MARY FELZKOWSKI
STATE SENATOR • 12TH SENATE DISTRICT

Testimony on Senate Bill 3
Committee on Health
February 9, 2021

Good afternoon Chairman Testin and committee members, and thank you for the opportunity to testify on Senate Bill 3, relating to regulation of Pharmacy Benefit Managers. The bill before you today is the compromise reached at the end of last session amongst all of the stakeholders involved. I am grateful to my co-author, Rep. Michael Schraa, who has worked tirelessly on this legislation over the last two years.

Pharmacy Benefit Managers (PBMs) are businesses that administer and manage prescription drug benefits, typically on behalf of health insurers. PBMs create formularies, contract with pharmacies, and process and pay prescription drug claims. Because of the contracts they negotiate with manufacturers, health plans, and pharmacies, PBMs play a crucial role in the prescription drug supply chain, including influencing pricing and drug selection.

PBMS were initially created to help keep prescription drug prices affordable. However, we have brought forward SB 3 today because some current PBM practices are having an adverse effect on pharmacies and patients, and you will hear examples of both during testimony today. The purpose of this bill is to put regulations in place that help PBMs operate as originally intended to lower out-of-pocket drug costs and increase access to prescribed medications, while also protecting patients and pharmacies.

The bill accomplishes the following provisions:
Prohibiting Gag Clauses: This bill prohibits a PBM from banning a pharmacist from informing a patient that there is a lower cost option to paying for a prescription drug.

Clawbacks: Sometimes, a patient's copay is more than the cost of the medication if the patient were to pay cash. For example, a patient could have a $15 copay for a medication with a cash price of $5, and the PBM would charge the patient $15 – driving up healthcare costs and forcing patients to spend more of their hard-earned money. This bill prohibits PBMs from charging a copay greater than the amount that the pharmacy would charge if the patient was not using insurance.

Rebate Transparency: PBMs contract with drug manufacturers, receiving a rebate (discount or kickback) for including drugs in their formulary. Each PBM will submit an annual report to the Office of the Commissioner of Insurance (OCI) indicating the amount of rebates received from pharmaceutical manufacturers and the portion of that rebate that was retained by the PBM and not passed through to the health plan or their customers. These reports will be protected as trade secrets.

Pharmacy Transparency: Pharmacies must post signage informing customers of legal drug substitutions and how to access the FDA list of approved substitutions.

Drug Formulary Changes: Decisions about prescription medication regimens should be made between prescribers and patients. Patients that have been taking the same prescription drug for years should not be at-risk of losing access to these drugs, or be charged more to obtain them, because of a decision that financially

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benefits a PBM. This bill requires a 30 day written notice of removal or increased cost along with information on how to request an exception—unless an equal or lower cost alternative is added to the formulary.

Fair Business Practices: PBMs often practice retroactive claim reduction. After a pharmacy has filled a prescription at an agreed-upon price, the PBM changes the reimbursement amount. This practice will not be allowed unless there was some impropriety on the part of the pharmacy.

Fair Audit Provisions: Predatory audits make it difficult for responsible pharmacies to continue to stay in business to serve their communities. Under the bill, PBMs must give two weeks' notice before conducting an audit at a pharmacy. The audit period cannot exceed a lookback period of two years, and clerical or record-keeping errors shall not be subject to the recoupment of funds unless the errors are intentionally fraudulent.

Licensure with OCI: This bill requires PBMs to be licensed annually with OCI. The insurance commissioner can also require reports and conduct examinations to ensure that PBMs are acting in the best interests of the consumer, just like they can with insurance companies.

The authors are also bringing forward an amendment to address the effective date of the bill. Last session, if the bill had not been timed out due to COVID, the bill would have taken effect in June of 2021. The amendment would change the effective date of the bill to the beginning of the next plan year, January 1, 2022, except for the provisions concerning gag clauses, clawbacks, and predatory audits, which would remain effective upon enactment.

As a legislator who serves a very rural district across eleven counties, I can tell you firsthand that independent pharmacies are crucial for access to health care for my constituents. This bill will go a long way to helping these pharmacies stay in business and continue to serve our communities. It will also put necessary parameters in place that ultimately best serve the patient.

Thank you again for your time. I am happy to answer any questions you may have.

MICHAEL SCHRAA
STATE REPRESENTATIVE • 53RD ASSEMBLY DISTRICT

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Senate Bill 3 Testimony

Thank you, Chairman Testin and Committee Members, for the opportunity to testify in favor of Senate Bill 3. This bill will improve the health of our constituents by putting an end to unfair business practices and make the purchase of prescription drugs affordable and accessible.

Last session, this crucial bill had overwhelming bipartisan support, and it is no less critical today. Our citizens are struggling with unemployment, business setbacks, and business closures. The last thing they need is to pay more for their medications or lose their local pharmacy due to unfair business practices.

Access to medication is very personal to me. It's why I became aware of Pharmacy Benefit Managers in the first place. Last year, my wife testified about her great difficulty obtaining the medication that her doctor prescribed. She spent 23 hours on the phone with our PBM and I was about to take her to the emergency room before our PBM finally relented and covered the medication her physician had prescribed. Not everyone has the tenacity to advocate for themselves. How many of your constituents are suffering because they've been denied medications that had previously been prescribed and covered?

This bill is essentially the same as the bill you heard in this committee on February 12 of last year. Let me go over the main provisions of the bill that were agreed upon last session.

- **Prohibiting Gag Clauses**: The pharmacist is allowed to tell the patient there is a lower cost option to paying for a prescription drug.
- **Cost sharing limitation (Clawbacks)**: The co-pay charged to a patient cannot be more than the amount that the pharmacy would charge if the patient was not using insurance, the "cash" price.
- **Rebate Transparency**: PBMs claim to save money by contracting with drug manufacturers for a rebate (discount or kickback) on the drugs they include in the formulary. Each PBM will submit a confidential annual report to OCI indicating the amount of rebates and the amount they kept instead of passing it on to the health plan or patients. These reports will be protected as trade secrets.

- **Pharmacy Transparency**: Pharmacies must post signage informing customers of legal drug substitutions and how to access the FDA list of those approved substitutions.
- **Drug Formulary Changes**: PBMs must provide a 30 day written notice if a drug is removed from the formulary or increases in cost. They must also provide information on how to request an exception. If they add a drug of equal or lower cost to the formulary, no notice is required.
- **Retroactive Claim Reduction (Clawbacks):** After a pharmacy has filled a prescription at an agreed-upon price, the PBMs will no longer be allowed to unilaterally change the reimbursement amount.
- **Fair Audit Provisions:** Only audits for waste, fraud, and abuse will be allowed, putting an end to predatory audits aimed at high-return clerical errors.
- **Licensure with OCI**: This bill requires PBMs to be licensed annually with OCI. Through the rule-making process, OCI will allow for adequate time for PBMs to comply with their requirements.

I'd like to also mention some of the key provisions we negotiated away to get to this place.

- Consistent copays for the patient: This bill allows PBMs to continue to use financial incentives to drive patients to mail order, specialty, or retail pharmacies owned by the PBM.
- Keeping drugs on the formulary for the benefit year: Under this bill, PBMs are still allowed to make changes to the approved list of drugs after patients have selected the plan that covers the drug they need.
- Published transparency reports: Information on how PBMs pass on or keep the rebates they get from drug manufacturers, will not be available to the public. This bill only has confidential reports to OCI.

The insurance and pharmaceutical industry is complex and opaque. While they are responsible to their stockholders and their consciences, we are responsible to guard the health and pocketbooks of our constituents. I would never want to keep a legitimate business from making a fair profit. On the other hand, it is our responsibility to protect the citizens of Wisconsin from any bad actors that would engage in disreputable business practices.

In closing, it is my privilege to again work with this bipartisan group of legislators to protect the health of our constituents.

Coalition of Wisconsin Aging & Health Groups

Financial Empowerment – Personal Advocacy – Victim Rights

"Advocating for all Generations"

The Coalition of Wisconsin Aging and Health Groups is a nonprofit, nonpartisan, statewide membership organization that was founded in 1977.

2/9/2021

Coalition of Wisconsin Aging and Health Groups (CWAG) and Wisconsin Pharmacy Patient Protection Coalition (WPPPC) Testimony in Support of SB 3
Senate Committee on Health

Chair Testin, Vice Chair Kooyenga, members of the Committee, thank you for the opportunity to speak today. I'm Rob Gundermann, President and CEO of the Coalition of Wisconsin Aging and Health Groups and Chair of the Wisconsin Pharmacy Patient Protection Coalition. We strongly support SB 3, as there are several provisions in the bill, such as the removal of the gag clause on pharmacists, that are important to our Coalition partners.

Gag clauses are being used to bar pharmacists from telling consumers when it would cost less to pay cash for a prescription than paying the copayment on their insurance. People deserve to know the lowest price they can pay for their medications at their pharmacy and gag clauses imposed by PBMs are preventing this. The provision in this bill preventing the use of gag clauses corrects this problem and will enable people to pay less for their prescriptions and will save them money.

This legislation also addresses the issue of drug substitution or non-medical switching which is important to our coalition partners. For some people, switching medications can have serious consequences. For example, when a patient is taking multiple medications, their doctor needs to find the right combination that works without causing negative side effects, and that becomes difficult as more drugs are added into what essentially becomes a drug cocktail. The bill doesn't provide as much protection in this area as we would like, but this legislation puts us in a better place than we are in today. On behalf of the Coalition, I urge you to not only support this important legislation but to insist upon rapid implementation as soon as this legislation is passed. These changes are critical to the people we represent, and they have already waited far too long for these changes to be implemented.

Thank you for your time and consideration.

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WPHCA
Wisconsin Primary Health Care Association

February 8, 2021

To: Chair Sanfelippo
Assembly Committee on Health
From: Wisconsin Primary Health Care Association
RE: Considerations for Health Centers and Patients in Senate Bill 3

Members of the Assembly Committee on Health:

The Wisconsin Primary Health Care Association, the member association for Wisconsin's 17 Federally Qualified Health Centers ("Health Centers"), is writing to share considerations to protect and serve Health Centers and their patients through Pharmacy Benefit Manager (PBM) regulation. In 2019, across nearly 200 Wisconsin service locations, Health Centers served over 300,000 patients, providing primary care, dental, behavioral health, and pharmacy services for Wisconsinites who are often missed by the traditional health care system – regardless of a patient's ability to pay.

WPHCA appreciates this opportunity to provide feedback regarding Assembly Bill 7 (AB 7), supports the bipartisan proposal, and appreciates your continued leadership and dedication to action on this key issue. Health Centers work with PBMs to meet the needs of patients who use private insurance or Medicare for prescriptions. Several Health Centers operate in-house pharmacies, some rely strictly on contract pharmacies, and several use both methods for prescription distribution or supplement with mail order options. Key areas of concern for Health Centers related to PBMs include the potential for cost inflation passed along to consumers, discriminatory contracting and steering patients to particular pharmacies thereby reducing patient choice, and clawbacks. We are pleased to see that AB 7 addresses many of these issues.

WPHCA supports the following provisions in AB 7 and believes they will result in direct benefits for Health Centers and their patients:

- **Prohibiting Gag Clauses, Imposing Cost-Sharing Limitations, and Notification of Formulary Changes (Sec. 15):** Health Center pharmacies are dedicated to ensuring that patients can access low-cost medications. Pharmacy staff appreciate the flexibility to inform patients when a medication is available at a lower cost, support the cost-sharing limitations intended to make sure that patients do not over-pay for life-saving products, and support the formulary change notification provisions.
- **Fair Business Practices (Sec. 21):** Health Center pharmacies recognize the value of certification and accreditation. However, compliance with requirements that change often or with little notice can be administratively burdensome and yield minimal or no patient benefits. Requiring notice and implementing minimum frequency requirements for certification or accreditation changes as a condition of network participation would support meeting quality measures while reducing overly burdensome administrative processes, further freeing up pharmacy resources for patient care.
- **Clawbacks (Sec. 21):** Health Centers appreciate the protections against unfair claim reductions included in AB 7. However, WPHCA seeks clarification on the definition of a PBM "quality program" which may be interpreted broadly. Health Centers are concerned that PBMs may apply retroactive claim reductions for "quality programs" that may not actually be substantively beneficial to the provision of quality patient care. An effective quality program defines standards proactively and transparently measures against those standards consistently, with a clear tie to improved outcomes. Further, as a requirement of their FQHC status, Health Centers must maintain and manage a quality improvement program. They already report an extensive set of quality data annually to the Health Resources and Services Administration, known as the Uniform Data System.

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WPHCA
Wisconsin Primary Health Care Association

- **Auditing Practices and Use of Audit Results (Sec. 21):** Health Centers appreciate the transparency requirements related to both the completion of an audit and restrictions regarding use of audit results. Implementing such changes will facilitate audit processing and ultimately support quality care.

WPHCA recognizes the need for compromise legislation that will begin to move the needle on PBM issues, which AB 7 does well. We would like to highlight the following provisions from 2020 AB 114/SB 100 (unamended) and requests that they be considered in future PBM regulatory or legislative efforts:

- The original 2020 bill's provisions related to PBM Networks are critical to ensuring that patients and Health Centers are not subjected to unfair practices. The issues related to patient "steering" will continue without further regulatory intervention. Discriminatory contracting is *the most* critical issue for Health Centers, which is not addressed in AB 7. The following provisions should be considered in future action:
    - Prohibit a PBM from reimbursing a pharmacy or pharmacist an amount less than the amount that the PBM reimburses an affiliate of the PBM for providing the same services. This is especially critical for pharmacies that participate in the 340B Drug Pricing Program, as PBMs may impose unfair conditions of participation in a PBM network or penalize Health Center-operated pharmacies due to their participation in the program.
    - Prohibit an insurer, self-insured health plan, or PBM from requiring or penalizing a person who is covered under a disability insurance policy or self-insured health plan for not using a specific retail, specific mail order, or other specific pharmacy provider within the network of pharmacy providers under the policy or plan.
- Require PBMs to establish and follow a written appeals process that allows a pharmacy or pharmacist to appeal the final report of an audit and allow the pharmacy or pharmacist as part of the appeal process to arrange for, at the cost of the pharmacy or pharmacist, an independent audit.
- Provide restrictions on the use of audit results, including:
    - Refrain from using extrapolation in calculating the recoupments or penalties for an audit.
    - Base a finding of overpayment or underpayment of a claim on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
- Prohibit PBMs from requiring that a pharmacy or pharmacist enter into one contract in order to enter into another contract.

WPHCA affirms our shared goals to ensure that all Wisconsin residents have access to high quality care, including affordable pharmaceutical products, and appreciates your ongoing dedication to protecting patients. On behalf of Wisconsin's Health Centers, thank you for the consideration of our comments and your leadership on this critical issue.

Sincerely,

Richelle Andrae

Richelle Andrae
Government Relations Specialist
Wisconsin Primary Health Care Association
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P: (608) 443-2953
www.wphca.org

AHI
ALLIANCE OF HEALTH INSURERS

AHIP
America's Health Insurance Plans

Wisconsin Association of Health Plans

To: Members, Senate Committee on Health and Human Services
From: Rebecca Hogan, on behalf of the Alliance of Health Insurers
Mary Haffenbredl, on behalf of America's Health Insurance Plans
Tim Lundquist, on behalf of the Wisconsin Association of Health Plans
Date: February 9, 2021
Re: Written testimony on SB 3 – amendment request

The Alliance of Health Insurers (AHI), America's Health Insurance Plans (AHIP) and the Wisconsin Association of Health Plans (WAHP) are nonprofit advocacy organizations improving consumer access to affordable health insurance in Wisconsin, both via the private sector and public programs, and are committed to market-based solutions that improve affordability, value, access and well-being for consumers.

Our members and employers work with pharmacy benefit managers (PBMs) because they attempt to mitigate increasing costs by using their expertise and technology solutions to administer certain essential functions of a prescription drug benefit for health plans by:

- Using clinically based services to reduce medication errors, achieve higher rates of medication adherence, and improve health outcomes.
- Negotiating directly with manufacturers and pharmacists to lower total drug costs. The level of comparable volume and cost reductions PBMs can generate cannot be achieved by many health plans, most employers, or individuals.
- Implementing cost-saving strategies that include discount pharmacy networks, incentives to use therapeutic alternatives, formulary management (including manufacturer rebates), mail-order pharmacies, drug-use reviews, and disease management.
- Educating their consumers about safe, effective, and lower cost generic drugs.

AHI, WAHP and AHIP sincerely appreciated the opportunity to work through issues with policymakers last session to ensure PBM reform did not inadvertently raise drug costs. Instead, the negotiated compromise:

- Reaffirms a pharmacy's ability to inform an enrollee under the policy or plan of the lowest cost option for their drug.
- Requires a pharmacy to have available to the public a listing of the retail price, updated monthly or more often, of the 100 most prescribed prescription drugs available for purchase at the pharmacy.
- Requires a PBM to be licensed with the Office of the Commissioner of Insurance (OCI) or to have an employee benefit plan administrator license under current law.
- Clarifies when a PBM can retroactively deny a pharmacy or pharmacist's claim.
- Requires PBMs to report aggregate rebate amounts that the PBM received from all pharmaceutical manufacturers but retained and did not pass through to health benefit plan sponsors and the percentage of the aggregate rebate amount that is retained rebates.

Unfortunately, the bill's original effective date of 14 months from last session's agreement was removed and replaced by an immediate effective date. An immediate effective date for this type of reform is not possible and we are interested in partnering with policymakers to develop a more feasible implementation timeline. We have a joint goal to address the rising cost of prescription drug medications and offer affordable plans to employers and our enrollees.

Thank you for this opportunity to submit testimony today.

GWaar
Greater Wisconsin
Agency on Aging Resources, Inc.

Date: February 9, 2021

To: Chairman Testin, Vice-Chairman Kooyenga, and Members of the Senate Committee on Health

From: Janet L. Zander, Advocacy & Public Policy Coordinator

Re: **For Information Only – SB 3** – relating to: pharmacy benefit managers, prescription drug benefits, and granting rule-making authority

The Greater Wisconsin Agency on Aging Resources, Inc. (GWAAR) is a nonprofit agency committed to supporting the successful delivery of aging programs and services in our service area consisting of 70 counties (all but Dane and Milwaukee) and 11 tribes in Wisconsin. We are one of three Area Agencies on Aging in Wisconsin. We provide lead aging agencies in our service area with training, technical assistance, and advocacy to ensure the availability and quality of programs and services to meet the changing needs of older people in Wisconsin. Our mission is to deliver innovative support to lead aging agencies as we work together to promote, protect, and enhance the well-being of older people in Wisconsin.

Thank you for this opportunity to share testimony for information only on SB 3. In addition to providing training and technical assistance to county and tribal aging units/aging and disability resource centers (ADRCs) regarding Older Americans Act and other aging service programs, GWAAR also operates an Elder Law and Advocacy Center providing legal supervision for many of the Elder Benefit Specialist (EBS) programs at the local level. EBSs provide benefit counseling and assistance with appeals in the areas of Medicare, Medicaid, Social Security, Supplemental Security Income, FoodShare, housing, consumer debt, and other health insurance coverage issues. Over 75 percent of the closed EBS cases last year in the GWAAR service area were related to health insurance benefits, a significant portion of which were regarding prescription drug coverage and related prescription drug cost appeals and concerns.

According to a 2019 Kaiser Family Foundation Tracking Poll nearly 90% of older adults reported they were taking prescription medication and many reported taking multiple medications. Over 75% of older adults reported the cost of prescription drugs was unreasonable, even for those with prescription drug coverage. Nearly one-fourth of older adults taking prescription drugs indicated it was difficult to afford their prescription drugs (this is especially true for those nearing Medicare age) and nearly one-tenth said it was very difficult to afford their medications. Additionally, over 20% reported they did not take their medication as prescribed due to the cost. Prescription drug costs accounted for over 20% of out-of-pocket health care expenses (not including premiums) for Medicare beneficiaries (2016).

Reducing prescription drug costs for older consumers and improving drug price transparency is a high priority for GWAAR and the Wisconsin Aging Advocacy Network. As such, GWAAR is specifically supportive of the following provisions included in SB 3:

- Prohibiting pharmacy benefit managers (PBMs) from banning pharmacists from informing customers that there is a lower cost option to paying for a prescription drug,
- Prohibiting PBMs from charging a copay greater than the amount the pharmacy would charge customer if he/she were not using insurance,
- Prohibiting PBMs from financially penalizing a consumer by charging higher co-pays for utilizing a particular in-network pharmacy versus another (choice of in-network provider is essential),
- Requiring pharmacies to have a public listing of the retail prices of the 100 most commonly prescribed prescription drugs available for purchase,
- Preventing the removal of prescription drugs from a formulary during a plan year, and
- Requiring a health insurance policy, health plan or PBM to provide at least a 30-day advanced written notice to members regarding any formulary change that removes a prescription drug from the formulary or reassigns the prescription drug to a higher benefit tier with higher deductibles, co-pays, or co-insurance and including information on the procedure for requesting an exception as part of this notice.

We appreciate the interest in and efforts of policy makers to address growing concerns related to the high cost of prescription drugs and look forward to continuing to work with you on policies that improve the quality of life of older people in Wisconsin.

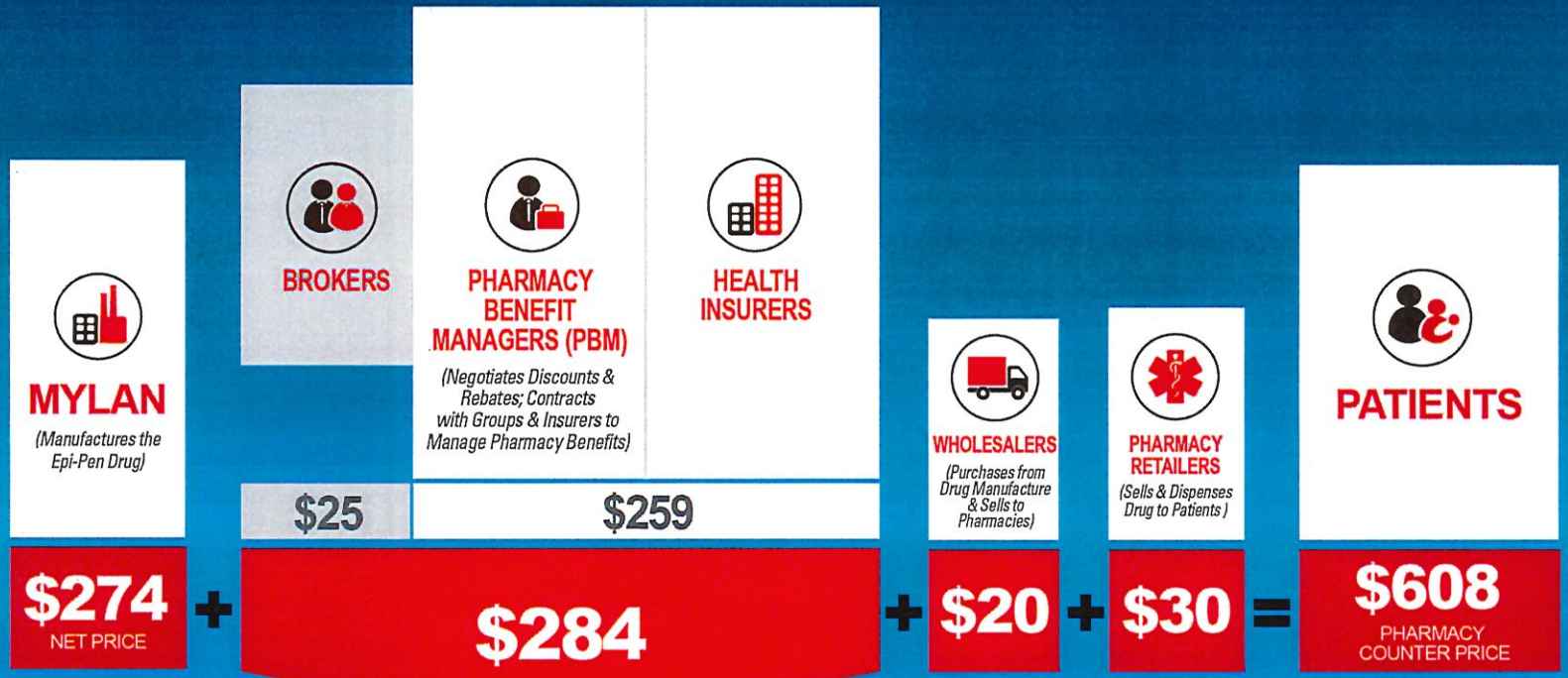
Thank you for your consideration of these comments regarding SB 3.

Contact: Janet Zander, Advocacy & Public Policy Coordinator, MPA, CSW
Greater Wisconsin Agency on Aging Resources, Inc.
janet.zander@gwaar.org
(715) 677-6723 or (608) 228-7253 (cell)

EPIGATE

Where the Money *Really* Goes

Pharmacists United for TRUTH & TRANSPARENCY



DEMAND TRANSPARENCY

TruthRX.org

HUMALOG

Where the Money *Really* Goes

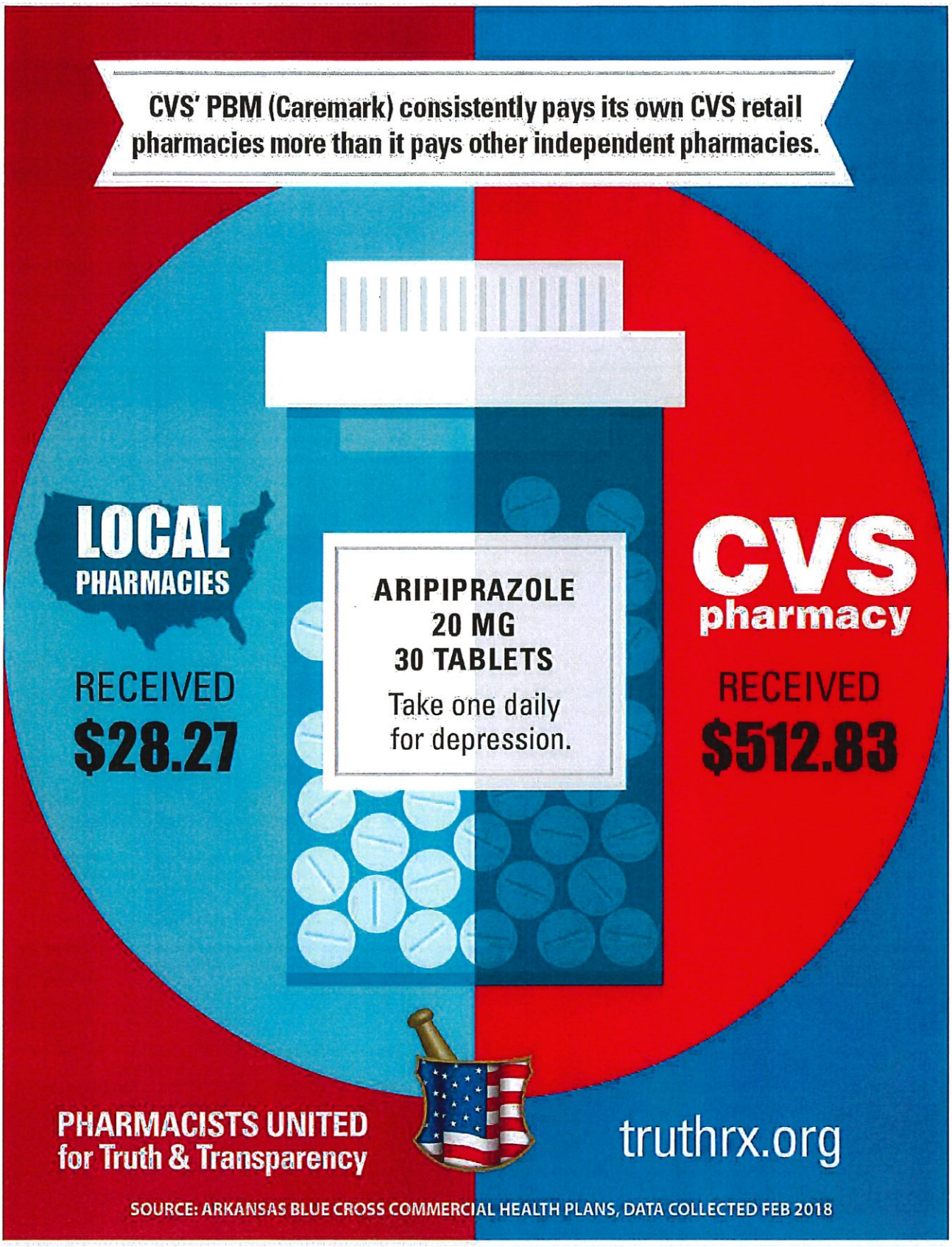
Pharmacists United for TRUTH & TRANSPARENCY

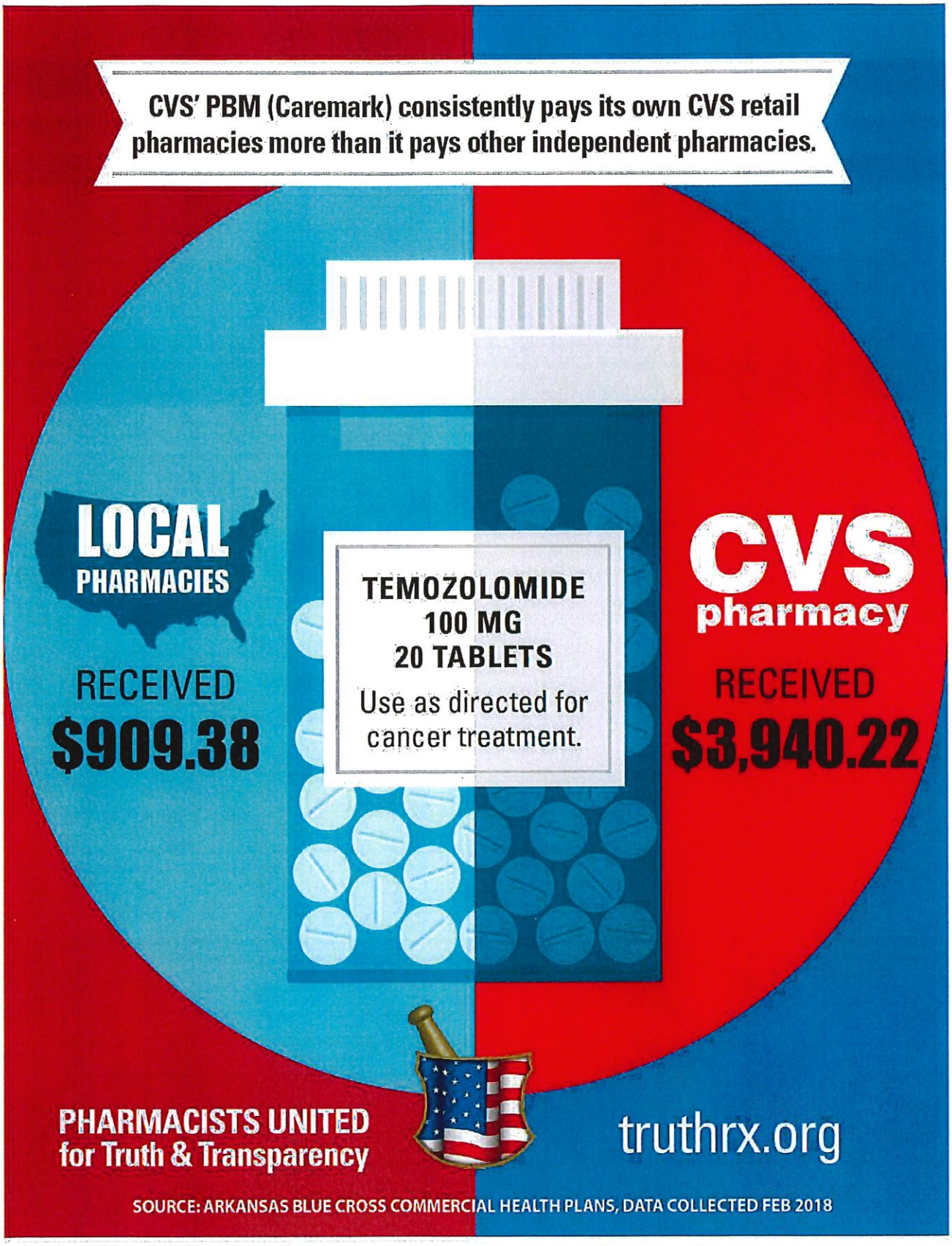
DEMAND TRANSPARENCY

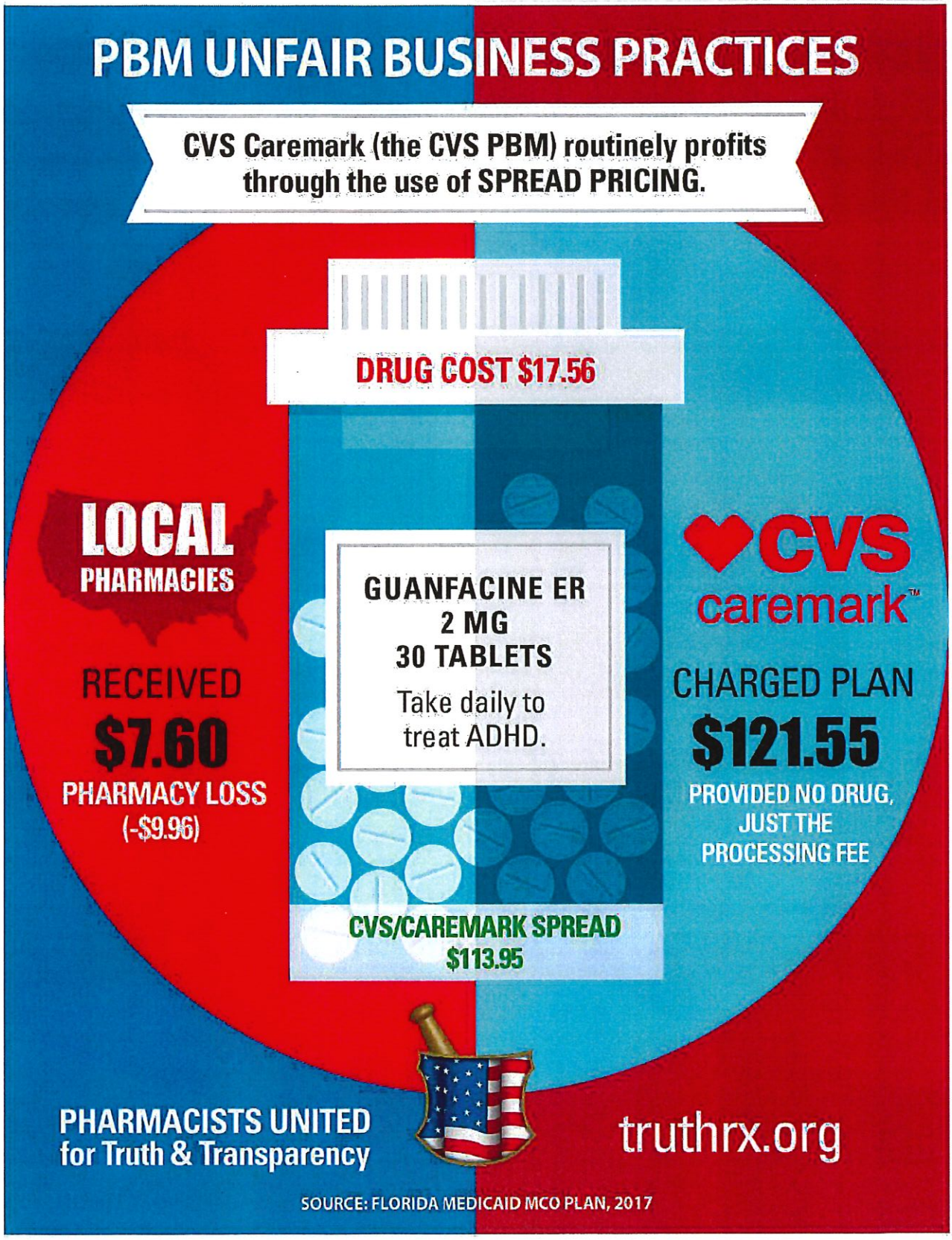
*As reported by Eli Lilly 3/24/2019.

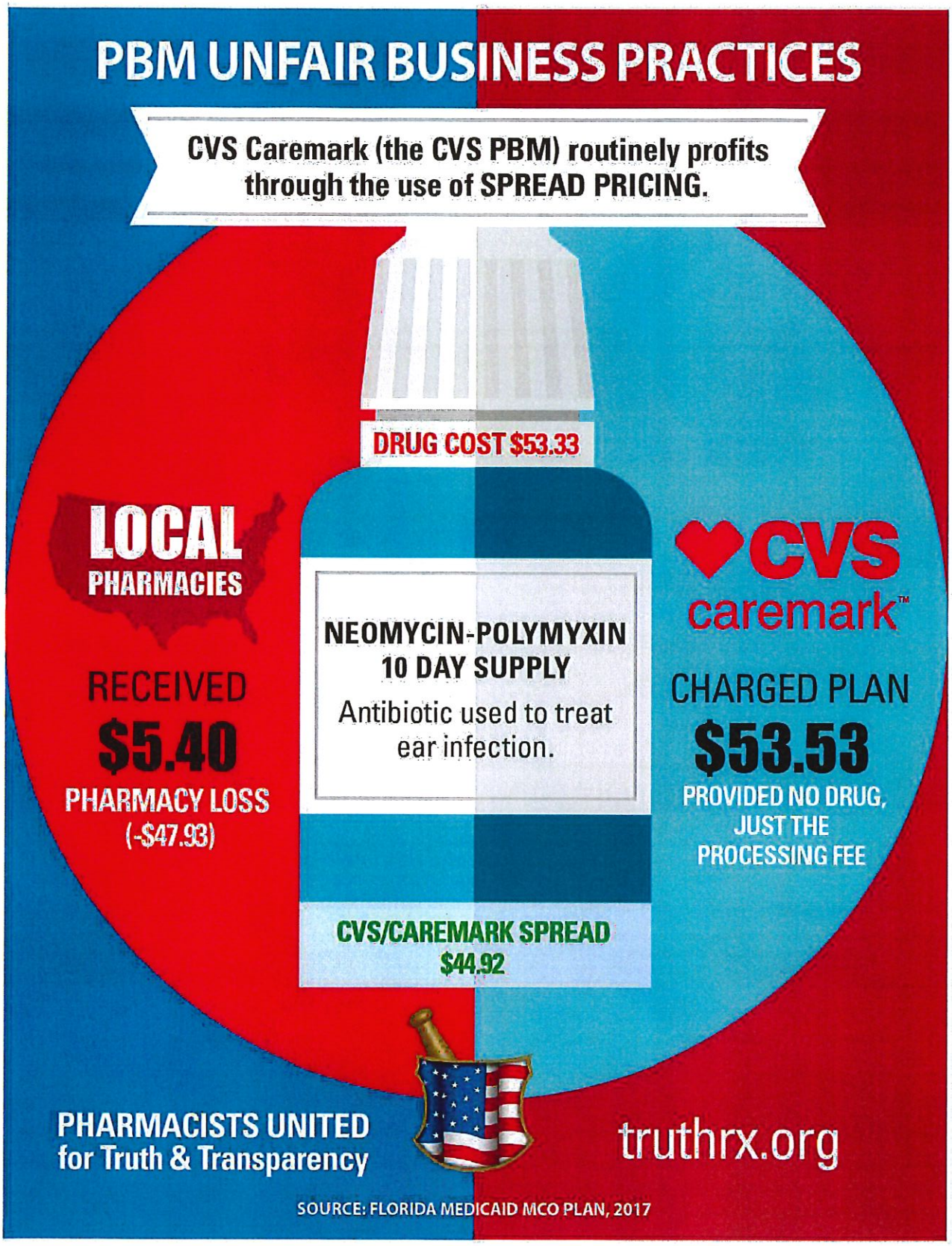
**Conservative estimate, actual price may be closer to $1. Most pharmacies in contact with PUTT have reported losses on all insulin dispensed due to below-cost reimbursements.

TruthRX.org


CVS' PBM (Caremark) consistently pays its own CVS retail pharmacies more than it pays other independent pharmacies.
LOCAL PHARMACIES
RECEIVED
$28.27
ARIPIPRAZOLE
20 MG
30 TABLETS
Take one daily for depression.
CVS pharmacy
RECEIVED
$512.83
PHARMACISTS UNITED for Truth & Transparency
truthrx.org
SOURCE: ARKANSAS BLUE CROSS COMMERCIAL HEALTH PLANS, DATA COLLECTED FEB 2018


CVS' PBM (Caremark) consistently pays its own CVS retail pharmacies more than it pays other independent pharmacies.
LOCAL PHARMACIES
RECEIVED
$909.38
TEMOZOLOMIDE
100 MG
20 TABLETS
Use as directed for cancer treatment.
CVS pharmacy
RECEIVED
$3,940.22
PHARMACISTS UNITED for Truth & Transparency
truthrx.org
SOURCE: ARKANSAS BLUE CROSS COMMERCIAL HEALTH PLANS, DATA COLLECTED FEB 2018


PBM UNFAIR BUSINESS PRACTICES
CVS Caremark (the CVS PBM) routinely profits through the use of SPREAD PRICING.
DRUG COST $17.56
LOCAL PHARMACIES
GUANFACINE ER
2 MG
30 TABLETS
Take daily to treat ADHD.
CVS caremark™
RECEIVED
$7.60
PHARMACY LOSS
(-$9.96)
CHARGED PLAN
$121.55
PROVIDED NO DRUG, JUST THE PROCESSING FEE
CVS/CAREMARK SPREAD
$113.95
PHARMACISTS UNITED for Truth & Transparency
truthrx.org
SOURCE: FLORIDA MEDICAID MCO PLAN, 2017


PBM UNFAIR BUSINESS PRACTICES
CVS Caremark (the CVS PBM) routinely profits through the use of SPREAD PRICING.
DRUG COST $53.33
LOCAL PHARMACIES
RECEIVED
$5.40
PHARMACY LOSS
(-$47.93)
NEOMYCIN-POLYMYXIN
10 DAY SUPPLY
Antibiotic used to treat ear infection.
CVS/CAREMARK SPREAD
$44.92
CVS caremark™
CHARGED PLAN
$53.53
PROVIDED NO DRUG, JUST THE PROCESSING FEE
PHARMACISTS UNITED for Truth & Transparency
truthrx.org
SOURCE: FLORIDA MEDICAID MCO PLAN, 2017

Example 1 - Lack of Information
Misc. fees with no reason – "Not Specified"

5102051	$15,199.35
Forwarding Balance	-$8.36
Manual WriteOff	$619.13
Misc Not Specified	$5,184.80
Overpayment	-$21.25
Performance Network Fee	$1,102.59
Transaction Fee	$2,817.65
Weekly Portion of DIR Recouped - Caremark	$5,504.79

Example 2 – Lack of Information
Misc. fees with no reason – "Not Specified"

Wisconsin Med...	5101287	11/17/2020	$10.99	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-14.31	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-10.99	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$14.31	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-498.18	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$16.93	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-27.37	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-16.34	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-16.93	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$27.37	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$16.34	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/17/2020	$-316.87	Misc Not Specified	501916...	11/18/2020
Wisconsin Med...	5101287	11/30/2020	$-193.36	Misc Not Specified	501924...	12/01/2020
Wisconsin Med...	5101287	11/30/2020	$15.37	Misc Not Specified	501924...	12/01/2020
Wisconsin Med...	5101287	11/30/2020	$-48.43	Misc Not Specified	501924...	12/01/2020

Example 3 –
Payments & Claw backs

Transaction Ledger

Claim Information

Parent PBM	NABP	Fill Date	Prescription #	Co Pay	Total Due	Total Paid
OptumRx	5136127	8/15/2020	6040049	$167.52	$0.00	$0.00

Payment Admin Information

Status	Monetary Amount	Posted By	Post Date
Complete	N/A	Jessica Howle	1/15/2021

Transactions for 8/15/2020 Fill Date

Add

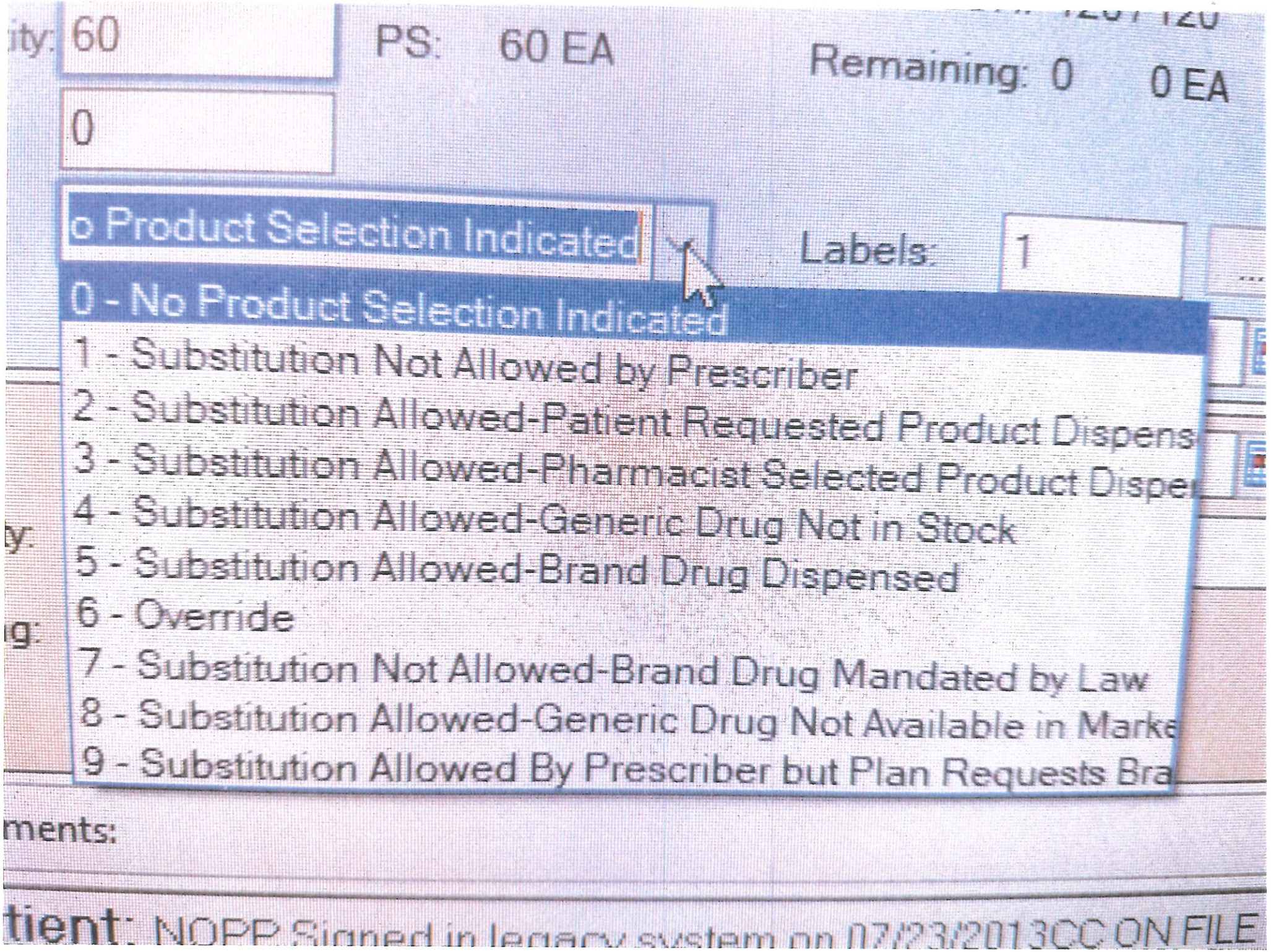
Type	PBM	BIN	PCN	Group	OCC	Auth #	Total	Post Date	Trans/Pay Date	Check #
835 - 3rd Party Payment	Change Healthcare						$2.50	1/15/2021	1/14/2021 12:00:00 AM	6376199
Overpayment	OptumRx						-$2.50	1/15/2021	11/20/2020 12:00:00 AM	
Overpayment	OptumRx						$2.50	11/24/2020	11/20/2020 12:00:00 AM	
835 - 3rd Party Payment	Change Healthcare						-$2.50	11/21/2020	11/20/2020 12:00:00 AM	6345149
835 - 3rd Party Payment	Change Healthcare						$100.00	10/24/2020	10/23/2020 12:00:00 AM	6329325
Manual Claim	Change Healthcare						-$100.00	11/23/2020	9/25/2020 12:00:00 AM	
Manual Claim	Change Healthcare						$100.00	9/28/2020	9/25/2020 12:00:00 AM	
835 - 3rd Party Payment	Change Healthcare						-$100.00	9/26/2020	9/25/2020 12:00:00 AM	6308961
835 - 3rd Party Payment	OptumRx						$16.84	9/15/2020	9/14/2020 12:00:00 AM	121000242190429
B2A - Reversed Claim	OptumRx	610279	9999	UHEALTH	0	202283588422265999	-$116.84	9/4/2020	9/2/2020 1:35:49 PM	
835 - 3rd Party Payment	OptumRx						-$16.84	8/25/2020	8/24/2020 12:00:00 AM	121000242184470
B1P - Payable Claim	OptumRx	610279	9999	UHEALTH	0	202283588422265999	$116.84	8/17/2020	8/15/2020 11:58:17 AM	

12 Transaction(s)

Balance: $0.00

Pharmacy Name: WATERTOWN HOMETOWN PHARMACY

Rx #	Drug Name	Fill Date	Disc Code	Billed Qty	Billed Day Supply	Val Qty	Val Day Supply	Initial Over Payment	Paid Amount	Comments
705209	NOVOLOG FLEXPEN	02/27/2019	3J	15.000	30.00	0.000	0.00	$ 520.36	$ 520.36	
705209	NOVOLOG FLEXPEN	03/25/2019	3J	15.000	30.00	0.000	0.00	$ 520.36	$ 520.36	
719301	AZOPT	02/15/2019	1N	10.000	30.00	10.000	37.00	$ 0.00	$ 266.17	
720208	NOVOLOG FLEXPEN	02/22/2019	1N,4K	15.000	30.00	15.000	34.00	$ 0.00	$ 545.36	
720208	NOVOLOG FLEXPEN	07/02/2019	1N,4K	15.000	30.00	15.000	34.00	$ 0.00	$ 545.36	
720208	NOVOLOG FLEXPEN	08/06/2019	1N,4K	15.000	30.00	15.000	34.00	$ 0.00	$ 543.64	
720208	NOVOLOG FLEXPEN	09/25/2019	1N,4K	15.000	30.00	15.000	34.00	$ 0.00	$ 543.64	
729210	BASAGLAR KWIKPEN U-100	03/28/2019	1N	15.000	30.00	15.000	68.00	$ 0.00	$ 313.70	
729210	BASAGLAR KWIKPEN U-100	07/13/2019	1N	15.000	30.00	15.000	68.00	$ 0.00	$ 313.70	
729210	BASAGLAR KWIKPEN U-100	10/22/2019	1N	15.000	30.00	15.000	68.00	$ 0.00	$ 312.67	
730679	ADVAIR DISKUS	04/16/2019	1K	60.000	30.00	0.000	0.00	$ 304.62	$ 304.62	Final DAW pricing adjustments to be made by Medimpact
730679	ADVAIR DISKUS	08/21/2019	1K	60.000	30.00	0.000	0.00	$ 303.62	$ 303.62	Final DAW pricing adjustments to be made by Medimpact
730679	ADVAIR DISKUS	10/08/2019	1K	60.000	30.00	0.000	0.00	$ 298.62	$ 298.62	Final DAW pricing adjustments to be made by Medimpact
730679	ADVAIR DISKUS	02/13/2020	1K	60.000	30.00	0.000	0.00	$ 303.62	$ 303.62	Final DAW pricing adjustments to be made by Medimpact
730679	ADVAIR DISKUS	03/30/2020	1K	60.000	30.00	0.000	0.00	$ 303.62	$ 303.62	Final DAW pricing adjustments to be made by Medimpact
732815	NOVOLOG FLEXPEN	05/10/2019	3J	15.000	30.00	0.000	0.00	$ 520.36	$ 520.36	
732815	NOVOLOG FLEXPEN	06/21/2019	3J	15.000	30.00	0.000	0.00	$ 520.36	$ 520.36	
733082	JANUMET	05/14/2019	1X	60.000	30.00	0.000	0.00	$ 391.84	$ 391.84	
734704	BREO ELLIPTA	07/08/2019	4U	180.000	30.00	60.000	30.00	$ 681.97	$ 1022.95	
737188	XULANE	07/05/2019	1N	9.000	62.00	9.000	84.00	$ 0.00	$ 325.73	
748093	NOVOLOG FLEXPEN	11/15/2019	1N	15.000	30.00	15.000	34.00	$ 0.00	$ 543.64	
748093	NOVOLOG FLEXPEN	12/18/2019	1N	15.000	30.00	15.000	34.00	$ 0.00	$ 543.64	
748093	NOVOLOG FLEXPEN	02/12/2020	1N	15.000	30.00	15.000	34.00	$ 0.00	$ 543.64	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0 - No Product Selection Indicated
1 - Substitution Not Allowed by Prescriber
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3 - Substitution Allowed-Pharmacist Selected Product Dispe
4 - Substitution Allowed-Generic Drug Not in Stock
5 - Substitution Allowed-Brand Drug Dispensed
6 - Override
7 - Substitution Not Allowed-Brand Drug Mandated by Law
8 - Substitution Allowed-Generic Drug Not Available in Marke
9 - Substitution Allowed By Prescriber but Plan Requests Bra
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PCMA

February 10, 2021

The Honorable Patrick Testin
Chair, Senate Health Committee

The Honorable Joe Sanfelippo
Chair, Assembly Health Committee
Wisconsin State Capitol
2 East Main Street
Madison, Wisconsin

Senate Bill 3 / Assembly Bill 7 – Regarding Pharmacy Benefit Managers

Dear Chairman Testin, Chairman Sanfelippo, Members of the Senate Health Committee, and Members of the Assembly Health Committee:

I am writing on behalf of the Pharmaceutical Care Management Association ("PCMA"), which is the national association representing America's pharmacy benefit managers ("PBMs") who administer prescription drug benefits for over 270 million Americans. In Wisconsin, PCMA members include CVS Health, Cigna, and OptumRx. Our members manage prescription drug benefits on behalf of health plans, large and small employers, labor unions and government programs. I remain grateful for the opportunity to work with members of the legislature to address the rising cost of prescription drugs, and provide information on how PBMs provide high quality, cost effective prescription drug management programs.

PCMA has worked on the legislative proposals referenced above for more than a year. We have met on multiple occasions with interested parties, crafted compromise language, and negotiated in good faith toward the goal of enacting comprehensive legislation that will support the state's goal of lowering prescription drug costs for Wisconsin patients. To that end, we had agreed to the compromises set forth in last year's draft of this legislation and will continue to do so provided no further substantive changes are made. That said, it is our that hope that an agreement can be reached regarding the effective date of the bill – one that both satisfies the need to enact important provisions in a timely manner, and allows fair time for these reforms to be made operationally feasible for our members.

I appreciate the opportunity to weigh in and am happy to answer any questions you may have.

Sincerely,

Heather R. Cascone

Heather Cascone
Assistant Vice President, State Affairs
202-744-8416 / hcascone@pcmanet.org

February 10, 2021

The Honorable Patrick Testin, Chair
Senate Committee on Health
Wisconsin State Legislature
Room 8 South
State Capitol
PO Box 7882
Madison, WI 53707

The Honorable Dale Kooyenga, Vice Chair
Senate Committee on Health
Wisconsin State Legislature
Room 310 South
State Capitol
PO Box 7882
Madison, WI 53707

RE: Testimony re SB 3 (LRB-1116/1) - "Relating to: Pharmacy Benefit Managers, Prescription Drug Benefits, and Granting Rule-Making Authority"

Dear Chairman Testin, Vice Chairman Kooyenga, and Distinguished Members of the Committee:

Navitus Health Solutions, LLC ("Navitus") is providing these comments regarding Senate Bill 3 (SB 3) (LRB-1116/1) - "Relating to: Pharmacy Benefit Managers, Prescription Drug Benefits, and Granting Rule-Making Authority" which would increase the regulation of operations of pharmacy benefit managers or "PBMs" and promote transparency in PBMs.

As background, Navitus is a 100% pass-through, fully transparent, pharmacy benefit manager (PBM). Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Across the country, Navitus administers pharmacy benefits for over six million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business. In addition, we serve over 80 clients with approximately 790,000 member lives in Wisconsin. Finally, Navitus' corporate headquarters is in Madison, we have a large operations center in Appleton, and our specialty pharmacy, Lumicera Health Services, has a location in Madison between which we employ hundreds of Wisconsinites.

At Navitus, we appreciate the Legislature's goal of lowering prescription drug costs for Wisconsin consumers who desperately need medications and increasing transparency in drug pricing, as these goals have been part of our corporate mission from the start of our company. We support the goal of consumers paying less for their prescription drugs, and we applaud several substantive changes that have been made to the bill since previous versions last session as well as are appreciate of the Legislature's ongoing discussions with stakeholders across the supply chain to develop a fair, compromise bill.

We are appreciative that the bill removed provisions that would have regulated private contracts between PBMs and pharmacies, which would have harmed market competition. The bill has reduced the increased expansion of government overreach into the PBM industry, which would have allowed the Legislature to redefine marketplace contracts and their financial terms through regulations, which threatens the principles of a free market economy. We caution the State's intervention between the negotiations of private parties and we oppose any effort to do so.

We continue to have a few reservations, however, regarding portions of the proposed bill that we believe have the likelihood of increasing drug prices while benefiting pharmacies at the expense of patients and their benefit plans. Additionally, if enacted, the proposed bill will still result in increased administrative and operational costs for PBMs, which will ultimately be passed on to benefit plan sponsors and their members, the individuals the proposed bill is intended to protect.

While we believe the bill represents marked improvements in many areas, Navitus has some remaining concerns with SB 3 and is providing testimony on the following topics:

- **Pharmacy Disclosures to Consumers**
- **Retroactive Claim Reduction Limits Encourages Errors and Prevents Them from Being Corrected**
- **Audit Procedure Requirements Will Decrease the Quality of Care and Increase Costs**
- **Reporting Requirements Would Increase Costs Without Providing Actionable Information**
- **Requiring Advanced Written Notice of Formulary Changes**
- **Limitations on Mid-Year Formulary Changes Reduces Consideration of Costs Versus Benefits**
- **Cost Sharing Limitation Language Changes**
- **Other Comments**

Pharmacy Disclosures to Consumers. We greatly support the inclusion of Section 7 of the bill, which adds §450.13(5m) to the statutes to require pharmacies to publicize their "usual and customary" (U&C) price for commonly prescribed medications.[1] We do, however, request that the bill be clarified as to how these disclosures to consumers will be verified. The same comment applies to §450.135(8m) and §450.135(9).

Retroactive Claim Reduction Limits Encourages Errors and Prevents Them from Being Corrected (and increases costs). Significant improvements have been made to this section from earlier drafts of the bill; however, Navitus has a few remaining concerns regarding the proposed addition of §632.865(5) entitled "Retroactive Claim Reduction."[2] This section prohibits PBMs from retroactively denying or reducing a claim unless the claim was fraudulent, the payment for the original claim was incorrect, the services were not rendered, the pharmacy or pharmacist violated state or federal law, or the reduction is permitted in a contract pursuant to a quality program.

Although this section provides for increased exceptions in certain situations, including a pharmacist violating state or federal law, it still does not hold pharmacies fully responsible for their own errors. This provision does not allow for recoveries for clearly inaccurate claims submitted by a pharmacy, unless the PBM can prove fraud was committed, the payment for the original claim was incorrect, the pharmacy did not provide the services claimed, the pharmacist or pharmacy violated state or federal law, or the reduction was permitted pursuant to a quality program in a contract. That standard creates too high a barrier to ensuring proper care is taken. It does not take into account the clerical and record keeping errors that are commonly discovered during an audit. Such errors should be subject to recoupment, even if it is not considered fraudulent.

Most of the issues that pharmacies have with auditing are due to inattention to the applicable rules rather than fraud. This should be expanded to reflect fraud, waste, or abuse—not just fraud. If waste or abuse is systemic, this is a widely recognized reason for recovery by payers including Medicare and Medicaid and

[1] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 6, Lines 10-24.
[2] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 13, Lines 1-12.

we do not believe it is Wisconsin's intent to give a pass to abuse and waste at the expense of the insurance sponsor. While an issue may not necessarily be fraud, it may be a situation where a pharmacy participates in waste or abuse. Additionally, the provision states that monies cannot be recovered after the pharmacy has been paid, with specific exceptions. By definition, audits are performed retroactively; often many weeks or months after the fact. This prohibition on retroactive recoveries essentially means that pharmacies would only sometimes be liable for their mistakes that are caught by audits. If the intent behind adding "the payment for the original claim was incorrect" encompasses these concerns to cover issues that are not also considered fraudulent—meaning the payment for the original claim was incorrect for any number of reasons—we ask that that be clarified.

Pharmacies and PBMs regularly agree to contract terms requiring the pharmacy to comply with provisions required to be met for payment to be made, including requirements that the pharmacy submit the correct drug information, the correct amount dispensed, the correct patient information, etc. Most audit recoveries are due to a pharmacy not complying with state or federal law, or with a plan's benefit coverage, and this provision would effectively remove the requirement that a pharmacy must follow applicable law. In addition, there are many programs and insurance regulations and requirements that may cause a claim to be retroactively denied beyond fraud. The changes to this provision represent improvements, but we still have concerns as it continues to infringe upon contractual agreements between two private parties. Pharmacies and PBMs should have the freedom to agree on what types of circumstances would be permissible in allowing retroactive payment denials or reductions.

Audit Procedure Requirements Will Decrease the Quality of Care and Increase Costs. Navitus recognizes the Legislature's desire to protect the rights of pharmacies in our local communities related to pharmacy audits and potentially abusing practices. Navitus approaches pharmacy claim auditing as working in partnership with the pharmacies, but needs to have reasonable latitude to protect its clients from pharmacies that engage in practices that cause fraud, waste, or abuse, as well as correcting errors that are made in claims for reimbursement from pharmacies. Navitus believes that the following provisions may actually increase costs and decrease the quality of care provided by pharmacies, because PBMs and plans will have fewer ways to ensure pharmacies are providing quality care.

When audit procedures are conducted appropriately and fairly, they improve quality and reduce cost rather than the opposite. We realize that PBMs employ a variety of audit practices and philosophies, up to and including the heavy- handed approach of reversing and recouping the entire cost of a claim regardless of the errors found. We believe this legislation is designed to protect pharmacies from those practices. As stated before, Navitus approaches pharmacy auditing as a partnership opportunity to improve quality and accuracy of pharmacy billing practices. To that end, Navitus will only correct and collect the difference rather than reversing the entire claim wherever possible. Navitus must retain the ability to ensure that the client's pharmacy benefit dollars are being used appropriately and accurately, and audit functions are integral to that.

Audits Within the First Five Days of the Month - With regard to §632.865(6)(b)(2), it states that audits should not be conducted within the first 5 days of a month unless agreed upon by the pharmacy.[3] There is no reason to exempt a pharmacy from being audited during the first 5 days of a month. This appears to be unnecessary rulemaking by the Legislature and places additional restrictions on PBMs with no basis. The

[3] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 14, Lines 4-6.

addition of this provision is unnecessary at it is likely in response to an anachronistic process that led to increased prescription volume the first week of the month and which is no longer common practice.

Clinical/Professional Judgment - Under the proposed bill, §632.865(6)(b)(3) states that when the audit involves clinical or professional judgement, the audit must be conducted by or in consultation with a pharmacist licensed in any state.[4] Navitus requests that this language be clarified. Navitus utilizes certified pharmacy technicians to perform our audits, under the supervision and oversight of a licensed pharmacist, and believes that this methodology is reasonable and effective and that it meets or exceeds the intent of this proposal.

Limitation of Two Years on Audit Lookback - The proposed bill states under §632.865(6)(b)(5) that an audit must be limited to claims submitted no more than two years before the audit, unless otherwise required by state or federal law.[5] Navitus generally limits its audits to two years; however, federal and state government programs can often go back ten years or more under applicable auditing requirements and thus we need the ability to lookback beyond two years. This language limiting the lookback period to two years is improved but remains too restrictive. Although language has been added to allow for an exception where state or federal law requires audits to go back more than two years, CMS requirements allow audits to go back ten years but do not require them.

Pharmacist Record Retention - Another concern is §632.865(6)(b)(6), which states that a pharmacist or pharmacy is allowed to use the records of a health care provider to validate the pharmacist's records and use any prescription that complies with the requirements of the pharmacy board to validate claims in connection with a prescription, refill, or change in prescription.[6] Pharmacists have a responsibility to maintain their own records, and prescriptions must be maintained at the pharmacy premises, not in the offices of another profession's office. The records of a health care provider may be used by the pharmacist in addition to the legal prescription in the case of the dispensing pharmacist having concerns about the potential validity of the prescription, but health care records are not a substitute for the actual prescription.

Calculation of Actual Amounts for Overpayments and Underpayments and Extrapolation - Navitus generally does not employ extrapolation with regard to audits, but there may be cases where the costs of auditing each claim would be significantly higher than extrapolating based on information provided by a pharmacy with regard to its own patterns of practice, and, in such case, extrapolation may be the most reasonable resolution. Additionally, extrapolation for overpayment is also industry standard for Medicare, Medicaid, and Tricare. We appreciate that this provision from earlier versions of the bill has been removed.

Restrictions on Implementing Audit Penalties - Navitus does not agree with the restriction on implementing penalties for an audit at §632.865(6)(c)(4).[7] This raises the question as to whether a payer can compel compliance to process if there is not a mechanism to employ fees to the pharmacy if they are not cooperating with the payer or PBM and following the rules. Under this provision, a pharmacy would have every incentive to keep inaccurate records that constantly result in overpayments, and the PBM would be unable to recover the costs incurred by auditing to correct the pharmacies errors when the pharmacy was not complying with the requirements to which it agreed. It is important that pharmacies are not unreasonably protected against the consequences of non-cooperation or noncompliance.

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[4] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 14, Lines 7-8.
[5] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 14, Lines 11-12.
[6] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 14, Lines 13-18.
[7] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 15, Line 20-22.

Exclusion of Dispensing Fees from Overpayments - §632.865(6)(c)(6) of the proposed bill states that dispensing fees may not be excluded from calculations of overpayments.[8] Navitus does not agree with this provision. Dispensing fees are an integral component of the overall cost and reimbursement for a prescription and the pharmacy should only receive it if the claim is dispensed correctly and appropriately. If the claim is wrong, the reimbursement must be recalculated in a way that includes all components of the claim. For example, suppose that a finding found that the pharmacy dispensed the wrong drug or strength and it could not be used. The full cost of the claim should be allowed to be recovered.

Recoupment of Funds and Clerical/Record-Keeping Errors - In §632.865(6)(c)(8) of the proposed bill, funds may not be recouped based on a clerical or record-keeping error (including a typographical or computer error), unless the error resulted in an overpayment to the pharmacy or pharmacist.[9] Navitus does not agree with this provision. The term is frequently and inappropriately used by dispensing pharmacists to dispute audit findings. Most audit recoveries are due to a pharmacy not complying with state or federal law, or with a plans' benefit coverage. The current hurdle remains too high. Most of the issues that a pharmacy has with auditing are due to reckless inattention to the rules to which a pharmacy has agreed to comply. Not every such error may be fraud, but could be considered waste or abuse. A pharmacy must take responsibility for errors, even if it is a clerical or record-keeping error and retains responsibility to process the claim correctly. This goes back to the issue of accreditation. A pharmacy can be licensed by a state, but a good quality pharmacy is accredited with effective policies and procedures. Payers must expect and demand good quality providers in its networks. Use of recoveries is a reasonable method to compel or maintain quality.

Payment of Auditors - With regard to §632.865(6)(f), an auditor may not be paid based on a percentage of the amount recovered in an audit.[10] Navitus does not use this method of paying auditors but does not believe the amounts paid to the auditors should affect the validity of the audit.

Applicability – For the same reasons discussed in our response to §632.865(5), we believe that waste and abuse should be added to fraud under §632.865(6)(g) to ensure a comprehensive scope.[11]

Reporting Requirements Would Increase Costs Without Providing Actionable Information. Under §632.865(7) of the proposed bill, PBMs would need to provide an annual report to the commissioner that provides the aggregate rebate amount received from all drug manufacturers but retained and not passed through to health benefit plan sponsors and the percentage of aggregate rebate amount that is retained rebates. The Commissioner of Insurance would then consider this information as a trade secret.

As previously stated, Navitus is a 100% pass-through, fully transparent PBM. All negotiated rebates are passed through to the plan sponsor. As such, there would be nothing for us to report on the retained rebates report even though we would still be required to submit the report. While Navitus supports additional transparency in principle, these additional reporting requirements would only impose additional costs incurred without a plan for utilizing the information to effect public policy or helping benefit plans make better decisions. Much of the information requested above would also be too old to take action on given time required to create annual reports. Additionally, with the pending changes in the safe harbor related to rebates for Medicare Part D proposed by HHS, we anticipate that the pharmaceutical industry

[8] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 15, Line 25.
[9] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 16, Lines 5-8.
[10] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 16, Line 19-21.
[11] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 16, Line 22 to Page 17, Line 3.

may restructure rebates in a way that makes these reporting requirements ineffective, although the status of that regulation is currently in limbo.[12]

We believe that a better alternative would be to require PBMs to provide that information to their benefit plan clients on a quarterly basis with claim-level detail for rebates that PBM had received from manufacturers along with the percentage of the rebates that the PBM retained. Navitus passes all of the rebates it receives on to its clients, but other PBMs may reach agreements with clients about retaining rebates to pay for the PBM's services.

Besides the additional administrative costs that would be incurred as a result of the reporting requirements, Navitus is also concerned that reporting of certain information could compromise law enforcement or agency investigations related to fraud, waste, or abuse. Oftentimes, law enforcement and agency investigations are related to recoveries, recoupments, pharmacy network participation, and other activities tied to fraud, waste, and abuse. Such information should be excluded from any reporting requirements as an exception until after the law enforcement investigation is completed.

Requiring Advanced Written Notice of Formulary Changes. The proposed bill at §632.861(4) requires a health plan or PBM to provide at least 30 days advanced written notice of an upcoming formulary change that removes a prescription drug from the formulary or that change's a drug's tier to one that has a higher deductible, copayment, or coinsurance and must provide information on how to request an exception from the formulary change.[13] Advanced notice is not required when the drug is no longer approved by the FDA, no longer subject to an FDA safety notice or other announcement, or has been approved by the FDA for use without a prescription. Advanced written notice is also not required when the plan or PBM also adds an FDA-approved generic to the formulary that is approved for use as an alternative or is in the same pharmacologic class. We support the current version as written.

Cost Sharing Limitation Language Changes. Section 632.861(3) of SB 3 would prohibit a health plan or PBM from requiring an individual to pay at the point of sale any more than the lowest of the following: 1) the applicable copay for the drug or 2) the amount the person would pay for the drug if the person purchased the drug without insurance or any other source of drug benefits or discounts.[14]

We are thankful that §632.861(3)(b) and (d) were removed as they would have conflicted with Navitus' "lower of logic" methodology for determining the amount of patient cost sharing. For example, on a $4.00 generic drug, the patient might pay the full $4.00 amount, depending on the deductible and co-pay required under a plan, and this amount should not be reduced if the PBM or health plan is not reimbursing the pharmacy but is still processing the claim in accordance with the cost sharing required under the applicable plan. Similarly, on benefit plans with a deductible, the patient would pay the full amount of the claim for drugs until they reached the value of the deductible, and the pharmacy or pharmacist would not be reimbursed by the PBM or health plan at all.

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[12] Final Rule re "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees," (HHS 2020), 85 Fed. Reg. 76666 et seq. (Nov. 30, 2020).

[13] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 9, Line 17 to Page 11, Line 2.

[14] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 9, Lines 7-16.

Additionally, under §632.861(3)(2), it states that the allowable cost to consumer can mean "The amount a person would pay for the prescription drug if the enrollee purchased the prescription drug at the dispensing pharmacy without using any health plan or health insurance coverage." This language needs to be clarified. It is unclear whether this is intended to mean only a cash-paying customer or if it would include other situations, such as discount cards and coupons that a health benefit plan would not necessarily have information about or an ability to negotiate with the pharmacies.

Other Comments.

The Proposed Bill Has Uncertain Social and Financial Impacts - There is no guarantee that adoption of the proposed bill will decrease the cost of prescription drugs for Wisconsin consumers. In OCI's Social and Financial Impact Report letter dated January 28, 2021, addressed to Senate Chief Clerk, Mr. Michael J. Queensland, and Assembly Chief Clerk, Ms. Julie Martyn, OCI acknowledges that it "is unable to determine to what extent, if any, the proposals could decrease the cost of prescription pharmaceuticals and devices to consumers if, at the point of sale, consumers are provided the proposed out-of-pocket cost comparison information. OCI is unable to determine if these proposals could increase access and affordability through the additional requirements including notice of formulary changes, formulary substitutions, and licensure of pharmacy benefit managers."[15] In addition, the letters state that it is unclear the number of people who would be affected by the proposed bill.[16]

In addition to the uncertain social impact, OCI also acknowledges that the financial impact of the proposed bills cannot be determined. According to the OCI's social and financial impact report letters, although the legislation is intended to "increase consumer access to and affordability of prescription drugs and devices through a series of requirements and restrictions," there likely will be increased administrative costs as a result of the numerous requirements and restrictions."[17] As addressed in these comments, the proposed rules require PBMs to follow certain requirements related to audits, reporting, licensure of PBMs, and limitation on cost-sharing, which will increase administrative costs for PBMs. These administrative costs will eventually become the financial burden of consumers. Furthermore, the OCI letter states that the bill "may limit insurers from utilizing certain methods currently employed to reduce pharmaceutical costs, which may result in additional prescription costs for insurers" and thus they are unable to determine the total impact on administrative and claims costs.[18] OCI also acknowledges that it is uncertain as to the proposed bills' impact on premiums costs to consumers and employers.[19]

PBMs Are Already Regulated in Wisconsin - PBMs are already regulated in Wisconsin as employee benefit plan administrators (EBPA) or third party administrators (TPAs). In order to do business in Wisconsin, PBMs must be licensed in Wisconsin through the OCI and must comply with statutory requirements to remain in good standing. It is unnecessary to adopt this bill since OCI already requires PBMs to be licensed as an EBPA or TPA through the OCI. The addition of this language creates unclear intent and is likely to create confusion for PBMs as to whether the PBM licensure has different requirements than the administrator license. Similar to what is already provided for in the bill, the EBPA license requires a licensing fee and penalties or revocation for failure to comply with statutory requirement. The additional regulatory burden provided for under the proposed bill will only increase costs for Wisconsin businesses and consumers.

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[15] https://docs.legis.wisconsin.gov/2021/related/fe/sb3/sb3_inins.pdf at 1.
[16] *Id.*
[17] *Id.* at 2.
[18] *Id.*
[19] *Id.*

"Gag Clauses" Are Already Federally Regulated – Navitus does not and has not used gag clauses. §632.861(2)(a)-(b) prevents plans and PBMs from restricting pharmacies from informing enrollees about differentials in out-of-pocket costs under the plan versus the cost without using health coverage.[20] We do not, however, believe additional legislation is needed in this area given recent federal action under Division BB, Title II, Section 201 of the Consolidated Appropriations Act of 2021.[21]

Accreditation for Network Participation – Pursuant to §632.865(4), within 30 days of receiving a written request from a pharmacy, PBMs must supply a written notice of certification and accreditation requirements used by the PBM to determine network participation.[22] This is a reasonable and attainable standard that does not preclude PBMs requiring accreditation and other credential tools nor prevent us from requiring multiple accreditations or accreditations beyond state pharmacy licensure where appropriate.

In addition, however, the section states PBMs may not change accreditation requirements more frequently than once every 12 months. We have concerns about this provision because there are instances in which accreditation requirements may need to be changed more frequently than every 12 months. If Medicare or Medicaid develop new program requirements for pharmacies, Navitus would be required to incorporate those into the credentialing process regardless of the 12-month limit. As a result, this provision should have a caveat "unless required by state or federal law."

Thank you for the opportunity to provide feedback on SB 3 and for considering my requests on behalf of Navitus. If we can provide any additional information, please let us know. Please also let us know if you would like to meet with us at our facilities in Madison or Appleton.

Sincerely,

Brent J. Eberle, RPh
Senior Vice President & Chief Pharmacy Officer

CC: Members, Wisconsin Senate Committee on Health

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[20] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 8, Line 15 to Page 9, Line 6.
[21] H.R. 133, 116th Congress, 2nd Sess. (U.S. 2020) (Enrolled Bill), Pages 1709-1713.
[22] S.B. 3, 105th Leg., Reg. Sess. (Wis. 2021), Page 12, Lines 17-23.