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House Industry, Business and Labor Committee
HB 1473 – 2/10/25
Rep. Jonathan Warrey - Chairman

Chairman Warrey and member of the committee, for the record, my name is Mike Schwab, Executive Vice President of the ND Pharmacists Association. We are here today in support of HB 1473.

HB 1743 centers around what is known in the healthcare industry as the 340B Program. Established in 1992, the 340B program enables certain healthcare providers such as Federally Qualified Health Centers (FQHC's), Community Health Centers, Critical Access Hospitals and other non-profit hospitals to purchase outpatient drugs at discount prices from drug manufacturers. The entities mentioned above are considered "covered entities" by definition under the federal 340B program. The goal of the 340B program is to stretch scarce federal resources and dollars as far as possible to serve low-income, underinsured and uninsured populations. The 340B program allows covered entities to provide increased access to care, discounted medications and allows additional services to be offered.

Covered entities can contract with pharmacies to help dispense medications to patients who are receiving care from the covered entities. In this instance, pharmacies that elect to participate in an agreement with a covered entity are considered "contract pharmacies" by definition under the federal 340B program. Contract pharmacies participate in 340B program through an agreement with the covered entity to help serve and provide access to the covered entities patients. The contract pharmacy is responsible for keeping a separate inventory for the program, lots of back-and-forth reporting to the covered entity, processes claims, inventory ordering, etc. all of which are subject to audits and compliance checks. The 340B program is administered by the Health Resources & Services Administration (HRSA) which is a division of the U.S. Department of Health and Human Services.

So why are we here today supporting this specific bill? HB 1473 is trying to address issues that critical access hospitals, federally qualified health centers, non-profit hospitals, community health

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centers and contract pharmacies are experiencing due to restrictions or mandates that drug manufacturers have implemented on their own. In 2010, HRSA authorized and stated covered entities could use more than one contract pharmacy. In recent years, drug manufacturers have taken it upon themselves to try and change how the 340B program operates. Currently, in a number of instances, drug manufacturers are restricting or holding covered entities to the use of no more than one contract pharmacy contrary to HRSA's 2010 published rule. Drug manufacturers have also attempted to gain access to patient claims data, utilization data and other encounter data. Federally, HRSA has sent numerous letters and follow-up warning letters to drug manufacturers regarding their attempts to change how the federal program is supposed to operate.

To-date, I believe there are at least eight states that have passed laws to stop drug manufacturers from implementing contract pharmacy restrictions and more than 10 states have introduced legislation this year, similar to North Dakota. In 2021, Arkansas was the first state to pass legislation that required drug manufacturers to adhere to HRSA's 2010 rule allowing covered entities to use more than one contract pharmacy. The pharmaceutical industry decided to sue Arkansas following the passage of the law. The State of Arkansas won in their lower federal court. The pharmaceutical industry decided to appeal that decision to the 8th Circuit of Appeals. The 8th Circuit of Appeals upheld the lower court's decision in favor of the State of Arkansas. The pharmaceutical industry then appealed the 8th Circuit decision to the U.S. Supreme Court. In late 2024, just before this legislative assembly came into session, the U.S. Supreme Court denied their appeal and sided with the 8th Circuit and lower court in favor of the State of Arkansas. As a reminder, North Dakota is also in the 8th Circuit of Appeals which is important to note as this committee continues to discuss HB 1473.

Drug manufacturers state the 340B program has seen outsized growth over recent years and they disagree with how federally HRSA is running the program. North Dakota does not appear to be the problem regarding the outsized growth of contract pharmacies. Some of the information and materials taken directly from the PhRMA's own website state the following:

- PhRMA states 60% of 340B contract pharmacies represent 5 large corporate chains (CVS, Walgreens, Wal-Mart, Rite-Aid and Kroger).

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- PhRMA further states there has been a growing number of Pharmacy Benefit Manager (PBM) owned specialty pharmacies now participating as contract pharmacies in the program.
- Additional information on PhRMA's website states "PBM's now own the vast majority of pharmacies. The big three PBM-owned specialty pharmacies account for 26% of contract pharmacy arrangements."

As you can see, the vertical integration of the insurance carriers/PBMs and large chain pharmacy corporations account for over 85% of 340B contract pharmacies according to PhRMA's own information. Blanket restrictions applied across the program by drug manufacturers have a negative effect on a small rural state like North Dakota.

We have been told there are roughly 250 out-of-state contract pharmacies participating in the ND 340B program effort. Yes, there are a number of contract pharmacies in our border communities like Moorhead, Aberdeen, etc. However, there are a large number of contract pharmacies representing PBM specialty pharmacies and other PBM owned pharmacies. In addition, sometimes covered entities are required to sign agreements with a suite of chain pharmacies. Often times, the suite of out-of-state pharmacies aren't used very much, if at all, and would be considered dormant contract pharmacies.

I also think it is important to talk about "duplicate discount" prevention requirements briefly. Federally, HRSA prohibits duplicate discounts, that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate. This would cause the drug manufacturer to pay two discounts on the same drug. North Dakota Medicaid already has an established process in place to avoid duplicative discounts between the two programs. Most of the concern around duplicative discounts seems to come from when a PBM administers Medicaid programs for states under a managed care agreement (basically a PBM administers the prescription drug benefit for State Medicaid Departments). A few years back, North Dakota used a PBM to administer the Medicaid Expansion prescription drug benefit. However, after a number of questions and concerns, North Dakota Department of Health and Human Services (Medicaid) and the ND Legislative Assembly made the

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decision to move Medicaid Expansion back in-house with traditional Medicaid. The state saved $17+ million dollars the next biennium by removing the PBM from administering the ND Medicaid Expansion program. Again, we feel a lot of the concerns drug manufacturers raise regarding duplicative discounts are already addressed because of how North Dakota operates and complies with existing 340B laws. We also do not see Medicaid managed care for the prescription drug benefit in ND like you do in a large number of states.

HB 1473 adds a new section to 43-15. 3-08 under the Board of Pharmacy's prohibited acts section. The prohibited acts section is automatically tied to the penalties section under 43-15 3-09 which is how other prohibited acts are referenced already. The Board of Pharmacy already licenses drug manufacturers and other states have taken this same approach for enforcement purposes. The Board of Pharmacy would be in charge of enforcing these sections.

In conclusion, HB 1473 helps to stop drug manufacturers from implementing their own rules outside of an already established federal program. If and when federal reforms to the program take place, we are ready and more than willing to comply with any of those changes. By supporting HB 1473, you are supporting your local critical access hospitals, federally qualified health centers, non-profit hospitals, contract pharmacies and community health centers. If HB 1473 is not passed, drug manufacturers will continue to provide fewer discounted drugs to North Dakota contrary to how the federal 340B program is supposed to be operating according to HRSA and HHS.

Thank you for your time and attention. I will try my best to answer any questions. There are a number of others who will be testifying today, who can hopefully answer your questions if I am not able to do so.

Respectfully submitted,

Mike Schwab

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