Estrada, Michele (DIFS)

From: Miguel Rodriguez <mrodriguez@aprx.org>
Sent: Friday, June 9, 2023 10:09 AM
To: Estrada, Michele (DIFS)
Cc: Michael Wright; Ryan Burtka
Subject: Comments of American Pharmacies to Proposed Administrative Rules for Pharmacy Benefit Manager Licensure and Regulation Act Rule Set 2023-10 IF
Attachments: Comments of American Pharmacies to Rule Set 2023-10 IF 6.9.2023.pdf

Dear Ms. Estrada,

Attached please find the comments of American Pharmacies to the Proposed Administrative Rules for Pharmacy Benefit Manager Licensure and Regulation Act (Rule Set 2023-10 IF)

Please let me know if you have any questions.

Thank you,
Miguel

Miguel S. Rodriguez
General Counsel
American Pharmacies

802 N. Carancahua, Suite 540, Corpus Christi, Texas 78401
(361) 887-6100

June 9, 2023

Via Electronic Mail (EstradaM1@michigan.gov)
Michele Estrada
Department of Insurance and Financial Services
Office of Research, Rules, and Appeals
P.O. Box 30220
Lansing, MI 48909-7720

Re: Comments of American Pharmacies to Proposed Administrative Rules for Pharmacy Benefit Manager Licensure and Regulation Act
Rule Set 2023-10 IF

Dear Ms. Estrada,

American Pharmacies appreciates the opportunity to present these comments in response to the Department of Insurance and Financial Services' (DIFS) request for comments on the administrative rules for the Pharmacy Benefit Manager Licensure and Regulation Act. American Pharmacies is a member-owned cooperative. Our members are hundreds of independent pharmacy owners located across more than 35 states, including Michigan. Our mission is to protect, defend and enhance the business of independent pharmacy so that our members can better serve their patients.

American Pharmacies was a strong supporter of the Pharmacy Benefit Manager Licensure and Regulation Act (the "Act") and our members are looking forward to the full implementation of the Act in 2024. The U.S. Supreme Court's decision in *Rutledge v. PCMA*, 141 S.Ct. 474 (2020) greatly expanded the authority of states to enforce state pharmacy benefit manager (PBM) laws like the Act when PBMs are administering claims of ERISA plans. Following *Rutledge*, courts across the country have consistently upheld the power of states to enforce state PBM laws over PBMs administering claims for ERISA plans and Medicare Part D plans. *See, e.g., PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021) (holding certain challenged provisions of North Dakota PBM reform law were not preempted by ERISA or Medicare Part D); *PCMA v. Mulready*, 598 F.Supp.3d 1200 (W.D. Okla. 2022) (holding certain challenged provisions of Oklahoma PBM reform law were not preempted by ERISA or Medicare Part D).

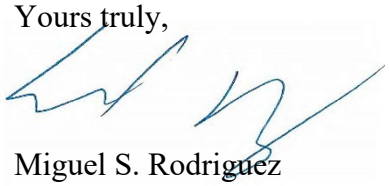
American Pharmacies thanks DIFS for the proposed rules which are an important step towards fully implementing the Act and which will rein in many abusive PBM practices while increasing the accessibility of Michigan patients to pharmacy services throughout the state. We and our members stand ready to work with DIFS to ensure that the Act's provisions are closely adhered to by PBMs in Michigan.

We believe that the proposed rules are clearly stated and well supported in the Act. Therefore, we are confining our comment to one suggested point of clarification to be included in the proposed rules or in subsequent rulemaking.

Section 11(4) of the Act permits the Director to refuse to issue a license to a PBM that has had a PBM "certificate of authority or license denied or revoked for cause in another state." Further, Section 11(5)(e)-(f) of the Act permits the Director to deny, suspend, or revoke the license of a PBM if the Director finds that either "any individual responsible for the conduct of affairs of the [PBM] has been convicted of, or has entered a plea of guilty or nolo contendere to, a felony without regard to whether adjudication was withheld" or that "the [PBM's] license has been suspended or revoked in another state." Since both of these provisions govern the granting or maintenance of a license, we suggest that a new subrule (c)(iv) be added to Rule 500.33 to require a PBM to disclose whether these matters have occurred so that the Director is informed and remains apprised of any such occurrences.

American Pharmacies appreciates this opportunity to provide input to DIFS on its proposed rules. If I can be of any assistance, please do not hesitate to contact me.

Yours truly,



Miguel S. Rodriguez
General Counsel, American Pharmacies

Estrada, Michele (DIFS)

From: Peter Fjelstad <pfjelstad@pcmanet.org>
Sent: Wednesday, May 31, 2023 5:54 PM
To: Estrada, Michele (DIFS)
Cc: Sean Stephenson; Peter Fjelstad
Subject: PCMA Comments on R 500.31 – R 500.39 Pharmacy Benefit Manager Licensure and Regulation Act
Attachments: MI DIFS Licensing 5.31.23 (final).pdf

Dear Ms. Estrada:

On behalf of the Pharmaceutical Care Management Association (PCMA), please see the attached comments regarding R 500.31 – R 500.39 Pharmacy Benefit Manager Licensure and Regulation Act, as proposed by the Michigan Department of Insurance and Financial Services (DIFS).

We appreciate the opportunity to comment on this proposed rule. And we respectfully request that our attached comments be included as part of the record for the DIFS hearing currently scheduled for June 9, 2023.

If you have any questions, please do not hesitate to contact either myself or my colleague Sean Stephenson, CCed on this email.

Sincerely,

Peter Fjelstad
Directory of State Regulatory & Legal Affairs, PCMA

Peter Fjelstad | PCMA | *Director, State Regulatory and Legal Affairs* **|** 202-756-5749
325 7th Street NW, 9th Floor, Washington, DC 20004
pfjelstad@pcmanet.org

May 31, 2023

Michele Estrada
Department of Insurance and Financial Services, Office of Research, Rules and Appeals
P.O. Box 30220
Lansing, MI 48909-7720
Email: EstradaM1@michigan.gov

SENT VIA EMAIL

Re: PCMA Comments on R 500.31 – R 500.39 Pharmacy Benefit Manager Licensure and Regulation Act

Dear Ms. Estrada:

The Pharmaceutical Care Management Association ("PCMA") appreciates the opportunity to comment on the proposed rules ("Proposed Rule") published by Michigan's Department of Insurance and Financial Institutions ("DIFS") on March 14, 2023., This Proposed Rule creates a new regulatory framework regarding the licensure of pharmacy benefit managers ("PBMs") as a result of 2022 Public Act 11 (the "Pharmacy Benefit Manager Licensure and Regulation Act").

PCMA is the national trade association representing PBMs. PCMA's member companies administer drug benefits for more than 275 million Americans, including most West Virginias, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

Below are PCMA's comments, concerns, and recommendations regarding specific provisions in the Proposed Rule.

R 500.31 (1)(b) Definitions

> **As Drafted:** "Client" means any health plan or carrier for which the pharmacy benefit manager contracts with a pharmacy or pharmacy services administration organization to provide pharmacy health services to covered individuals.
>
> **Proposed Suggested Change:**
> ~~Client" means any health plan or carrier for which the pharmacy benefit manager contracts with a pharmacy or pharmacy services administration organization to provide pharmacy health services to covered individuals~~. Delete the entire provision as this is unsupported by the law.

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

R 500.33 (2)(b) Application contents and fee; supplemental documents

As Drafted: A document providing the names, addresses, dates of birth, social security numbers, official positions, and professional qualifications of each individual who owns, legally or beneficially, 10% or more of the equity in the entity that is applying for a license.

Proposed Suggested Change: A document providing the names, addresses, dates of birth, social security numbers, official positions, and professional qualifications of each ~~individual~~ officer and director who own, legally or beneficially, 10% or more of the equity in the entity that is applying for a license.

R 500.33 (2)(c)(i) Application contents and fee; supplemental documents

As Drafted: A list of every client on whose behalf the applicant intends to contract to provide pharmacy health services to residents of this state.

Proposed Suggested Change #1: Delete the provision because it is too burdensome for PBMs to list all businesses that it "intends to contract" with.

Proposed Suggested Change #2: At the time of application, a list of health plans or carriers that a PBM contracts with to provide pharmacy health services to individuals covered by the health plan or carrier.

R 500.33 (2)(c)(ii) Application contents and fee; supplemental documents.

As Drafted: (ii) A list of the staff who shall participate in the applicant's operations in this state. The list must clearly indicate the job functions of each staff member identified.

Proposed Suggested Change:. ~~(ii) A list of the staff who shall participate in the applicant's operations in this state. The list must clearly indicate the job functions of each staff member identified.~~ Delete the entire provision as it is too broad and would be difficult for a company to quantify.

R 500.33 (2)(c)(iii) Application contents and fee; supplemental documents

As Drafted: A statement indicating all jurisdictions where the applicant has an application pending or has been registered, licensed, or otherwise certified to transact business as a pharmacy benefit manager.

Proposed Suggested Change: A statement indicating all jurisdictions where the applicant ~~has an application pending or~~ has been registered, licensed, or otherwise certified to transact business as a pharmacy benefit manager.

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325 7th Street, NW, 9th Floor
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www.pcmanet.org

R 500.35(1) Suspension, revocation, and restriction of licensure; fines

As Drafted: The director may suspend the license of a pharmacy benefit manager as provided in sections 11(5) and (6) of the act, MCL 550.821. A pharmacy benefit manager whose license is suspended shall not operate within this state as a pharmacy benefit manager during the suspension.

Suggested Changes: Delete the entire provision. If a PBM stops operating in the state, then enrollees will not have access to the pharmacy benefits – creating serious patient safety issues. An order to revoke a license should not take effect immediately.

PCMA appreciates the opportunity to comment on the Proposed Rule. We look forward to a continued dialogue with DIFS regarding both the Proposed Rule and additional issues as they arise. Please feel free to contact either myself or my colleague Sean Stephenson, Director of State Affairs (sstephenson@pcmanet.org or 240-909-1544) with any questions or for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Director, State Regulatory & Legal Affairs

CC: Sean Stephenson
Director, State Affairs

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

Estrada, Michele (DIFS)

From: Jill McCormack <JMcCormack@NACDS.org>
Sent: Thursday, June 8, 2023 5:37 PM
To: Estrada, Michele (DIFS)
Subject: NACDS Comments on PBM Licensure and Regulation Act
Attachments: MI PBM Licensure Rulemaking Comment Letter06-2023.pdf

Dear Ms. Estrada:

Thank you for the opportunity to comment on these important proposed rules. Please see our letter attached.

Thank you,
Jill

Jill McCormack | Regional Director, State Government Affairs
National Association of Chain Drug Stores
2296 Forest Hills Drive
Harrisburg, PA 17112
717.592.8977 (cell)

JMcCormack@nacds.org | http://www.nacds.org

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 9, 2023

Michele Estrada
Department of Insurance and Financial Services
Office of Research, Rules, and Appeals
P.O. Box 30220, Lansing, MI 48909-7720

RE: R 500.31 – 500.39 Pharmacy Benefit Manager Licensure and Regulation Act

Dear Ms. Estrada:

On behalf of our member pharmacies operating in Michigan, the National Association of Chain Drug Stores (NACDS) is pleased to submit this letter in support of the Department of Insurance and Financial Services' (DIFS) proposed rule regarding pharmacy benefit manager (PBM) licensure and regulation. We urge the Department to bring to bear its full enforcement authority to ensure that PBMs operating in the state do not bypass laws meant to support pharmacies as they fulfill their duty to deliver reliable services to the patients who trust them.

NACDS supported the Michigan Legislature's efforts in 2022 to pass comprehensive legislation that would provide relief to the state's pharmacies and patients from the unfair and abusive tactics commonly employed by PBMs. The proposed rules would add another layer of protection by giving the Department enforcement authority to uncover and penalize PBM misconduct, including revoking the ability of PBMs to operate in the state if they do not comply.

Another crucial piece in enforcement is the ability for DIFS to uncover wrongful conduct based on complaints filed by patients and pharmacies. A public complaint process will help provide DIFS with a line of sight into PBM tactics prohibited by the Act that directly affect patients and pharmacies at the store level. Therefore, NACDS asks that the Department develop a simple and reliable filing process for complaints.

Additionally, NACDS wishes to affirm its understanding that the state has the authority to establish statutory minimum and other standards for PBMs that serve state-regulated health plans. And to a limited extent, states may also regulate PBMs that serve self-insured Employee Retirement Income Security Act of 1974 (ERISA)-regulated group health plans. Under *PCMA v. Rutledge*, the U.S. Supreme Court determined that state regulations that do not directly affect "central matters of plan administration or interfere with nationally uniform plan administration" are not preempted by ERISA. Accordingly, we encourage the state to ensure the application of the protections of the law to self-insured plans, in the same way, it would for other plans, to the extent the law does not directly impact plan administration.

NACDS thanks DIFS for the opportunity to comment on this proposed rule and applauds the Department for taking this key step in the process to ensure PBM accountability and transparency. For questions or further discussion, please contact Jill McCormack, Director of State Government Affairs, at JMcCormack@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer

Estrada, Michele (DIFS)

From: Anne Cassity <anne.cassity@ncpa.org>
Sent: Tuesday, May 2, 2023 4:58 PM
To: Estrada, Michele (DIFS)
Subject: NCPA Comments on Rules Implementing Act No. 11, Public Acts of 2022 (H.B. 4348)
Attachments: Final_NCPA comments on rules implementing Act No 11, Public Acts 2022_HB 4348.pdf

Dear Ms. Estrada,

On behalf of the National Community Pharmacists Association (NCPA), I am submitting comments on rules implementing Act. No. 11, Public Acts of 2022, which encourages the Department to fully implement House Bill 4348.

NCPA represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the United States, including 801 independent community pharmacies in Michigan. These Michigan-based pharmacies employ more than 9,800 residents and filled nearly 51 million prescriptions in 2021 alone.

Thank you for your attention and consideration.

Anne Cassity
SVP, Government Affairs
National Community Pharmacists Association
100 Daingerfield Road
Alexandria, Virginia 22314-2888
703.838.2682 direct
703.282.9906 mobile
Anne.Cassity@ncpa.org

VIA ELECTRONIC MAIL

May 2, 2023

Michele Estrada
Michigan Department of Insurance and Financial Services
Office of Research, Rules, and Appeals
530 West Allegan Street, 7th Floor
Lansing, MI 48933
EstradaM1@michigan.gov

Re: **Comments on Rules Implementing Act No. 11, Public Acts of 2022 (H.B. 4348)**

Dear Ms. Estrada:

As you know, on February 23, 2022, Governor Gretchen Whitmer signed House Bill 4348 into law. Now known as Public Act 11 of the Public Acts of 2022, the law regulates the anticompetitive practices of pharmacy benefit managers or PBMs.

House Bill 4348 was a crowning achievement for Governor Whitmer, whose Prescription Drug Task Force had recommended its enactment into law. As she noted upon signing the legislation, "For too long, unlicensed pharmacy benefit managers have been able to engage in practices that drive up costs for Michiganders whose lives and health depend on critical prescription drugs like insulin." It is therefore no wonder House Bill 4348 achieved final passage in the House 101 to 4 and in the Senate 30 to 9.

In light of the legislation's overwhelming bipartisan support, we were a bit surprised—and frankly disappointed—to see that your Department has failed to propose regulations needed to fully implement the legislation. House Bill 4348 includes comprehensive provisions designed to regulate the anti-competitive business practices of PBMs. But rather than address this conduct, your Department has proposed only to clarify the rules around the process for applying for, renewing, and suspending a PBM's license. *See* Proposed Rules on Pharmacy Benefit Manager Licensure and Regulation (Mar. 13, 2023). Put simply, more is needed to help Governor Whitmer and the Legislature achieve their vision of holding PBMs accountable.

As the voice for independent pharmacy, the National Community Pharmacists Association (NCPA) submits these comments to encourage you to complete the Department's important work—by fully implementing House Bill 4348. Founded in 1898, NCPA represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the United States, including 801

independent community pharmacies in Michigan. These Michigan-based pharmacies employ more than 9,800 residents and filled nearly 51 million prescriptions in 2021 alone. And overall, NCPA's members employ over 239,000 individuals on a full or part-time basis and dispense roughly 40% of the nation's retail prescriptions.

We have organized our comments into two main sections. First, we explain the reasons why the State of Michigan enacted House Bill 4348, including the anticompetitive practices of PBMs giving rise to the legislation. Second, we explain places where the Department should promulgate regulations to implement the legislation consistent with the text and purpose of the law.

NCPA is committed to offering our assistance as the Department works through the rulemaking process.

I. The Reasons Michigan Enacted House Bill 4348

House Bill 4348 was enacted against an evolving backdrop: PBMs have assumed an outsized role in limiting access to prescription drugs while increasing costs for patients, and the Supreme Court of the United States recently clarified the important part States play in regulating PBMs.

A. Abusive PBM Business Practices

Pharmacy benefit managers are not health plans or insurers. Rather, "PBMs serve as intermediaries between prescription-drug plans and the pharmacies that beneficiaries use." *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 478 (2020). PBMs enter into contracts with benefit plans and insurers to provide beneficiaries with access to prescription drugs. PBMs deliver this access by contracting separately with pharmacies to create networks where beneficiaries can fill their prescriptions. Notably, the three largest PBMs claim to provide benefit-management services for more than 268 million Americans—which amounts to over eighty-five percent of all Americans with health insurance.

As a third-party service provider, PBMs are under no obligation to act in the best interests of the plans and patients they purport to serve—and frequently they do not. For example, PBMs derive a significant portion of their revenue by charging plans one price for prescriptions and then reimbursing pharmacies at a lesser amount—keeping the difference as profit. PBMs consider their price lists proprietary and do not disclose them to the plans they claim to serve. For instance, when the State of Ohio investigated the PBMs responsible for servicing the State's Medicaid plans, it discovered that PBMs had realized undisclosed profits of $224.8 million off this difference in a single year—all to

the detriment of taxpayers. Dave Yost, *Ohio's Medicaid Managed Care Pharmacy Services Auditor of State Report* 2 (Aug. 16, 2018).[1]

Separately, PBMs have had a negative effect on pharmacy. Because the three largest PBMs dominate the market, pharmacies have limited bargaining power when negotiating with PBMs. Refusing to accept a PBM's contract could mean the inability to serve the majority of patients in a pharmacy's community. As a result, PBM-pharmacy contracts generally grant PBMs unilateral authority to dictate the amount of reimbursement paid to pharmacies for generic drugs, require pharmacies to fill and dispense prescriptions regardless of the amount the pharmacy is reimbursed, and impose a variety of other restrictions on the practice of pharmacy. For example, PBMs have barred pharmacists from informing patients of instances in which the patient could pay less out of pocket for a prescription drug than that patient would pay if the claim were processed through the PBM.

Evidence suggests that PBM reimbursement practices have driven more than sixteen percent of independent rural pharmacies out of business. Abiodun Salako *et al.*, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis (July 2018).[2] This, in turn, means that Americans—particularly in underserved areas—can face barriers to accessing lifesaving medications.

PBMs also own mail-order pharmacies that compete directly with the retail pharmacies in a PBM's network, and PBMs have used their position as middleman to steer—and even force—patients to use PBM-affiliated pharmacies. This practice negatively affects patients in at least three ways. First, it requires patients to go through mail-order pharmacies for medications that are otherwise available at their corner drug store. Second, some PBM-affiliated pharmacies have experienced delays in timely filling orders and have spoiled temperature-sensitive medication. Alex Smith, *Extreme Temperatures May Pose Risks To Some Mail-Order Meds*, NPR, Jan. 7, 2019.[3] Finally, many PBMs engage in the highly questionable practice of reimbursing their own affiliated pharmacies substantially more than they pay non-affiliated pharmacies. CVS Caremark, for example, paid CVS pharmacies forty-six percent more for generic drugs than it paid pharmacies at Walmart and Sam's Club. Marty Schladen & Cathy Candisky, *CVS paid itself far more than some major competitors*, Columbus Dispatch, Jan. 20, 2019 (citing a report by the State of Ohio).[4] And CVS Caremark paid itself over five times as much as it reimbursed independent pharmacies in Arkansas for some medications—or $324.91

[1] https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

[2] https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

[3] https://www.npr.org/sections/health-shots/2019/01/07/673806506/extreme-temperatures-may-pose-risks-to-some-mail-ordermeds.

[4] https://www.dispatch.com/news/20190120/cvs-paid-itselffar-more-than-some-major-competitors-report-says.

more on a single transaction. Linette Lopez, *What CVS is doing to mom-and-pop pharmacies in the US will make your blood boil*, Business Insider, Mar. 30, 2018.[5] As a result, there is substantial evidence that PBM steering—an inherent conflict of interest—not only decreases access to medications, but also increases costs to plans and their patients.

B. House Bill 4348

In response to these and other practices, Michigan enacted House Bill 4348, which mirrors a wave of legislative activity across the country. Indeed, nearly every State—big and small; red and blue—has enacted laws regulating PBMs. In addition, the Attorneys General of forty-six States (Michigan included) and the District of Columbia signed onto briefs in the Supreme Court of the United States making clear that States have robust authority to regulate in this space—a position that the Supreme Court affirmed unanimously in *Rutledge*.

House Bill 4348 includes a number of key features borrowed from the successes of sister States, including Arkansas and North Dakota. Notably, PBMs had attempted to challenge many of these provisions in court, but they have been rebuffed by the Supreme Court and other federal courts. As a result, most of the provisions of House Bill 4348 have already withstood legal challenge—and all are safely defensible.

1. Section 11 – Licensing

The first substantive section of House Bill 4348, Section 11, requires PBMs to obtain a license to offer their services in the State of Michigan. It defines the basic obligations for a PBM to apply for a license, sets forth a process for renewal, and authorizes the Director of the Department of Insurance and Financial Services to suspend or revoke a PBM's license in certain circumstances.

3. Section 13 – Director's Authority to Promulgate Regulations

Section 13 provides that the Director "shall" promulgate "rules that are necessary or required to implement this act." In addition, Section 13 provides that, in exercising her authority, the Director "must" promulgate rules that "include fines, suspension of licensure, restriction of licensure, and revocation of licensure in according with this act."

3. Section 15 – Duty of Good Faith and Fair Dealing

Section 15 provides that a PBM shall exercise "good faith and fair dealing" in the performance of its contractual duties to both health plans and network pharmacies. Notably, the phrase "good faith and fair dealing" is undefined.

The remaining subsections of Section 15 spell out several specific duties that PBMs owe. Among other things, PBMs:

[5] https://www.businessinsider.com/cvs-squeezing-us-momand-pop-pharmacies-out-of-business-2018-3.

- must notify the health plans they serve in writing of potential conflicts of interest;
- may not charge a pharmacy a fee related to a claim or reduce the amount of the claim at the time of the claim's adjudication or after the claim is adjudicated; and
- except for the recoupment of money following an audit done in conformance with the law, a PBM may not recoup money from a pharmacy that has been paid unless authorized by law.

4. Section 17 – Regulation of PBM-Pharmacy Networks

Section 17 of House Bill 4348 regulates the quality of the networks that PBMs sell to health plans in the State of Michigan. As noted above, PBMs create networks by contracting with pharmacies and then sell plans access to these networks.

Subsection 1 of Section 17 states that a PBM shall provide a "reasonably adequate and accessible retail pharmacy benefit manager network for the provision of drugs for a health plan that must provide for convenient enrollee access to pharmacies within a reasonable distance from an enrollee's residence, as determined by the director." Notably, the phrases "reasonably adequate and accessible" and "reasonable distance" are not defined.

Subsections 2 through 5 require PBMs to file reports on network adequacy and allow the director to grant a waiver from the law's adequacy requirements if the PBM satisfies certain conditions.

The remaining subsections focus on a PBM's relationship with its network pharmacies. Subsection 6 bans PBMs from conducting spread pricing in Michigan, and subsection 7 precludes PBMs from charging pharmacies a fee to process claims.

5. Section 19 – Regulation of PBM Business Practices

Section 19 regulates anti-competitive business practices of PBMs, including discrimination against nonaffiliated pharmacies and favoritism of pharmacies in which the PBM has an ownership interest. This includes provisions aimed at forcing and steering patients to affiliated PBM pharmacies and penalizing or discouraging patients for using unaffiliated pharmacies.

6. Section 21 – Patient Access to Fair Information and Pricing

Section 21 ensures that patients have access to fair information about the drugs they have been prescribed, including information about the cost of those drugs and more affordable alternatives. This provision effectively bans PBMs from imposing gag clauses that had restricted pharmacies from providing this information to their patients. In

addition, Section 21 prohibits a PBM from charging a copayment or cost-sharing amount to a patient that exceeds the cost of the patient's medication.

7. Section 23 – PBM Transparency Reporting

Section 23 requires PBMs to file transparency reports with the Director. These reports require the disclosure of aggregate information about costs, rebates, fees, and reimbursement amounts, among other things. The section specifically precludes the disclosure of any information that would identify a specific health plan or enrollee, or the specific price charged for a specific drug.

8. Section 27 – Regulation of PBM Maximum Allowable Cost Lists

Section 27 regulates the use of maximum allowable cost (MAC) lists, which are the principal means by which PBMs reimburse pharmacies for dispensing generic drugs. Notably, PBMs keep their pricing lists secret, maintain more than one MAC list, and sometimes reimburse pharmacies under these lists less than any pharmacy could acquire the drug in question. Under Section 27, PBMs must provide pharmacies with access to their MAC lists, update those lists at least once every 7 days; and provide pharmacies with a reasonable appeals process for challenging a reimbursement under a MAC list.

9. Section 28 – Fair Audits

Section 28 places limitations on a PBM's ability to audit a pharmacy. Among other things, this section requires PBMs to provide advanced written notice of an audit, places limitations on the substance of such an audit (such as by requiring a PBM to employ a pharmacist if the audit turns on clinical judgments), and sets up an appeals process.

10. Section 29 – Regulation of PBM Restrictions on Pharmacy

Section 29 places limitations on a PBM's ability to place restrictions on the services that pharmacies can perform. For example, Section 29 provides that a pharmacy may deliver certain drugs to a patient, limits a PBM's ability to impose accreditation or recertification standards in excess of State licensing standards, and prohibits PBMs from retaliating against pharmacists for availing themselves of the protections of the Act.

11. Section 30 – Enforcement of the Act by the Director

Section 30 provides that the Director shall enforce the Act. It also empowers the Director to examine or audit the books and records of PBMs.

12. Section 31 – PBM Compliance with the Act

Section 31 provides that a contract between a PBM and an insurer that exists on the date of licensure of the PBM must comply with the requirements of the Act as a condition of the PBM's license.

13. Section 33 – Retention of Records

Section 33 provides that the Director shall establish a retention schedule for all records, books, papers, and other data on file with the Department related to the enforcement of the Act.

14. Section 35 – Clarification on Interaction with Federal Law

Section 35 provides that the Act shall be applied on a claim-by-claim basis, and that the Act does not apply only "with respect to a claim that is entirely preempted by federal law, including Medicare Part D or the employee retirement income security act" (also known as ERISA).

15. Effective Date

The Act takes effect January 1, 2024.

II. Provisions the Department Should Implement Through Regulations

In the section that follows, we discuss those portions of the new law where, consistent with Section 13, regulations are "necessary or required" to implement the Act. In particular, the Department should promulgate regulations that address six major areas of the new law: (A) clarifying the limited scope of the provision on federal preemption, (B) defining the "duty of good faith and fair dealing," (C) establishing standards for determining whether a PBM's network is "reasonably adequate and accessible," and includes pharmacies within a "reasonable distance" of an enrollee; (D) clarifying the scope of a PBM's duties not to discriminate against "nonaffiliated" pharmacies; (E) defining Maximum Allowable Cost (MAC) lists to ensure PBMs cannot engage in semantics to evade compliance with the law; and (F) establishing the steps the Director will take to enforce the law.

A. Regulations Clarifying the Limited Scope of the Provision on Preemption

As noted above, Section 35 provides that the "act does not apply with respect to a claim that is entirely preempted by federal law," including ERISA and Medicare Part D.

Although it may appear obvious, the Director should clarify that the Act applies to claims that are *not* entirely preempted by federal law, including claims not entirely preempted by ERISA and Medicare Part D. As it stands now, opponents of the Act could argue that it does not apply whenever a PBM is handling a claim involving a plan regulated by ERISA or Medicare Part D. That would not be a fair or accurate interpretation of the language of Section 35. But because Section 35 clarifies the scope of the new law, it is imperative that the Director speak clearly on when she has authority to enforce the new law.

In interpreting Section 35, the Director's task is to give meaning to the words selected by the Legislature. Here, the Legislature rejected any interpretation of the Act

that would prevent it from applying wholesale to PBMs serving plans regulated by ERISA and Medicare Part D.

For one thing, the Legislature did not say that the Act could not apply to PBMs serving plans regulated by ERISA and Medicare Part D. Quite the opposite, the Legislature said that the Act does not apply only with respect to a "claim" that is "entirely" preempted by federal law.

By using the term "claim," Section 35 clarifies that any preemption analysis must be conducted on a claim-by-claim basis. That's because "claim" is a defined term that "means a request for payment for administering, filling, or refilling a drug or for providing a pharmacy service or medical supply or device to an enrollee." H.B. 4348 § 5(d).

Similarly, by using the term "entirely," the Legislature clarified that the Act would apply to a claim to the extent it is not completely preempted by ERISA or Medicare Part D. After all, the plain meaning of the term "entirely" means "completely."

In addition, this understanding of Section 35 is consistent with the legal backdrop under which House Bill 4348 was passed. As noted above, shortly before the Legislature enacted House Bull 4348, the Supreme Court of the United States clarified that ERISA does not completely preempt State laws that apply to PBMs—even when PBMs are providing services to plans that are subject to regulation by ERISA. And federal courts have expressed similar views about Medicare Part D. In *PCMA v. Wehbi*, for example, the U.S. Court of Appeals for the Eighth Circuit explained that Medicare Part D "does not preempt all state laws as applied to Medicare Part D; rather, it preempts only those that occupy the same 'place'—that is, that regulate the same subject matter as—federal Medicare Part D standards." 18 F.4th 956, 971 (8th Cir. 2021).

Together, this strongly suggests that the Legislature wanted to limit the scope of the Act to only those "claims" that are "entirely" preempted by federal law. Otherwise, to the extent that an individual claim is not preempted by federal law, the State of Michigan can—and should—enforce its law. The Director's clarification around this issue is therefore critical.

B. Regulations Clarifying the "Duty of Good Faith and Fair Dealing"

Section 15 provides that a PBM shall exercise "good faith and fair dealing" in the performance of its contractual duties to both health plans and network pharmacies. Critically, however, the phrase "good faith and fair dealing" is undefined.

The Director should promulgate regulations defining the statutory duty of good faith and fair dealing imposed by Section 15. And the Director should clarify that this statutory duty is distinct from the contractual duty of good faith and fair dealing that is presumed to exist in the performance of all contracts under Michigan law (except

employment contracts). *See Hammond v. United of Oakland, Inc.*, 193 Mich. App 146, 151–152 (1992).

Opponents of the legislation may argue that the statutory duty is indistinct from the contractual duty that exists in all contracts, but they would be wrong. For one thing, if the opponents were correct, then there would have been no need for the Legislature to have created a statutory duty of good faith and fair dealing, because, as noted just above, courts already impose a contractual duty of good faith and fair dealing. In divining the will of the Legislature, the Director should avoid any interpretation of the Act that would render any of its provisions superfluous. *E.g.*, *Danto v. Michigan Bd. of Med.*, 168 Mich. App. 438, 442 (1988). And that means that the statutory duty of good faith and fair dealing must mean something different than the general duty of good faith and fair dealing that arises by contract.

As for substance, the Director should clarify that the statutory duty of good faith and fair dealing requires that:

- a PBM may not reimburse a pharmacy less than the pharmacy's cost to acquire a drug, because such action is inconsistent with, and would frustrate, the common understanding of "reimburse," which means to "repay";
- a PBM must pay a reasonable dispensing fee, separate and apart from whatever the PBM reimburses a pharmacy for a drug, to ensure that the PBM has reimbursed the pharmacy for the full cost of its services, which includes both the acquisition cost of its drug and overhead on any given prescription;
- a PBM may not accept a rebate or other payment from a pharmaceutical manufacturer that is not completely and fully disclosed to the health plan or third-party payor that the PBM purports to serve; and
- a PBM must disclose to the health plan or third-party payor that the PBM purports to serve the difference between what the PBM charges the health plan or third-party payor and what it reimburses pharmacies in the aggregate for the drugs it processes for the health plan or third-party payor;

These provisions are all necessary to give meaning to the statutory duty of good faith and fair dealing that the Legislature has imposed upon PBMs in their relationships with pharmacies and health plans. As noted above, in the absence of these specific duties, PBMs have engaged in abusive behavior that has frustrated the reasonable expectations of the pharmacies and plans that contract with PBMs.

In addition, in *Rutledge*, the Supreme Court of the United States held that ERISA does not preempt State laws that regulate the economic relationship among PBMs,

pharmacies, and ERISA plans. *See* 141 S. Ct. at 480-81. Thus, there is no legal obstacle to promulgating regulations of the type outlined above.

C. Regulations Defining the Standards for PBM-Pharmacy Networks

Section 17 of House Bill 4348 regulates the quality of the networks that PBMs sell to health plans in the State of Michigan. As noted above, the section imposes a duty on PBMs to ensure that their pharmacy networks are "reasonably adequate and accessible" and a "reasonable distance" to enrollees. But not one of these quoted terms is defined.

The Director should promulgate regulations that define a PBM's duties to create adequate and accessible pharmacy networks within the State of Michigan. Although less than perfect, as a stopgap, the Director should adopted the network adequacy standards established by the Centers for Medicare and Medicaid Services (CMS) that apply to plans subject to regulation under Medicare Part D. *See* 42 C.F.R. § 423.120. But the Director should make one important tweak to these stopgap standards: Unlike CMS's access standards, the Director's standards should apply to both standard and preferred networks.

Once the Director implement's CMS's network adequacy standards as a stopgap that apply to both standard and preferred networks in the State of Michigan, the Director should solicit comments on changes to Michigan's network adequacy standards to ensure that they provide sufficient access to retail pharmacies throughout the State—including the State's rural and urban markets.

In the absence of clear guidance upfront as to what is expected of PBMs, it will be next to impossible for the Director to ensure compliance on a case-by-case basis with the Legislature's otherwise undefined network adequacy standards. In addition, without clear guidance, PBMs and pharmacies will not know the rules by which PBMs are being judged.

D. Regulations Defining a PBM's Duty Not to Discriminate

Among Section 19's prohibitions, it provides that a PBM "shall not discriminate against a nonaffiliated pharmacy that is a retail pharmacy." The Act does not define the scope of this prohibition.

The Director should clarify that a PBM's duty includes not discriminating against a nonaffiliated retail pharmacy that wishes to join a PBM's standard or preferred pharmacy network, provided that pharmacy is willing and able to abide by the terms and conditions for network participation. In the absence of such a prohibition, PBMs have regularly discriminated against retail pharmacies in an effort to steer patients to PBM-affiliated mail-order pharmacies. This is not only anti-competitive, but also limits patient access to prescription medications at their corner drugstores.

Increasingly, States are enacting such anti-discrimination measures, which are also known as any-willing-provider (AWP) provisions. A federal district court in Oklahoma recently blessed such a provision, *see PCMA v. Mulready*, 598 F. Supp. 3d 1200, 1207-08 (W.D. Okla. 2022); the Attorney General of Michigan signed onto an *amicus curiae* brief expressing the view that ERISA does not preempt such a provision, *see* Br. of 34 States and the District of Columbia as *Amici Curiae*, No. 22-6074 (10th Cir. filed Oct. 18, 2022); and the United States government filed a brief taking a similar position that State AWP provisions are not preempted by ERISA as applied directly to third-party PBMs, *see* Br. of United States as *Amicus Curiae*, *PCMA v. Mulready*, No. 22-6074 (10th Cir. filed Apr. 10, 2023). Thus, there is explicit authority for promulgating such a requirement.

In addition, the Director should promulgate regulations providing that PBMs may not reimburse an affiliated pharmacy more than an unaffiliated pharmacy that operates in the same network as the affiliated pharmacy—whether standard or preferred. Otherwise, PBMs have engaged in discriminatory reimbursement practices that have forced the closure of independent pharmacies. As noted above, CVS Caremark has reimbursed CVS pharmacies *five times* more than independent pharmacies. Linette Lopez, *What CVS is doing to mom-and-pop pharmacies in the US will make your blood boil*, Business Insider, Mar. 30, 2018. Adding insult to injury, after under-reimbursing independent pharmacies CVS sent letters to pharmacists in Arkansas and Ohio stating that selling their businesses to CVS was an "attractive and practical option" in the face of "declining reimbursements." *Id.* (linking to CVS letter).

Finally, the Director should promulgate regulations providing that PBMs may not charge enrollees different copayment or cost sharing amounts at un-affiliated pharmacies than the PBM charges at affiliated pharmacies within the same network—whether standard or preferred. PBMs have otherwise used the discriminatory practices to steer patients to their own pharmacies—which often charge higher fees to the health plans the PBMs purport to serve.

E. Regulations Further Defining Maximum Allowable Cost

Section 27 regulates how PBMs may use maximum allowable cost (MAC) lists to reimburse pharmacies for generic drugs. Section 7(c) defines maximum allowable cost to mean "the maximum amount that a pharmacy benefit manager will reimburse a network pharmacy for the ingredient cost for a generic drug." Together, the purpose behind these provisions is to ensure that PBMs employ a fair process for reimbursing pharmacies for generic drugs.

Unfortunately, when faced with similar provisions in other jurisdictions, PBMs have engaged in a game of semantics, calling their MAC lists something else, and then claiming that a given State's laws no longer applied. For that reason, States like Arkansas have been forced to re-define the term MAC to ensure that PBMs cannot evade the purpose of MAC-based legislation, which is to ensure a fair process for reimbursing pharmacies for dispending generic drugs. *See* Ark. Code § 17-92-507(a)(1)(A) & (B).

As a result, the Director should promulgate regulations that define MAC broadly to include any label attached by a PBM defining the process for reimbursing pharmacists for generic drugs. Taken the lead for Arkansas, the Director's regulation should provide:

> "Maximum Allowable Cost List" means a listing of drugs or other methodology used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable cost on which reimbursement payment to a pharmacy or pharmacist may be based for a generic drug, brand-name drug, biologic product, or other prescription drug.
>
> "Maximum Allowable Cost List" includes without limitation:
>
> (i) Average acquisition cost, including national average drug acquisition cost;
>
> (ii) Average manufacturer price;
>
> (iii) Average wholesale price;
>
> (iv) Brand effective rate or generic effective rate;
>
> (v) Discount indexing;
>
> (vi) Federal upper limits;
>
> (vii) Wholesale acquisition cost; and
>
> (viii) Any other term that a pharmacy benefits manager or a healthcare insurer may use to establish reimbursement rates to a pharmacist or pharmacy for pharmacist services.

F. Regulations Ensuring PBM Compliance with House Bill 4348

Finally, House Bill 4348 imposes various duties that PBMs owe to pharmacies. As examples, Section 27 regulates the use by PBMs of MAC lists, and Section 28 places limitations on a PBM's ability to audit a pharmacy. Notably, these provisions are silent on enforcement.

The Director should promulgate regulations that allow pharmacies to petition the Department to bring an enforcement action against a PBM for non-compliance with the House Bill 4348. Such a regulation would be consistent with Section 30, which provides that the Director "shall enforce this act." Indeed, by soliciting petitions from pharmacies and developing an orderly system for adjudicating their claims, the Director would tap into a wealth of information about alleged PBM non-compliance.

The enforcement protocols established by the Director should include: (1) a standardized form that allows a pharmacy, pharmacist, or pharmacy services administrative organization to quickly and easily file an administrative complaint with

the Department; (2) an electronic system for submitting such complaints and tracking the Department's investigation and resolution of any such complaint; (3) allowance for the Director to delegate her adjudicative function to subordinate employees of the Department and hold fact-finding hearings to adjudicate complaints; and (4) establishment of a process for timely resolution of such complaints.

* * * * *

As we explained at the outset, House Bill 4348 is intended to regulate anti-competitive practices by PBMs that have increased costs while limiting patient choice. It is modeled off legislation adopted by other States, and its provisions have already survived legal challenges mounted by PBMs. As such, there are no valid legal obstacles to promulgating the regulations proposed in these comments.

NCPA is committed to helping the Department of Insurance and Financial Services to ensure that the laudable goals of this legislation are fully realized.

Very truly yours,

Anne Cassity
Senior Vice President of Government Affairs
National Community Pharmacists Association

Estrada, Michele (DIFS)

From: Eric Roath <eroath@michiganpharmacists.org>
Sent: Friday, June 9, 2023 2:31 PM
To: Estrada, Michele (DIFS)
Cc: Mark Glasper; Farah Jalloul; Sammy Salem
Subject: Michigan Pharmacists Association Comments on PBM Rules
Attachments: Pharmacy PBM Comments 06-2023.pdf

Michele Estrada,

Please consider the attached comments related to the proposed rules for Pharmacy Benefit Manager Licensure and Regulation. Please reach out to me if you have any questions regarding our comments. We would be delighted to be a resource for you and your team.

Sincerest thanks,

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Thank you for the opportunity to provide comments on the Rules for Pharmacy Benefit Manager Licensure and Regulation. Michigan Pharmacists Association (MPA) represents pharmacy practitioners across the state of Michigan. We represent pharmacists and pharmacy technicians in all practice areas, from community outpatient practice to inpatient health systems.

The proposed rules regarding licensure are an excellent start. Still, we feel that there are certain ambiguities in the statute that merit further clarification. We humbly request that additional rules be promulgated to address the following concerns:

Good Faith and Fair Dealing

I. GOOD FAITH AND FAIR DEALING

Public Act 11, 2022

Sec. 15. (1) A pharmacy benefit manager shall exercise good faith and fair dealing in the performance of its contractual duties to a health plan or network pharmacy. A provision in a contract that attempts to waive or limit the obligation under this subsection is void.

MPA recognizes that the phrase "good faith and fair dealing" have not been adequately defined. We request an addition to the promulgated rules that defines this term to meet the following conditions:

A pharmacy benefit manager shall exercise good faith and fair dealing in the performance of its contractual duties. Therefore:

1. **A PBM may not reimburse a pharmacy less than the pharmacy's cost to acquire a drug, because such action is inconsistent with, and would frustrate, the common understanding of "reimburse," which means to "repay."**
2. **A PBM must pay a reasonable dispensing fee, separate and apart from whatever the PBM reimburses a pharmacy for a drug, to ensure that the PBM has reimbursed the pharmacy for the full cost of its services, which includes both the acquisition cost of its drug and overhead on any given prescription. Minimum dispensing fees shall be:**
    a. **The professional dispensing fee for drugs indicated as specialty medications is $15 or the pharmacy's submitted dispensing fee, whichever is less.**
    b. **The professional dispensing fee for all other drugs is $8.10 or the pharmacy's submitted dispensing fee, whichever is less.**
3. **A PBM may not accept a rebate or other payment from a pharmaceutical manufacturer that is not completely and fully disclosed to the health plan or third-party payor that the PBM purports to serve; an**

4. **A PBM must disclose to the health plan or third-party payor that the PBM purports to serve the difference between what the PBM charges the health plan or third-party payor and what it reimburses pharmacies in the aggregate for the drugs it processes for the health plan or third-party payor.**

MPA recognizes that dispensing fees vary across the state. In accordance with CMS regulations, the State of Michigan has conducted a cost of dispensing study and determined estimates for the cost of dispensing for different classes of medications. We have suggested that a "reasonable" cost of dispensing by placed at 75% of what has been determined by the study conducted by the State of Michigan.

II. Reasonable and Adequate Access:

Public Act 11, 2022

Sec. 17. (1) A pharmacy benefit manager shall provide a reasonably adequate and accessible retail pharmacy benefit manager network for the provision of drugs for a health plan that must provide for convenient enrollee access to pharmacies within a reasonable distance from an enrollee's residence, as determined by the director.

MPA recognizes that the phrase, "reasonably adequate and accessible" and "reasonable distance" is not defined. We requestion an addition to the promulgate rules that defines this as:

- **"Reasonably and adequate and accessible," means having a pharmacy within a reasonable distance of the patient's home address.**
- **"Reasonable distance," means a distance consistent with 42 CFR § 423.120.**

III. Non-discrimination against nonaffiliated pharmacies

Public Act 11, 2022

Sec. 19. (1) A pharmacy benefit manager shall not discriminate against a nonaffiliated pharmacy that is a retail pharmacy.

MPA suggests that additional details be listed in the rules regarding what "discrimination" classifies. Specifically, we ask that the following language be included.

- **PBM's duty includes not discriminating against a nonaffiliated retail pharmacy that wishes to join a PBM's standard or preferred pharmacy network, provided that pharmacy is willing and able to abide by the terms and conditions for network participation.**
- **PBMs may not reimburse an affiliated pharmacy more than an unaffiliated pharmacy that operates in the same network as the affiliated pharmacy—whether standard or preferred.**
- **For a drug intended for administration by a prescriber, the PBM shall not require that a patient receive the drug via distribution from a mail-order or any other affiliated pharmacy for subsequent transportation to the prescriber's office prior to administration. Nor shall that PBM impose any monetary penalties or price discrepancies between drugs accessed by a retail pharmacy and a mail-order or affiliated pharmacy.**

IV. Non-discrimination against nonaffiliated pharmacies

Public Act 11, 2022

Sec. 27. (1) For each drug that a pharmacy benefit manager establishes a maximum allowable cost, the pharmacy benefit manager shall do all of the following:
(a) Provide each pharmacy subject to a maximum allowable cost list with access to the maximum allowable cost list and the source used to determine the maximum allowable cost for each drug.
(b) Update its maximum allowable cost list at least once every 7 calendar days.
(c) Provide a process for each pharmacy subject to the maximum allowable cost list to receive prompt notification of an update to the maximum allowable cost list.
(d) Establish and maintain a reasonable administrative appeals process to allow a pharmacy subject to the maximum allowable cost list or an agent of a pharmacy subject to the maximum allowable cost list to challenge the adjudication of a pharmacy's claim.
(e) Investigate and resolve an appeal under this subsection within 14 calendar days after the pharmacy benefit manager receives the appeal. An appeal under this subsection must be submitted to the pharmacy benefit manager not later than 45 calendar days after the date the pharmacy's claim for reimbursement has been adjudicated.
(f) Respond in writing to any appealing pharmacy or an appealing pharmacy's agent not later than 30 calendar days after receipt of an appeal if the pharmacy filed the appeal more than 10 calendar days after the date the pharmacy's claim for reimbursement is adjudicated.
(g) If an appeal is denied, provide the appealing pharmacy or the appealing pharmacy's agent the national drug code number available for purchase in this state at or below the appealed maximum allowable cost.
*(h) If an appeal is granted, permit the pharmacy to reverse and rebill the claim and all claims for the drug.*MPA suggests that additional details be listed in the rules regarding what "discrimination" classifies. Specifically, we ask that the following language be included.

In addition to the stated regulations, MPA recommends further clarification regarding "Maximum Allowable Cost Lists" or "MAC" list. We recommend the following language be added to the rules:

- **"Maximum Allowable Cost List" means a listing of drugs or other methodology used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable cost on which reimbursement payment to a pharmacy or pharmacist may be based for a generic drug, brand-name drug, biologic product, or other prescription drug.**
- **"Maximum Allowable Cost List" includes without limitation:**
    - **(i) Average acquisition cost, including national average drug acquisition cost;**
    - **(ii) Average manufacturer price;**
    - **(iii) Average wholesale price;**
    - **(iv) Brand effective rate or generic effective rate;**
    - **(v) Discount indexing.**
    - **(vi) Federal upper limits;**
    - **(vii) Wholesale acquisition cost; and**
    - **(viii) Any other term that a pharmacy benefits manager or a healthcare insurer may use to establish reimbursement rates to a pharmacist or pharmacy for pharmacist services.**

Thank you again for the opportunity to provide comments on these rules. If you have any questions or require clarification regarding our remarks, please do not hesitate to reach out.

Respectfully submitted,

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