#### Written Testimony of The Partnership for Safe Medicines

Michigan Senate Bills 3, 4, and 5 Michigan State Senate - Finance, Insurance, and Consumer Protection committee April 23, 2025

Thank you for the opportunity to comment on this legislation. For the reasons we outline below, the Partnership for Safe Medicines (PSM) believes that while well-intentioned, the track record of Prescription Drug Affordability Boards (PDABs) in the U.S. has not enhanced patient safety or saved money. These three pieces of legislation, in their current form, are likely to end up costing the state money, fail in their goal of lowering the cost of medicine, and weaken the closed, secure drug supply chain.

To that end we oppose SB 3, 4, and 5 in their current forms. Below we outline the risks PDABS pose to the supply chain and one suggestion for a better policy approach.

### Challenges of Upper Payment Limits as a Policy Tool

At its origin, the idea of creating a PDAB to reduce financial barriers to accessing medicine is an excellent goal. However, these financial barriers and even just the price of a medicine are the result of an overly complex health system. In other states, PDABs charged with reducing the cost of prescription medicine have discovered that insurance plans and PBMs impede patient access to medicine through tricks like high copays and step therapy requirements. Michigan's proposed PDAB would have Upper Payment Limits (UPLs) as its sole policy tool, but UPLs cannot address many of the impediments, including the two described above..

Most importantly, UPLs may cause supply shortages that will have a direct impact on patient safety.

Since World War II, price controls have been associated with the creation of black markets, and black markets for medicine are particularly dangerous. If Michigan puts UPLs on medicine, actors will be incentivized to arbitrage medicine out of the state of Michigan, causing shortages that will harm Mighican patients.

Setting UPLs is likely to reduce supply, as many parts of the supply chain won't be able to afford to sell UPL-regulated medicines in Michigan. In situations where medicines are in short supply, patients will order risky drugs from outside the legitimate supply chain. PSM has seen cases where those patients have received diverted and counterfeit products.



# Upper Payment Limits as Designed in SB3 will Force Pharmacies to Lose Money

As an initial point it's critical to point out that pharmacies across the country are already financially stressed because of existing reimbursement practices and that is harming patient access to medicines: The U.S. lost almost 30 percent of its retail U.S. pharmacies between 2010 and 2021. Because pharmacies have the least amount of pricing power in the drug supply chain, they are often forced to dispense medications and lose money because the reimbursement is not guaranteed to cover the acquisition cost of the medication.

It is a normal but unfortunate matter of PBM business practice today that independent pharmacies are not receiving dispensing fees that make up these losses or even cover their costs.

While SB 3 requires that a UPL does not include dispensing fees and also requires that independent pharmacies are reimbursed no less than the UPL, this doesn't address the basic financial problem that pharmacies will still lose money under SB3 in its current form.

Example: An independent pharmacy purchases a UPL-controlled medicine for \$900 and dispenses it, receiving \$900 as reimbursement and a dispensing fee of \$0.25. This dispensing fee is so small that it doesn't cover the cost of the pharmacy's rent, staff salaries/wages, utilities, insurance, compliance, and other basic costs of operating as a health care provider. Without a fair dispensing fee pharmacies lose money and either go out of business or are forced to stop filling key prescriptions their patients need.

We can see the impact of legislation like this at the national level: Inflation Reduction Act price controls will <u>end</u> <u>up causing one third of independent pharmacies to cease carrying negotiated price medicines</u> and pharmacies that choose to dispense the medicines anyway to <u>lose \$40,000 to \$46,000 per year in revenue per pharmacy annually</u>.

SB 3 in its current form will force pharmacies to dispense medicines without covering their costs, and this will have a detrimental impact on patient access to treatment. **SB 3 in its current form is detrimental to independent pharmacy.** 

## Risk: Arbitrage and diversion of medicine from Michigan

Attempts to control the increased prices for products often distort the market in ways that don't benefit consumers (see "Why price controls should stay in the history books." Federal Reserve Bank of St. Louis). A UPL is a price control, and if a UPL creates a guaranteed supply of a medicine cheaper than can be found in every other state besides Michigan, a gray market in Michigan-priced medicine would emerge.

Examples of out-of-state supply chain leakage include:

**Arbitrage of medicines in shortage**: PSM has studied the gray market in lidocaine, an injectable anesthetic available from multiple manufacturers that is currently in shortage. Following a tip from a hospital pharmacy in West Virginia that was forced to purchase lidocaine for a 500% markup over its regular wholesale price, PSM found a small community pharmacy in Texas that had adopted an arbitrage model where it purchased lidocaine injections that it never intended to dispense for the purpose of selling them to a licensed gray market wholesaler. This was happening at the same time physicians in Texas were struggling to get lidocaine for orthopedic arthritis patient injections. (See: "Why pay 500% markup for lidocaine?" on PSM's YouTube channel)

**Pharmacy-to-pharmacy online marketplaces**: Technically, it is legal for pharmacies to sell each other product without track and trace documentation for a *named patient need*. This is an important way for pharmacies to address shortages. Online marketplaces, like Amazon marketplace but for pharmacies, have sprung up to facilitate these transactions, and are an obvious route that pharmacies and wholesalers with access to cheap UPL-governed medicine could use to sell price-controlled medicine out of state.

A UPL on a medicine would create the unintended consequence of making it more profitable for any player in the supply chain to sell that medicine outside Michigan than to dispense it. Even if only one or two self-serving supply chain participants did this, it would have an outsized effect on patient access. The resulting shortage would decrease access to that medicine, fueling additional risky behavior on the part of patients.

We understand that this is not the intended goal of the legislative sponsors of the Prescription Drug Affordability Board, and we sympathize with the challenges of making change in a complex economic system. However, the warning signs of a black market are very clear, and economists who study black markets created by price controls recommend that the government instituting them create and fund an entity that enforces the rules around these controls.

SB 3, 4, and 5 do not contain any restrictions on selling UPL-controlled medicine outside the state of Michigan. Even if they did, there is no Michigan law enforcement authority resourced to take on this new enforcement challenge.

## Risk: Patient access issues will create targets for diversion

When patients have difficulty getting the medicine they need, they are more likely to encounter counterfeit and diverted medicines. This isn't theoretical. We have a recent example.

In November 2021 one of the top five PBMs removed one of two state-of-the-art anticoagulants from their drug formulary. These new products, Eliquis and Xarelto, are successors to warfarin, which requires more monitoring and blood testing and is no longer the preferred method of treatment.

The formulary change forced U.S. patients into a non-medical switch. For many medicines, this is a problem. Physicians and patients often work together to find the exact right dosage of a medicine that is therapeutically effective, and once found, any change could result in therapeutic failure. Therapeutic failure for anticoagulants, which treat deep vein thrombosis, blood clots, and stroke, are extremely dangerous for patients when conducting any kind of switch, especially one not driven by treatment need.

#### Mexican counterfeiters enter the market to exploit patient need

Soon after the PBM removed Eliquis from their formulary, PSM received word that placebo counterfeits of Eliquis and Xarelto had been found in border pharmacies in three cities in Mexico, including Los Algodones. These pharmacies cater to U.S tourists and are often within a short walk or drive from the border checkpoint. Los Agodones, for example, is a twenty-five minute drive from Yuma, AZ and a three-hour drive from Phoenix, AZ.

The examples that undercover purchasers working for manufacturer anticounterfeiting teams found were extremely convincing fakes.













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UC purchases of fake blood thinner, photo credit Pharmaceutical Security Institute

As you can see in the examples, the first two instances of these fakes are labeled in English. The medicines themselves were nothing but filler powder. They contained no active ingredient at all. The third medicine was the same product, but a counterfeiter had translated the label into Spanish to make it look like a local product. It, too, contained pills with no active ingredients.



Manufacturers of the legitimate products learned about these fakes when concerned patients called their quality hotlines. Patient harm was reported, but not publicly documented. These fakes spread along the Mexican border pharmacies until they finally reached Cancun. In June 2022 the PBM put Eliquis back on their formulary, reducing the need for patients to seek alternative sources. Anticounterfeiting team members told me that after that, the fake anticoagulants were no longer easy to find in Mexican border pharmacies, though you can still find black market versions for sale online.

The criminal black market is absolutely responsive to economic conditions that affect patients. If anything reduces access to UPL-regulated medicine in Michigan patients will face treatment interruptions. They may have to travel to other states to get treatment (an unacceptable burden) or, the black market will step in, likely with unsafe medicine.

Because prosecutions of counterfeit therapeutic medicines are not well-funded or a high priority, it would be wise to tread very carefully when making policy decisions that might result in reduced access to medicine.

#### Conclusion

Prescription Drug Affordability Boards do not do their work in a vacuum and must take into account existing conditions of the market to avoid unintended consequences from their policy work. The track record to date for PDABs is not one of success. In fact to date PDABs in six states to date have held 111 meetings consuming over 200 hours. They have been staffed by 90 board members earning little to no pay and cost the states over \$16 million in operating costs without a single successful implementation to demonstrate cost savings.

On the other hand, there are very successful examples of reforms that have documented savings, including:

PBM reform in the Medicaid program in Ohio In Ohio, the state reformed how the Medicaid program managed medication benefits. The audited results of the reforms reveal that over the first two years of implementation the program has yielded a savings of over \$140 million for the state, reduced administrative costs resulting in savings of \$333 million, increased access and choice for patients to choose the best pharmacy for them, provide a fair dispensing fee for pharmacies resulting in the highest level of pharmacy openings in Ohio over the last five years, and reversed a ten-year decline in small chain pharmacies.

West Virginia's Medicaid program achieved \$54.4 million in savings with PBM reform. These techniques are not only applicable to Medicaid; they could save money in the private insurance market as well.

While the goals of Prescription Drug Affordability Boards are laudable, problems in our healthcare system are complex, and using payment caps in just one part of the supply chain will yield unintended consequences.

Upper Payment Limits have many flaws and are unlikely to lower the price of medicine, but they are likely to reduce access and encourage a black market in medicines subject to a UPL. This will do more harm than good for



patients, and that is the opposite of the stated mission of Prescription Drug Affordability Boards. Michigan should not enact these policy proposals in their current form. At the very least, Michigan should give the PDAB equal power to reform the business practices of PBM that interfere with the price of medicine as it does to create Upper Payment Limits.