded Products of Interest TRx	Reflects the branded commercial volume for the products of interest.	Brand Only
Commercial Products of Interest Co-pay Card TRx	Represents the branded products of interest that were filled with a co-pay card.	Brand Only

Results:

Despite continued public attention, patient co-pay assistance program claims only make up a small proportion of commercial, prescription volume for post-LOE products with co-pay card programs. As demonstrated in Figure 2, a small subset of commercial volume is represented by post-LOE brands with evidence of a manufacturer-sponsored co-pay card programs. While co-pay cards are still being utilized by patients on brand scripts after LOE, the use is limited and only makes up 0.4% of the total commercial market volume. The total commercial volume for post-LOE products with a co-pay card program available (the brands and their generic counterparts) represent 11.1% of commercial volume. For prescriptions filled with a post-LOE brand that sponsors a patient support program, 14.5% of claims are associated with these programs.

Figure 2: Claims Volume by Market Cohort (2017)



Source: IQVIA NSP, NPA, and FIA data sets; IQVIA Analysis

Implications:

While some manufacturers may implement strategies to retain brand volume after the loss of exclusivity, manufacturer co-pay assistance programs appear to have limited use and represent only part of a brand's potential retention strategy. Formulary exclusions and automatic generic substitution at the pharmacy are effective tools for promoting generic uptake, thereby curtailing co-pay card use among post-LOE brands. Additionally, co-pay card use on branded scripts post-LOE represents a sliver of the total commercial market, making up only 0.4% of volume across all products. When narrowing in on the total commercial volume for products where manufacturer co-pay assistance is available, only 3.4% of total volume is attributable to prescriptions using these programs. If patient savings programs were having a substantial impact on generic product uptake after loss of exclusivity, one would expect to see higher utilization in the market.

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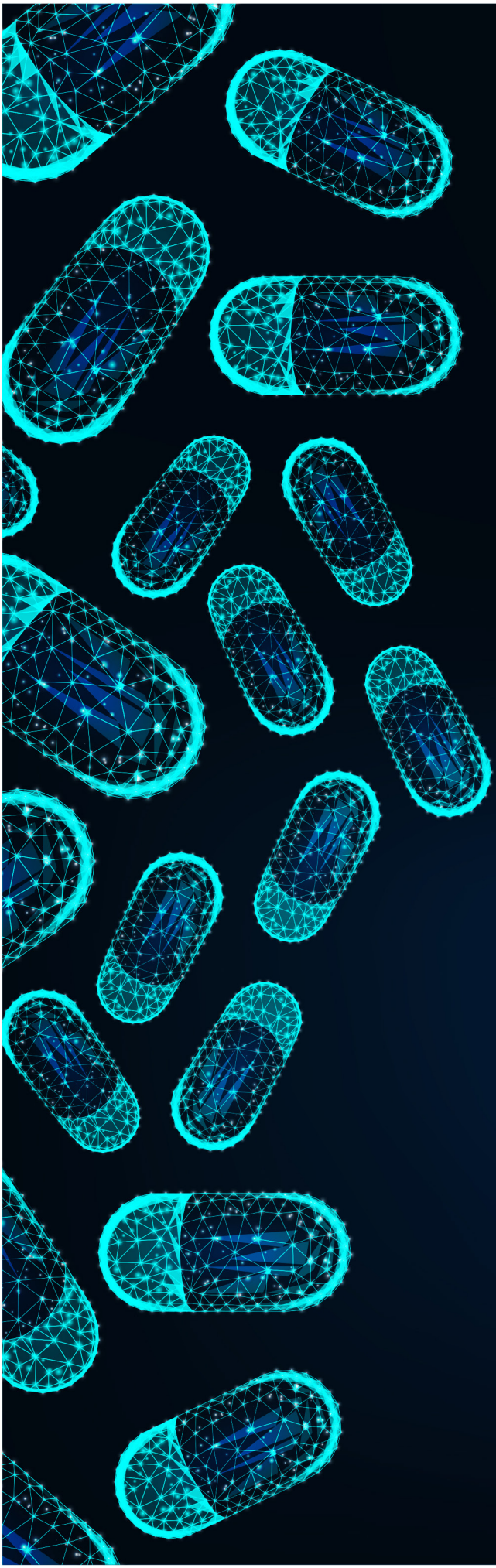


Prescription Drug Transparency and Affordability Council

2020

Report of Recommendations

Executive Summary

Created in 2019 in House Bill 166 of the Ohio 133rd General Assembly, the Prescription Drug Transparency and Affordability Advisory Council is comprised of a diverse group of government, industry, and consumer experts convened to assess the transparency, pricing, and accessibility of prescription drugs in the State of Ohio.

Purpose
The Council was organized and led by the Ohio Department of Administrative Services and was tasked with providing recommendations to the General Assembly, Governor Mike DeWine, and the Joint Medicaid Oversight Committee regarding Ohio's best path forward for:

- Achieving prescription drug price transparency in the State of Ohio.
- Establishing new payment models or other avenues to create the most affordable environment for purchasing prescription drugs.
- Leveraging Ohio's purchasing power across all state agencies, boards, commissions, and similar entities.
- Creating efficiencies across different health care systems, to reduce duplicative service delivery, ensure patients receive high quality and affordable prescription drugs, and support quality care and outcomes.
- Identifying which critical outcomes can be measured and used to improve this state's system of purchasing affordable prescribed drugs.
- Examining how federal, state, and local resources are being used to optimize outcomes and identify where the resources can be better coordinated or redirected to meet the needs of consumers.

Council members:

- **Matt Damschroder**, Director, Ohio Department of Administrative Services (statutory member)
- **Lance Himes**, former Interim Director, Ohio Department of Health (statutory member) *Dr. Amy Acton at the onset of the Council's creation*
- **Maureen Corcoran**, Director, Ohio Department of Medicaid (statutory member)
- **Lori Criss**, Director, Ohio Department of Mental Health and Addiction Services (statutory member)
- **Stephanie McCloud**, former Administrator, Ohio Bureau of Workers' Compensation (statutory member)
- **Steve Ferris**, Government and Public Affairs Director, Discount Drug Mart (appointed by the Ohio Senate)
- **Ryan Augsburger**, Managing Director of Public Policy Services, Ohio Manufacturers' Association (appointed by the Ohio Senate)
- **Holly L. Pendell**, Director, Advocacy and Activist Engagement, National Multiple Sclerosis Society (appointed by the Ohio Senate)
- **James Flynn**, Managing Partner, Bricker & Eckler (appointed by the Ohio House of Representatives)
- **Latoya Peterson**, Associate State Director for Advocacy, AARP (appointed by the Ohio House of Representatives)
- **Mark Totman**, Vice President, International Union of Operating Engineers (appointed by the Ohio House of Representatives)
- **The Honorable Christina Muryn**, Mayor of Findlay, Ohio (appointed by Governor Mike DeWine)
- **Pat Tiberi**, President and CEO, Ohio Business Roundtable (appointed by Governor Mike DeWine)

Meetings
The Council held six public meetings featuring in-depth discussions and review of relevant topics, and presentations from industry and government experts, as well as the bipartisan policy thought leaders and trade associations. While the first meeting of the Council was held in-person, all subsequent meetings were held virtually due to the COVID-19 pandemic. All meeting materials and recordings of all virtual meetings are archived on the Department of Administrative Services website at das.ohio.gov.

February 26, 2020
The Council's inaugural meeting on Feb. 26, 2020 featured a presentation from the National Governor's Association (NGA), which seeks bipartisan solutions to priority issues and matters of public policy and governance at the state, national and global levels. For several years, the NGA has worked with governors and their senior policy advisors in the states on the issue of prescription drug access and affordability. Representatives from the NGA's Center for Best Practices joined Horvath Health Policy to present an overview of the prescription drug supply and financing chain.

May 27, 2020
The Council next met on May 27 and heard a presentation from the West Virginia University School of Pharmacy that explained its Rational Drug Therapy prior authorization program. A separate presentation reviewed the State of New Jersey pharmacy benefit manager (PBM) reverse auction process that requires PBMs to engage in a competitive bidding process to manage benefits for New Jersey's public employees and dependents.

June 15, 2020
A June 15 meeting explored pharmacy programs within several State of Ohio agencies, including the Ohio Bureau of Workers' Compensation and the Ohio Departments of Administrative Services, Medicaid, and Mental Health and Addiction Services. The agencies manage programs that provide prescription drugs, and pharmaceutical services and supplies to State of Ohio employees, Ohio injured workers, and Medicaid recipients as well as other State facilities, county health departments, community mental health agencies, free clinics, county jails, and non-profit organizations.

July 8, 2020
The Council heard presentations from two biopharmaceutical and biotechnology trade associations during its July 8 meeting. The Biotechnology Innovation Organization (BIO) represents biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. PhRMA represents the United States' leading biopharmaceutical research companies and supports the search for new treatments and cures. Topics of discussion included pharmaceutical research and development, rebates, pricing, and cost sharing.

August 19, 2020
Presenters during the August 19 meeting included representatives from three organizations representing the interests of PBMs, large employers and older Americans. The Pharmaceutical Care Management Association, a national association representing PBMs, presented on the role of PBMs in the health care system. The American Association of Retired People, a membership organization for Americans age 50 and older reviewed that organization's perspective on the importance of the national discussion on prescription drug costs to its constituency and consumers in general. The final presentation was delivered by ERIC, a national advocacy organization

representing large employers that provide health, retirement, paid leave and other benefits to their nationwide workforce. ERIC's presentation covered the issue of unsustainable prescription drug prices, solutions to addressing the issue, and suggested supply chain solutions.

August 26, 2020
The Council's meeting on August 26 featured a full agenda of three presentations, as well as written testimony from two additional interested parties. A representative of the Ohio Pharmacists Association and 3 Axis Advisors spoke about concerns related to transparency in the drug pricing system, particularly in relation to brand specialty drugs, and delved into common business practices of PBMs such as spread pricing and ownership of specialty pharmacies. The National Multiple Sclerosis (MS) Society then provided an overview of its organization, price trends for MS disease modifying treatments, experiences of people with MS obtaining needed medications, and suggested policy solutions that would benefit the MS community. Equitas Health, a regional nonprofit community health care system that is also one of the largest health care organizations serving LGBTQ+ people and people living with HIV/AIDS in the United States, detailed its use of the 340B Program. The program provides discounts on outpatient prescription and over-the-counter drugs to certain safety net health providers. Equitas advocated for policies to protect the 340B Program as well as ban co-pay accumulators that can unexpectedly increase prescription drug costs for vulnerable patients.

In written testimony, Tom Whiston, a Morrow County Commissioner, pharmacist, and Past President of the Ohio Pharmacist's Association detailed his family's experience managing its community pharmacy that he argues was forced to close due to market forces. Gary Dougherty with the American Diabetes Association in written testimony offered suggested solutions for controlling the cost of insulin for diabetes patents.

Recommendations

Following six months of research, discussion, and engagement with experts and stakeholders, the Council is pleased to recommend further exploration of the following policies and actions that could bring needed transparency to prescription drug pricing and payment modeling while improving efficiency in the delivery of health care to Ohioans[1].

1 Consider a single prescription drug purchasing plan for public employers across the state.

The State of Ohio can currently only bid for services and cover benefits for State of Ohio employees and their families. Ohio is home to numerous other public entities that are also constrained in their bidding flexibility. The Council recommends further research into laws, rules, and policies that restrict the ability of public entities to create a single prescription drug purchasing plan.

A single plan that combines individual entities' purchasing power would yield greater savings with a larger pool of covered individuals. Such a plan would require strict oversight and transparency to uphold the best interests of Ohio patients and taxpayers.

This recommendation addresses Ohio Revised Code Sections 125.95 (C) (1) and 125.95 (C) (3).

[1] The Council recognizes some recommendations may require policy changes or revisions to the Ohio Revised Code, Ohio Administrative Code, or collective bargaining agreements.

2 Further research how a reverse auction process may be implemented in Ohio.

The State of New Jersey presented the Council with a summary of its legislatively-established reverse auction process[2], defined as "an automated bidding process conducted online that starts with an opening price and allows qualified bidders to counter offer a lower price, for as many rounds of bidding as determined by the division."

The Council recommends the State of Ohio consider a similar program, with specific consideration to establishing statewide purchasing authority to cover at least all State entities involved in prescription drug purchasing. As discussed in the first recommendation of this report, greater savings can be realized with a larger pool of covered individuals.

This recommendation addresses Ohio Revised Code Sections 125.95 (C) (2) and 125.95 (C) (5).

3 Consider establishing a single formulary across State entities

A formulary is a list of drugs covered under a medical plan. The Ohio Bureau of Workers' Compensation has its own pharmacy and therapeutics (P&T) committee, allowing the agency to create and manage its own formulary. The Council recommends researching the possibility of establishing a P&T committee to create and manage a statewide formulary, including a meaningful appeals process, and harness the combined purchasing power of all covered entities.

This recommendation addresses Ohio Revised Code Sections 125.95 (C) (3) and 125.95 (C) (5).

[2] State of New Jersey S887: njleg.state.nj.us

4 Find additional ways to benefit the consumer.

While issues surrounding prescription drug pricing and policies invite debate from a wide range of interests, at the core is the direct impact on the consumer, a recurrent topic of presentations delivered by the wide range of experts this Council engaged during its research. For purposes of this recommendation, "consumer" means the private or public sector employer that often pays all or most of the cost of the prescription drug benefit, as well as the end beneficiary. First and foremost, policymakers must consider the patient's needs, quality customer service, and access to pharmacies while taking action to lower prescription drug costs. Following are recommendations for additional actions that could benefit Ohioans managing their health care and prescription drug costs:

- Expand options for the use of copayment programs produced by drug manufacturers to help defray the cost of expensive medications. Customers would benefit if these copayment programs could be applied to members' deductibles and out of pocket maximums.
- A high deductible health plan features a deductible and out of pocket maximum floor established by the Federal Government, and sometimes allows for lower member contributions. The financial burden on individuals with these plans could be reduced if the plans covered certain medications without applying a deductible.
- Rebates are earned and paid to the employer or insurance company based on the volume of drugs purchased. Members are typically not afforded rebates at the point of sale. Allowing health plans to apply drug rebates at the point of sale would lessen member responsibility by sharing part of the negotiated savings.

This recommendation addresses Ohio Revised Code Sections 125.95 (C) (4).

5 Consider health equity when developing prescription drug policies.

As detailed in the State of Ohio COVID-19 Minority Health Strike Force Interim Report[3], "the coronavirus pandemic has emphasized deep-seated inequities in health care for communities of color and amplified social and economic factors that contribute to poor health outcomes." The report highlights long-existing patterns of adverse outcomes for minority communities that lack access to resources that support overall health and wellbeing. As prescription drug policies evolve, it is important for policymakers to gather and continue to collect data to inform health equity decisions across racial and socioeconomic spectrums.

This recommendation addresses Ohio Revised Code Sections 125.95 (C) (6).

[3] COVID-19 Minority Health Strike Force Interim Report: coronavirus.ohio.gov

6 Require clarity and accountability in PBM contract terms.

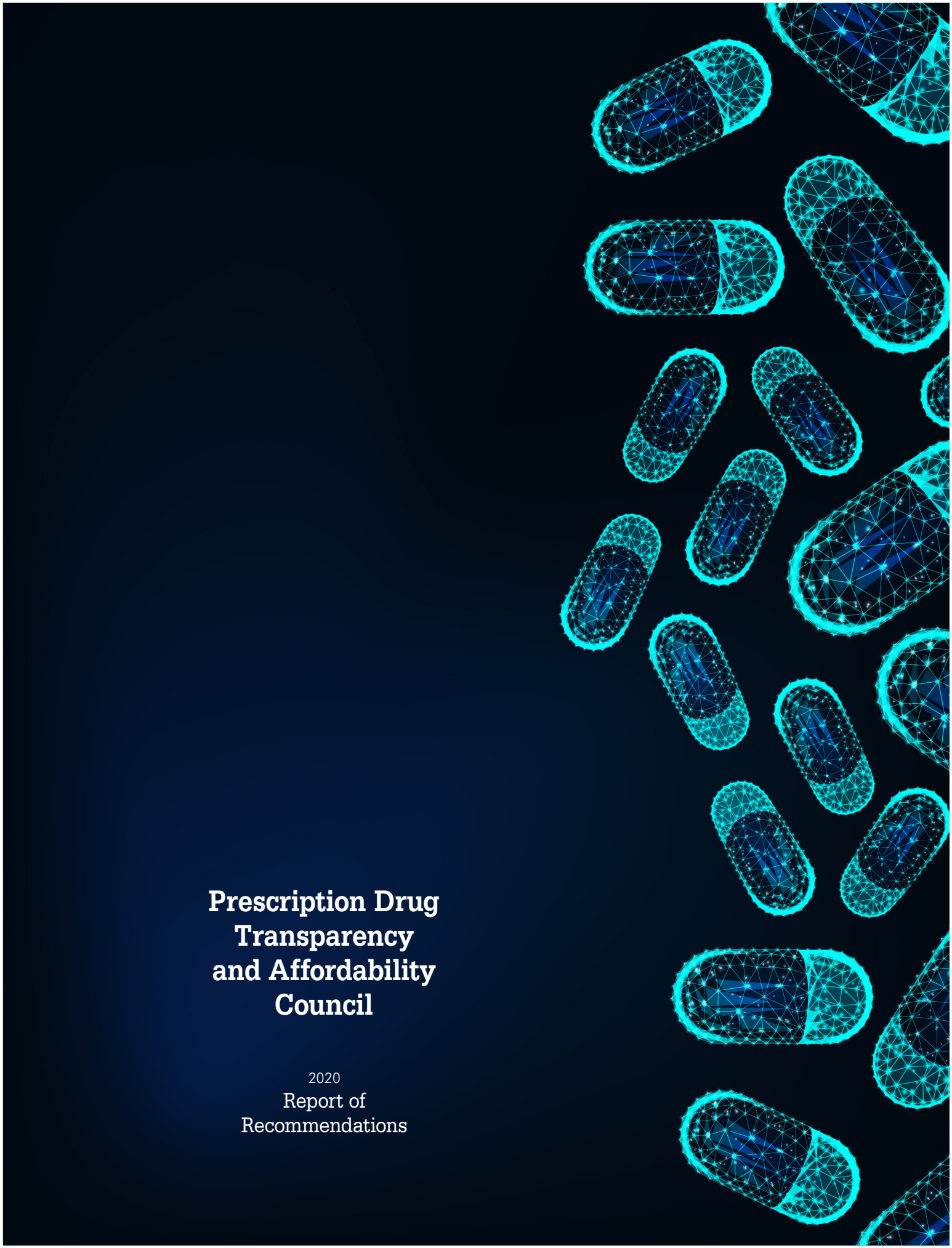
Contract terms must be clearly defined and PBMs should be encouraged to prioritize plan sponsor initiatives. PBMs and plan sponsors must agree to precise and unambiguous contract terms that clearly define roles and responsibilities at the onset of a business relationship in order align expectations and ensure transparency and accountability. PBMs should also be required to allow annual audits of all claims, as well as frequent market checks to provide detailed transparency and hold them accountable to plan sponsors and consumers.

This recommendation addresses Ohio Revised Code Sections 125.95 (C) (1) and 125.95 (C) (4).

Conclusion

The Prescription Drug Transparency and Affordability Council is committed to pursuing change that will relieve the burden on Ohioans in need of prescription medications while preserving taxpayer dollars, improving transparency, and creating efficiencies across health care systems. The Council is pleased to make these recommendations and fully recognizes the need to carve a path forward to smart policies that will benefit Ohioans only after thoughtful assessment of their complete impact on the health care system and private business operations. The Council was also reminded during this process of the complexities that exist in the operations of individual State agencies. The laws that govern agencies and their unique relationships with Ohioans and the pharmaceutical industry can create barriers to cross-agency coordination. Significant internal discussions among State agencies will be required to determine the future path toward the coordination required to make meaningful progress for the citizens of Ohio.

The Council appreciates the opportunity to contribute to Governor DeWine and the Ohio Legislature's efforts to bring needed change that puts Ohioans first by increasing transparency, affordability, and efficiency in prescription drug pricing and healthcare delivery.



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