2021 HOUSE HUMAN SERVICES

HB 1032

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1032
1/6/2021

Relating to prescription drug cost transparency

Chairman Weisz opened the hearing at 1:30 pm.

Representatives	Roll Call
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Rising Cost of Prescription Drugs
- Wholesale Acquisition Cost (WAC)
- Prescription Drug Wholesalers
- PSAO's
- Rebates
- Drug Pricing/Drug Discovery

Jennifer Clark, Legislative Council (1:35) testified neutral.

Jack McDonald, America's Health Insurance Plans (1:40) testified in favor and submitted testimony #116.

Josh Askvig, AARP of ND (1:42) testified in favor and submitted testimony #21.

Marnie Walth Sanford Health Plan (1:53) introduced Daniel Weiss

Daniel Weiss, Pharmacy Senior Executive Director Sanford Health Plan (1:54) testified in favor and submitted testimony #91.

Dennis Pathroff, Zuger, Kirmis and Smith (2:02) introduced Alex Sommer.

Alex Sommer, Prime Therapueutics (2:02) testified in opposition and submitted testimony #61.

Caprice Knapp, Medicaid Director Dept. Human Services (2:17) testified in opposition and submitted testimony #100.

Amy Cleary (2:19) introduced Peter Fjelstad

Peter Fjelstad, PhRMA Senior Director of Public Policy (2:20) testified in opposition and submitted testimony #75.

Michelle Mack, Director State Affairs PCMA (2:30) testified in opposition and submitted testimony #124.

Additional written testimony: #15, #18, #19, #20, #23, #69, #78, #82, #120, #123, #134, #269

Chairman Weisz closed the hearing at 2:36 pm

Tamara Krause, Committee Clerk

Wednesday, January 6, 2021

House Human Services Committee
HB 1032

CHAIRMAN WEISZ AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm appearing on behalf of America's Health Insurance Plans or, as it is commonly known, AHIP.

As we stated in the interim committee process, AHIP sees this bill as a first step to provide much needed transparency in this market. AHIP supports this bill with the amendments we are suggesting below.

We are supportive of efforts to shed light on the "black box" that drug manufacturers are permitted to operate in with respect to their pricing. There continues to be a need for more transparency regarding drug pricing and HB 1032 includes several positive elements – including:

- Limiting the disclosure of proprietary or trade secret data and limits the publication of data that is non-public, or that is unrelated to the price of the prescription drug;
- Placing pharmaceutical manufacturers on similar footing as other sectors of the health care industry regarding financial disclosures; and
- Providing notification of excessive significant drug price increases by pharmaceutical manufacturers.

However, there are elements of the bill that could be improved. We ask that the bill mandate submission of health insurer information to the Insurance Department (Department) rather than the Board of Pharmacy. Carriers are accustomed to submitting data to the Department, and it has mechanisms in place to receive carrier information. It is also critical that competitive and proprietary information be protected. The Board of Pharmacy is comprised of engaged and active market participants whose access to sensitive market data could result in a conflict of interest.

Thank you for your time and consideration. I'd be happy to answer any questions.

PROPOSED AMENDMENTS TO HB 1032

Page 5, line 8, delete “board” and insert in lieu thereof “commissioner”

Page 5, delete lines 20 – 25

Page 5, line 30, delete “the board reports” and insert in lieu thereof “submitted”

Renumber accordingly

House Human Services Committee
HB 1032
Prescription Drug Cost Transparency
January 6, 2021
Josh Askvig, AARP North Dakota
jaskvig@aarp.org – (701) 355-3642

Chairman Weisz and members of the House Human Services Committee,

My name is Josh Askvig, State Director for AARP North Dakota. I appreciate your time today and look forward to working with you on an issue that is crucial to our members and one we are already seeing that they are passionate about.

Before I get into the reason we are working so hard to fight the high cost of prescription drug prices I'd like to spend just a moment reminding you who we are and why we are here. AARP is a nonpartisan, nonprofit, nationwide organization with nearly 38 million members. 86,000 of those members live in North Dakota – a staggering number when you consider the overall population of our state.

Our story dates back 60 years, to when our founder, Dr. Ethel Percy Andrus found a former colleague of hers living in a chicken coop. I know we talk about that often, but we think it says a lot about why we fight for what we do. A lot of issues touch older Americans and their ability to live safe, independent and healthy lives. Most of our work fits into three areas; helping people choose where they live, remain financially secure and access affordable health care.

The rising cost of prescription drugs hits our members, and frankly all North Dakotans, in all three areas. It's a high priority for us right now, not only at the

state level, but at the federal level as well. Let me outline just a couple of the reasons why.

In AARP's 2020 survey of North Dakota adults, in the past two years, one-quarter reported not filling a prescription that was provided by their doctor- 44 percent of those adults- decided not to fill a prescription that their doctor had given them because of the **cost** of the drug.

And as you can see in one of my handouts in the circle in the middle between 2012 and 2017, the average annual cost of prescription drug treatment increased 57.8 percent, while the annual income for North Dakotans only increased 6.7 percent.

Increasing drug prices hit older North Dakotans particularly hard. Most Medicare beneficiaries live on relatively modest incomes. A Kaiser Foundation study from 2016 shows the **median income for Medicare recipients is just over $26,000** – and a quarter of the people hover closer to $15,000. They also have very little savings. Half the Medicare population has less than $75,000 saved up. Their ability to absorb increasingly expensive prescription drugs is nearly impossible. Many people we have talked with recently tell us they have to make difficult decisions about how to live because of the price of those drugs.

On a second handout you can get a good feel for why they have to make that crushing choice. Near the top of the page are three common illnesses in North Dakota – cancer, diabetes and heart disease – with the number of residents of our state who have been diagnosed. More than 60,000 with cancer and nearly as many with diabetes. Below those numbers are common drugs used to treat them and their costs from 2017. Please, take note that we've included what those same drugs cost just five years earlier. **One nearly doubled, another jumped $100,000!**

On our Facebook page you can see some videos of North Dakotans facing these costs. There is one from Pat who told us a drug she took 10 years ago was $60. Now she pays $600! And Roger, who has found a way to import the leukemia drug he needs from Canada, saw the price of his medicine jump from

10 bucks to 24-hundred bucks in a month! Why? Because he moved from his great PERS plan to Medicare.

Now, we know states can't solve this problem alone. But there are some things that can be done and we appreciate this committee's willingness to bring this issue to the forefront. We believe transparency from manufacturers, PBMs and insurance companies can help the state and consumers get a handle on these increasing prices and be prepared for when things are going to change. We appreciate that the bill draft in its current form addresses transparency at all three levels. Furthermore, the thorough description of what should be disclosed is encouraging.

We do, however, have a couple of suggestions.

On page one of the bill, we would suggest deleting the lines 18-20 (the definition of "Manufacturer-packaged drug container") and replacing with "'Wholesale acquisition cost (WAC) Unit' means the lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group as indicated by the State Board of Pharmacy, it is the total number of WAC units in the drug group."

Next, under section 2, subsection A, at the top of page 3 is unclear because it does not set a timeframe for the cost of the drug. Meaning, it states "a cost of $70 or more" but does not say whether that $70 is incurred for one pill, one month's supply or one year's supply. We believe the language should be clarified to specify the timeframe.

In addition, under Section 2, subsection a on page 3 we'd suggest adding per WAC unit to line 6 as follows "...acquisition cost of seventy dollars or more <u>per WAC Unit</u> ~~for a manufacturer-packaged drug~~..."

Also, and more importantly, we believe an independent board or committee should receive the report and that the report should be presented in a way

consumers can understand it. Maybe the State Board of Pharmacy has time to receive this report, sort through it and make it understandable. But we think the Board likely already has enough to deal with. A transparency bill should be about getting information to the general public in a way that interested North Dakotans can not only access it, but understand it. An independent board should review prices and allow for consumer review and input.

Again, we fully appreciate the positive momentum nationwide and in North Dakota to truly affect change in this alarming pocketbook issue. Medicare Part D enrollees take an average of four-and-a-half prescriptions per month and more than two-thirds have two or more concurrent chronic illnesses. These patients will likely be taking their medicine every year for the rest of their lives.

That makes this issue relevant not only to the thousands of individual North Dakotans fighting disease, but it also affects those paying for health coverage and to the state. Spending increases driven by escalating drug prices are passed along to everyone with health insurance coverage in the form of higher premiums and deductibles. It increases costs for taxpayer-funded programs too – making this a relevant issue for every North Dakotan whether they are taking prescription medicine or not.

Thank you again for your thoughtful work on this issue. We wholeheartedly appreciate any effort to make medicine more affordable. This bill is a step in the right direction and we look forward to working with you during the interim to make it the best possible bill for North Dakotans.

Thank you.

#91

House Human Services
HB 1032
Jan. 6, 2021

Chairman Weisz, Members of the House Human Services Committee:

My name is Daniel Weiss, Senior Executive Director, Pharmacy Benefits, Sanford Health Plan (SHP). I appreciate the opportunity to share with the committee a few comments on HB 1032 dealing with Prescription Drug Price Transparency. For your information, Sanford Health Plan provided comments during the deliberations of the Interim Health Committee and we stand in support of this legislation, as amended.

As you know, many states have passed legislation aimed at improving transparency in drug pricing and accordingly, to address the issue of skyrocketing drug prices. Sanford Health recognizes the importance of providing North Dakota consumers with affordable, access to quality health care services and treatments. Prescription drugs play an important role in the management of health, particularly for those with chronic illnesses.

HB 1032 will facilitate the disclosure of some of the data needed to address and understand why prescription drug prices are rising, and hopefully provide incentives for the distribution chain to act in a fiscally responsible way.

We are committed to working with North Dakota on the critical issue of drug price transparency and this legislation. We applaud Rep. Keiser for his ongoing efforts to help consumers and address health care costs. In that spirit, we offer the following suggestions. We believe Rep. Keiser considers these friendly amendments:

1) Consider adding provisions requiring wholesalers to disclose their business practices in a similar manner as the Pharmacy Benefit Manager (PBM). This will provide information and awareness of unknown discounts and rebates offered and retained by the pharmacies
2) Consider including in this legislation another important entity in the North Dakota prescription drug chain—Pharmacy Service Administration Organizations (PSAO). A PSAO is a contracting entity hired by pharmacies to manage their PBM contracts.

   While I cannot speak to all existing relationships between PSAOs and pharmacies, in our current network, we have approximately 76% of all pharmacies contracted through these organizations. That represents 159 of the 209 network pharmacies. Where these organizations can provide critical support in contracting and negotiation, there can also be conflicts of interest due to ownership influence.

Thank you for your time and consideration. I am happy to answer any questions and provide clarification.

Respectfully submitted,
Daniel Weiss
Pharmacy Benefits Senior Executive Director
Sanford Health Plan
Daniel.Weiss@Sanfordhealth.org

January 5, 2020

#61

The Honorable Robin Weisz, Chair
House Human Services Committee
North Dakota State Legislature
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: House Bill No. 1032

Dear Chairman Weisz:

Thank you for the opportunity to comment on House Bill No. 1032 today. I represent Prime Therapeutics, a pharmacy benefit manager (PBM) owned by 18 not- for-profit Blue Cross and Blue Shield insurers, subsidiaries or affiliates of those insurers, including Blue Cross and Blue Shield of North Dakota (BCBSND). For the reasons stated herein, we oppose this bill.

Prime Therapeutics helps people get the medicine they need to feel better and live well by managing pharmacy benefits for health plans, employers, and government programs including Medicare and Medicaid. Our company manages pharmacy claims for more than 30 million people nationally and offers clinical services for people with complex medical conditions. Our business model relies on transparency and advocating for simpler, lowest-net-cost pricing for drugs. Importantly, Prime is not focused on driving profit margins or attaining the largest rebate. To control costs, Prime's clients rely on our clinical expertise and drug management tools to reduce overall drug spending.

As an initial matter, this bill will harm Prime's efforts to reduce drug spending by further consolidating the power of North Dakota pharmacies and pharmacists via the delegation of oversight and power to the Board of Pharmacy (Board). The Supreme Court held in *North Carolina State Board of Dental Examiners v. FTC* that oversight of a market cannot be abandoned "to the unsupervised control of active market participants . . .."[1] Similar to that case, the Board's members are active market participants in the market this bill aims to regulate. Its pharmacist members negotiate contracts with PBMs, which are one of the tools PBMs use to drive down overall spending on drugs. Requiring a PBM to disclose its confidential and proprietary data related to the terms of these contracts would eliminate competition in the pharmacy space by creating a *de facto* collective bargaining arrangement among North Dakota pharmacists. The result of such an arrangement would be an increase in overall drug spending and thus increased prices for North Dakota citizens.

[1] 135 S. Ct. 1101 (2015)

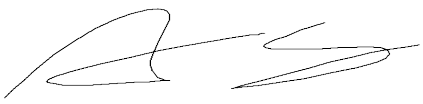
Next, this bill does not adequately protect a PBM's proprietary or confidential information. Prime only supports one health plan in North Dakota, BCBSND. As written, the data in the bill's required reports can easily be tied back to Prime and BCBSND. Further, requiring Prime to report this data to the Board would be entirely inappropriate considering the role of the Board's members in the prescription drug supply chain and their negotiations with PBMs. Additional protections are needed for this data to ensure that proprietary and confidential data remains as such. We look forward to working with the Committee on this issue to ensure our competitive data is not subject to open records requests.

This bill also raises concerns in its targeting of rebates. On pg. 3, starting at line 22, the bill presumes that an "increase in pharmacy benefit manager rebates" would be a cause for an increase in the price of a drug. In fact, the price for a rebate-eligible drug (*i.e.,* brand-name drugs) is set independently by the drug manufacturer. Prime uses rebates to secure price concessions on those list prices from drug manufacturers and then passes those rebate dollars back to its health plan clients, such as Blue Cross and Blue Shield of North Dakota. Rather than increasing the price of a drug, which is done by drug manufacturers alone, rebates soften the financial burden on the healthcare system by driving down the overall cost of care.

Finally, Prime has concerns about the scope of data being requested. This bill would require PBMs to report on "aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer." This is too broadly written and would encompass financial arrangements outside of the scope of administering the pharmacy benefit for a health care plan. Further, the bill would require PBMs to report "aggregated rebates passed on to employers." Prime passes rebate dollars to its health care plan clients. It is up to those health care plan clients what to do with those rebate dollars, such as passing them to employers. In short, this information is either unrelated or outside of Prime's control and thus does not fit within a reporting scheme for Prime.

Prime supports *meaningful* transparency across the prescription drug supply chain and appreciates the opportunity to comment on this proposed solution. Ultimately, it delegates too much authority to PBMs' competitors (thus harming competition in the prescription drug marketplace) and targets PBM tools (*e.g.*, rebates) that help lower the overall cost of care. For these reasons, Prime opposes House Bill No. 1032.

Sincerely,



Alex Sommer, J.D.
Prime Therapeutics
Alexander.Sommer@primetherapeutics.com

Testimony
House Bill 1032 - Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman

January 6, 2021

Chairman Weisz and members of the Human Services Committee, I am Brendan Joyce, Administrator, Pharmacy Services for the Department of Human Services (Department). I appear today to provide testimony on House Bill 1032.

The Department is opposed to House Bill 1032 as it is currently written simply due to the concern that the definitions of "health insurer" and "pharmacy benefits manager" could be interpreted to include North Dakota Medicaid and the programs we process through our systems (e.g. traditional, expansion, children's health insurance program, AIDS drug assistance program, special health services, and county jails).

As the House Human Services Committee knows, the Department provides detailed reporting to the legislature during sessions and during the interim to multiple committees. The Department feels it would be burdensome to provide the reporting specified in House Bill 1032. The Department will continue to provide detailed reporting as required by federal requirements and to the legislature as it has done so in the past.

The Department would ask that clarification is added to the definitions to make it such that the Department, and the current programs administered by the Department (some of which are for Department of Health programs) are not included in the requirements of House Bill 1032.

This concludes my testimony, and I am happy to answer any questions you may have.

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to House Bill 1032 –
Prescription Drug Cost Transparency Legislation
January 6, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes House Bill 1032, which would require significant reporting mandates, will not help patients, could threaten access to needed prescription medications, and potentially chill the innovation of future treatments.

Discussions about cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries, and other preventable procedures. All of which translate to lower health care costs. New medicines are making crucial contributions to medical advances and changing the direction of health care as we know it. With more than 4,500 medicines in the pipeline (74% which have the potential to be first in class medicines and 42% of which could be personalized medicines), patients have greater hope than ever before. However, this transparency bill is likely to skew important discussions of policy issues in ways that are systematically biased against innovation and ignores the value of medicines to patients, the overall health care system, and the economy of North Dakota.

Proposals to mandate *additional* disclosure of proprietary information by biopharmaceutical companies would neither benefit patients nor decrease health care costs.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies currently report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures in 10-K filings. Proposals to mandate public disclosure of additional confidential and proprietary information by biopharmaceutical companies ignore the large amount of information already publicly reported on an annual basis by companies and are based on the faulty assumption that prescription drug spending is the major driver of increases in health care costs.

The reporting requirements for manufacturers do not reflect the total investment of industry because of the long-term nature of research and development. Manufacturers pursue research efforts that include many failures and iterations on the path to development of a single approved drug. In fact, according to Tuft's Center for Study of Drug Development (CSDD), only 12% of medicines in the pipeline make it through the approval process by the federal Food and Drug Administration (FDA).[1] An 88% failure rate underscores how expensive and risky drug development is.

Drug costs are the *only* costs in the health care system that *decrease* over time due to market changes, such as brand to brand competition and patent expirations.

It is important to note that medicines are the *only* part of the health care system where costs *decrease* over time. When brand name medicines face brand competition, or when they lose their patent protection and generic drugs become available, prices drop, often significantly. In fact, it is projected that from 2019-2023, there will be approximately $105 billion in savings due to competition from generic and biosimilar products as patents for brand

1 Tufts Center for the Study of Drug Development (CSDD), "Briefing: Cost of Developing a New Drug," Nov 2014.
2 QuintilesIMS Institute, "Medicines Use and Spending in the U.S." May 2017.

medicines expire.[2] In addition, nearly 90% of all medicines dispensed in the U.S. are generic and cost pennies on the dollar.[3] Generics offer a cheaper alternative for patients when their health care provider deems a generic appropriate. However, one component of health spending that is not decreasing, is health insurance. Instead, it is seeing significant increases. Between 2007 – 2017, deductibles for patients have tripled and co-insurance has doubled. The Kaiser Family Foundation has routinely shown patient costs are increasing faster than insurers' costs. Morevover, health insurance and health plan administration costs are rising at more than twice the rate of drug spending.

According to new research from the Berkeley Research Group (BRG), rebates, discounts, and fees paid by manufacturers, are on the increase, while the share received by manufacturers has decreased over time.[4] In fact, nearly half (46%) of total spending on brand medicines went to the supply chain and other entities in 2018. This is a 13%-point increase from 2013, when other stakeholders retained 33% of brand medicine spending. This data reaffirms that we need to look at the entire supply chain in order to solve patient affordability challenges. Misaligned incentives must be fixed in the supply chain, including the broken rebate system, to ensure patients benefit at the pharmacy counter from the significant discounts and rebates.

In addition, brand and generic biopharmaceutical companies, unlike other sectors of health care, generated $41 million in rebates to the State of North Dakota and federal government in 2018. This is 55% of the total Medicaid spending on prescription drugs in the state.[5]

If the intent of House Bill 1032 is to improve access and affordability to needed medicines, the language of the bill is misguided.

The legislation does nothing to address how much consumers ultimately pay for a medicine, an amount determined by insurers, *not* biopharmaceutical companies. This legislation should do something to help patients afford their prescription medicines, such as passing on the rebates directly to the patients at the point of sale at the pharmacy counter. Instead, these rebates are going to the plans and other supply chain stakeholders. Recent data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket (OOP) costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan. A recent IQVIA study that looked at OOP patient spending for brand name medicines from 2015 – 2019 and showed that patient's spend on deductibles and co-insurance accounted for more than 2/3 of total OOP spend for brand medicines in five out of seven therapy areas examined. For two therapy areas (oncology and multiple sclerosis), it accounted for more than 90%.[6] This occurrence is contrary to the purpose of insurance—to spread the costs of health care utilization, so that patients can access needed care, including medicines.

Today, a patient pays only about 3% for OOP hospital costs, but 13% or more for their medicines.[7] Additionally, insurers are increasing utilization management techniques to aggressively restrict a patient's use of medicine. Currently, three major pharmacy benefit managers (PBMs) negotiate steep discounts on prescription drugs for more than 70% of all prescriptions filled in the U.S. Express Scripts alone covers about 90 million Americans.[8]

The biopharmaceutical industry supports over 800 jobs in North Dakota, with a generous annual average compensation

3 IQVIA Institute Drug Channels Institute
4 Berkeley Research Group (BRG). Revisiting the Pharmaceutical Supply Chain: 2013-2018. http://www.thinkbrg.com/newsroom-publications-revisit-pharma-supply-chain.html
5 The Facts About Medicaid in North Dakota. http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/ND-One-Pager_19.pdf.
6 Spending and Affordability in the U.S., Aug. 4, 2020. http://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us
7 Avalere Health analysis of the US Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, 2015. http://meps.ahrq.gov/mepsweb. Accessed February 2018 (analysis includes individuals with any source of health care coverage, public or private; this includes individuals who had health coverage without coverage for prescription drugs, which can be expected to account for less than 2% of those with health coverage).
8 http://lab.express-scripts.com/lab/drug-trend-report
9 Biopharmaceutical Section Impact on North Dakota's Economy. http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_GB_StateFactSheet/PhRMA_GB_StateFactsheet_2019_North-Dakota.pdf.

of $80,097 per year, as compared to the average job salary in North Dakota of $56,226. That translates into $10 million in both state and federal taxes annually, as well as a total annual economic output of $207 million for the state. The industry is committed to working with lawmakers, patients, doctors, and other health care stakeholders to pursue policies that promote manufacturing, R&D, and innovation, while ensuring consumers have access to needed medicines.

Prescription medicines have transformed the trajectory of many debilitating diseases and conditions, including COVID-19, HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Better use of medicines could eliminate up to $213 billion in U.S. health care costs annually, which represents 8% of the nation's health care spending.[10] Therefore, instead of focusing on reporting of information that does nothing to help the patient, perhaps the conversation should focus on better use of medicines, which yields significant health gains by avoiding the need for other, more costly, medical services.

House Bill 1032 is not the way to accomplish improved access and affordability, therefore, PhRMA respectfully urges North Dakota lawmakers to oppose this bill.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone.

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

House Human Services Committee
HB 1032
January 6, 2021 – 1:30 pm
PCMA Testimony in Opposition to HB 1032

CHAIRMAN WEISZ AND COMMITTEE MEMBERS:

My name is Michelle Mack and I represent the Pharmaceutical Care Management Association commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs. To give you a bit of information on PCMA and what PBMs are and what they do, I am including a document describing this in addition to my testimony.

As we stated in the interim committee process, PCMA supports meaningful transparency across the supply chain, including transparency that empowers patients, prescribers, clients, and policymakers to make informed decisions that lead to optimal health outcomes and lower costs. HB 1033, does not achieve these goals and therefore we oppose and urge you to give HB 1033 a Do Not Pass recommendation.

We also feel the need to ensure the protection of competitive and proprietary financial information. Therefore, we are **very concerned** about the data being collected by the Board of Pharmacy. The FTC issued a letter on this issue when the Mississippi legislature passed a law granting the Board of Pharmacy with the authority to regulate PBMs.

> "[b]ecause pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board."[1]

Similarly, the FTC has opposed regulatory boards composed of market participants in other industries. In *North Carolina State Board of Dental Examiners v. Federal Trade Commission,* the United States Supreme Court looked into the question as to whether the state board could decide that a certain procedure could only be performed under the supervision of a dentist, thereby driving lower priced non-dentists out of the market. The FTC questioned the North Carolina Board of Dental Examiners' ability to regulate an industry in which they were active participants noting, '"common sense and economic theory…. dictate the conclusion that Board actions in this area could be self interested"[2]

We believe that the Department of Insurance would be the appropriate agency for such competitive data. The Board of Pharmacy is comprised of active market participants whose access to market sensitive data could result in a conflict of interest and undermine competition in the prescription drug marketplace.

The industry worked with various stakeholders in Texas throughout the process there to amend similar language on disclosure. A key amendment included in the final passage of Texas HB 2536 aggregates the rebate information reported by PBMs and health plans before publishing the data.

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[1] FTC letter to Representative Mark Formby, Mississippi House of Representatives, (March 22, 2011).

[2] Emory University School of Law, "Legal Studies Research Paper Series". Joanna Shepherd 2013

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

This important clarification protects proprietary, private business and competitively sensitive information. PCMA respectfully requests the insertion of similar language such as the following:

> ***"The Insurance Commissioner shall collect and aggregate all the collected data and publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager or health plan [Carrier/Insurer]"*** in the section entitled "*Disclosure of pharmacy benefit manager information"* and the section entitled "*Disclosure of health insurer spending information"*.

PCMA also suggests the following language be included so the data submitted to the Department of Insurance is not subject to open records requests, except for the aggregated and de-identified data that is in the published report.

> **Rulemaking - Forms - Services - Records.**
>
> 4. A report received by the ~~board~~ **commissioner** is ~~an exempt~~ a **confidential** record as defined by section 44-04-17.1.

North Dakota open records laws have three classes of public records. Given the sensitive nature of the information within this bill's scope, it is more properly deemed "confidential information" rather than "exempt record."

In addition, PCMA respectfully requests the section involving penalties be either updated or removed from the bill. If anything, administrative penalties imposed by the regulator would be more appropriate to levy than civil penalties, especially when reporting to the Department of Insurance.

I would like to make note, that drug manufacturers are responsible for setting the list price of drugs. No evidence exists to suggest that rebates cause higher drug prices. A study of list prices and rebates for the top 200 most prescribed drugs between 2011 and 2016 indicated that there is no correlation between rebates and list price increases or launch prices for individual drugs.[3] Of these drugs, there were prices that increased significantly, some that increased slightly, and some rebates that were high, and some that were low. Top brand drugs that offered little to no commercial sector rebate during this time period still increased their prices, and manufacturers are increasing drug prices regardless of rebate levels negotiated by PBMs. Among the top 200 brand drugs by 2016 sales, the launch prices for drugs introduced from 2012 to 2016 were double the launch prices for those introduced prior to 2012. There was no correlation found between the prices and rebates.

[3] Increasing Prices Set by Drugmakers Not Correlated with Rebates, Analysis prepared by Visante on behalf of PCMA, Jan. 2017, available at: https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf.

Again, pharmaceutical manufacturers set drug prices. Therefore, the language on page 3 beginning on line 20 relating to the factors that led to drug price increase will likely yield better information if the language is amended to read as follows:

> ***"A definitive statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation of the role of each factor's impact on the cost."***

PCMA requests that the due date for annual data collection be changed to July 1st to ensure comprehensive reporting of information for the preceding calendar year. This request will allow for a complete and accurate accounting of information that by its nature lags at least one quarter behind. Stated differently, while information can be reported on April 1st of each year, it will not represent complete information for the preceding calendar year.

PBMs negotiate on behalf of their clients and consumers to help drive down the cost of prescription drugs by using market-based tools that encourage competition among drugmakers and drugstores. PBMs support and practice transparency that empowers patients, their providers, plan sponsors, and policymakers, so that there is informed decision-making that can lead to lower prescription drug costs.

We appreciate your interest and commitment to keeping the costs of drugs affordable for the citizens of North Dakota and look forward to working with you in your efforts to pass meaningful legislation.

Thank you for your time and consideration. I'd be happy to answer any questions.

Michelle Mack
Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org

TESTIMONY OF SCOTT MILLER

House Bill 1032 – Prescription Drug Cost Transparency

Good afternoon, my name is Scott Miller. I am the Executive Director of the North Dakota Public Employees Retirement System, or NDPERS. I appear before you today in a neutral position on House Bill 1032. I am available should there be any questions related to the impact of the bill on any of the NDPERS benefits.

#18

How North Dakota Residents Are Impacted By High Rx Costs

60,228
North Dakota Residents
have been diagnosed with cancer.[1]

58,718
North Dakota Residents
have pre-diabetes or diabetes.[1]

22,311
North Dakota Residents
have heart disease.[1]

Between 2012 and 2017, the price of these name brand drugs increased:

Revlimid
treats forms of cancer

from $147,413/yr

to $247,496/yr[2]

Lantus
treats diabetes

from $2,907/yr

to $4,702/yr[2]

Aggrenox
treats heart disease

from $3,030/yr

to $5,930/yr[2]

Rx 31%

In 2017, 31% of North Dakota Residents stopped taking medication as prescribed due to cost.[3]

Sources:

[1] Total does not include skin cancer. Source: AARP Public Policy Institute analysis using 2017 data from the Behavioral Risk Factor Surveillance System.
[2] Stephen W. Schondelmeyer and Leigh Purvis. Rx Price Watch Reports. Washington, DC: AARP Public Policy Institute, June 2019, https://doi.org/10.26419/ppi.00073.000.
[3] Among 19-64 year old population. State Health Access Data Assistance Center (SHADAC) analysis of National Health Interview Survey data, State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed September 5, 2019

STOP GREED CUT DRUG PRICES NOW™ AARP Real Possibilities

#19

Rx PRICE GOUGING vs. 50+ INCOME

Americans pay among the highest drug prices in the world and many are having to choose between buying the medications they need and other essentials. Meanwhile, brand name drug prices continue to increase at rates that far exceed general inflation. These relentless price increases could force many Americans to pay drug prices that exceed their entire income for a year.

AVG. ANNUAL COST

The average annual cost for one brand name drug, used on a chronic basis, was around $6,800 in 2017, almost $1,000 more than in 2015.[1]

PhRMA SPENDS BILLIONS

Big Pharma spent nearly $169 million for lobbying and more than $6 billion for advertising in 2018. [5]

IN OUR STATE

The average annual cost of prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for North Dakotans only increased 6.7%.[6]

NUMBER OF PRESCRIPTIONS

The average older American takes 4.5 prescription drugs, typically on a chronic basis.[2]

AMERICANS PAY MORE

Americans can pay double what similar countries pay for the same name brand drugs.[4]

RESEARCH & DEVELOPMENT?

Nearly 80% of every Big Pharma dollar goes to something other than research and development.[3]

STOP Rx GREED
CUT DRUG PRICES NOW℠

AARP® Real Possibilities

[1,2] Stephen W. Schondelmeyer and Leigh Purvis, "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2017 Year-End Update," AARP Public Policy Institute, Washington, DC, September 2018.
[3] https://www.csrxp.org/wp-content/uploads/2019/05/CSRxP_One_pager_III_FINAL-SITERELEASE.pdf
[4] https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf
[5] https://www.opensecrets.org/lobby/induscode.php?id=H4300&year=2018 and https://jamanetwork.com/journals/jama/fullarticle/2720029
[6] Based on the price associated with taking 4 widely used brand name prescription drugs. Income is based on median person-level income.

STOP Rx GREED
CUT DRUG PRICES NOW™

#20

Prescription Drug Transparency

Description

Prescription drug pricing transparency efforts require drug manufacturers to report the reasons behind high prices and price increases. The principle behind the bills is that increased disclosure around pricing practices will result in more meaningful and actionable information for states and accountability for manufacturers. Drug pricing transparency legislation will also help payers determine whether a drug price or price increase is justified. Moreover, the added scrutiny brought on by transparency legislation could encourage drug manufacturers to reconsider their standard practice of setting high launch prices and then increasing them year after year.

AARP strongly supports increased transparency in the drug development and pricing process and generally throughout the prescription drug supply chain. However, because too much transparency within the drug supply chain can actually reduce competition and lead to higher drug prices, transparency legislation should strike a careful balance between the desire for more information and the possibility that such disclosures could harm competition and lead to higher drug prices.

How does this work?

Transparency bills require pharmaceutical companies to provide specific information about their pricing practices. Transparency legislation generally requires pharmaceutical companies to provide information about how a drug is priced, and to justify large price increases (or launch prices) that exceed a predetermined threshold.

A transparency model bill drafted by NASHP (National Academy of State Health Policy) includes the following manufacturer reporting requirement triggers:

- For brand-name drugs: A 20 percent increase per WAC (wholesale acquisition cost) unit during any 12-month period;
- For generics: A WAC unit price of $100 or more, and a 20 percent increase per WAC unit during any 12-month period;
- For new drugs: A WAC of $670 or more; and

- Used for Pharmacy Benefit Managers (PBMs) and wholesalers: The state will require PBMs and wholesalers to report on specific drugs identified as being of interest following state review of manufacturer and insurer reports.

Some states have also included penalties in their bill language for manufacturers that fail to report. The NASHP model language includes a penalty of $30,000/day. The model language also invokes subpoena authority if reporting entities do not provide the required data or if the data they provide is unclear or inadequate.

What does a transparency law mean for consumers?

Transparency bills, while by themselves do not reduce prescription drug prices, should be considered important building blocks for other legislative efforts, such as cost review commissions and drug affordability boards that can more directly address costs. In addition, transparency laws may provide consumers with advance warning of increases in their drug costs, allowing consumers to discuss lower cost alternatives with their health providers. Moreover, in order to avoid reporting requirements set forth by transparency laws, manufacturers may limit their price increases to keep them below the reporting threshold.

Where has this state legislative policy been enacted?

In 2016, Vermont passed the nation's first transparency law, which has led to many state legislatures considering bills requiring more disclosure and transparency from drug manufacturers. In total, according to NASHP data, 12 states (CA, CT, CO, ME, MN, NH, NV, MD, OR, TX, VT, WA) have enacted drug transparency laws. In 2019, approximately 27 states filed 53 bills on transparency with 6 states (CO, ME, NV, OR, TX, WA) successfully passing the following laws in 2019.

- Colorado – HB 1131 requires a drug manufacturer or its agent to provide a prescriber the wholesale acquisition cost of a drug when marketing or providing information on a drug to a prescriber.
- Maine – LD 1162 requires manufacturers to report annually to the Maine Health Data Organization (MHDO) about drug prices when the manufacturer has, during the prior calendar year, increased the wholesale acquisition cost (WAC) of a brand-name drug or a generic drug by a certain per pricing unit percentage.
- Nevada – SB 262 expands existing law, which requires transparency around drugs used to treat diabetes, and requires new transparency for drugs used in the treatment of asthma. The law also authorizes the state to collect monetary penalties for noncompliance.
- Oregon – HB 2658 amends transparency legislation passed in 2018 and requires manufacturers of prescription drugs to report to the state any specified increase in price of certain prescription drugs at least 60 days before the date of such increase.

- Texas – HB 2536 requires drug manufacturers to disclose pricing information to the state on drugs with a wholesale acquisition cost of $100 or more for a 30-day supply, or that increase 40 percent or more over the preceding three calendar years or 15 percent or more in the preceding calendar year. Pharmacy Benefit Managers and insurers are also required to make annual reports to the state. All information disclosed will be posted publicly.
- Washington - HB 1224 requires drug manufacturers to disclose the 25 most-prescribed drugs, the 25 costliest drugs by total plan spending, the 25 drugs with the highest year-over-year increase in spending, and a summary analysis of the impact on drug costs on health premiums. Manufacturers must submit annually a description of the factors used to make the decision to increase the wholesale acquisition cost (WAC) of the drug and the amount of the increase, along with a justification for the increase. This law also requires a pharmacy benefit manager (PBM) to submit an annual transparency report.

A number of states that have passed transparency laws are using this legislation as a springboard to establish prescription drug rate review or rate setting commissions. State rate review commissions analyze drug pricing data from manufacturers, recommend policy options to the state for decreasing prices and, in some cases, establish drug price ceilings.

TESTIMONY OF REBECCA FRICKE

HOUSE BILL 1032 – Prescription drug transparency

Good afternoon, my name is Rebecca Fricke. I am the Chief Benefits Officer of the North Dakota Public Employees Retirement System, or NDPERS. I appear before you today in a neutral position on House Bill 1032. I am available should there be any questions related to the impact of the bill on any of the NDPERS benefits.

January 6, 2021

Chair Weisz and Members of the House Human Services Committee,

My name is Ellen Schafer. I live in Bismarck and I am an advocacy volunteer and member of AARP North Dakota's Executive Council. I am testifying this afternoon in support of House Bill 1032.

The rising cost of prescription drugs impacts all North Dakotans, but hits older North Dakotans particularly hard. Most Medicare beneficiaries live on relatively modest incomes. Their ability to absorb increasingly expensive prescription drugs is nearly impossible. Many of my friends, neighbors and family talk about the difficult decisions about how to live because of the price of those drugs.

My sister was diagnosed with chronic lymphocytic leukemia. The medication used to treat her leukemia is called Sprycel. Currently the drug costs $15,000 per month. She is retired and cannot afford this medication. The doctor placed her on a catastrophic list and which has helped her obtain a grant to pay for this medication. The cost of her medication will now be covered until December of 2021. After that she is not sure what will happen. If she is required to pay for the medication herself, she will have to quit this life saving medication.

Another drug the doctor has ordered for her is a respiratory inhaler called Trilogy to help her breathing. This medication currently costs $450.00 a month. She had to quit taking it because she cannot afford to pay for it.

My sister is not alone, AARP research shows that between 2012 and 2017, the average annual cost of prescription drug treatment increased 57.8%, while the annual income of North Dakotans only increased 6.7%. In AARP's 2020 survey of North Dakota adults, 44% of respondents decided not to fill a prescription that their doctor had given them because of the drug's cost. We cannot afford higher drug prices and bills like this one will shed some light on why ND's prescription prices are sky high so we can find solutions to bring down the price.

Thank you again for listening to mine and other AARP members concerns as you work on this issue. I wholeheartedly appreciate any effort to make medicine more affordable. House Bill 1032 is a step in the right direction and I hope you give the bill a favorable recommendation.

Thank you.

Margaret Reynolds
State Government Affairs Principal

#78

January 5, 2021

The Honorable Robin Weisz, Chair
Human Services Committee
North Dakota State Legislature
State Capitol
600 East Boulevard
Bismarck, ND 58505

900 Cottage Grove Road, B6LPA
Bloomfield, CT 06002
651-341-3161
margaret.reynolds@Cigna.com

Dear Chairman Weisz and Committee Members:

Cigna is a national health insurance provider that has been on the front lines of providing patient access and coverage during the COVID-19 pandemic. Express Scripts is a pharmaceutical benefit manager (PBM) that cares for over 80 million lives in the United States. Together, Cigna and Express Scripts have created a new health services leader. The combined companies are increasing affordability, choice and predictability for our customers while enhancing quality care and producing better health outcomes.

We appreciate the ability to submit comments on HB1032 as the committee is considering it.

We believe that it is really imperative that the Insurance Commissioner, as the regulator, collect and aggregate the data requested by PBMs instead of the Board of Pharmacy. The Department of Insurance is the licensing and regulatory agency for PBMs per North Dakota Chapter 26.1-27.1. As such, the Department is well-situated to handle such competitive data. The highly sensitive and proprietary information is best collected by the enforcement agency and removes the conflict of interest presented by the Board of Pharmacy. We suggest striking "board" on page 4, line 13, and replacing it with "commissioner". With that change, section 3 on the top of page 5 should also reflect a change to the Commissioner. The language could read as follows:

> (3) Within thirty days of receipt of a report under this section, the reported information shall be formatted for publication on the commissioner's website. The information provided may not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.

We have similar concerns with the section pertaining to health insurers. As the Commissioner is the regulator for this industry, we would suggest striking "board" on page 5, line 8, and inserting "commissioner". With that change, section 1 (b) on page 5 should also reflect the change to Commissioner. The language could read as follows:

> (b) Within thirty days of receipt of a report under this section, the reported information shall be formatted for publication on the commissioner's website. The combined aggregated data from the reports must be provided in a manner that does not disclose or tend to disclose proprietary or confidential information of any health insurer.

Thank you very much for your consideration of our concerns. We look forward to working together.

Sincerely,

Margaret Reynolds, State Government Affairs Principal

#82

January 5, 2021

The Honorable Chairman Robin Weisz
The Honorable Vice-chair Karen M. Rohr
North Dakota House Human Services Committee
North Dakota State Capitol
Bismarck, ND

Dear Chairman Weisz, Vice-chair Rohr and members of the House Human Services Committee,

The Biotechnology Innovation Organization (BIO) opposes HB 1032.

BIO is the world's largest trade association representing over 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

BIO is opposed to HB 1032, as we believe that any prescription drug pricing transparency provisions should focus on what matters most for patients: their out-of-pocket costs. That includes ensuring patients know what their cost-sharing obligations are, how health plans and pharmaceutical benefit managers (PBMs) are using manufacturer rebates, and what prescription drugs are available on any formulary. This type of information can assist to determine which health plan most appropriately meets that patient's medical needs.

Further, this legislation could harm the fragile ecosystem that provides for small, innovative companies to exist. Many of these companies have no existing pipeline in which to fund research and development, but instead rely on venture capital and angel investors. Biopharmaceutical discovery and development is already the riskiest of endeavors, and this legislation could have the unintended consequence of driving these vital funding sources to other industries due to the required release of propriety or confidential information.

Finally, the legislation does not take into consideration the savings to the health care system provided by the effective use of biopharmaceuticals.

BIO believes that transparency in healthcare spending is vitally important. But we also believe transparency provisions should focus on what matters most for patients, their out-of-pocket costs.

Sincerely,

/s/

Greg Hoke
Director, State Government Affairs

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

Testimony of Dennis Pathroff in Opposition to HB 1032

Good afternoon Chairman Weisz and members of the House Human Services Committee.

My name is Dennis Pathroff, and I am an attorney with the Zuger Kirmis & Smith law firm in Bismarck. I am here today representing Prime Therapeutics, a pharmacy benefit manager ("PBM"). Prime's sole insurer that it represents in ND is BCBSND.

We oppose HB 1032 in its current form. As drafted, HB 1032 requires PBMs to disclose competitive financial data to the state board of pharmacy. *See* page 4, lines 12-13 of the bill. While we don't necessarily oppose the disclosure, we oppose disclosure to the board of pharmacy.

PBMs' disclosure of competitive financial data to the board of pharmacy creates an inherent conflict of interest. This is because the board of pharmacy is made up of pharmacists – direct competitors of PBMs. Pharmacists and PBMs negotiate prices that plan sponsors pay for prescription drugs at retail pharmacies; the lower the price that PBMs negotiate, the lower the profits for pharmacies. HB 1032 gives the pharmacist-controlled board of pharmacy the opportunity to weaken PBMs' competitive bargaining positions, and in turn, benefit pharmacies. As was suggested by the US Supreme Court in *North Carolina State Board of Dental Examiners v. F.T.C.*, 574 U.S. 494 (2015), there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state.

To avoid the conflict of interest in providing competitive financial data to a market adversary, HB 1032 could be amended to require that the data be disclosed to the Insurance Commissioner – a neutral third party.

Attached to my testimony is a memorandum more fully explaining the problems associated with disclosing PBMs' financial data to the board of pharmacy. Please review this memorandum at your convenience.

As currently drafted, I urge a do not pass recommendation on HB 1032. Chairman Weisz and members of the committee, thank you for the opportunity to comment on HB 1032. I'd also like to mention that Prime's Principal Government Affairs Lobbyist, Alex Sommer, is in the Zoom que and would like to testify on this bill.

I'd stand for questions.

MEMORANDUM

TO: House Human Services Committee
FROM: Dennis Pathroff contract lobbyist for Prime Therapeutics
DATE: 1/6/2021
RE: HB 1032 (21.0006.05000) – Disclosure of Pharmacy Benefits Manager Information to the State Board of Pharmacy

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INTRODUCTION

As drafted, the Prescription Drug Cost Transparency Bill requires a pharmacy benefit manager ("PBM") to disclose competitive financial data to the state board of pharmacy. The bill also provides the state board of pharmacy with discretion to disseminate the data. This memo analyzes the problems associated with the disclosure and recommends the data be classified as a "confidential record" and be disclosed only to the Insurance Commissioner.

DISCUSSION

A. The Disclosure Requirement

The bill provides in pertinent part as follows:

1. On or before April first of each year, **a pharmacy benefits manager providing services for a health care plan shall file a report with the board**. The report must contain the following information for the previous calendar year:
   a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer;
   b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer which were passed to health insurers;
   c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to enrollees at the point of sale; and
   d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the pharmacy benefits manager.
2. Reports submitted by pharmacy benefits managers under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.
3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may

not disclose or tend to disclose proprietary or confidential information of anypharmacy benefit manager.[1]

B. Problem of Disclosing Information to a Competitor

A PBM's disclosure of its competitive financial information to the state board of pharmacy may lead to a Federal Trade Commission ("FTC") complaint or lawsuits resulting from an anticompetitive restriction on trade. This is because the state board of pharmacy is made up of pharmacists, the direct competitors of PBMs.

Pharmacists and PBMs are competitors in two different areas of the prescription drug market.[2] First, pharmacists and PBMs negotiate prices that plan sponsors will pay for prescription drugs at retail pharmacies; the lower the price that PBMs negotiate, the lower the profits for pharmacies.[3] Second, retail pharmacies directly compete with PBM-owned mail-order pharmacies for prescription drug sales; the more prescription drugs sold by mail-order pharmacies, the fewer drugs sold by retail pharmacies.[4]

As currently drafted, the Prescription Drug Cost Transparency Bill gives the pharmacist-controlled board of pharmacy the opportunity to exploit the disclosure of the PBMs' competitive data in ways that benefit pharmacies at the expense of PBMs. Wielding the competitive financial information disclosed by PBMs, the board could establish various rules or practices that improve pharmacists' bargaining position as they negotiate with PBMs for retail prescription drug prices.[5] Similarly, the board could establish rules that restrict cost-saving practices that attract consumers to mail-order pharmacies and away from retail pharmacies.[6]

In a letter addressing the likely consequences of allowing a state board of pharmacy to regulate PBMs and gather competitive financial data from PBMs, the FTC opined:

> Because pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board. Indeed, the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state. . . . [A]llowing the Pharmacy Board to demand confidential business

[1] HB 1032, Pages 4-5 (emphasis added).

[2] Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 NW J.L. & SOC. POL'Y.1 (2013), p. 9.

[3] *Id.*

[4] *Id.*

[5] *Id.* at 10.

[6] *Id.*

> information from PBMs and to disclose it presents a significant threat to competition that could lead to higher prescription drug prices.[7]

Similarly, the FTC has opposed regulatory boards composed of market participants in other industries. In 2010, the FTC filed an administrative complaint charging the North Carolina Dental Board with violations of federal antitrust law. The FTC alleged that the board's concerted action to exclude non-dentists from the market for teeth whitening services in North Carolina constituted an anticompetitive and unfair method of competition. At the time, the dental board consisted of six licensed dentists, one licensed hygienist, and one consumer member. In its analysis of the regulatory framework of the North Carolina Board of Dental Examiners, the FTC stated that when a state regulatory body is controlled by participants in the very industry it purports to regulate, "common sense and economic theory . . . dictate the conclusion that Board actions in this area could be self interested."[8] In response to the FTC's administrative complaint, the North Carolina Dental Board argued for the state-action exemption from antitrust law and moved to dismiss the complaint. The state-action exemption provides immunity for (1) public actors performing state-mandated activities or (2) private actors working under the oversight of the state. Ultimately, in *North Carolina State Board of Dental Examiners v. F.TC.,* 574 U.S. 494 (2015), the United States Supreme Court held that the North Carolina Dental Board was a sovereign entity controlled by active market participants that did not receive active supervision by the state, and therefore, the board's anticompetitive actions were not entitled to immunity from antitrust law.

As was suggested by the FTC and Supreme Court in *North Carolina Dental,* it is safe to assume that the members of a professional board that are competitors to a group they are charged with regulating may act in their own self-interest. Requiring the disclosure of a PBM's competitive and proprietary financial data to the state board of pharmacy creates an inherent conflict of interest by giving pharmacists an advantage over their natural competitors in the marketplace. Ultimately, this may lead a potential lawsuit or FTC complaint.

To avoid the inherent conflict of interest in providing financial data to a competitor, the Prescription Drug Cost Transparency Bill could simply require a PBM to disclose the data to the Insurance Commissioner – a neutral third party. Note that the Insurance Commissioner is already reviewing PBM's competitive, proprietary financial data for other reasons.[9] Also note that in states that have adopted similar legislation, the reports go to the insurance regulatory authority.[10]

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[7] Letter from Susan S. DeSanti et al., Director Fed, Trade Comm'n, et. Al. to Mark Formby, Representative, Mississippi House of Representatives (Mar. 22, 2011).

[8] Joanna Shepherd at p. 10 (quoting Opinion of the Commission, NC Bd. of Dental Examiners, Docket No.9343 (Feb. 8. 2011).

[9] See N.D.C.C. 26.1-27.1-06 (2)-(3) ("[T]he commissioner shall examine any contract between the covered entity and a pharmacy benefits manager and any related record . . . the covered entity shall disclose annually to the commissioner the benefits of the payment received by the pharmacy benefits manager received under any contract with a pharmacy benefits manager . . . [a]ny information disclosed to the commissioner under this section is considered a trade secret under chapter 47-25.1).

[10] *See e.g.,* Minnesota (Minn. Stat. § 62W.06), Texas (Tex. Ins. Code § 1369.502), Arkansas (A.C.A § 23-92-505), and Iowa (Iowa Code §510C.2).

C. Protection from Open Records Requests

Reports containing a PBM's competitive financial data should not be subject to open records requests. As currently drafted, the Prescription Drug Cost Transparency Bill gives the state board of pharmacy the discretion to disclose a PBM's competitive financial data. In pertinent part the bill provides:

> 4. A report received by the board is an **exempt record** as defined by 44-04-17.1.[11]

In North Dakota "all records of a public entity are public records, open and accessible for inspection . . . [e]xcept as otherwise specifically provided by law."[12] Because the open records law does not apply "if otherwise specifically provided by law," public records need not be disclosed if they fall within a specific exemption from the open records law.[13] There are 3 classes of public records under ND law:

(1) Confidential – disclosure of these documents is generally prohibited;
(2) Exempt – disclosure is discretionary; and
(3) Subject to open records law – disclosure of these documents is required.[14]

As drafted, the reports containing PBMs' competitive financial data are "exempt records." Therefore, it is in the pharmacy board's discretion to disclose a PBM's competitive financial data via an open records request. As explained in Section B, *supra*, the members of the board of pharmacy are competitors of PBMs, and therefore, may act in a manner that disadvantages PBMs. Indeed, imagine a scenario where a pharmacist or drug manufacturer makes an open records request for the competitive financial data. It's not hard to imagine the board coming up with some viable reason to provide the information. If, in fact, the board does disclose PBMs' data on rebates, fees, and price protection payments via an open records request, it will reduce PBMs' bargaining power to negotiate discounts with pharmacies and rebates with drug manufacturers because both pharmacies and drug manufacturers are less likely to offer the same price terms to PBMs when they know rival pharmacies and manufacturers can learn the specifics of the arrangement. Ultimately, the open records request disclosure of the competitive data would likely lead to reduced discounts and rebates that PBMs can pass on to consumers and health plan sponsors. Therefore, the reports containing PBMs' competitive financial data should not be classified as "exempt records" but rather "confidential records" – not subject to open records requests.

CONCLUSION

Granting the state board of pharmacy control to collect PBMs' competitive financial data creates an inherent conflict of interest by giving a group of pharmacists regulatory control of their natural

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[11] HB 1032, Page 6, line 10 (emphasis added).

[12] N.D.C.C. § 44-04-18.

[13] *See* ND AG Open Records Manual, August 2019, Page 23.

[14] *Id*. at 24-25 (citing § N.D.C.C. 44-04-17.1(3) and § 44-04017(5)).

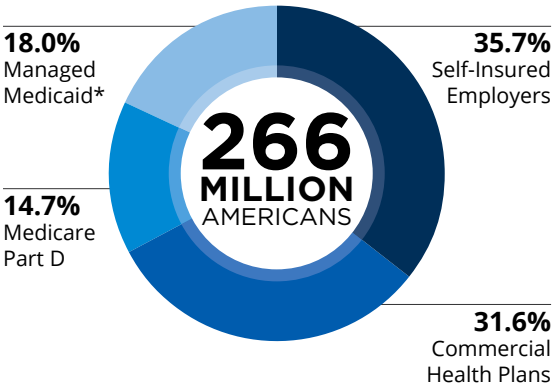
competitors in the marketplace. Under the current reporting scheme in the Prescription Drug Transparency Bill, the board of pharmacy will have the opportunity to weaken PBMs' competitive positions, and in turn, benefit pharmacies. This issue could likely be resolved by requiring the data disclosure to the Insurance Commissioner and classifying the competitive financial data as "confidential records".

ABOUT PCMA

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health coverage from a variety of sponsors. PCMA continues to lead the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs, increasing access, and improving outcomes.

PBMs serve consumers across plan types

Americans With Drug Benefits Managed by PBMs, by Type of Coverage



* Excludes "Medicare/Medicaid Dual Eligibles" where drugs are covered by Medicare Part D

How PBMs reduce drug costs

- Encouraging the use of generics and affordable brand medications
- Reducing waste and increasing adherence to improve health outcomes
- Offering home delivery of medications and creating networks of affordable and high quality pharmacies
- Negotiating rebates from drug manufacturers and discounts from drugstores
- Managing high-cost specialty medications

PBMs promote pharmacy access

PBMs work with health plans, employers, and government programs to ensure that their members and employees have access to necessary medications through a variety of pharmacies, including retail, community, mail order, and specialty pharmacies.

PBM savings

PBMs are projected to save employers, unions, government programs and consumers an average of $962 per person per year.

$962
PER PERSON
PER YEAR

Source: Visante, estimates prepared for PCMA. (2020).

#123

PCMA MEMBERS

ABARCA
CERPASSRX
CVSHealth
envolve Pharmacy Solutions
EXPRESS SCRIPTS
Humana Pharmacy Solutions
ingenioRx
IPM INTEGRATED PRESCRIPTION MANAGEMENT
MagellanRx MANAGEMENT
MAXORplus
MedImpact
OPTUMRx
PERFORMRX Next Generation Pharmacy Benefits
PRIME THERAPEUTICS
SERVE YOU Rx
welldyne Better Begins Today

Sixty-seventh
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1032

#134

Introduced by

Legislative Management

(Health Care Committee)

A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to prescription drug cost transparency; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new chapter to title 19 of the North Dakota Century Code is created and enacted as follows:

Definitions.

As used in this chapter:

1. "Board" means the state board of pharmacy.
2. "Commissioner" means the insurance commissioner.
3. "Concession" includes a free good, delayed billing, and billing forgiveness.
4. "Drug" has the same meaning as provided under section 19-02.1-01.
5. "Health care plan" means an individual, blanket, or group plan, policy, or contract for health care services issued or delivered in this state by a health insurer.
6. "Health insurer" means an insurance company, nonprofit health service corporation, health maintenance organization, third-party payer, health program administered by a state agency, or other person engaged as principal in the business of insurance which issues or delivers a health care plan in this state.
7. "Manufacturer-packaged drug container" means a manufacturer-prepared supply of medication packaged in a container with a unique product-identifying national drug code number.
8. "Net spending" means the cost of drugs minus any discounts that lower the price of the drugs, including a rebate, fee, retained price protection, retail pharmacy network spread, and dispensing fee.

9. "Pharmacy benefits manager" has the same meaning as provided under section 19-03.6-01.

10. "Prescription drug" means a:

a. Substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

b. Drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(1) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or other legend that complies with federal law; or

(2) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

c. Drug or device required by federal or state law to be dispensed on prescription or restricted to use by a practitioner.

11. "Rebate" includes any discount, financial incentive, or concession that affects the price of a drug to a pharmacy benefits manager or health insurer for a drug manufactured by the pharmaceutical manufacturer.

12. "Specialty drug" has the same meaning as provided under section 19-02.1-16.2.

13. "Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

14. "Wholesale acquisition cost" means, with respect to a prescription drug, the manufacturer's list price for the prescription drug to wholesalers or direct purchasers in the United States for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data, such as Medi-Span Price Rx, Gold Standard Drug Database, or First Databank drug data. The term does not include a rebate, prompt pay, or other discount or other reduction in price.

Disclosure of drug pricing information.

1. Each drug manufacturer shall submit a report to the board no later than the fifteenth day of January, April, July, and October with the current wholesale acquisition cost

information for the United States food and drug administration-approved drugs sold in or into the state by that manufacturer.

2. a. Not more than thirty days after an increase in wholesale acquisition cost of forty percent or greater over the preceding five calendar years or ten percent or greater in the preceding twelve months for a prescription drug with a wholesale acquisition cost of seventy dollars or more for a manufacturer-packaged drug container, a drug manufacturer shall submit a report to the board. The report must contain the following information:

(1) Name of the drug;

(2) Whether the drug is a brand name or a generic;

(3) The effective date of the change in wholesale acquisition cost;

(4) Aggregate, company-level research and development costs for the previous calendar year;

(5) Aggregate rebate amounts paid to each pharmacy benefits manager for the calendar year;

(6) The name of each of the manufacturer's drugs approved by the United States food and drug administration in the previous five calendar years;

(7) The name of each of the manufacturer's drugs that lost patent exclusivity in the United States in the previous five calendar years; and

(8) A statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost, such as raw ingredient shortage or increase in pharmacy benefits manager rebates.

b. The quality and types of information and data a drug manufacturer submits to the board pursuant to this subsection must be the same as the quality and types of information and data the manufacturer includes in the manufacturer's annual consolidated report on securities and exchange commission form 10-K or any other public disclosure.

3. A drug manufacturer shall notify the board in writing if the manufacturer is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare part D program.

a. The notice must include a statement of rationale regarding the factor or factors that caused the new drug to exceed the Medicare part D program price.

b. The drug manufacturer shall provide the written notice within three calendar days following the release of the drug in the commercial market.

c. A drug manufacturer may make the notification pending approval by the United States food and drug administration if commercial availability is expected within three calendar days following the approval.

4. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website.

Disclosure of pharmacy benefits manager information.

1. On or before April first of each year, a pharmacy benefits manager providing services for a health care plan shall file a report with the board. The report must contain the following information for the previous calendar year:

a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer;

b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer which were passed to health insurers;

c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to enrollees at the point of sale;

d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the pharmacy benefits manager; and

e. The aggregated rebates passed on to employers.

2. Reports submitted by pharmacy benefits managers under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.

3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.

Disclosure of health insurer spending information.

1. a. On or before April first of each year, each health insurer shall submit a report to the board. The report must contain the following information for the previous two calendar years:
   (1) Names of the twenty-five most frequently prescribed drugs across all plans;
   (2) Names of the twenty-five prescription drugs dispensed with the highest dollar spend in terms of gross revenue;
   (3) Percent increase in annual net spending for prescription drugs across all plans;
   (4) Percent increase in premiums which is attributable to prescription drugs across all plans;
   (5) Percentage of specialty drugs with utilization management requirements across all plans; and
   (6) Premium reductions attributable to specialty drug utilization management.

   b. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The combined aggregated data from the reports which the board provides to the commissioner must be provided in a manner that does not disclose or tend to disclose proprietary or confidential information of any health insurer.

2. A report submitted by a health insurer may not disclose the identity of a specific health benefit plan or the prices charged for specific prescription drugs or classes of prescription drugs.

Website.

1. The commissioner shall develop a website to publish information the board reports to the commissioner under this chapter. The commissioner shall make the website

available on the commissioner's website with a dedicated link prominently displayed on the home page, or by a separate, easily identifiable internet address.

2. Within thirty days of receipt of reported information from the board, the commissioner shall publish the reported information on the website developed under this section.

Rulemaking - Forms - Services - Records.

1. The board and the commissioner may adopt rules to implement this chapter.
2. In consultation with the commissioner, the board shall develop forms that must be used for reporting required under this chapter.
3. The board may contract for services to implement this chapter.
4. A report received by the board is an exempt record as defined by section 44-04-17.1.

Civil penalty.

A health care plan, drug manufacturer, or pharmacy benefits manager that violates this chapter is subject to the imposition by the attorney general of a civil penalty not to exceed ten thousand dollars for each violation. The fine may be collected and recovered in an action brought in the name of the state.

State of North Dakota
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536
STATE BOARD OF PHARMACY
Email= Mhardy@ndboard.pharmacy
www.ndboard.pharmacy

Mark J. Hardy, PharmD
Executive Director

House Bill No 1032 – Prescription Drug Cost Transparency
Human Services Committee – Pioneer Room
1:30 PM - Wednesday – January 6th 2021

Chairman Weisz, Members of the House Human Services Committee for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy and I thank you for providing me the opportunity to offer testimony on HB 1032 relative to prescription drug cost transparency.

The Board of Pharmacy has been engaged with the Interim Health Care Committee on this bill draft which is now before your committee. The Board of Pharmacy certainly understands and respects the desires of many to bring transparency to prescription drug costs. We are monitoring many of the initiatives taken by other states, similar to this bill draft, to address the public and patient's concerns with the continued escalation of drug pricing. We, the Board and profession of Pharmacy, found particularly troubling, the testimony we heard during the Interim Committee on the huge amount of prescription drug costs that were attributed to rebates shared between manufacturers and Pharmacy Benefit Managers [PBMs]. The Trump Administration and Center of Medicare through the Medicaid Services has taken notice of these rebates in their recent executive orders.

The Board of Pharmacy stands ready to act on any legislation that the Legislature implements on this topic. We understand there are several more initiatives yet to be introduced surrounding drug costs. We do feel that drug pricing is and will continue to be an issue that states will struggle with trying to enact meaningful legislation as, ultimately the true reform would have to be addressed on a Federal level to achieve any meaningful change in these convoluted dynamics of the entities involved. The reality we see and hear from our pharmacists, pharmacies and, most importantly, their patients is that there continues to be escalating drug prices while the business challenges of reimbursement to a pharmacy continue to plummet, which naturally asks the question "*where is the money going*"?

We have been encouraged by much of the Federal action that has been attempted on drug pricing. However, it remains to be seen how much meaningful change actually occurs moving forward. While everyone points the finger as the various parties involved the true reality of this situation is that the patient care can be compromised when affordability is an issue.

While the Board of Pharmacy does not have a formal position on this legislation, we stand ready to work with you on any legislation we can be of assistance on.

I would be happy to answer any questions you may have and hope to be a resource to you in any way you deem appropriate.

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1032
2/16/2021

Relating to prescription drug cost transparency

Chairman Weisz opened the committee meeting at 11:06 a.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Database creation
- Hospital & pharmacy addition
- Wholesale distributors
- Rebates

Rep. Matthew Ruby (11:07) presented **Amendment 21.0006.05002** - #6741

Rep. Matthew Ruby (11:08) moved to adopt **Amendment 21.0006.05002**

Rep. Karen Rohr (11:08) second

Voice Vote – Motion Carried

Rep. Karen Rohr (11:11) moved **Do Pass As Amended**

Rep. Mary Schneider (11:11) second

Representatives	Vote
Representative Robin Weisz	N
Representative Karen M. Rohr	N
Representative Mike Beltz	N

Representative Chuck Damschen	N
Representative Bill Devlin	N
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	N
Representative Dwight Kiefert	N
Representative Todd Porter	N
Representative Matthew Ruby	N
Representative Mary Schneider	Y
Representative Kathy Skroch	N
Representative Bill Tveit	N
Representative Greg Westlind	N

Motion Failed Do Pass As Amended 2-12-0

Rep. Bill Devlin (11:15) moved **Do Not Pass As Amended**

Rep. Matthew Ruby (11:15) second

Representatives	Vote
Representative Robin Weisz	Y
Representative Karen M. Rohr	Y
Representative Mike Beltz	Y
Representative Chuck Damschen	Y
Representative Bill Devlin	Y
Representative Gretchen Dobervich	N
Representative Clayton Fegley	Y
Representative Dwight Kiefert	Y
Representative Todd Porter	Y
Representative Matthew Ruby	Y
Representative Mary Schneider	N
Representative Kathy Skroch	Y
Representative Bill Tveit	Y
Representative Greg Westlind	Y

Motion Carried Do Not Pass As Amended 12-2-0

Bill Carrier: Rep. Greg Westlind

Chairman Weisz adjourned at 11:17 p.m.

Tamara Krause, Committee Clerk

DP 2/16/21
1 of 3

21.0006.05002
Title.06000

Prepared by the Legislative Council staff for
Representative M. Ruby
February 12, 2021

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1032

Page 1, line 18, after "7." insert ""Hospital" means a facility licensed under chapter 23-16.

8."

Page 1, line 21, replace "8." with "9."

Page 2, line 1, replace "9." with "10. "Pharmacy" means a pharmacy or drugstore registered under chapter 43-15.

11."

Page 2, line 3, replace "10." with "12. "Pharmacy services administrative organization" means an entity that provides contracting and other administrative services to a pharmacy to assist the pharmacy in the pharmacy's interaction, including reimbursement rate negotiations with a third-party payer, pharmacy benefit manager, wholesale drug distributor, and other entities.

13."

Page 2, line 14, replace "11." with "14."

Page 2, line 17, replace "12." with "15."

Page 2, line 18, replace "13." with "16."

Page 2, line 21, replace "14." with "17."

Page 2, line 22, replace "wholesalers" with "wholesale drug distributors"

Page 2, after line 27, insert:

"18. "Wholesale drug distributor" has the same meaning as provided under section 43-15.1-01."

Page 5, after line 28, insert:

"**Disclosure of pharmacy services administrative organization information.**

1. On or before April first of each year, a pharmacy services administrative organization providing services for a pharmacy shall file a report with the board. The report must contain the following information for the previous calendar year:

   a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer or wholesale drug distributor;

   b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer or wholesale drug distributor which were passed to pharmacies;

c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to pharmacies at the point of sale; and

d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers or wholesale drug distributors which were retained as revenue by the pharmacy services administrative organization.

2. A report submitted by a pharmacy services administrative organization under this section may not disclose the identity of a specific health benefit plan or enrollee or the prices charged for specific drugs or classes of drugs.

3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy services administrative organization.

Disclosure of wholesale drug distributor information.

1. On or before April first of each year, a wholesale drug distributor in this state shall file a report with the board. The report must contain the following information for the previous calendar year:

   a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer;

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   d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the wholesale drug distributor; and

   e. The aggregated rebates passed on to employers.

2. Reports submitted by wholesale drug distributors under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.

3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any wholesale drug distributor.

Disclosure of hospital and pharmacy information.

1. On or before April first of each year, a pharmacy and a hospital shall file a report with the board. The report must contain the following information for the previous calendar year:

   a. The aggregated rebates, fees, price protection payments, and any other payments collected for a pharmacy benefits manager;

   b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer or pharmacy benefits manager which were retained as revenue by the pharmacy or hospital; and

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2. Reports submitted by a pharmacy or hospital under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.

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Page 6, line 12, after the second underscored comma insert "hospital, pharmacy, wholesale drug distributor, pharmacy services administrative organization,"

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1032: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO NOT PASS** (12 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). HB 1032 was placed on the Sixth order on the calendar.

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21.0006.05002
Title.

Prepared by the Legislative Council staff for
Representative M. Ruby
February 12, 2021

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2021 SENATE HUMAN SERVICES

HB 1032

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1032
3/16/2021

A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to prescription drug cost transparency; and to provide a penalty.

Madam Chair Lee opened the hearing on HB 1032 at 10:31 a.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Required reporters
- Fiscal impact
- Actuarial study
- Rebate amounts
- Data collection
- Consumer costs

[10:31] Representative George Keiser, District 47. Introduced HB 1032.

[10:43] Jennifer Clark, Attorney, Legislative Council. Provided an overview of the language on HB 1032.

[10:49] Jon Godfread, ND Insurance Commissioner. Provided oral neutral testimony.

[10:54] Brendan Joyce, Administrator, Pharmacy Services, DHS. Provided neutral testimony #9234 and proposed amendment (testimony #8962).

[11:04] Janelle Moos, Associate State Director of Advocacy, AARP ND. Provided testimony #9263 and #9264 in opposition.

[11:06] Mark Hardy, Executive Director, ND Board of Pharmacy. Provided testimony #9274 in opposition.

[11:17] Kathi Schwan, Volunteer State President, AARP ND. Provided testimony #9359, #9360, #9361, and #9362 in favor.

[11:25] Mike Schwab, Executive Vice President, ND Pharmacists Association. Provided testimony #9550 in opposition.

[11:34] Brett Michelin, Senior Director, State Government Affairs, Association for Accessible Medicines. Provided testimony #8996 in opposition.

[11:43] Michelle Mack, Director, State Affairs, Pharmaceutical Care Management Association (PCMA). Provided testimony #9378 in opposition.

[11:48] Peter Fjelstad, PhRMA. Provided testimony #9338, #9339, #9340, #9341, and #9342 in opposition.

[11:54] Alex Sommer, J.D., Prime Therapeutics. Provided testimony #9397 in opposition.

[11:58] Margaret Mire, State Affairs Manager, Americans for Tax Reform. Provided testimony #9424 in opposition.

[12:02] Leah Lindahl, Senior Director, State Government Affairs, Healthcare Distribution Alliance. Provided testimony #9435 in opposition.

Additional written testimony: (5)

Senator Judy Lee, District 13. Testimony #8964, proposed amendment 21.0006.06001

Thomas Schatz, President, Council for Citizens Against Government Waste. Written testimony #9236 in opposition.

Robert Harms, Lobbyist, CVS Health. Provided written testimony #9401 from Larry Johnson, Regional Government Affairs Director, CVS Health.

Scott Pace, Pharmacy Services Administrative Organization. Written testimony #9440 in opposition.

Dustin Gawrylow, Lobbyist, ND Watchdog Network. Written testimony #9441 in opposition.

Madam Chair Lee closed the hearing on HB 1032 at 12:06 p.m.

Justin Velez, Committee Clerk

Testimony
Engrossed House Bill 1032 - Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairman

March 16, 2021

Chairman Lee and members of the Human Services Committee, I am Brendan Joyce, Administrator, Pharmacy Services for the Department of Human Services (Department). I appear today to provide testimony on Engrossed House Bill 1032.

The Department would be neutral to Engrossed House Bill 1032 if it is amended to exclude the Department and all programs the Department processes through our system (e.g. traditional Medicaid, Medicaid expansion, children's health insurance program, AIDS drug assistance program, special health services, county jails).

The Department provides detailed reporting to the legislature during sessions and during the interim to multiple committees. The Department feels it would be burdensome to provide the reporting specified in Engrossed House Bill 1032. The Department will continue to provide detailed reporting as required by federal requirements and to the legislature as it has done so in the past.

The Department would ask that clarification is added to the definitions to make it such that the Department, and the current programs administered by the Department (some of which are for Department of Health programs) are not included in the requirements of Engrossed House Bill 1032.

This concludes my testimony, and I am happy to answer any questions you may have.

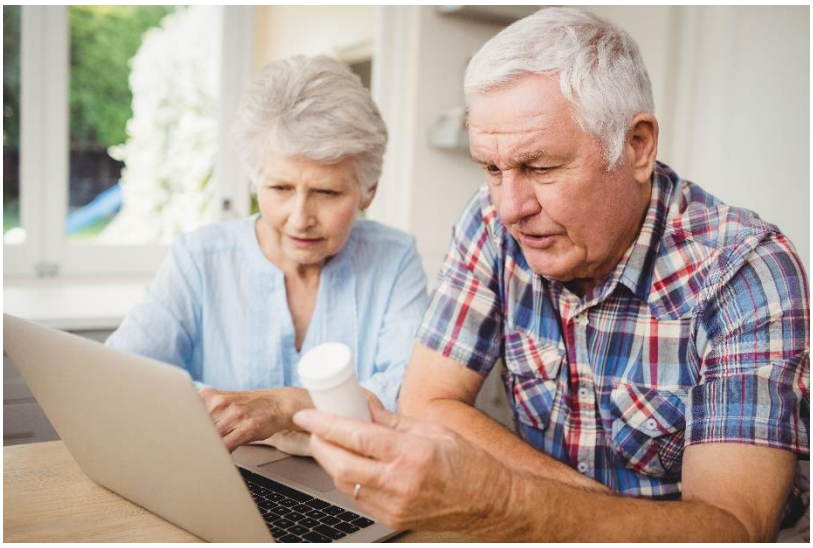
PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1032

Page 1, line 16, after "agency" insert ", excluding the department of human services and state department of health"

Page 2, line 3, after "19-03.6-01" insert ", excluding the department of human services and state department of health"

Renumber accordingly

Lowering Prescription Drug Costs
Transparency Frequently Asked Questions



The rising cost of prescription drugs impacts all North Dakotans, especially those 50 and older. That's why AARP North Dakota is supporting two policy solutions to help lower prescription drug costs: wholesale importation and transparency.

Prescription Drug Cost Transparency

Q. What is transparency?

A. Transparency bills require pharmaceutical companies to provide specific information about their pricing practices. Transparency legislation generally requires pharmaceutical companies to provide information about how a drug is priced, and to justify large price increases (or launch prices) that exceed a predetermined threshold.

Q. What does a transparency law mean for consumers?

A. Transparency bills, while by themselves do not reduce prescription drug prices, are important building blocks for other legislative efforts that can more directly address costs. In addition, transparency laws may provide consumers with advance warning of increases in their drug costs, allowing consumers to discuss lower cost alternatives with their health providers. Moreover, in order to avoid reporting requirements set forth by transparency laws, manufacturers may limit their price increases to keep them below the reporting threshold. The principle behind the bills is that increased disclosure around pricing practices will result in more meaningful and actionable information for states and accountability for manufacturers. Drug pricing transparency legislation will also help payers determine whether a drug price or price increase is justified.

Q. Where has this state legislative policy been enacted?

A. In 2016, Vermont passed the nation's first transparency law, which has led to many state legislatures considering bills requiring more disclosure and transparency from drug manufacturers. In total,12 states (CA, CT, CO, ME, MN, NH, NV, MD, OR, TX, VT, WA) have enacted drug transparency laws. In 2019, approximately 27 states filed 53 bills on transparency with 6 states (CO, ME, NV, OR, TX, WA) successfully passing Rx transparency laws in 2019.

For more information contact:
Janelle Moos
Associate State Director-Advocacy
jmoos@aarp.org
701-390-0161

AARP® North Dakota

Senate Human Services Committee
IN SUPPORT- HB 1032
Prescription Drug Cost Transparency
March 16, 2021
Janelle Moos, AARP North Dakota
jmoos@aarp.org – (701) 355-3641

Chair Lee and members of the Senate Human Services Committee,

My name is Janelle Moos, Associate State Director of Advocacy for AARP North Dakota. I appreciate your time today and look forward to working with you on an issue that is crucial to our members.

Transparency bills, while by themselves do not reduce prescription drug prices, are ***important building blocks for other legislative efforts,*** that can more directly address costs. In addition, transparency laws may provide consumers with advance warning of increases in their drug costs, allowing consumers to discuss lower cost alternatives with their health providers.

Moreover, in order to avoid reporting requirements set forth by transparency laws, manufacturers may limit their price increases to keep them below the reporting threshold. **The principle behind the bills is that increased disclosure around pricing practices will result in more meaningful and actionable information for states and accountability for manufacturers.** Drug pricing transparency legislation will also help payers determine whether a drug price or price increase is justified.

In an article from the National Academy for State Health Policy (NASHP) shows that laws like these provide valuable information- including information about consumer impacts- **that can help the state drive down prescription drug costs.**

For example- the reporting Nevada requires mostly around diabetes drugs shows "Financial assistance to consumers accounted for 14 percent of the manufacturers' estimated total revenues after rebates, ***although most manufacturers reported offering no financial assistance.***

Information like that can be gleaned from transparency bills like HB 1032 and similar information can help formulate ideas to directly impact prescription drug costs. Here is the report: https://www.nashp.org/what-are-we-learning-from-state-reporting-on-drug-pricing/#toggle-id-1

We believe that the two points should be clarified and added to the bill as possible amendments.

We would like to suggest adding a definition for Wholesale Acquisition Cost (WAC) unit under Section 1 as follows:

"Wholesale acquisition cost (WAC) Unit" is the lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. If reporting by drug group as indicated by [the State Agency], it is the total number of WAC units in the drug group.

Next, under section 2, subsection A, at the top of page 3 is unclear because it does not set a timeframe for the cost of the drug. Meaning, it states "a cost of $70 or more" but does not say whether that $70 is incurred for one pill, one month's supply or one year's supply. We believe the language should be clarified to specify the timeframe.

In addition, we'd like to suggest adding per WAC unit to line 6, acquisition cost of seventy dollars or more per WAC unit for a manufacturer-packaged drug, under Section 2, subsection a on page 3.

Also, and more importantly, we believe an independent board or committee should receive the report and that the report should be presented in a way consumers can understand it. Maybe the State Board of Pharmacy has time to receive this report, sort through it and make it understandable. But we think the Board likely already has enough to deal with. A transparency bill should be about getting information to the general public in a way that interested North Dakotans can not only access it, but understand it. An independent board should review prices and allow for consumer review and input.

We appreciate your consideration of our suggested amendments. Thank you again for your thoughtful work on this importation issue. We urge a favorable recommendation on HB 1032.

State of North Dakota
Doug Burgum, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536
STATE BOARD OF PHARMACY
Email= Mhardy@ndboard.pharmacy
www.ndboard.pharmacy

Mark J. Hardy, PharmD
Executive Director

House Bill No 1032 – Prescription Drug Cost Transparency
Senate Human Services Committee – Sakakawea Room
10:30 AM - Tuesday – March 16th 2021

Madam Chair Lee, Members of the Senate Human Services Committee for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy and I thank you for providing me the opportunity to offer testimony on HB 1032 relative to prescription drug cost transparency.

The Board of Pharmacy has been engaged with the Interim Health Care Committee on this bill draft which is now before your committee. The Board of Pharmacy certainly understands and respects the desires of many to bring transparency to prescription drug costs. We are monitoring many of the initiatives taken by other states, similar to this bill draft, to address the public and patient's concerns with the continued escalation of drug pricing. We, the Board and profession of Pharmacy, found particularly troubling, the testimony we heard during the Interim Committee on the huge amount of prescription drug costs that were attributed to rebates shared between manufacturers and Pharmacy Benefit Managers [PBMs]. The Trump Administration and Center of Medicare through the Medicaid Services has taken notice of these rebates in their recent executive orders.

The Board of Pharmacy stands ready to act on any legislation that the Legislature implements on this topic. The Board does have deep concerns with the tenets of this bill. The amendments made on the House side made this bill a much larger undertaking, with the addition of Wholesalers, Pharmacies and Pharmacy Service Administration Organizations [PSAOs]. The data reporting would prove to be an extensive and extremely expensive software programming that the Board of Pharmacy would undertake to implement this legislation which this amended version would require. We also need to point out that there is no funding mechanism in this legislation that would assist the Board of Pharmacy in this complicated endeavor.

We were not asked for a fiscal note. However, we would anticipate that we see 1-2 additional employees would be needed to collect and monitor the information this Bill requires. There will also be extensive costs associated with a programmed system that would be, hopefully, electronically capturing this information, including pricing and descriptions. Lastly, we would be expected to transmit the appropriate information/data to the ND Insurance Commissioner's Office.

As the Board of Pharmacy is a self-sustaining licensing agency, our only option for revenue is through licensure fees. We would have some opportunity to administratively raise some pharmacy licensure fees. However, it would probably not be sufficient to cover the costs this Bill would cause the Board to incur.

We do feel that drug pricing is and will continue to be an issue that states struggle with trying to enact meaningful legislation as, ultimately the true reform would have to be addressed on a Federal level to achieve any effective change in these convoluted dynamics of entities involved. We have been encouraged by much of the Federal action that has been attempted on drug pricing. However, it remains to be seen how much meaningful change actually occurs moving forward. While everyone points the finger as the various parties involved the true reality of this situation is that the patient care can be compromised when affordability is an issue.

I would be happy to answer any questions you may have and hope to be a resource to you in any way you deem appropriate.

Senate Human Services Committee
HB 1032
Prescription Drug Cost Transparency
March 16, 2021
Kathi Schwan, Volunteer State President
AARP North Dakota

Chair Lee and members of the Senate Human Services Committee,

My name is Kathi Schwan, Volunteer State President, for AARP North Dakota. I live in West Fargo and have been involved in AARP for several years before my current two terms as President. It has provided me a unique understanding of the needs of the 50+ in every corner of ND.

I appreciate your time today and look forward to talking with you about an issue that is crucial to our members and one that you've already heard they are passionate about during the first half of the legislative session.

Before I get into the reasons we are working so hard to fight the high cost of prescription drug prices I'd like to spend just a moment reminding you who we are and why we are here. AARP is a nonpartisan, nonprofit, nationwide organization with nearly 38 million members. 88,000 of those members live in North Dakota – a staggering number when you consider the overall population of our state.

A lot of issues touch older Americans and their ability to live safe, independent and healthy lives. Most of our work fits into three areas; helping people choose where they live, remain financially secure and access affordable health care.

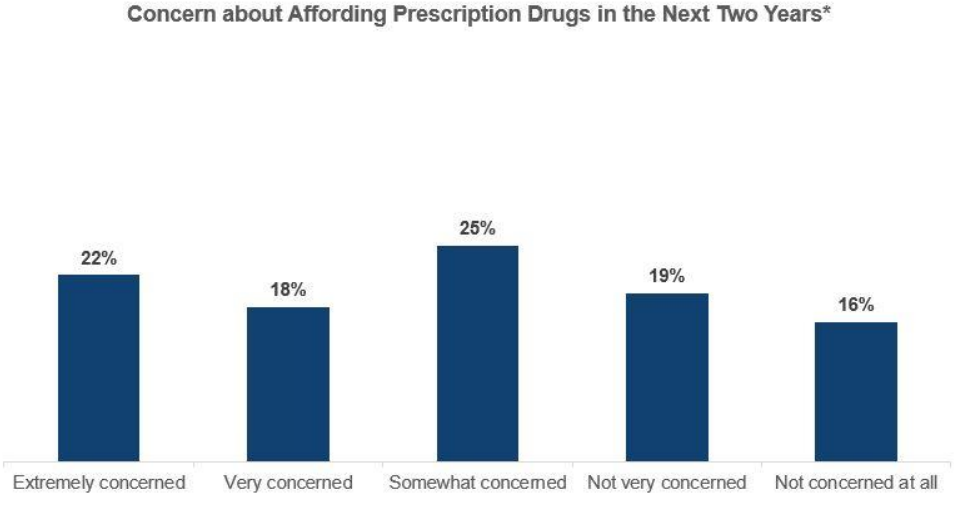
The rising cost of prescription drugs hits our members, and frankly all North Dakotans, in all three areas. It's a high priority for us right now, not only at the state level, but at the federal level as well. Let me outline just a couple of the reasons why.

The average older American takes 4.5 prescription drugs on a chronic basis. The average annual cost of prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for North Dakotans only increased 6.7%.

The high cost of prescription drugs doesn't just impact Medicare beneficiaries it impacts all North Dakotans, especially those age 50 and older. In AARP's 2020 survey of North Dakota adults, almost 1 in 4 individuals did not fill a prescription they were prescribed in the last two years. Of those who didn't fill a prescription, 44% of respondents said they had decided not to fill a prescription that their doctor had given them because of the **cost** of the drug. Further, 65% of them are at least somewhat concerned about being able to afford prescription drugs.

PRESCRIPTION DRUGS

Nearly two-thirds (65%) of North Dakota residents age 45+ are at least somewhat concerned about being able to afford prescription drugs over the next two years.



PER5. How concerned are you about being able to afford the cost of needed prescription drugs over the next two years? (n=722)
*Not equal to one-hundred percent due to removal of small cells; see annotation for all categories

Increasing drug prices hit older North Dakotans particularly hard. Most Medicare beneficiaries live on relatively modest incomes. A Kaiser Foundation study from 2016 shows the **median income for Medicare recipients is just over $26,000** – and a quarter of the people hover closer to $15,000. They also have very little savings. Half the Medicare population has less than $75,000 saved up. Their ability to absorb increasingly expensive prescription drugs is nearly impossible. Many people we have talked with recently tell us they have to make difficult decisions about how to live because of the price of those drugs.

One of the most staggering statistics I've seen is on a sheet included in the packet I handed out. **Twenty-eight percent** of people, when faced with the cost of the medicine they need, choose not to take it – not to pay for it. That's more than one in four.

On that same handout you can get a good feel for why they have to make that crushing choice. Near the top of the page are three common illnesses in North Dakota – cancer, diabetes and heart disease – with the number of residents of our state who have been diagnosed. More than 60,000 with cancer and nearly as many with diabetes. Below those numbers are common drugs used to treat them and their costs from 2017. Please, take note that we've included what those same drugs cost just five years earlier. **One nearly doubled, another jumped $100,000!**

There is much talk about the low cost of drugs in Canada. We are familiar with the Canadian reputation for safety standards. However, many ND snowbirds fly to Arizona in the winter. From there, they travel to a city called Los Algodones, 5 miles south of Yuma, where they find incredible prices on pharmaceuticals they can't afford in ND.

Why pay $168 for a single tube of Retina-A for your skin cancer, when you can get two tubes for $2.50 in Mexico? Or $300 for a single, tiny 30-drop bottle of Restasis eye drops when you can pick up a 6 month supply for $25? Many of these

products are manufactured in the US, but sold more inexpensively across the border.

While this bill does not deal with prescription drug importation, I know your committee considered several bills that did, in the first half of the session. Transparency bills, like HB 1032, are ***important building blocks for other efforts, like importation.*** This bill can help shed some additional light for consumers on what is driving price increases. It lays out specific reporting requirements that can help inform you as policy makers and us as consumers to understand when prices will increase and what drives those increases. It may also shed some light on why we pay so much more here than what you see and hear from snowbirds. *The Mexican vendors are so familiar with North Dakotans, they sell NDSU and UND souvenirs in their gift shops.*

Now, we know states can't solve this problem alone. But there are some things that can be done and we appreciate this committee's willingness to bring this issue to the forefront. We believe transparency from manufacturers, PBMs and insurance companies can help the state and consumers get a handle on these increasing prices and be prepared for when things are going to change. We appreciate that the bill draft in its current form addresses transparency at all three levels. Furthermore, the thorough description of what should be disclosed is encouraging.

That makes this issue relevant not only to the thousands of individual North Dakotans fighting disease, but it also affects those paying for health coverage and to the state. Spending increases driven by escalating drug prices are passed along to everyone with health insurance coverage in the form of higher premiums and deductibles. It increases costs for taxpayer-funded programs too – making this a relevant issue for every North Dakotan whether they are taking prescription medicine or not.

Thank you again for your thoughtful work on this issue. We wholeheartedly appreciate any effort to make medicine more affordable. This bill is a step in the

right direction and we look forward to working with you during the interim to make it the best possible bill for North Dakotans.

Thank you,

Kathi

#9360

How North Dakota Residents Are Impacted By High Rx Costs

60,228
North Dakota Residents
have been diagnosed with cancer.[1]

58,718
North Dakota Residents
have pre-diabetes or diabetes.[1]

22,311
North Dakota Residents
have heart disease.[1]

Between 2012 and 2017, the price of these name brand drugs increased:

Revlimid
treats forms of cancer

from $147,413/yr

to $247,496/yr[2]

Lantus
treats diabetes

from $2,907/yr

to $4,702/yr[2]

Aggrenox
treats heart disease

from $3,030/yr

to $5,930/yr[2]

Rx 31%

In 2017, 31% of North Dakota Residents stopped taking medication as prescribed due to cost.[3]

Sources:

[1] Total does not include skin cancer. Source: AARP Public Policy Institute analysis using 2017 data from the Behavioral Risk Factor Surveillance System.
[2] Stephen W. Schondelmeyer and Leigh Purvis. Rx Price Watch Reports. Washington, DC: AARP Public Policy Institute, June 2019, https://doi.org/10.26419/ppi.00073.000.
[3] Among 19-64 year old population. State Health Access Data Assistance Center (SHADAC) analysis of National Health Interview Survey data, State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed September 5, 2019

STOP GREED CUT DRUG PRICES NOW™ AARP Real Possibilities

#9361

Prescription Drug Transparency

Description

Prescription drug pricing transparency efforts require drug manufacturers to report the reasons behind high prices and price increases. The principle behind the bills is that increased disclosure around pricing practices will result in more meaningful and actionable information for states and accountability for manufacturers. Drug pricing transparency legislation will also help payers determine whether a drug price or price increase is justified. Moreover, the added scrutiny brought on by transparency legislation could encourage drug manufacturers to reconsider their standard practice of setting high launch prices and then increasing them year after year.

AARP strongly supports increased transparency in the drug development and pricing process and generally throughout the prescription drug supply chain. However, because too much transparency within the drug supply chain can actually reduce competition and lead to higher drug prices, transparency legislation should strike a careful balance between the desire for more information and the possibility that such disclosures could harm competition and lead to higher drug prices.

How does this work?

Transparency bills require pharmaceutical companies to provide specific information about their pricing practices. Transparency legislation generally requires pharmaceutical companies to provide information about how a drug is priced, and to justify large price increases (or launch prices) that exceed a predetermined threshold.

A transparency model bill drafted by NASHP (National Academy of State Health Policy) includes the following manufacturer reporting requirement triggers:

- For brand-name drugs: A 20 percent increase per WAC (wholesale acquisition cost) unit during any 12-month period;
- For generics: A WAC unit price of $100 or more, and a 20 percent increase per WAC unit during any 12-month period;
- For new drugs: A WAC of $670 or more; and

- Used for Pharmacy Benefit Managers (PBMs) and wholesalers: The state will require PBMs and wholesalers to report on specific drugs identified as being of interest following state review of manufacturer and insurer reports.

Some states have also included penalties in their bill language for manufacturers that fail to report. The NASHP model language includes a penalty of $30,000/day. The model language also invokes subpoena authority if reporting entities do not provide the required data or if the data they provide is unclear or inadequate.

What does a transparency law mean for consumers?

Transparency bills, while by themselves do not reduce prescription drug prices, should be considered important building blocks for other legislative efforts, such as cost review commissions and drug affordability boards that can more directly address costs. In addition, transparency laws may provide consumers with advance warning of increases in their drug costs, allowing consumers to discuss lower cost alternatives with their health providers. Moreover, in order to avoid reporting requirements set forth by transparency laws, manufacturers may limit their price increases to keep them below the reporting threshold.

Where has this state legislative policy been enacted?

In 2016, Vermont passed the nation's first transparency law, which has led to many state legislatures considering bills requiring more disclosure and transparency from drug manufacturers. In total, according to NASHP data, 12 states (CA, CT, CO, ME, MN, NH, NV, MD, OR, TX, VT, WA) have enacted drug transparency laws. In 2019, approximately 27 states filed 53 bills on transparency with 6 states (CO, ME, NV, OR, TX, WA) successfully passing the following laws in 2019.

- Colorado – HB 1131 requires a drug manufacturer or its agent to provide a prescriber the wholesale acquisition cost of a drug when marketing or providing information on a drug to a prescriber.
- Maine – LD 1162 requires manufacturers to report annually to the Maine Health Data Organization (MHDO) about drug prices when the manufacturer has, during the prior calendar year, increased the wholesale acquisition cost (WAC) of a brand-name drug or a generic drug by a certain per pricing unit percentage.
- Nevada – SB 262 expands existing law, which requires transparency around drugs used to treat diabetes, and requires new transparency for drugs used in the treatment of asthma. The law also authorizes the state to collect monetary penalties for noncompliance.
- Oregon – HB 2658 amends transparency legislation passed in 2018 and requires manufacturers of prescription drugs to report to the state any specified increase in price of certain prescription drugs at least 60 days before the date of such increase.

- Texas – HB 2536 requires drug manufacturers to disclose pricing information to the state on drugs with a wholesale acquisition cost of $100 or more for a 30-day supply, or that increase 40 percent or more over the preceding three calendar years or 15 percent or more in the preceding calendar year. Pharmacy Benefit Managers and insurers are also required to make annual reports to the state. All information disclosed will be posted publicly.
- Washington - HB 1224 requires drug manufacturers to disclose the 25 most-prescribed drugs, the 25 costliest drugs by total plan spending, the 25 drugs with the highest year-over-year increase in spending, and a summary analysis of the impact on drug costs on health premiums. Manufacturers must submit annually a description of the factors used to make the decision to increase the wholesale acquisition cost (WAC) of the drug and the amount of the increase, along with a justification for the increase. This law also requires a pharmacy benefit manager (PBM) to submit an annual transparency report.

A number of states that have passed transparency laws are using this legislation as a springboard to establish prescription drug rate review or rate setting commissions. State rate review commissions analyze drug pricing data from manufacturers, recommend policy options to the state for decreasing prices and, in some cases, establish drug price ceilings.

Rx PRICE GOUGING #9362 vs. 50+ INCOME

Americans pay among the highest drug prices in the world and many are having to choose between buying the medications they need and other essentials. Meanwhile, brand name drug prices continue to increase at rates that far exceed general inflation. These relentless price increases could force many Americans to pay drug prices that exceed their entire income for a year.

AVG. ANNUAL COST

The average annual cost for one brand name drug, used on a chronic basis, was around $6,800 in 2017, almost $1,000 more than in 2015.[1]

PhRMA SPENDS BILLIONS

Big Pharma spent nearly $169 million for lobbying and more than $6 billion for advertising in 2018. [5]

IN OUR STATE

The average annual cost of prescription drug treatment increased 57.8% between 2012 and 2017, while the annual income for North Dakotans only increased 6.7%.[6]

NUMBER OF PRESCRIPTIONS

The average older American takes 4.5 prescription drugs, typically on a chronic basis.[2]

AMERICANS PAY MORE

Americans can pay double what similar countries pay for the same name brand drugs.[4]

RESEARCH & DEVELOPMENT?

Nearly 80% of every Big Pharma dollar goes to something other than research and development.[3]

STOP Rx GREED
CUT DRUG PRICES NOW℠

AARP® Real Possibilities

[1,2] Stephen W. Schondelmeyer and Leigh Purvis, "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2017 Year-End Update," AARP Public Policy Institute, Washington, DC, September 2018.
[3] https://www.csrxp.org/wp-content/uploads/2019/05/CSRxP_One_pager_III_FINAL-SITERELEASE.pdf
[4] https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf
[5] https://www.opensecrets.org/lobby/induscode.php?id=H4300&year=2018 and https://jamanetwork.com/journals/jama/fullarticle/2720029
[6] Based on the price associated with taking 4 widely used brand name prescription drugs. Income is based on median person-level income.

#9550
1641 Capitol Way
Bismarck ND 58501-2195
Tel 701-258-4968
Fax 701-258-9312
Email: mschwab@nodakpharmacy.net

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

Senate Human Services Committee
HB 1032 – Madam Chair Judy Lee
3/16/2021 - 10:30 AM

Madam Chair and members of the committee, for the record, my name is Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association. We are here in opposition to HB 1032.

To be honest with you, we find this bill interesting and well-intended. However, this bill is a beast and does very little (if anything) to lower prescription drug costs. I know there are a lot of individuals from the various industries that will testify to their specific section of the bill. We all want transparency, right? We want the same thing. However, it needs to be the right transparency and it needs to be meaningful transparency.

Again, HB 1032 is well-intended but does little to bring about meaningful transparency and actually lower costs to consumers. The bill does require a ton of data to be reported. However, the data is all reported in the aggregate which tells us little to all most nothing at the end of the day. The more important question we have is after we gather all of this information, what are we going to do with it? How can it be used or how will it be used? I am unsure if it can be used in a meaningful way to actual lower costs to consumers.

As far as pharmacy is concerned, the pharmacy benefit managers have pushed reimbursement so far down to the floor that our members are willing to show you whatever your heart desires. We are even willing to show you our entire PBM contracts, if the PBMs will allow us to do so without being sued or kicked out of their networks. Madam Chair and members of the committee pharmacy is tired of taking the blame of the high cost of prescription drugs when we have little to do with the actual cost of prescriptions. PBMs and others will tell you pharmacies get "rebates" from their wholesalers. The reality is pharmacies receive "volume discounts" from their wholesaler based off purchases. These fluctuate month-to-month, are dependent on patient volume as well as which prescriptions practitioners

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

1641 Capitol Way
Bismarck ND 58501-2195
Tel 701-258-4968
Fax 701-258-9312
Email: mschwab@nodakpharmacy.net

prescribe. These volume discounts are not guaranteed on a month-to-month basis either. Even if you factor in the volume discounts (which pharmacies are not guaranteed), pharmacies still lose money filling prescriptions for certain PBMs.

In full transparency (no pun intended), the main reason we are opposed to this bill is because "pharmacy" is going to end up paying for the costs associated with implementing this bill which we wholeheartedly oppose. Let me explain, further. This bill falls in the lap of the ND Board of Pharmacy which regulates and licenses pharmacies, pharmacists and pharmacy wholesalers for example. It is our understanding the ND Board of Pharmacy will need at least one if not two employees to comply with the bill if it were to become law. In addition, the ND Board of Pharmacy will also need a significant data base upgrade which will cost six figures, plus ongoing annual costs. The ND Board of Pharmacy does not receive any state general funds. They are funded through licensing fees mainly from drug wholesalers, pharmacies, and pharmacists. Guess whose fees are going to up and go up significantly to pay for the implementation of this bill? If you guessed the profession of pharmacy, you would be correct.

There is already a Senate bill over in the House that requires drug wholesaler fees to increase to help pay for the implementation of that bill. That only puts even more pressure on pharmacists and pharmacies to pay even more in fees for the implementation of this bill. Our members have been reaching out to our office asking "why is the profession of pharmacy having to pay for the implementation of a bill that touches on so many more industry players and players that have way more to do with the actual cost of prescriptions than we do? I have struggled to answer their questions.

In an effort, to wrap my comments up, we support transparency, but it needs to meaningful transparency and transparency that lowers costs for consumers. Again, we mainly oppose this bill because the profession of pharmacy is going to have to pay to implement this legislation. You have other large industry players mentioned in the bill that not only can actually do something about the high cost of prescription drugs but have the means to pay for the implementation of legislation such as HB 1032.

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

1641 Capitol Way
Bismarck ND 58501-2195
Tel 701-258-4968
Fax 701-258-9312
Email: mschwab@nodakpharmacy.net

I would be happy to try and answer any questions you might have for me today. Thank you for your time and attention.

Respectfully,

Mike

Mike Schwab
EVP - NDPhA

March 12, 2021

Senator Judy Lee
Chairwoman, Senate Human Service Committee

Dear Senator Lee,

The Association for Accessible Medicines (AAM) is opposed to House Bill 1032. AAM is the leading trade association for generic and biosimilar manufacturers. Its core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

North Dakota saved over $914 million by using generic medications in 2019 alone. In fact, 90% of all prescriptions are filled with generic drugs yet these account for only 20% of all drug spending. Unfortunately, HB 1032 will not lead to lower costs for patients and could result in additional confusion.

The bill requires manufacturers to report the wholesale acquisition cost (WAC) for every drug sold into the state. However, the WAC has little to do with what a patient pays at the pharmacy counter because that is established by the insurer and pharmacy benefit manager---not the generic manufacturer. Reporting, and posting by the state, of thousands of generic drugs will not provide beneficial information for patients as they have little control over which product of the very same drug will be dispensed by the pharmacy. For example, there are 38 manufacturers of the generic form of Prozac with WACs ranging from $1.61 to nearly $800. However, the patient cost, as established by the insurer and PBM, will be the same at a pharmacy regardless of which manufacturers product is used. The wholesaler and pharmacy have the incentive to purchase the lowest cost generic product and it is this competition that saves patients money. In fact, 92% of all generic prescriptions are filled for $20 or less.

Further, the bill requires manufacturers to report an increase in the WAC of 40% over five years or 10% over the preceding 12 months for any drug with a WAC over $70. This provision will only impact generic drugs—which are not driving the increasing costs of healthcare. Studies show generic drug spending is only 3% of the total of U.S. healthcare costs and brand drugs are 10%. However, this bill will not capture an expensive brand drug costing $10,000 that increases by 9% or $900. But, it will capture a lower price drug costing $2.50 that increases 10% or $00.25. This bill will not result in lower costs for the state or patients.

Should you have any questions regarding AAM's opposition to this bill, please feel free to contact me at brett.michelin@accessiblemedicines.org.

Sincerely,

Brett Michelin

Brett Michelin
Senior Director, State Government Affairs
Association for Accessible Medicines

Cc: Senate Human Service Committee

#9378

March 15, 2021

The Honorable Judy Lee, Chair Senate Human Services Committee
The Honorable Kristin Roers, Vice Chair Senate Human Services Committee
North Dakota Senate Human Services Committee Members
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: **HB 1032 – Relating to the Prescription Drug Cost Transparency**
PCMA Testimony in Opposition to HB 1032

Dear Chair Lee, Vice Chair Roers and Committee Members:

My name is Michelle Mack and I represent the Pharmaceutical Care Management Association commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs. To give you a bit of information on PCMA and what PBMs are and what they do, I am including a document describing this in addition to my testimony.

As we stated in the interim committee process, PCMA supports meaningful transparency across the supply chain, including transparency that empowers patients, prescribers, clients, and policymakers to make informed decisions that lead to optimal health outcomes and lower costs. HB 1032, does not achieve these goals and therefore we oppose and urge you to give HB 1032 a Do Not Pass recommendation.

In addition, the House Human Service Committee urged a DO NOT Pass on HB 1032; unfortunately, some of the House members who were not on the Committee and did not hear the testimony, made inaccurate statements on the Floor and urged the House to override the Committee and recommendation and pass the bill. The statements made were:

1. PBMs cause drug prices to increase;
2. PBMs charge as much as 50% of rebates and put those dollars in their pockets – that North Dakota consumers end up paying; and
3. Generic drug prices go up because of PBMs.

We would like to refute these statement and set the record straight as follows:

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

According to researchers, PBMs, who are hired by plan sponsors (i.e. health insurance companies, large employer and other payers) to maximize the value of prescription drug benefits, help patients and payers save $962 per person per year in prescription drug costs,[1] equaling over $1 trillion over the next 10 years.[2] Plan sponsors use these savings to benefit patients by lowering premiums, deductibles, and cost sharing.

It is always the drug manufacturer who decides what the price of a given drug will be. PBMs do not set drug prices—rather, PBMs evolved as a means to lower the cost of drug benefits by negotiating price concessions with manufacturers and pharmacies on behalf of plan sponsors, such as large employers, government programs, and insurers. In addition, PBMs lower costs by encouraging use of generics, offering specialty pharmacy services, and helping patients with drug adherence. PBMs would not serve 266 million American through all kinds of health plans if they did not bring down costs.

PBMs negotiate rebates from manufacturers of brand name drugs that compete with therapeutically similar brands and generics. Manufacturers typically provide a rebate if their product is "preferred" which means it is assigned a copay lower than that of competing products. It must be noted that rebates are not offered on all brand drugs. Therefore, it is totally up to the manufacturer as to if a rebate is offered, how much is offered and for how long.

PBMs are transparent to clients on rebates, in accordance with contractual requirements. Nearly half of employer plan sponsors negotiating to receive manufacturer rebates elect to receive 100% of the rebate amounts and pay administrative fees to the PBM. Other payers negotiate for their PBMs to receive a portion of the rebates. Plan sponsors may negotiate any combination of these payment methods and other provisions, and always have the right to audit their PBMs' performance under their contracts. **On average, PBMs pass back 90 percent of negotiated rebates from drug manufacturers, which payers use to lower enrollees' and their own health spending.**

Finally, PBMs always have encouraged the use of generic drugs. According to the Association for Accessible Medicines (AAM), 90 percent

[1] Visante, The Return on Investment (ROI) on PBM Services, February 2020.
[2] Visante, Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, January 2020.

> of prescriptions filled in the United States are generics. When a generic alternative to a brand drug is available, the generic version is substituted for the branded drug 97 percent of the time, a rate that has been steady since 2013. This would not be possible if PBMs didn't incentivize generics to branded drugs. Here again, the manufacturer sets the price of a prescription drug, not the PBM.

Going back to the bill at hand, we feel the need to ensure the protection of competitive and proprietary financial information. Therefore, we are **very concerned** about the data being collected by the Board of Pharmacy. The FTC issued a letter on this issue when the Mississippi legislature passed a law granting the Board of Pharmacy with the authority to regulate PBMs.

> "[b]ecause pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board."[3]

Similarly, the FTC has opposed regulatory boards composed of market participants in other industries. In *North Carolina State Board of Dental Examiners v. Federal Trade Commission,* the United States Supreme Court looked into the question as to whether the state board could decide that a certain procedure could only be performed under the supervision of a dentist, thereby driving lower priced non-dentists out of the market. The FTC questioned the North Carolina Board of Dental Examiners' ability to regulate an industry in which they were active participants noting, '"common sense and economic theory…. dictate the conclusion that Board actions in this area could be self interested"[4]

We believe that the Department of Insurance would be the appropriate agency for such competitive data. The Board of Pharmacy is comprised of active market participants whose access to market sensitive data could result in a conflict of interest and undermine competition in the prescription drug marketplace.

The industry worked with various stakeholders in Texas throughout the process there to amend similar language on disclosure. A key amendment included in the final passage of Texas HB 2536 aggregates the rebate information reported by PBMs and health plans before publishing the data. This important clarification protects proprietary, private business and competitively sensitive information. PCMA respectfully requests the insertion

[3] FTC letter to Representative Mark Formby, Mississippi House of Representatives, (March 22, 2011).

[4] Emory University School of Law, "Legal Studies Research Paper Series". Joanna Shepherd 2013

of similar language such as the following:

> ***"The Insurance Commissioner shall collect and aggregate all the collected data and publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager or health plan [Carrier/Insurer]"*** in the section entitled "*Disclosure of pharmacy benefit manager information"* and the section entitled "*Disclosure of health insurer spending information"*.

PCMA also suggests the following language be included so the data submitted to the Department of Insurance is not subject to open records requests, except for the aggregated and de-identified data that is in the published report.

> **Rulemaking - Forms - Services - Records.**
>
> 4. A report received by the ~~board~~ **commissioner** is ~~an exempt~~ a **confidential** record as defined by section 44-04-17.1.

North Dakota open records laws have three classes of public records. Given the sensitive nature of the information within this bill's scope, it is more properly deemed "confidential information" rather than "exempt record."

In addition, PCMA respectfully requests the section involving penalties be either updated or removed from the bill. If anything, administrative penalties imposed by the regulator would be more appropriate to levy than civil penalties, especially when reporting to the Department of Insurance.

As I indicated above, drug manufacturers are responsible for setting the list price of drugs. No evidence exists to suggest that rebates cause higher drug prices. A study of list prices and rebates for the top 200 most prescribed drugs between 2011 and 2016 indicated that there is no correlation between rebates and list price increases or launch prices for individual drugs.[5] Of these drugs, there were prices that increased significantly, some that increased slightly, and some rebates that were high, and some that were low. Top brand

[5] Increasing Prices Set by Drugmakers Not Correlated with Rebates, Analysis prepared by Visante on behalf of PCMA, Jan. 2017, available at: https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf.

drugs that offered little to no commercial sector rebate during this time period still increased their prices, and manufacturers are increasing drug prices regardless of rebate levels negotiated by PBMs. Among the top 200 brand drugs by 2016 sales, the launch prices for drugs introduced from 2012 to 2016 were double the launch prices for those introduced prior to 2012. There was no correlation found between the prices and rebates.

Again, pharmaceutical manufacturers set drug prices. Therefore, the language on page 3 beginning on line 20 relating to the factors that led to drug price increase will likely yield better information if the language is amended to read as follows:

> ***"A definitive statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation of the role of each factor's impact on the cost."***

PCMA requests that the due date for annual data collection be changed to July 1st to ensure comprehensive reporting of information for the preceding calendar year. This request will allow for a complete and accurate accounting of information that by its nature lags at least one quarter behind. Stated differently, while information can be reported on April 1st of each year, it will not represent complete information for the preceding calendar year.

PBMs negotiate on behalf of their clients and consumers to help drive down the cost of prescription drugs by using market-based tools that encourage competition among drugmakers and drugstores. PBMs support and practice transparency that empowers patients, their providers, plan sponsors, and policymakers, so that there is informed decision-making that can lead to lower prescription drug costs.

We appreciate your interest and commitment to keeping the costs of drugs affordable for the citizens of North Dakota and look forward to working with you in your efforts to pass meaningful legislation.

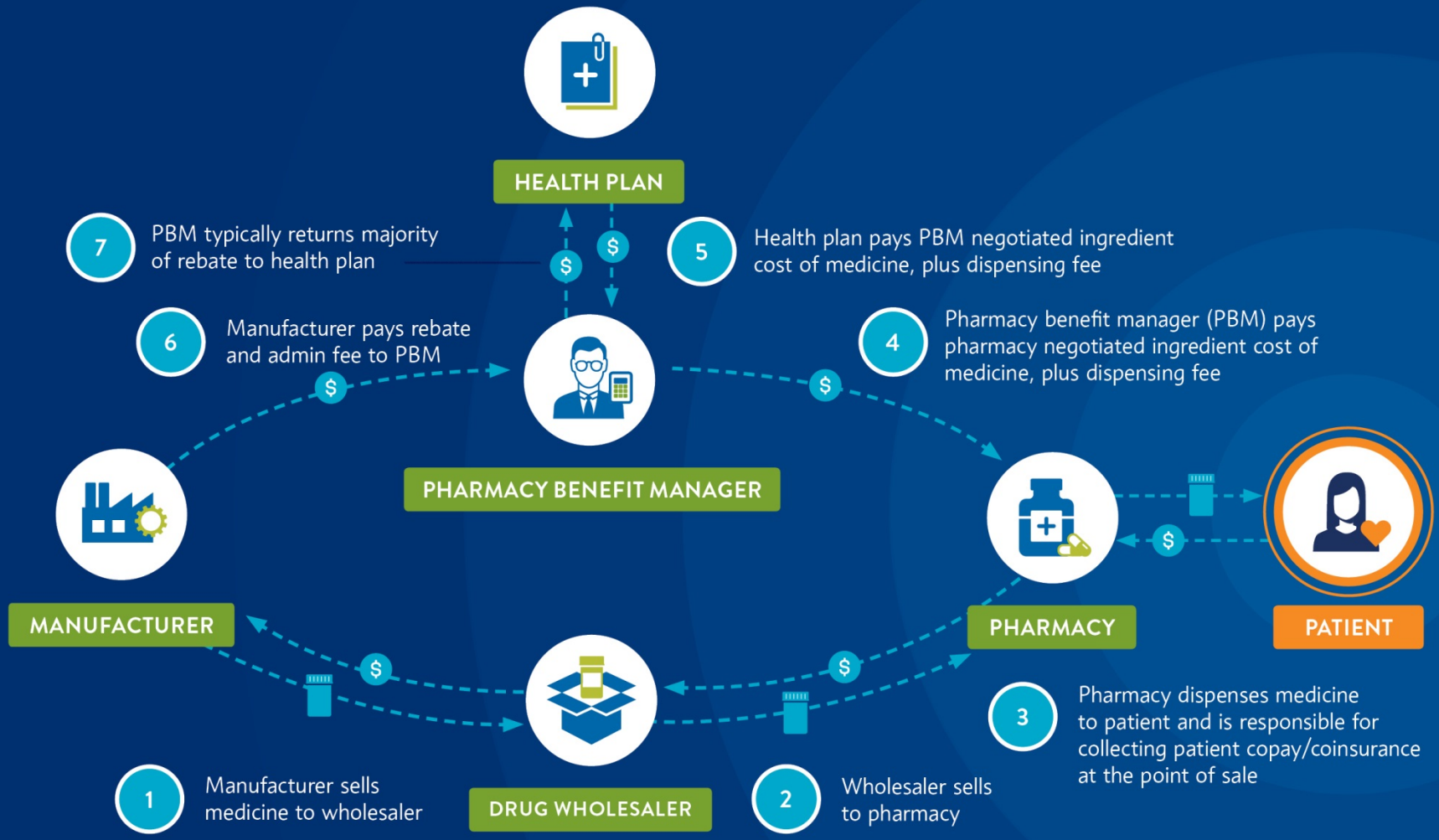
Thank you for your time and consideration. I'd be happy to answer any questions.

Michelle Mack
Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org

#9338

Distribution and Financial Flow

FOR RETAIL BRAND DRUGS



PhRMA RESEARCH · PROGRESS · HOPE

Source: Adapted from Pembroke Consulting

IQVIA: Medicine Spending and Affordability in the U.S.

August 2020

Key Findings:

Overall Prescription Medicine Findings, 2019:

- Brand medicine net prices increased 1.7% on average, below the rate of inflation for the third year in a row.
- Net spending (net manufacturer revenue) on all medicines increased 5.2%.
- Manufacturers received less than half (46%) of total WAC (list price) spending on prescription medicines.

Patient Spending Findings, 2019:

- Just 1.1% of all prescriptions have final out-of-pocket costs above $125.
- Overall, 90% of all patients pay less than $500 out of pocket per year on their prescription medicines.
- Patients saved a total of $12 B in out-of-pocket costs due to the use of copay coupons
- Spending in the deductible and through coinsurance, which often exposes patients to the undiscounted price of the medicine, now accounts for half (49%) of total patient out-of-pocket spending on all medicines but just 9.5% of all prescriptions filled
- 60% of new prescriptions with final OOP costs above $500 are abandoned at the pharmacy, compared to just 5-6% of new prescriptions with cost sharing less than $10.

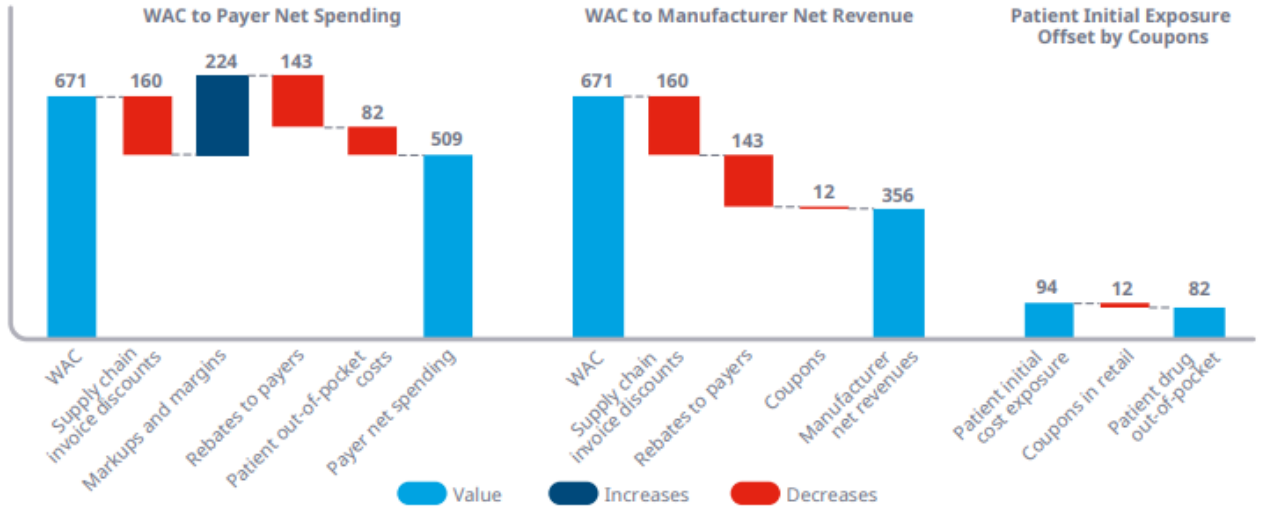
Full Summary:

Drug Prices and Spending Trends:

2019 Total Spending:

- Net spending (net manufacturer revenue) on all medicines increased 5.2%
- Total WAC (list price) spending on prescription medicines was $671 B, total net payer spending on medicines was $509 B, and total manufacturer net sales was $356 B (less than half, 46%, of total WAC spending)
- Payers received $143 B in rebates from manufacturers and supply chain and other entities retained $224 B in mark-ups and margins on prescription drugs

Exhibit 2: Differences Between Various Spending Levels for U.S. Prescription Medicines in 2019, US$Bn



Source: IQVIA Institute, Jun 2020; CMS National Health Expenditures (NHE), Dec 2019

- In 2019 alone, loss of exclusivity lowed medicine spending by $21.1 B

#9340

Meet MAT

medicine assistance tool.org

It's the biopharmaceutical industry's mission to find lifesaving treatments. It's also our responsibility to help patients access them.

To help provide patients with more transparency about medicine costs, PhRMA member companies created the Medicine Assistance Tool, or MAT. The platform provides patients, caregivers and health care providers with information to help them connect to financial assistance programs for the medicines patients need. MAT also links to member company websites, referenced in company direct-to-consumer television advertising, where information about the cost of the prescription medicine is available.

WHAT IS PHRMA'S MEDICINE ASSISTANCE TOOL?

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in accessing medicines. These include various biopharmaceutical industry programs offered to those who need financial support due to their lack of insurance or inadequate prescription medicine coverage. It also helps people learn more about the costs surrounding their medicines, as well as provides resources to help them better navigate their insurance coverage. MAT is not its own patient assistance program, but rather a search engine for many of the support programs and resources that the biopharmaceutical industry has been offering for decades.

HOW DOES MAT WORK?

MAT is a search engine that contains information on more than 900 public and private assistance programs that help patients access their prescription medicines, including some free or nearly free options. To use MAT, go to MAT.org and select whether you are a patient, loved one or health care professional. Next, enter the name of the medicines you, your loved one or your patient are prescribed and then enter your personal information or that of your loved one or patient (i.e. age, location, income, insurance coverage and household size). MAT will produce search results that identify programs and resources that might be able to help you. Any information provided is kept strictly confidential and will not be used to for any purpose other than providing the search results.

WHO IS INVOLVED IN MAT?

MAT was created by PhRMA, which represents America's top innovative biopharmaceutical research companies. There are hundreds of programs offered by PhRMA's members companies to help qualifying patients. PhRMA works in partnership on MAT with health care providers, pharmacists, patient advocacy organizations and community groups in an ongoing effort to make it easier for those with financial need to access their prescription medicines.

HOW CAN MAT HELP PATIENTS LEARN MORE ABOUT THEIR MEDICINE COSTS?

MAT provides patients, caregivers and health care providers with links to websites, referenced in company television advertising, where information about the cost of the prescription medicine is available. These websites may include information such as the list price of the medicine, out-of-pocket costs and other context about the potential costs of the medicine.

LET'S TALK ABOUT COST

10 THINGS YOU SHOULD KNOW ABOUT MEDICINE SPENDING AND COSTS

1 Today, there are more than 7,000 medicines in development, including 140 personalized medicines. And 42% of new medicines in development have the potential to be personalized therapies that can be targeted to specific patients and their individual health needs.

2 Nearly half of total spending on brand medicines – the sum of all payments made at the pharmacy or paid on a claim to a health care provider – went to the supply chain and other entities in 2018.

3 Due to negotiations in the market, net prices for brand medicines grew just 1.7%, on average, in 2019, less than the rate of inflation. And spending on medicines for one of the nation's largest pharmacy benefit managers (PBMs) grew just 2.3% last year.

4 91% of all medicines dispensed in the United States are generic copies that cost a fraction of the price of the initial brand medicine. In addition, competition from generics and biosimilars is expected to reduce U.S. brand sales by $121 billion from 2020 to 2024.

5 Unlike care received at an in-network hospital or physician's office, half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price.

6 The market-based Average Sales Price system helps control costs and spending in Medicare Part B. It is estimated that the government and seniors have saved $132 billion from 2005 to 2017 as a result of switching to this system. In 2018, Part B medicine spending was just 10% of total Part B spending and just 5% of total Medicare spending.

1.7% **The amount prices for brand medicine increased in 2019, after factoring in discounts and rebates.**

Innovative biopharmaceutical companies that research, develop and manufacture medicines retained just 54% of total point-of-sale spending on brand medicines.

7 Hospitals mark up medicine prices, on average, nearly 500%. An analysis of 20 medicines also found the amount hospitals receive after negotiations with commercial payers is, on average, more than 250% what they paid to acquire the medicine.

8 The biopharmaceutical industry spends three times more on research and development (R&D) than on marketing and promotion. To put this into context, U.S. biopharmaceutical companies spent $90.5 billion in 2016 on R&D, three times the $28.1 billion spent on marketing and promotion that year.

9 We have a responsibility to not just develop treatments and cures, but to also help patients access them. That's why we created the Medicine Assistance Tool, or MAT. This free search engine contains information on more than 900 public and private assistance programs that help patients access their prescription medicines, including some free or nearly free options. Visit **www.mat.org** for more information.

10 We are also working to fix the health care system so it works better for patients by making sure rebates and discounts are shared with patients at the pharmacy counter, eliminating barriers to innovative payment arrangements and making insurance work like insurance again. Sharing negotiated discounts could save certain commercially insured patients with high deductibles and coinsurance $145 to $800 annually and would increase premiums about 1% or less.

Learn more at LetsTalkAboutCost.org

PhRMA
RESEARCH • PROGRESS • HOPE

STATEMENT

#9342

In Opposition to House Bill 1032 –
Prescription Drug Cost Transparency
March 16, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes House Bill (HB) 1032, which would require significant reporting mandates, will not help patients, could threaten access to needed prescription medications, and potentially chill the innovation of future treatments.

Discussions about cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries, and other preventable procedures. All of which translate to lower health care costs. New medicines are making crucial contributions to medical advances and changing the direction of health care as we know it. With more than 4,500 medicines in the pipeline (74% which have the potential to be first in class medicines and 42% of which could be personalized medicines), patients have greater hope than ever before. However, this transparency bill is likely to skew important discussions of policy issues in ways that are systematically biased against innovation and ignores the value of medicines to patients, the overall health care system, and the economy of North Dakota.

Proposals to mandate *additional* disclosure of proprietary information by biopharmaceutical companies would neither benefit patients nor decrease health care costs.

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. Companies currently report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures in 10-K filings. Proposals to mandate public disclosure of additional confidential and proprietary information by biopharmaceutical companies ignore the large amount of information already publicly reported on an annual basis by companies and are based on the faulty assumption that prescription drug spending is the major driver of increases in health care costs.

The reporting requirements for manufacturers do not reflect the total investment of industry because of the long-term nature of research and development. Manufacturers pursue research efforts that include many failures and iterations on the path to development of a single approved drug. In fact, according to Tuft's Center for Study of Drug Development (CSDD), only 12% of medicines in the pipeline make it through the approval process by the federal Food and Drug Administration (FDA).[1] An 88% failure rate underscores how expensive and risky drug development is.

Drug costs are the *only* costs in the health care system that *decrease* over time due to market changes, such as brand to brand competition and patent expirations.

It is important to note that medicines are the *only* part of the health care system where costs *decrease* over time. When brand name medicines face brand competition, or when they lose their patent protection and generic drugs become available, prices drop, often significantly. In fact, it is projected that from 2019-2023, there will be approximately $105 billion in savings due to competition from generic and biosimilar products as patents for brand

1 Tufts Center for the Study of Drug Development (CSDD), "Briefing: Cost of Developing a New Drug," Nov 2014.
2 QuintilesIMS Institute, "Medicines Use and Spending in the U.S." May 2017.

medicines expire.[2] In addition, nearly 90% of all medicines dispensed in the U.S. are generic and cost pennies on the dollar.[3] Generics offer a cheaper alternative for patients when their health care provider deems a generic appropriate. However, one component of health spending that is not decreasing, is health insurance. Instead, it is seeing significant increases. Between 2007 – 2017, deductibles for patients have tripled and co-insurance has doubled. The Kaiser Family Foundation has routinely shown patient costs are increasing faster than insurers' costs. Morevover, health insurance and health plan administration costs are rising at more than twice the rate of drug spending.

According to new research from the Berkeley Research Group (BRG), rebates, discounts, and fees paid by manufacturers, are on the increase, while the share received by manufacturers has decreased over time.[4] In fact, nearly half (46%) of total spending on brand medicines went to the supply chain and other entities in 2018. This is a 13%-point increase from 2013, when other stakeholders retained 33% of brand medicine spending. This data reaffirms that we need to look at the entire supply chain in order to solve patient affordability challenges. Misaligned incentives must be fixed in the supply chain, including the broken rebate system, to ensure patients benefit at the pharmacy counter from the significant discounts and rebates.

In addition, brand and generic biopharmaceutical companies, unlike other sectors of health care, generated $41 million in rebates to the State of North Dakota and federal government in 2018. This is 55% of the total Medicaid spending on prescription drugs in the state.[5]

If the intent of HB 1032 is to improve access and affordability to needed medicines, the language of the bill is misguided.

The legislation does nothing to address how much consumers ultimately pay for a medicine, an amount determined by insurers, *not* biopharmaceutical companies. This legislation should do something to help patients afford their prescription medicines, such as passing on the rebates directly to the patients at the point of sale at the pharmacy counter. Instead, these rebates are going to the plans and other supply chain stakeholders. Recent data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket (OOP) costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan. A recent IQVIA study that looked at OOP patient spending for brand name medicines from 2015 – 2019 and showed that patient's spend on deductibles and co-insurance accounted for more than 2/3 of total OOP spend for brand medicines in five out of seven therapy areas examined. For two therapy areas (oncology and multiple sclerosis), it accounted for more than 90%.[6] This occurrence is contrary to the purpose of insurance—to spread the costs of health care utilization, so that patients can access needed care, including medicines.

Today, a patient pays only about 3% for OOP hospital costs, but 13% or more for their medicines.[7] Additionally, insurers are increasing utilization management techniques to aggressively restrict a patient's use of medicine. Currently, three major pharmacy benefit managers (PBMs) negotiate steep discounts on prescription drugs for more than 70% of all prescriptions filled in the U.S. Express Scripts alone covers about 90 million Americans.[8]

The biopharmaceutical industry supports over 800 jobs in North Dakota, with a generous annual average compensation

3 IQVIA Institute Drug Channels Institute
4 Berkeley Research Group (BRG). Revisiting the Pharmaceutical Supply Chain: 2013-2018. http://www.thinkbrg.com/newsroom-publications-revisit-pharma-supply-chain.html
5 The Facts About Medicaid in North Dakota. http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Medicaid-2019/ND-One-Pager_19.pdf.
6 Spending and Affordability in the U.S., Aug. 4, 2020. http://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us
7 Avalere Health analysis of the US Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, 2015. http://meps.ahrq.gov/mepsweb. Accessed February 2018 (analysis includes individuals with any source of health care coverage, public or private; this includes individuals who had health coverage without coverage for prescription drugs, which can be expected to account for less than 2% of those with health coverage).
8 http://lab.express-scripts.com/lab/drug-trend-report
9 Biopharmaceutical Section Impact on North Dakota's Economy. http://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_GB_StateFactSheet/PhRMA_GB_StateFactsheet_2019_North-Dakota.pdf.

of $80,097 per year, as compared to the average job salary in North Dakota of $56,226. That translates into $10 million in both state and federal taxes annually, as well as a total annual economic output of $207 million for the state. The industry is committed to working with lawmakers, patients, doctors, and other health care stakeholders to pursue policies that promote manufacturing, R&D, and innovation, while ensuring consumers have access to needed medicines.

Prescription medicines have transformed the trajectory of many debilitating diseases and conditions, including COVID-19, HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Better use of medicines could eliminate up to $213 billion in U.S. health care costs annually, which represents 8% of the nation's health care spending.[10] Therefore, instead of focusing on reporting of information that does nothing to help the patient, perhaps the conversation should focus on better use of medicines, which yields significant health gains by avoiding the need for other, more costly, medical services.

HB 1032 is not the way to accomplish improved access and affordability, therefore, PhRMA respectfully urges North Dakota lawmakers to oppose this bill.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone.

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

PRIME THERAPEUTICS®

March 15, 2021

The Honorable Judy Lee, Chair
Senate Human Services Committee
North Dakota State Legislature
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: House Bill No. 1032

Dear Madame Chair Lee:

Thank you for the opportunity to comment on House Bill No. 1032 today. I represent Prime Therapeutics, a pharmacy benefit manager (PBM) owned by 18 not- for-profit Blue Cross and Blue Shield insurers, subsidiaries or affiliates of those insurers, including Blue Cross and Blue Shield of North Dakota (BCBSND). For the reasons stated herein, we oppose this bill.

Prime Therapeutics helps people get the medicine they need to feel better and live well by managing pharmacy benefits for health plans, employers, and government programs including Medicare and Medicaid. Our company manages pharmacy claims for more than 30 million people nationally and offers clinical services for people with complex medical conditions. Our business model relies on transparency and advocating for simpler, lowest-net-cost pricing for drugs. Importantly, Prime is not focused on driving profit margins or attaining the largest rebate. To control costs, Prime's clients rely on our clinical expertise and drug management tools to reduce overall drug spending.

As an initial matter, this bill will harm Prime's efforts to reduce drug spending by further consolidating the power of North Dakota pharmacies and pharmacists via the delegation of oversight and power to the Board of Pharmacy (Board). The Supreme Court held in *North Carolina State Board of Dental Examiners v. FTC* that oversight of a market cannot be abandoned "to the unsupervised control of active market participants . . .."[1] Similar to that case, the Board's members are active market participants in the market this bill aims to regulate. Its pharmacist members negotiate contracts with PBMs, which are one of the tools PBMs use to drive down overall spending on drugs. Requiring a PBM to disclose its confidential and proprietary data related to the terms of these contracts would eliminate competition in the pharmacy space by creating a *de facto* collective bargaining arrangement among North Dakota pharmacists. The result of such an arrangement would be an increase in overall drug spending and thus increased prices for North Dakota citizens.

[1] 135 S. Ct. 1101 (2015)

Next, this bill does not adequately protect a PBM's proprietary or confidential information. Prime only supports one health plan in North Dakota, BCBSND. As written, the data in the bill's required reports can easily be tied back to Prime and BCBSND. Further, requiring Prime to report this data to the Board would be entirely inappropriate considering the role of the Board's members in the prescription drug supply chain and their negotiations with PBMs. Additional protections are needed for this data to ensure that proprietary and confidential data remains as such. We look forward to working with the Committee on this issue to ensure our competitive data is not subject to open records requests.

Finally, this bill raises concerns in its targeting of rebates. On pg. 3, starting at line 27, the bill presumes that an "increase in pharmacy benefit manager rebates" would be a cause for an increase in the price of a drug. In fact, the price for a rebate-eligible drug (*i.e.,* brand-name drugs) is set independently by the drug manufacturer. Prime uses rebates to secure price concessions on those list prices from drug manufacturers and then passes those rebate dollars back to its health plan clients, such as Blue Cross and Blue Shield of North Dakota. Rather than increasing the price of a drug, which is done by drug manufacturers alone, rebates soften the financial burden on the healthcare system by driving down the overall cost of care.

Prime supports *meaningful* transparency across the prescription drug supply chain and appreciates the opportunity to comment on this proposed solution. Ultimately, it delegates too much authority to PBMs' competitors (thus harming competition in the prescription drug marketplace) and targets PBM tools (*e.g.*, rebates) that help lower the overall cost of care. For these reasons, Prime opposes House Bill No. 1032.

Sincerely,

Alex Sommer, J.D.
Prime Therapeutics
Alexander.Sommer@primetherapeutics.com

AMERICANS for TAX REFORM

#9424

March 16, 2021

722 12th Street N.W.
Fourth Floor
Washington, D.C.
20005
T: (202)785-0266
F:(202)785-0261
www.atr.org

Members of the Senate Human Services Committee
North Dakota State Legislature State Capitol
600 East Boulevard Bismarck, ND 58505-0360

Re: Oppose House Bill 1032

Dear Senator,

On behalf of Americans for Tax Reform (ATR) and our supporters across North Dakota, **I urge you to oppose House Bill 1032,** the Drug Cost Transparency Legislation. While I have no doubt that the intentions behind HB 1032 are good, **I worry this bill – which is a step towards price controls – would result in a number of unintended negative consequences for patients across North Dakota.**

The biopharmaceutical industry is one of the most heavily regulated industries in the United States. It costs more than $2.5 billion and can take over a decade for just one new drug to make it through the Food and Drug Administration (FDA) approval process. **Piling on more red tape at the state level, such as HB 1032, would only make pharmaceutical development even more difficult.**

HB 1032 would burden pharmaceutical manufacturers with significant reporting requirements – including the disclosure of proprietary information – that would not accurately reflect the true costs of drug development nor the price paid by patients. **This would jeopardize pharmaceutical innovation and access to medicines, as it would result in pharmaceutical manufacturers wasting even more resources on compliance and lawyers instead of research and development for the next generation of lifesaving, life-improving medications.**

The fact is pharmaceutical development is a very costly and complicated process. This additional government intervention would not do anything to help patients afford their medications. Instead, **it is likely to result in the people of North Dakota being left with even fewer, lower quality choices, which would actually lead to higher healthcare costs over the long term.**

The best thing state lawmakers can do to mitigate rising healthcare costs is remove protectionist policies and government-imposed barriers to care. This would promote the competition that spurs innovation, improves quality, increases the number of available options, and naturally keeps prices low.

ATR opposes HB 1032 and encourages the Senate Human Services Committee to vote NO.

Sincerely,

Margaret Mire
State Affairs Manager
Americans for Tax Reform

Healthcare Distribution Alliance

PATIENTS MOVE US.

#9435

March 16, 2021

North Dakota Legislative Assembly
Senate Human Services Committee
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: Healthcare Distribution Alliance (HDA) Opposition to HB 1032

Chairwoman Lee, Vice Chair Roers and Members of the Senate Human Services Committee,

The Healthcare Distribution Alliance (HDA), the national trade association representing primary pharmaceutical wholesale distributors, offers this letter to express our concerns regarding House Bill 1032, Prescription Drug Transparency as amended. On behalf of HDA's members, we believe the legislation inaccurately reflects the role and services provided by the wholesale distribution industry and increases regulatory burden on the state to gather information that is already publicly available.

The U.S. healthcare supply chain is highly complex. Each day, wholesale distributors work around the clock to ship nearly 15 million healthcare products (medicines, medical supplies, durable medical equipment, etc.) to pharmacies, hospitals, and other healthcare providers daily to keep their shelves stocked with the medications and products they need to treat and serve patients. Wholesale distributors are unlike any other supply chain participants. Their core business is not manufacturing, and they do not prescribe medicines, influence healthcare professionals prescribing patterns, dispense medications to patients, influence patient benefit designs, or set the Wholesale Acquisition Cost (WAC) of medications. Their key role is to serve as a conduit for medicines to travel from manufacturer to patient while ensuring the supply chain is fully secure and operating efficiently.

HDA supports the state's efforts in seeking a better understanding of the prices that consumers see at the pharmacy counter. However, wholesale distributors have no insight into patient-level data, nor are they privy to how products are dispensed at the patient level. These quantities vary significantly, not just by the type of payor but also the type of healthcare setting to which the distributor is shipping (local pharmacy vs hospital setting). The quantities sold by a wholesale distributor to a pharmacy customer to not align with how other supply chain entities calculate and negotiate drug prices. Comparing these two data sets provides misleading and inaccurate information.

Furthermore, North Dakota already has full access to publicly available pricing information reported to the Centers for Medicare and Medicaid Services (CMS) that would obviate much of the need for wholesale distributors to report pricing data. The National Average Drug Acquisition Cost (NADAC) data is determined for virtually every drug in the marketplace through a nationwide, pharmacy survey process and is the invoice price pharmacies pay wholesalers for their medication products. This information is not proprietary, is updated weekly and can be immediately available to benchmark pharmaceutical prices in North Dakota against national drug pricing trends, while at the same time creating a certain level of pricing transparency with very little concern for building out data systems, managing various data streams and contending with numerous confidentiality concerns.

In addition to NADAC, each pharmaceutical manufacturer also reports a list price for all products sold in the U.S. This Wholesale Acquisition Cost (WAC), set by the manufacturer of a drug product, is the "list price" that wholesalers are charged for the purchase of all drugs. WAC is reported in various published compendia, such as

First DataBank and Medi-Span, that the state likely already has access to in order to invoice manufacturers under the Medicaid Drug Rebate Program (MDRP) and any supplemental rebate programs.

Ultimately, unlike other supply chain entities, wholesale distributor operations do not influence the price a patient pays for their medication. In fact, the efficiency and streamlined distribution and the storage, security and financial services offered by wholesale distributors generates between $33 and $53 billion in estimated cost savings each year to our nation's healthcare system.

We ask the committee to vote down HB 1032, which would add additional costs onto the state while not achieving it's ultimate intent of reducing the costs of medicine. We welcome the opportunity to provide additional information or context to the committee on the wholesale distribution industry and the role our members play within the supply chain, please contact me at (303) 829-4121 or LLindahl@hda.org to discuss this issue further.

Sincerely,

Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance

21.0006.06001
Title.

Prepared by the Legislative Council staff for
Senator Lee
March 4, 2021

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1032

Page 1, line 20, replace "medication" with "a prescription drug"

Page 1, line 22, after the first "of" insert "prescription"

Page 1, line 23, after "the" insert "prescription"

Page 2, line 9, remove the underscored colon

Page 2, remove lines 10 through 17

Page 2, line 18, replace "c. Drug or device" with "drug for human use which is"

Page 2, line 18, after "law" insert "or regulation"

Page 2, line 18, remove the third "or"

Page 2, line 19, replace "restricted to use by a practitioner" with ", including finished dosage forms and active ingredients subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)]"

Page 2, line 21, after the first "a" insert "prescription"

Page 3, line 5, after "**of**" insert "**prescription**"

Page 3, line 8, after "administration-approved" insert "prescription"

Page 3, line 16, after "the" insert "prescription"

Page 3, line 17, after "the" insert "prescription"

Page 3, line 23, after "manufacturer's" insert "prescription"

Page 3, line 25, after "manufacturer's" insert "prescription"

Page 4, line 8, after "new" insert "prescription"

Page 4, line 10, after the second "the" insert "prescription"

Page 5, line 4, after "specific" insert "prescription"

Page 5, line 4, after the first "of" insert "prescription"

Page 5, line 5, after "specific" insert "prescription"

Page 5, line 5, after "of" insert "prescription"

Page 5, line 15, after "prescribed" insert "prescription"

Page 6, line 22, after "specific" insert "prescription"

Page 6, line 22, after "of" insert "prescription"

Page 7, line 12, after the second "specific" insert "prescription"

Page 7, line 13, after the first "of" insert "prescription"

Page 7, line 13, after "specific" insert "prescription"

Page 7, line 14, after "of" insert "prescription"

Page 7, line 31, after the second "specific" insert "prescription"

Page 8, line 1, after the first "of" insert "prescription"

Page 8, line 1, after "specific" insert "prescription"

Page 8, line 2, after "of" insert "prescription"

Renumber accordingly

COUNCIL for CITIZENS AGAINST GOVERNMENT WASTE

Thomas A. Schatz, *President*
1100 Connecticut Ave., N.W., Suite 650
Washington, D.C. 20036
ccagw.org

TESTIMONY SUBMITTED FOR THE RECORD

ON

HB 1032 – PRESCRIPTION DRUG COST TRANSPARENCY

NORTH DAKOTA SENATE COMMITTEE ON HUMAN SERVICES

THOMAS SCHATZ

PRESIDENT

COUNCIL FOR CITIZENS AGAINST GOVERNMENT WASTE

MARCH 15, 2021

The Council for Citizens Against Government Waste (CCAGW) is a private, nonpartisan, nonprofit, organization representing more than one million members and supporters nationwide, with 4,461 members in North Dakota. CCAGW's mission is to uncover, publicize, and eliminate waste, fraud, abuse, mismanagement, and inefficiency in the federal government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CCAGW was established to follow up on the work of the President's Private Sector Survey on Cost Control, also known as the Grace Commission. CCAGW appreciates the ability to submit comments on HB 1032.

CCAGW is concerned that HB 1032, which is intended to provide prescription drug cost transparency, is nothing more than a fishing expedition that will fail to lower the costs of drugs in North Dakota. Instead, it will raise costs and burden pharmaceutical manufacturers, insurers, pharmacy benefit managers, hospitals, and pharmacies with busy-work activities, and require the hiring of additional accountants and lawyers to provide accurate information in a limited time frame. This will reduce the amount of money needed for research and development of life-saving drugs like the vaccines for COVID-19, and the additional costs of compliance for the other stakeholders, including the state board of pharmacy, will be passed on to consumers and taxpayers. Furthermore, this bill was reported back from the House Human Services Committee as "do not pass" by a vote of 12 to 2.

Using the wholesale acquisition cost (WAC) of $70 or more to determine the 40 percent increase after five calendar years or the 10 percent-plus increase trigger within a year for reporting a price hike as required in HB 1032 is a faulty premise because it represents the list price and not what the patient usually pays. The reams of data that will be required to be reported include proprietary information, which if it becomes public would be available to competitors, undermining competition. Having this material published on the website would likely interfere with private negotiations that drive down costs.

The Federal Trade Commission (FTC) has acknowledged that disclosure of pricing information could undermine beneficial market forces within the industry, leading to higher, not lower prices. A July 2, 2015 FTC policy paper stated, "But transparency is not universally good. When it goes too far, it can actually harm competition and consumers. Some types of information are not particularly useful to consumers but are of great interest to competitors. We are especially concerned when information disclosures allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price or increases the likelihood that they can coordinate on higher prices."

Supporters of a free market understand that the best approach to lowering prices of any product is an environment that fosters competition and innovation, not more regulation and government intervention. It takes 10 to 12 years and an average of $2.6 billion to get a new drug through the Food and Drug Administration (FDA) approval process. According to the FDA, 90 percent of all drugs dispensed are generics.

Rather than pursuing HB 1032, North Dakota legislators should ask their congressional delegation to continue to hold the FDA's feet to the fire to make sure that generic drugs are approved in a timely manner. The FDA must also continue to adopt modern techniques that streamline and speed up clinical trials and approval processes. In addition, all levels of

government should provide an environment that encourages the development of "me-too" drugs that provide competition for pharmaceuticals that are still under patent and provide more patient choice.

These actions would be a far more effective way to help bring down the price of prescription drugs than passing this legislation. Again, HB 1032 should be opposed.

CVSHealth

1275 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

March 15, 2021

Senate Human Services Committee
North Dakota Legislature
State Capitol
Bismarck, North Dakota 58505

Re: HB 1032 Prescription Drug Cost Transparency
HB 1033 Biosimilar bill

Dear Chair Lee and Committee Members,

On behalf of CVS Health, I want to express our concurrence with the comments submitted by PCMA:

-In opposition (or amend) to HB 1032, the prescription drug cost transparency bill, and

-In support of HB 1033, the biosimilar bill.

CVS Health is a different kind of health care company. We are a diversified health services company with nearly 300,000 employees united around a common purpose of helping people on their path to better health. In an increasingly connected and digital world, we are meeting people wherever they are and changing health care to meet their needs. Built on a foundation of unmatched community presence, our diversified model engages one in three Americans each year. From our innovative new services at HealthHUB® locations, to transformative programs that help manage chronic conditions, we are making health care more accessible, more affordable, and simply better.

CVS Health has six retail pharmacy outlets in North Dakota, and employs **804** people, including **26** licensed pharmacists who filled **987,000** prescriptions for thousands of North Dakota consumers last year. CVS Health also operates one of the largest PBMs in the country, which manages **3,000,000** prescriptions for North Dakota consumers annually, on behalf of major employers and insurance companies who hire CVS Caremark to control the cost of prescription drugs for their members. It is that effort – to control the cost of drugs for our clients – that brings us to the North Dakota Legislature each session in order to defend the free market principles and tools that allow us to keep the cost of prescription drugs affordable for North Dakota consumers.

CVS Health concurs with the comments, concerns, and suggested amendments offered by PCMA. We are particularly concerned about HB 1032, which allows the Board of Pharmacy (Board) to collect competitively sensitive and proprietary information from PBMs and grants rulemaking authority to implement the bill, both of which would be a glaring and direct conflict of interest for the Board and the pharmacists serving on the Board. Please note that the Federal Trade Commission reviewed similar legislation that allowed Board oversight of PBMs and stated that "[b]ecause pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy board."[1] We

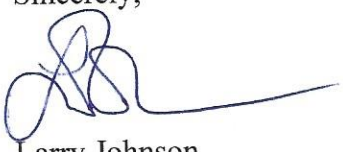
[1] Federal Trade Commission, Letter to Representative Mark Formby, Mississippi House of Representatives, March 22, 2011. Available at: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf

CVSHealth

believe that the Department of Insurance would be the appropriate agency for such oversight and that this would make HB 1032 consistent with other states that have similar laws in place. The Board is comprised of active market participants whose access to competitive data is a conflict of interest and would undermine competition in the marketplace.

We urge the Committee to **SUPPORT HB 1033**, and to **OPPOSE or AMEND, as suggested by PCMA, HB 1032**. CVS Health supports meaningful and actionable transparency for consumers and clients and does not believe HB 1032 achieves that goal. We look forward to working with the Committee in a manner that was not fully afforded because of COVID-19 restrictions during the interim, so we can help fashion appropriate public policy for the people and businesses of North Dakota.

Sincerely,



Larry Johnson
Regional Government Affairs Director
CVS Health

Pharmacy Services Administrative Organization (PSAO) Coalition
425 W. Capitol Ave, Ste 3525
Little Rock, AR. 72201
501-690-8735

March 15, 2021

Chair Judy Lee
Senate Human Services Committee
North Dakota Senate

Re: Comments HB 1032 – Prescription Drug Cost Transparency

Dear Chair Lee-

I am writing on behalf of the PSAO (Pharmacy Services Administrative Organization) Coalition to provide comments on HB1032 – Prescription Drug Cost Transparency.

PSAOs are optional service organizations that stand in the shoes of local pharmacies in their interactions with pharmacy benefits managers (PBMs). This includes working through disputes with PBMs, appealing low reimbursement claims from PBMs, helping to centralize and speed up payment from the PBMs, and executing contracts with PBMs. In short, the PSAOs serve as a back-office staff of the pharmacy to deal with the daily challenges pharmacies face when dealing with the PBMs. The PSAOs charge the pharmacies a transparent, flat monthly fee for providing their service.

The PSAO Coalition is comprised of Elevate (AmerisourceBergen), LeaderNET (Cardinal Health), and HealthMart Atlas (McKesson) PSAOs that collectively represent approximately 17,000 of the nation's 22,000 independent pharmacies, including some locally-owned regional chain pharmacies. Collectively, the three largest PSAOs only represent 13 percent of the current prescription volume filled in the U.S. This relatively small concentration does not provide any meaningful marketplace leverage when executing contracts with PBMs on behalf of their pharmacies.

Our coalition believes that prescription drug cost transparency is vital to controlling healthcare costs. We believe that the original, unamended version of HB1032 was a reasonable bill that focused its legislative attention on the PBMs and the health insurers, which are collectively the entities that control every aspect of where and how dollars are spent on prescription medications.

The amended bill, however, broadened the disclosure requirements to include entities that do not have any direct impact on prescription drug expenses, such as the PSAOs. If such a requirement was put into place, in would cause unnecessary reporting that would increase

administrative costs to the state, increase operating costs of the PSAOs, and produce no results in addressing the underlying costs of prescription medications.

We are not in support of the amended version of HB1032 and we respectfully request that the committee consider returning back to the original, unamended version of HB1032.

Respectfully submitted,

Scott Pace, Pharm.D., J.D.
Chair
pace@impactmanagement.com

HB 1032 – Testimony by Dustin Gawrylow (Lobbyist #266) North Dakota Watchdog Network

The North Dakota Watchdog Network is in favor of policies that lead to transparency for consumers.

Based on the expert reports and testimony previously provided, it appears there is a difference between transparency for consumers and transparency at the wholesale level – and that transparency at the wholesale level may not benefit transparency at the consumer level.

The State of North Dakota should work with industry to seek ways to lower costs and increase transparency. Judging by how some insurance companies are in favor of this bill, and other opposed – it appears that this bill is dragging the state into a turf war – and having the state pay for market research that may give some companies a competitive advantage over others.

Whenever various players in an industry take different sides on a bill such as this, legislators should factor in who wins and who loses with the proposed legislation.

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1032
3/23/2021

A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to prescription drug cost transparency; and to provide a penalty.

Madam Chair Lee opened the discussion on HB 1032 at 3:11 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Regulatory agency study
- Rebate amounts
- PBM regulation

[3:12] Senator Judy Lee, District. Provided the committee with proposed amendment 21.0006.06001 (testimony #8964).

[3:16] Jon Godfread, ND State Insurance Commissioner. Provided clarification to the committee on PBM (pharmacy benefits manager) regulation.

[3:23] Mark Hardy, Executive Director, ND State Board of Pharmacy. Provided clarification to the committee on a regulatory board study for PBM's.

Senator Anderson moves **DO NOT PASS.**
Senator K. Roers seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kristin Roers	Y
Senator Howard C. Anderson, Jr.	Y
Senator David A. Clemens	Y
Senator Kathy Hogan	N
Senator Oley Larsen	Y

The motion passed 5-1-0
Senator Anderson will carry HB 1032.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on HB 1032 at 3:33 p.m.

Justin Velez, Committee Clerk

REPORT OF STANDING COMMITTEE

HB 1032, as engrossed: Human Services Committee (Sen. Lee, Chairman) recommends **DO NOT PASS** (5 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). Engrossed HB 1032 was placed on the Fourteenth order on the calendar.

21.0006.06001
Title.

Prepared by the Legislative Council staff for
Senator Lee
March 4, 2021

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1032

Page 1, line 20, replace "medication" with "a prescription drug"

Page 1, line 22, after the first "of" insert "prescription"

Page 1, line 23, after "the" insert "prescription"

Page 2, line 9, remove the underscored colon

Page 2, remove lines 10 through 17

Page 2, line 18, replace "c. Drug or device" with "drug for human use which is"

Page 2, line 18, after "law" insert "or regulation"

Page 2, line 18, remove the third "or"

Page 2, line 19, replace "restricted to use by a practitioner" with ", including finished dosage forms and active ingredients subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)]"

Page 2, line 21, after the first "a" insert "prescription"

Page 3, line 5, after "**of**" insert "**prescription**"

Page 3, line 8, after "administration-approved" insert "prescription"

Page 3, line 16, after "the" insert "prescription"

Page 3, line 17, after "the" insert "prescription"

Page 3, line 23, after "manufacturer's" insert "prescription"

Page 3, line 25, after "manufacturer's" insert "prescription"

Page 4, line 8, after "new" insert "prescription"

Page 4, line 10, after the second "the" insert "prescription"

Page 5, line 4, after "specific" insert "prescription"

Page 5, line 4, after the first "of" insert "prescription"

Page 5, line 5, after "specific" insert "prescription"

Page 5, line 5, after "of" insert "prescription"

Page 5, line 15, after "prescribed" insert "prescription"

Page 6, line 22, after "specific" insert "prescription"

Page 6, line 22, after "of" insert "prescription"

Page 7, line 12, after the second "specific" insert "prescription"

Page 7, line 13, after the first "of" insert "prescription"

Page 7, line 13, after "specific" insert "prescription"

Page 7, line 14, after "of" insert "prescription"

Page 7, line 31, after the second "specific" insert "prescription"

Page 8, line 1, after the first "of" insert "prescription"

Page 8, line 1, after "specific" insert "prescription"

Page 8, line 2, after "of" insert "prescription"

Renumber accordingly

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1032
3/31/2021

A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to prescription drug cost transparency; and to provide a penalty.

Madam Chair Lee opened the discussion on HB 1032 at 11:28 a.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Insurance department
- Medicaid
- Regulatory boards

Senator Hogan moves to **RECONSIDER COMMITTEE ACTION.**
Senator Anderson seconded.

Voice Vote – Motion passed.

[11:32] Senator Howard Anderson, District 8. Advised the committee to hold committee action pending amendments drafted by Legislative Council.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on HB 1032 at 11:34 a.m.

Justin Velez, Committee Clerk

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1032
4/6/2021

A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to prescription drug cost transparency; and to provide a penalty.

Madam Chair Lee opened the discussion on HB 1032 at 3:44 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens, O. Larsen.

Discussion Topics:

- Proposed amendment
- Medicaid exclusion
- Aggregate data

[3:44] Senator Howard Anderson, District 8. Provided the committee with proposed amendment 21.0006.06004 (testimony #11417 and #11418).

Senator Anderson moves to **ADOPT AMENDMENT** 21.0006.06004
Senator Hogan seconded.

Voice Vote – Motion passed

Senator Anderson moves **DO PASS, AS AMENDED.**
Senator Hogan seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kristin Roers	Y
Senator Howard C. Anderson, Jr.	Y
Senator David A. Clemens	N
Senator Kathy Hogan	Y
Senator Oley Larsen	N

The motion passed 4-2-0
Senator Anderson will carry HB 1032.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on HB 1032 at 3:51 p.m.

Justin Velez, Committee Clerk

Prepared by the Legislative Council staff for
Senator Anderson
April 6, 2021

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1032

Page 1, line 1, replace "19" with "26.1"

Page 1, line 2, after the semicolon insert "to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation;"

Page 1, replace lines 4 and 5 with:

"**SECTION 1.** A new chapter to title 26.1 of the North Dakota Century Code is created and enacted as follows:"

Page 1, line 12, after "5." insert ""Drug manufacturer" means the entity that holds the national drug code for a drug which is engaged in the production, preparation, propagation, compounding, conversion, or processing of the drug or which is engaged in the packaging, repackaging, labeling, relabeling, or distribution of the drug. The term does not include a wholesale drug distributor or retail pharmacy licensed in this state.

6."

Page 1, line 14, replace "6." with "7."

Page 1, line 16, after "agency" insert "other than the department of human services or state department of health"

Page 1, remove line 18

Page 1, line 19, after "a" insert "drug"

Page 2, remove line 1

Page 2, line 2, replace "11." with "10."

Page 2, line 3, after "19-03.6-01" insert ". The term does not include the department of human services or state department of health"

Page 2, remove lines 4 through 8

Page 2, line 9, replace "13." with "11."

Page 2, line 9, remove "means a:"

Page 2, remove lines 10 through 18

Page 2, line 19, replace "restricted to use by a practitioner" with "has the same meaning as under section 43-15-01"

Page 2, line 20, replace "14." with "12."

Page 2, line 22, replace "pharmaceutical" with "drug"

Page 2, line 23, replace "15." with "13."

Page 2, line 24, replace "16." with "14."

Page 2, line 27, replace "17." with "15."

Page 2, line 27, after "the" insert "drug"

Page 2, line 28, replace "wholesale drug distributors" with "wholesalers"

Page 3, remove lines 3 and 4

Page 3, line 6, replace "board" with "commissioner"

Page 3, line 8, replace "United States food and drug administration-approved" with "prescription"

Page 3, line 9, after "that" insert "drug"

Page 3, line 14, replace "board" with "commissioner"

Page 3, line 21, after "the" insert "previous"

Page 3, line 23, after the first "the" insert "drug"

Page 3, line 25, after "the" insert "drug"

Page 3, line 27, after "A" insert "concise"

Page 3, line 31, replace "board" with "commissioner"

Page 4, line 1, after the first "the" insert "drug"

Page 4, line 1, after the second "the" insert "drug"

Page 4, line 4, replace "board" with "commissioner"

Page 4, line 4, after the second "the" insert "drug"

Page 4, line 7, after "a" insert "concise"

Page 4, remove lines 14 through 16

Page 4, line 19, replace "board" with "commissioner"

Page 5, line 3, after the underscored comma insert "the identity of a drug manufacturer,"

Page 5, remove lines 6 through 10

Page 5, line 12, remove "a."

Page 5, line 13, replace "board" with "commissioner"

Page 5, line 15, replace "(1)" with "a."

Page 5, line 16, replace "(2)" with "b."

Page 5, line 18, replace "(3)" with "c."

Page 5, line 20, replace "(4)" with "d."

Page 5, line 22, replace "(5)" with "e."

Page 5, line 24, replace "(6)" with "f."

Page 5, remove lines 25 through 30

Page 6, remove lines 4 through 31

Page 7, remove lines 1 through 31

Page 8, remove lines 1 through 7

Page 8, line 9, remove "the board reports to"

Page 8, line 10, after the first "commissioner" insert "receives"

Page 8, line 13, replace "thirty" with "sixty"

Page 8, line 13, replace "from the board" with "under this chapter"

Page 8, line 14, after the underscored period insert "The information the commissioner publishes may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information of any pharmacy, pharmacy benefits manager, drug wholesaler, or hospital."

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Page 8, line 17, replace "commissioner" with "board"

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Page 8, line 19, replace "board" with "commissioner"

Page 8, line 20, replace the first "board" with "commissioner"

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Page 8, after line 20, insert:

"**Drug pricing fund - Transfer - Continuing appropriation.**

The board may deposit up to six hundred dollars of every wholesaler license fee and every virtual wholesaler license fee collected by the board under section 43-15.3-12 to the drug pricing fund. All moneys in the fund, not otherwise appropriated, are appropriated to the insurance department to implement this chapter."

Page 8, line 22, replace "care plan" with "insurer"

Page 8, line 22, remove "hospital, pharmacy, wholesale drug distributor,"

Page 8, line 23, remove "pharmacy services administrative organization,"

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"**SECTION 2. AMENDMENT.** Section 43-15.3-12 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-12. Fees.

The board shall charge and collect the following fees under this chapter:

Chain drug warehouse	$200
Chain pharmacy warehouse	$200
Durable medical equipment distributor, medical gas distributor, or both	$200
Durable medical equipment retailer, medical gas retailer and distributor, or both	$300
Hospital offsite warehouse	$200
Jobber or broker	~~$400~~Not to exceed $1,000
Manufacturer	~~$400~~Not to exceed $1,000
Medical gas retailer, durable medical equipment retailer, or both	$200
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Outsourcing facility	$200
Own label distributor	~~$400~~Not to exceed $1,000
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Veterinary-only distributor	$200
Virtual manufacturer	$400
Virtual wholesaler or distributor	~~$400~~Not to exceed $1,000
Wholesaler or distributor	~~$400~~Not to exceed $1,000"

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1032, as engrossed: Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (4 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1032 was placed on the Sixth order on the calendar.

Page 1, line 1, replace "19" with "26.1"

Page 1, line 2, after the semicolon insert "to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation;"

Page 1, replace lines 4 and 5 with:

"**SECTION 1.** A new chapter to title 26.1 of the North Dakota Century Code is created and enacted as follows:"

Page 1, line 12, after "5." insert ""Drug manufacturer" means the entity that holds the national drug code for a drug which is engaged in the production, preparation, propagation, compounding, conversion, or processing of the drug or which is engaged in the packaging, repackaging, labeling, relabeling, or distribution of the drug. The term does not include a wholesale drug distributor or retail pharmacy licensed in this state.

6."

Page 1, line 14, replace "6." with "7."

Page 1, line 16, after "agency" insert "other than the department of human services or state department of health"

Page 1, remove line 18

Page 1, line 19, after "a" insert "drug"

Page 2, remove line 1

Page 2, line 2, replace "11." with "10."

Page 2, line 3, after "19-03.6-01" insert ". The term does not include the department of human services or state department of health"

Page 2, remove lines 4 through 8

Page 2, line 9, replace "13." with "11."

Page 2, line 9, remove "means a:"

Page 2, remove lines 10 through 18

Page 2, line 19, replace "restricted to use by a practitioner" with "has the same meaning as under section 43-15-01"

Page 2, line 20, replace "14." with "12."

Page 2, line 22, replace "pharmaceutical" with "drug"

Page 2, line 23, replace "15." with "13."

Page 2, line 24, replace "16." with "14."

Page 2, line 27, replace "17." with "15."

Page 2, line 27, after "the" insert "drug"

Page 2, line 28, replace "wholesale drug distributors" with "wholesalers"

Page 3, remove lines 3 and 4

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Page 3, line 8, replace "United States food and drug administration-approved" with "prescription"

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Page 3, line 25, after "the" insert "drug"

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Page 5, line 12, remove "a."

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Page 5, line 15, replace "(1)" with "a."

Page 5, line 16, replace "(2)" with "b."

Page 5, line 18, replace "(3)" with "c."

Page 5, line 20, replace "(4)" with "d."

Page 5, line 22, replace "(5)" with "e."

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Page 5, remove lines 25 through 30

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Veterinary-only distributor
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Virtual manufacturer
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Virtual wholesaler or distributor ~~$400~~Not to exceed $1,000
Wholesaler or distributor ~~$400~~Not to exceed $1,000"

Renumber accordingly

21.0006.06004
Title.

Prepared by the Legislative Council staff for
Senator Anderson
April 6, 2021

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1032

Page 1, line 1, replace "19" with "26.1"

Page 1, line 2, after the semicolon insert "to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation;"

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Renumber accordingly

21.0006.06004

Sixty-seventh
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED HOUSE BILL NO. 1032

Introduced by

Legislative Management

(Health Care Committee)

A BILL for an Act to create and enact a new chapter to title ~~19~~26.1 of the North Dakota Century Code, relating to prescription drug cost transparency; to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

~~**SECTION 1.** A new chapter to title 19 of the North Dakota Century Code is created and enacted as follows:~~

SECTION 1. A new chapter to title 26.1 of the North Dakota Century Code is created and enacted as follows:

Definitions.

As used in this chapter:

1. "Board" means the state board of pharmacy.
2. "Commissioner" means the insurance commissioner.
3. "Concession" includes a free good, delayed billing, and billing forgiveness.
4. "Drug" has the same meaning as provided under section 19-02.1-01.
5. "Drug manufacturer" means the entity that holds the national drug code for a drug which is engaged in the production, preparation, propagation, compounding, conversion, or processing of the drug or which is engaged in the packaging, repackaging, labeling, relabeling, or distribution of the drug. The term does not include a wholesale drug distributor or retail pharmacy licensed in this state.
6. "Health care plan" means an individual, blanket, or group plan, policy, or contract for health care services issued or delivered in this state by a health insurer.
~~6.~~7. "Health insurer" means an insurance company, nonprofit health service corporation, health maintenance organization, third-party payer, health program administered by a

state agency other than the department of human services or state department of health, or other person engaged as principal in the business of insurance which issues or delivers a health care plan in this state.

~~7. "Hospital" means a facility licensed under chapter 23-16.~~

8. "Manufacturer-packaged drug container" means a drug manufacturer-prepared supply of medication packaged in a container with a unique product-identifying national drug code number.

9. "Net spending" means the cost of drugs minus any discounts that lower the price of the drugs, including a rebate, fee, retained price protection, retail pharmacy network spread, and dispensing fee.

~~10. "Pharmacy" means a pharmacy or drugstore registered under chapter 43-15.~~

~~11.~~10. "Pharmacy benefits manager" has the same meaning as provided under section 19-03.6-01. The term does not include the department of human services or state department of health.

~~12. "Pharmacy services administrative organization" means an entity that provides contracting and other administrative services to a pharmacy to assist the pharmacy in the pharmacy's interaction, including reimbursement rate negotiations with a third-party payer, pharmacy benefit manager, wholesale drug distributor, and other entities.~~

~~13.~~11. "Prescription drug" ~~means a:~~

~~a. Substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;~~

~~b. Drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:~~

~~(1) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or other legend that complies with federal law; or~~

~~(2) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or~~

~~c. Drug or device required by federal or state law to be dispensed on prescription or restricted to use by a practitioner~~has the same meaning as under section 43-15-01.

~~14.~~12. "Rebate" includes any discount, financial incentive, or concession that affects the price of a drug to a pharmacy benefits manager or health insurer for a drug manufactured by the ~~pharmaceutical~~drug manufacturer.

~~15.~~13. "Specialty drug" has the same meaning as provided under section 19-02.1-16.2.

~~16.~~14. "Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

~~17.~~15. "Wholesale acquisition cost" means, with respect to a prescription drug, the drug manufacturer's list price for the prescription drug to ~~wholesale drug distributors~~wholesalers or direct purchasers in the United States for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data, such as Medi-Span Price Rx, Gold Standard Drug Database, or First Databank drug data. The term does not include a rebate, prompt pay, or other discount or other reduction in price.

~~18. "Wholesale drug distributor" has the same meaning as provided under section 43-15.1-01.~~

Disclosure of drug pricing information.

1. Each drug manufacturer shall submit a report to the ~~board~~commissioner no later than the fifteenth day of January, April, July, and October with the current wholesale acquisition cost information for the ~~United States food and drug administration-approved~~prescription drugs sold in or into the state by that drug manufacturer.

2. a. Not more than thirty days after an increase in wholesale acquisition cost of forty percent or greater over the preceding five calendar years or ten percent or greater in the preceding twelve months for a prescription drug with a wholesale acquisition cost of seventy dollars or more for a manufacturer-packaged drug container, a drug manufacturer shall submit a report to the ~~board~~commissioner. The report must contain the following information:

(1) Name of the drug;

(2) Whether the drug is a brand name or a generic;

(3) The effective date of the change in wholesale acquisition cost;

(4) Aggregate, company-level research and development costs for the previous calendar year;

(5) Aggregate rebate amounts paid to each pharmacy benefits manager for the previous calendar year;

(6) The name of each of the drug manufacturer's drugs approved by the United States food and drug administration in the previous five calendar years;

(7) The name of each of the drug manufacturer's drugs that lost patent exclusivity in the United States in the previous five calendar years; and

(8) A concise statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost, such as raw ingredient shortage or increase in pharmacy benefits manager rebates.

b. The quality and types of information and data a drug manufacturer submits to the ~~board~~commissioner pursuant to this subsection must be the same as the quality and types of information and data the drug manufacturer includes in the drug manufacturer's annual consolidated report on securities and exchange commission form 10-K or any other public disclosure.

3. A drug manufacturer shall notify the ~~board~~commissioner in writing if the drug manufacturer is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare part D program.

a. The notice must include a concise statement of rationale regarding the factor or factors that caused the new drug to exceed the Medicare part D program price.

b. The drug manufacturer shall provide the written notice within three calendar days following the release of the drug in the commercial market.

c. A drug manufacturer may make the notification pending approval by the United States food and drug administration if commercial availability is expected within three calendar days following the approval.

~~4. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website.~~

Disclosure of pharmacy benefits manager information.

1. On or before April first of each year, a pharmacy benefits manager providing services for a health care plan shall file a report with the ~~board~~commissioner. The report must contain the following information for the previous calendar year:
   a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer;
   b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer which were passed to health insurers;
   c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to enrollees at the point of sale;
   d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the pharmacy benefits manager; and
   e. The aggregated rebates passed on to employers.
2. Reports submitted by pharmacy benefits managers under this section may not disclose the identity of a specific health benefit plan or enrollee, the identity of a drug manufacturer, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.
~~3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.~~

Disclosure of health insurer spending information.

1. ~~a.~~ On or before April first of each year, each health insurer shall submit a report to the ~~board~~commissioner. The report must contain the following information for the previous two calendar years:
   ~~(1)~~a. Names of the twenty-five most frequently prescribed drugs across all plans;

~~(2)~~b. Names of the twenty-five prescription drugs dispensed with the highest dollar spend in terms of gross revenue;

~~(3)~~c. Percent increase in annual net spending for prescription drugs across all plans;

~~(4)~~d. Percent increase in premiums which is attributable to prescription drugs across all plans;

~~(5)~~e. Percentage of specialty drugs with utilization management requirements across all plans; and

~~(6)~~f. Premium reductions attributable to specialty drug utilization management.

~~b. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The combined aggregated data from the reports which the board provides to the commissioner must be provided in a manner that does not disclose or tend to disclose proprietary or confidential information of any health insurer.~~

2. A report submitted by a health insurer may not disclose the identity of a specific health benefit plan or the prices charged for specific prescription drugs or classes of prescription drugs.

~~**Disclosure of pharmacy services administrative organization information.**~~

~~1. On or before April first of each year, a pharmacy services administrative organization providing services for a pharmacy shall file a report with the board. The report must contain the following information for the previous calendar year:~~

~~a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer or wholesale drug distributor;~~

~~b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer or wholesale drug distributor which were passed to pharmacies;~~

~~c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to pharmacies at the point of sale; and~~

~~d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers or wholesale drug distributors which were retained as revenue by the pharmacy services administrative organization.~~

~~2. A report submitted by a pharmacy services administrative organization under this section may not disclose the identity of a specific health benefit plan or enrollee or the prices charged for specific drugs or classes of drugs.~~

~~3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy services administrative organization.~~

~~**Disclosure of wholesale drug distributor information.**~~

~~1. On or before April first of each year, a wholesale drug distributor in this state shall file a report with the board. The report must contain the following information for the previous calendar year:~~

~~a. The aggregated rebates, fees, price protection payments, and any other payments collected from each drug manufacturer;~~

~~b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer;~~

~~c. The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies;~~

~~d. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the wholesale drug distributor; and~~

~~e. The aggregated rebates passed on to employers.~~

~~2. Reports submitted by wholesale drug distributors under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.~~

~~3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any wholesale drug distributor.~~

~~**Disclosure of hospital and pharmacy information.**~~

~~1. On or before April first of each year, a pharmacy and a hospital shall file a report with the board. The report must contain the following information for the previous calendar year:~~

~~a. The aggregated rebates, fees, price protection payments, and any other payments collected for a pharmacy benefits manager;~~

~~b. The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer or pharmacy benefits manager which were retained as revenue by the pharmacy or hospital; and~~

~~c. The aggregated rebates passed on to employers.~~

~~2. Reports submitted by a pharmacy or hospital under this section may not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.~~

~~3. Within thirty days of receipt of a report under this section, the board shall provide the reported information to the commissioner in a format ready for publication on the commissioner's website. The information the board provides to the commissioner may not disclose or tend to disclose proprietary or confidential information of any pharmacy or hospital.~~

Website.

1. The commissioner shall develop a website to publish information ~~the board reports to~~ the commissioner receives under this chapter. The commissioner shall make the website available on the commissioner's website with a dedicated link prominently displayed on the home page, or by a separate, easily identifiable internet address.
2. Within ~~thirty~~sixty days of receipt of reported information ~~from the board~~under this chapter, the commissioner shall publish the reported information on the website

developed under this section. The information the commissioner publishes may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information of any pharmacy, pharmacy benefits manager, drug wholesaler, or hospital.

Rulemaking - Forms - Services - Records.

1. The ~~board and the~~ commissioner may adopt rules to implement this chapter.
2. In consultation with the ~~commissioner~~board, the ~~board~~commissioner shall develop forms that must be used for reporting required under this chapter.
3. The ~~board~~commissioner may contract for services to implement this chapter.
4. A report received by the ~~board~~commissioner is an exempt record as defined by section 44-04-17.1; however, as provided under section 44-04-18.4 any portion of a report which discloses trade secret, proprietary, commercial, or financial information is confidential if it is of a privileged nature and has not been previously publicly disclosed.

Drug pricing fund - Transfer - Continuing appropriation.

The board may deposit up to six hundred dollars of every wholesaler license fee and every virtual wholesaler license fee collected by the board under section 43-15.3-12 to the drug pricing fund. All moneys in the fund, not otherwise appropriated, are appropriated to the insurance department to implement this chapter.

Civil penalty.

A health ~~care plan~~insurer, drug manufacturer, ~~hospital, pharmacy, wholesale drug distributor, pharmacy services administrative organization,~~ or pharmacy benefits manager that violates this chapter is subject to the imposition by the attorney general of a civil penalty not to exceed ten thousand dollars for each violation. The attorney general may waive or reduce a fine under this section upon a finding of good cause, such as excusable neglect or other extenuating circumstances. The fine may be collected and recovered in an action brought in the name of the state.

SECTION 2. AMENDMENT. Section 43-15.3-12 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-12. Fees.

The board shall charge and collect the following fees under this chapter:

Chain drug warehouse	$200
Chain pharmacy warehouse	$200
Durable medical equipment distributor, medical gas distributor, or both	$200
Durable medical equipment retailer, medical gas retailer and distributor, or both	$300
Hospital offsite warehouse	$200
Jobber or broker	~~$400~~Not to exceed $1,000
Manufacturer	~~$400~~Not to exceed $1,000
Medical gas retailer, durable medical equipment retailer, or both	$200
Medical gas durable medical equipment distributor and retailer	$300
Outsourcing facility	$200
Own label distributor	~~$400~~Not to exceed $1,000
Pharmacy distributor	$200
Private label distributor	~~$400~~Not to exceed $1,000
Repackager	~~$400~~Not to exceed $1,000
Reverse distributor	$200
Third-party logistic provider	~~$400~~Not to exceed $1,000
Veterinary-only distributor	$200
Virtual manufacturer	$400
Virtual wholesaler or distributor	~~$400~~Not to exceed $1,000
Wholesaler or distributor	~~$400~~Not to exceed $1,000

2021 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Sakakawea Room, State Capitol

HB 1032
4/8/2021

A BILL for an Act to create and enact a new chapter to title 26.1 of the North Dakota Century Code, relating to prescription drug cost transparency; to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation; and to provide a penalty.

Madam Chair Lee opened the discussion on HB 1032 at 3:04 p.m. Members present: Lee, K. Roers, Hogan, Anderson, Clemens. Absent members: O. Larsen.

Discussion Topics:

- Proposed amendment
- Bill action
- ND Insurance Department

[3:06] Senator Howard Anderson, District 8. Provided the committee with proposed amendment 21.0006.06005 (testimony #11467).

Senator Anderson moves to **RECONSIDER COMMITTEE ACTION**
Senator K. Roers seconded.

Voice Vote – Motion passed.

Senator Anderson moves to **RECONSIDER AMENDMENT** 21.0006.06004
Senator K. Roers seconded.

Voice Vote – Motion passed.

Senator Anderson moves to **ADOPT AMENDMENT** 21.0006.06005
Senator K. Roers seconded.

Voice Vote – Motion passed.

Senator Anderson moves **DO PASS, AS AMENDED.**
Senator Hogan seconded.

Senators	Vote
Senator Judy Lee	Y
Senator Kristin Roers	Y
Senator Howard C. Anderson, Jr.	Y
Senator David A. Clemens	N
Senator Kathy Hogan	Y
Senator Oley Larsen	ABSENT

The motion passed 4-1-1
Senator Anderson will carry HB 1032.

Additional written testimony: N/A

Madam Chair Lee closed the discussion on HB 1032 at 3:13 p.m.

Justin Velez, Committee Clerk

SL 1034 4/9

21.0006.06005
Title.08000

Prepared by the Legislative Council staff for
Senator Anderson
April 8, 2021

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1032

In lieu of the amendments printed on pages 1263 through 1266 of the Senate Journal, Engrossed House Bill No. 1032 is amended as follows:

Page 1, line 1, replace "19" with "26.1"

Page 1, line 2, after the semicolon insert "to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation;"

Page 1, replace lines 4 and 5 with:

"**SECTION 1.** A new chapter to title 26.1 of the North Dakota Century Code is created and enacted as follows:"

Page 1, line 12, after "5." insert ""Drug manufacturer" means the entity that holds the national drug code for a drug which is engaged in the production, preparation, propagation, compounding, conversion, or processing of the drug or which is engaged in the packaging, repackaging, labeling, relabeling, or distribution of the drug. The term does not include a wholesale drug distributor or retail pharmacy licensed in this state.

6."

Page 1, line 14, replace "6." with "7."

Page 1, line 16, after "agency" insert "other than the department of human services or state department of health"

Page 1, remove line 18

Page 1, line 19, after "a" insert "drug"

Page 2, remove line 1

Page 2, line 2, replace "11." with "10."

Page 2, line 3, after "19-03.6-01" insert ". The term does not include the department of human services or state department of health"

Page 2, remove lines 4 through 8

Page 2, line 9, replace "13." with "11."

Page 2, line 9, remove "means a:"

Page 2, remove lines 10 through 18

Page 2, line 19, replace "restricted to use by a practitioner" with "has the same meaning as under section 43-15-01"

Page 2, line 20, replace "14." with "12."

Page 2, line 22, replace "pharmaceutical" with "drug"

Page 2, line 23, replace "15." with "13."

Page 2, line 24, replace "16." with "14."

Page 2, line 27, replace "17." with "15."

Page 2, line 27, after "the" insert "drug"

Page 2, line 28, replace "wholesale drug distributors" with "wholesalers"

Page 3, remove lines 3 and 4

Page 3, line 6, replace "board" with "commissioner"

Page 3, line 8, replace "United States food and drug administration-approved" with "prescription"

Page 3, line 9, after "that" insert "drug"

Page 3, line 14, replace "board" with "commissioner"

Page 3, line 21, after "the" insert "previous"

Page 3, line 23, after the first "the" insert "drug"

Page 3, line 25, after "the" insert "drug"

Page 3, line 27, after "A" insert "concise"

Page 3, line 31, replace "board" with "commissioner"

Page 4, line 1, after the first "the" insert "drug"

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Page 5, line 3, after the underscored comma insert "the identity of a drug manufacturer,"

Page 5, remove lines 6 through 10

Page 5, line 12, remove "a."

Page 5, line 13, replace "board" with "commissioner"

Page 5, line 15, replace "(1)" with "a."

Page 5, line 16, replace "(2)" with "b."

Page 5, line 18, replace "(3)" with "c."

Page 5, line 20, replace "(4)" with "d."

Page 5, line 22, replace "(5)" with "e."

Page 5, line 24, replace "(6)" with "f."

Page 5, remove lines 25 through 30

Page 6, remove lines 4 through 31

Page 7, remove lines 1 through 31

Page 8, remove lines 1 through 7

Page 8, line 9, remove "the board reports to"

Page 8, line 10, after the first "commissioner" insert "receives"

Page 8, line 13, replace "thirty" with "sixty"

Page 8, line 13, replace "from the board" with "under this chapter"

Page 8, line 14, after the underscored period insert "The information the commissioner publishes may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information of any pharmacy, pharmacy benefits manager, drug wholesaler, or hospital."

Page 8, line 16, remove "board and the"

Page 8, line 17, replace "commissioner" with "board"

Page 8, line 17, replace "board" with "commissioner"

Page 8, line 19, replace "board" with "commissioner"

Page 8, line 20, replace the first "board" with "commissioner"

Page 8, line 20, after "44-04-17.1" insert "; however, as provided under section 44-04-18.4 any portion of a report which discloses trade secret, proprietary, commercial, or financial information is confidential if it is of a privileged nature and has not been previously publicly disclosed"

Page 8, after line 20, insert:

"**Drug pricing fund - Transfer - Continuing appropriation.**

There is created in the state treasury the drug pricing fund, which consists of any money deposited in the fund by the board and any interest earned on moneys in the fund. The board may deposit up to six hundred dollars of every wholesaler license fee and every virtual wholesaler license fee collected by the board under section 43-15.3-12 to the drug pricing fund. All moneys in the fund, not otherwise appropriated, are appropriated to the insurance department to implement this chapter."

Page 8, line 22, replace "care plan" with "insurer"

Page 8, line 22, remove "hospital, pharmacy, wholesale drug distributor,"

Page 8, line 23, remove "pharmacy services administrative organization,"

Page 8, line 25, after the underscored period insert "The attorney general may waive or reduce a fine under this section upon a finding of good cause, such as excusable neglect or other extenuating circumstances."

Page 8, after line 26, insert:

"**SECTION 2. AMENDMENT.** Section 43-15.3-12 of the North Dakota Century Code is amended and reenacted as follows:

43-15.3-12. Fees.

The board shall charge and collect the following fees under this chapter:

Chain drug warehouse	$200
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Virtual manufacturer	$400
Virtual wholesaler or distributor	~~$400~~Not to exceed $1,000
Wholesaler or distributor	~~$400~~Not to exceed $1,000"

Renumber accordingly

REPORT OF STANDING COMMITTEE

HB 1032, as engrossed: Human Services Committee (Sen. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (4 YEAS, 1 NAY, 1 ABSENT AND NOT VOTING). Engrossed HB 1032 was placed on the Sixth order on the calendar.

In lieu of the amendments printed on pages 1263 through 1266 of the Senate Journal, Engrossed House Bill No. 1032 is amended as follows:

Page 1, line 1, replace "19" with "26.1"

Page 1, line 2, after the semicolon insert "to amend and reenact section 43-15.3-12 of the North Dakota Century Code, relating to wholesale drug license fees; to provide a continuing appropriation;"

Page 1, replace lines 4 and 5 with:

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6."

Page 1, line 14, replace "6." with "7."

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Page 1, remove line 18

Page 1, line 19, after "a" insert "drug"

Page 2, remove line 1

Page 2, line 2, replace "11." with "10."

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Page 2, remove lines 4 through 8

Page 2, line 9, replace "13." with "11."

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Page 2, line 28, replace "wholesale drug distributors" with "wholesalers"

Page 3, remove lines 3 and 4

Page 3, line 6, replace "board" with "commissioner"

Page 3, line 8, replace "United States food and drug administration-approved" with "prescription"

Page 3, line 9, after "that" insert "drug"

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Wholesaler or distributor ~~$400~~Not to exceed $1,000"

Renumber accordingly

21.0006.06005
Title.

Prepared by the Legislative Council staff for
Senator Anderson
April 8, 2021

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Renumber accordingly