MICHIGAN PHARMACY **PAGE REPORT** June 2025

The Summer of Impending Change



Regardless of your opinion on the current state of politics, one thing is clear: the legal and regulatory landscape is changing. Many of these issues are carry-overs from years past — the fight for provider recognition, the battle for pharmacy benefit manager (PBM) reform, the continued struggle for pharmacy's viability — but the landscape has changed. Federally, efforts to cut spending and balance the budget seem to threaten Medicaid and public health programs. Here in Michigan, pharmacy professionals eagerly await pending rule changes that will allow us to expand our clinical practice efforts while urging state government to enforce the PBM laws that have been in effect for over a year. Maybe it's just me, but it sure feels like things are a little more tumultuous than usual.

Throughout all of this, Michigan Pharmacists Association and Pharmacy PAC work to serve as your voice to state and federal officials. Just like you, we're working hard to ensure that the ultimate outcome of these winds of change results in positive outcomes for pharmacy patients, pharmacy businesses, and the pharmacy professionals that make it all happen. We can't, however, do any of this without you.

This edition of the **Pharmacy PAC Report** aims to provide you with an overview of all that's happened in the spring of 2025 while simultaneously making a plea. We need you to support our efforts in two ways. First, we want you to speak up using the **Advocacy Action Center** on our website to advocate for positive change in the pharmacy regulatory sphere. Secondly, we ask you support our efforts by donating to Pharmacy PAC in the **MPA Online Store**. Read on to learn more about the issues and how you can affect positive change.

And, as always, please reach out directly to me with your questions and concerns.

Sincerely,

Eric Roath, PharmD, MBA Director of Government Affairs Michigan Pharmacists Association

Scope of Practice: The Long Wait for Critical Reforms

In 2023, the Michigan Legislature passed, for the first time, legislation that gave prescriptive authority to pharmacists

for immunizations, point-of-care tests and antiviral medications for influenza and COVID-19. This was followed by the governor signing legislation, which was passed in 2024, that granted pharmacists prescriptive authority for hormonal contraceptives. While pharmacy professionals in Michigan should take a well-deserved victory lap, the question remains, "When can we start?" Unfortunately, that answer is... complicated.

In order for both laws to go into effect, the Michigan Board of Pharmacy needs to promulgate rules that, at a minimum, identify



the nature of the training requirements for pharmacists to provide these services. The timing for the 2023 bill was rather unfortunate given this requirement as the ruleset that needed to be updated was already going through the tailend of the promulgation process. We had to wait for the previous set of rules to finish the process before the Board of Pharmacy could even begin to craft the newly required rules.

The timing for the passage of the hormonal contraceptive package was far more fortuitous, and MPA advocated that the Board include the required rules for this practice among the revisions it was already working on. Now those rules have received their initial approval from the Board and are progressing through the process.

The Rule Promulgation Process

The process by which rules are promulgated differs significantly from the legislative process we tend to be more familiar with. Here is a brief summary of the process.

Request for Rulemaking

- A department submits a **Request for Rulemaking (RFR)** to the **Michigan Office of Administrative Hearings and Rules (MOAHR)**
- MOAHR reviews and approves the RFR and notifies the **Joint Committee on Administrative Rules (JCAR)**

Draft Rules

- Rules are drafted and submitted to MOAHR to review for legal authority. This draft is made by the **Rules Workgroup** and approved by the **Board of Pharmacy**
- MOAHR approves draft rules and notifies JCAR.
- MOAHR sends the draft to the Legislative Service Bureau (LSB) for informal editing.
- NOTE: This is where we are currently in the process for the Pharmacy General Rules.

Public Hearing

- A **Regulatory Impact Statement (RIS)** is prepared by the agency and sent to MOAHR for approval 28 days prior to the public hearing. MOAHR notifies JCAR.
- A **Notice of Public Hearing** is published online and in three newspapers, including one in the Upper Peninsula, not less than 10 days after but not more than 60 days prior to the hearing.
- Public comment is accepted by the agency (in our case, LARA) from the notice date up through the public hearing date.

JCAR Report

- The agency submits the final draft of the rules and the JCAR Report to MOAHR.
- MOAHR submits the final draft to LSB to formally certify the rules.
- MOAHR legally certifies the rules and sends the JCAR Report (which includes the rules, certifications, RFR and RIS) to JCAR

JCAR

- The JCAR Report must be submitted to JCAR within one year after the public hearing.
- The JCAR Report summarizes the purpose of the draft rules and any comments made at the public hearing or submitted in writing.
- The rules must be before JCAR for 15 session days, unless JCAR grants a waiver of the remaining days.
- During those 15 days, JCAR may object to the rules, but then must introduce legislation within another 15 session days to stop or delay the rules.

Great Seal

- After 15 session days, MOAHR can file the rules with the Office of the Great Seal (or after a waiver is granted)
- The agency director confirms the intent to adopt the rules by submitting a Certificate of Adoption to MOAHR.
- The rules may become effective immediately upon filing with the Office of the Great Seal, or at a later date specified by the agency in the rules.

What are the proposed changes?

As you can see, we still have a way to go in the process. The next stage is the "public comment period," where health care stakeholders have the opportunity to weigh in on all the proposed changes. Listed below are the changes proposed related to scope of practice.

Draft Immunization Rules (paraphrased)

Before ordering and administering a qualified immunizing agent, "a pharmacist shall successfully complete a training course on the administration of vaccines that is provided by an entity accredited by the ACPE."

Draft Hormonal Contraceptive Rules: Training (paraphrased)

Before issuing a prescription for a contraceptive, a pharmacist shall "successfully complete a training course on prescribing and dispensing contraceptives that is provided by an entity accredited by the ACPE."

Draft Test-to-Treat Rules (paraphrased)

"Before ordering and administering a qualified laboratory test and dispensing, without a prescription, a drug based on the test results" a pharmacist "shall complete a training program requiring the pharmacist to:

- Demonstrate sufficient knowledge of how to administer and interpret each laboratory test.
- Demonstrate sufficient **knowledge of each illness**, **condition, or disease** for which the pharmacist provides treatment based on the results of the laboratory test."

Any of the following is acceptable to meet this requirement:

- Employer-based training
- Training completed as part of a professional degree from a school of pharmacy accredited by the ACPE
- A certificate program

Draft Hormonal Contraceptive Rules: Standard Procedure (paraphrased)

Before issuing a prescription for a contraceptive, a pharmacist shall:

- Require the patient to **complete the self-screening risk assessment tool**.
- Review the patient's completed self-screening risk assessment tool before issuing a prescription.

Upon issuing a prescription for a contraceptive, a pharmacist shall:

- Refer the patient to the patient's primary care provider or another appropriate health professional.
- Refer the patient for a physical examination if the patient has not had one in 12 months.
- Provide the patient with a written record of the prescribed contraceptive to the patient and advise they consult with a physician or other licensed health professional.
- Dispense the prescribed contraceptive or transfer the prescription to the pharmacy of the patient's choosing.

If the pharmacist does not issue a prescription to the patient, the pharmacist shall refer the patient.

The rules also contain an appendix which specifies the minimum requirements for the self-screening risk assessment tool that must be used by the pharmacist as part of the hormonal contraceptive prescribing service.

What is the timeline?

Unfortunately, this is hard to say for sure. For reference, the last time the Board of Pharmacy – General Rules were modified, the RFR was filed on March 9, 2022. The rules were not filed and effective until Feb. 29, 2024. That made for a roughly a two-year process, and the most recent RFR for the same ruleset was filed on May 9, 2025. There were a number of complicating factors that prolonged the previous rule promulgation process, but an 18- to 24-month time horizon for implementation is not unreasonable.

Forecasting the Implications of "One Big Beautiful Bill"

The "**One Big Beautiful Bill Act**," has been sucking up a lot of oxygen in the news-media sphere. That said, there are several provisions that will directly impact the practice of pharmacy and our patients included in what its proponents call a "once in a generation piece of legislation." The bill was passed by the U.S. House of Representatives on May 22, 2025. Here's a closer look at some of the provisions.

PBM Regulations

One Big Beautiful Bill Act introduces several **pharmacy benefit manager (PBM) regulations** aimed at increasing transparency and reducing costs for consumers and pharmacies. Here are the key provisions:

• **Spread Pricing Ban**: PBMs will no longer be allowed to charge payers more for a drug than they reimburse pharmacies, eliminating hidden profit margins.



- **Pass-Through Pricing for Medicaid:** PBMs contracting with Medicaid must use a pass-through pricing model, ensuring that payments to pharmacies reflect the actual drug cost plus a professional dispensing fee.
- **Rebate Transparency:** The bill requires PBMs to disclose rebate amounts received from drug manufacturers and how they impact drug pricing for consumers.
- **Pharmacy Reimbursement Protections**: The legislation includes minimum reimbursement standards for pharmacies, preventing PBMs from underpaying independent pharmacies.
- Audit & Oversight Measures: PBMs will face stricter auditing requirements, ensuring compliance with new pricing and reimbursement rules.

These changes aim to curb abusive PBM practices that have inflated drug costs and limited pharmacy profitability. However, while the bill introduces more oversight, it does not fundamentally restructure PBM operations. This is somewhat expected, as any bill passed through the budget reconciliation process (as this bill aims to be) can only impact Medicaid and Medicare plans. For this reason, many of the larger reforms advocated by MPA and our national counterparts are better suited for a stand-alone bill on PBM practices.

Medicaid Provisions

The Bill also addresses a number of provisions that impact state Medicaid programs.

- Work Requirements:
 - Requires states to implement work requirements by Dec. 31, 2026, and the Secretary of Health and Human Services to develop guidance for states to implement these requirements by Dec. 31, 2025.
 - The work requirements would require able-bodied adults aged 19-64, without dependents, to work (or perform other qualifying activities) for at least 80 hours a month. There would be exemptions for certain individuals (e.g., pregnant women, those with serious medical conditions and tribal members).

States may issue hardship waivers for specific individuals facing short-term hardship (e.g., inpatient care, related outpatient care, natural disasters, high unemployment rate in county).

• Michigan previously had Medicaid work requirements under the Healthy Michigan Plan, but these requirements were ruled illegal by a federal judge in 2020 and later removed by Gov. Gretchen Whitmer in January 2025.

• Medicaid Expansion:

- Lowers the federal match for the expansion population (from 90% to 80% Federal Medical Assistance Percentage (FMAP)) if a state "provides any form of financial assistance, through Medicaid or under another program established by the state" that allows undocumented immigrants, except for children and pregnant women. Michigan offers limited financial assistance to undocumented immigrants through non-Medicaid programs such as Healthcare Access and Refugee Assistance Programs.
- Sunsets a temporary 5% enhanced FMAP for new states that expand Medicaid after the bill's enactment.
- Requires states to impose cost-sharing for individuals in Medicaid expansion with incomes up to 100% of the federal poverty level. Cost-sharing may not exceed \$35 per service or a total of 5% of an individual's income and would not apply to primary and other preventive care.
- Requires states to conduct eligibility determinations for their expansion population every six months by Dec. 31, 2026.

• Provider Taxes

- Prohibits states from establishing new provider taxes and freezes existing provider taxes at current rates. Overlaps with a CMS proposed rule released May 12, 2025.
- Modifies the criteria HHS must use to determine whether taxes are redistributive when considering a waiver of uniform tax requirement.
- May create future challenges for states to fund the state share of Medicaid. States would need to increase state general funds or cut benefits/coverage. Michigan uses provider taxes to fund more than 30% of the state share.

• State-Directed Payments

- Caps future state-directed payments at 100% and non-Medicaid expansion states at 110% of the Medicare rate.
- Most states require managed care plans to provide add-on payments to health providers (known as directed payments) to incentivize high-quality care, train new providers, or support safety net providers. Would limit a state's future options to incentivize high-quality care or improve access to care.

CMS Eligibility/Long-Term Care Staffing Rule Delays

O Delay the implementation of eligibility rules for Medicaid, CHIP, Basic Health Program, the Medicare Savings Program and long-term care staffing standards until 2035. Delaying the eligibility rules may result in additional individuals losing coverage and associated federal cost savings.

• Reproductive Health and Gender Transitions

• Prohibits the use of federal Medicaid funds for gender transitions for minors and adults. Also prohibits federal funding for Planned Parenthood and other abortion providers described as "nonprofit organizations, that are essential community providers that are primarily engaged in family planning services or reproductive services, provide for abortions other than the Hyde Amendment exceptions and which received \$1,000,000 or more."

Recommendations Regarding COVID-19 Vaccinations

Health and Human Services Secretary Robert F. Kennedy Jr. announced on May 27, 2025, that the Centers for Disease Control and Prevention (CDC) will no longer recommend COVID-19 vaccines for healthy children and pregnant



women. Kennedy made the announcement in a video posted on X, alongside FDA Commissioner Marty Makary and NIH Director Jay Bhattacharya. He stated that the change was based on "common sense and good science" and aligns with the administration's goal to "Make America Healthy Again".

However, the decision bypassed the usual CDC advisory process, which typically involves expert panel reviews before updating vaccine recommendations. Public health experts and medical associations have criticized the move, arguing that it could limit insurance coverage for vaccines and increase health risks for pregnant women and children.

Though the change in policy aligns the U.S. with European nations, which have already restricted annual COVID-19 boosters to

older adults and high-risk groups, the move has plenty of detractors within the US. The American Academy of Pediatrics opposes the decision, citing more than 11,000 children were hospitalized with COVID-19 during the last respiratory virus season. Likewise, the American College of Obstetricians and Gynecologists have criticized the move, emphasizing that pregnant women face higher risks of severe illness from COVID-19. Other organizations such as the Infectious Diseases Society of American and National Nurses United have expressed concerns regarding the move, arguing that it bypassed expert advisory processes and could limit insurance coverage for vaccines.

Given the unprecedented nature of this change, there remains much uncertainty regarding when these changes take effect. The official CDC vaccination schedule was changed on May 28 to remove the recommendation for vaccination during pregnancy, and the recommendation for healthy pediatric vaccines was changed to require new "shared clinical decision-making" criteria. On June 9, 2025, the <u>American Pharmacists Association released a statement</u> that it would "withhold endorsing" the new immunization schedule. On this same day, it was announced that all members of the Advisory Council on Immunization Practices had been removed from their positions by Secretary Kennedy due to "conflicts of interest."

MPA, at this time, is not offering any recommendation as to what changes, if any, should be made to existing pharmacist immunization practices for COVID-19. Michigan's Department of Health and Human Services is discussing the developments and may issue their own guidance in the near future.

Pharmacy PAC Honors Champions Among Advocates and Legislators

Each year, Michigan Pharmacy PAC recognizes individuals who work to advance legislative causes supportive of the pharmacy profession and public health. The awards are presented annually at the MPA Annual Convention & Exposition.

Representative of the Year



Rep. Julie Rogers (D - 41st District) has been a practicing physical therapist for more than 25 years. She also served on the Kalamazoo County Board of Commissioners for eight years and with part of that time as board chair. Last term, she was appointed to serve as chair of the House Committee on Health Policy. Rogers also co-chairs the Biosciences Legislative Caucus and is a co-chair of the Arts and Culture Legislative Caucus. Additionally, she has been appointed as an Assistant Democratic Caucus cochair this term and is a member of the National Council of State Legislatures Health Policy Committee.

As chair of the House Health Policy Committee in 2023 and 2024, Rogers was instrumental in the passage of the first expansions of pharmacists' scope of practice in well over a decade. Among these was the Women's Health Package of bills that ultimately resulted in pharmacists' authority to prescribe hormonal contraception—

one of the very few issues that managed to clear the legislature at the end of the 2024 session. This year, Rogers continues to support the implementation of a statewide Health Data Utility, a legislative priority that MPA has worked on in conjunction with the Michigan Health Information Network.

Senator of the Year

Sen. Mary Cavanagh (D - 6th district) is committed to supporting policies and budgets that focus on attainable housing, accessible and affordable health care, small business and community development supports, consumer protection, and workforce development initiatives.

She serves on nine committees, including as the chair of three – the Committee on Finance, Insurance and Consumer Protection; Subcommittee on the Department of Labor and Economic Opportunity; and Subcommittee on the Department of Licensing and Regulatory Affairs and the Department of Insurance and Financial Services. In addition, Cavanagh serves as vice chair to the Senate Committee on Community and Economic Development.



In the 2023-24 legislative session, Cavanagh sponsored several

health care-related initiatives, including a bill package aimed to improve maternal health and equity in Michigan; a bill

aimed at enhancing coverage of certain contraceptives; and a bill that addressed licensing issues related to providing reproductive health services.

Good Public Health Policy



NCPA CEO Doug Hoey has practiced in a variety of community pharmacy settings, including his own family pharmacy before coming to NCPA. He is an industry expert on community pharmacy practice issues, including drug supply and prescription drug pricing.

Doug has been on the forefront of pharmacy's fight for sustainable pharmacy reimbursement. Through Doug and NCPA's collaboration with MPA, we are fighting to ensure that independent community pharmacy remains strong in Michigan despite the extraordinary pressures facing our community pharmacy owners and their staff today.

Hank Fuhs Good Government Award

Wayne Seiler's pharmacy journey began in 2003 when he joined SRS Pharmacy Systems. Since then, he has fought hard to secure sustainable pharmacy reimbursement through PBM reform. Seiler was instrumental in the work to get Michigan's PBM Licensure and Regulation Act passed and has recently been actively engaged with the state's Attorney General on PBM issues. He has also been an advocate at the federal level and has attended the NCPA national fly-in for the past 16 years



Health Data Utility Legislation

MPA supported House Bills (HB) <u>4037</u> and <u>4038</u> that were passed out of the House Health Policy committee on May 21, 2025, with recommendation from the committee. They now await a full vote on the House floor. The bill package establishes the framework and funding mechanism for a Health Data Utility (HD), which would expand upon the existing health information exchanges established by the Michigan Health Information Network (MiHIN). HB 4037 establishes a HDU to improve health data exchange. It mandates compliance with cybersecurity laws and sets a deadline of March 1, 2026, for selecting a Health Information Exchange to operate it. House Bill 4038 provides funding for the HDU, starting with \$6 million this year and increasing to \$8 million per year by FY 2027, with adjustments for inflation. Though the legislation does not specifically identify MiHIN as the entity that will develop the state's HDU, the organization is uniquely equipped to serve this function in the state.

Prescription Drug Affordability Board

Senate Bills (SB) <u>3</u>, <u>4</u> and <u>5</u> passed out of the Senate on April 24, 2025, largely along party lines (20-15), making it clear that the legislation faces an uncertain future in the Republican-led House of Representatives. Parties supporting the legislation identify the need for something to be done to curb rapidly rising prices on brand-named prescription medications, while others point out the significant cost to tax-payers and the lack of discernable outcomes from states that have already implemented PDABs of their own.

The most notable feature of a PDAB is its ability to impose an "upper payment limit (UPL)" on medications determined to have been subject to an excessive increase in cost. The legislation relies on the concept that market forces would subsequently adjust the pricing of that drug all along the supply chain. Michigan's legislation contains a unique feature in that it includes a price floor where independent pharmacies (those owned by individuals with an ownership stake in seven or fewer stores) must be reimbursed at the UPL. MPA submitted written testimony during a committee hearing in the Senate on April 23 stating that it is imperative that *all* pharmacies be reimbursed at the UPL and that reimbursement includes a professional dispensing fee.

State Level 340B Protections

Legislation that would codify a federal drug pricing program cleared the Senate on March 6, 2025, with broad bipartisan support, although one opponent said more needs to be done to ensure the program is doing what it is intended to do.

Members voted 33-3 on the MPA-supported Senate Bill (SB) <u>94</u>, which would codify state-level protections for the federal 340B program. The program requires pharmaceutical manufacturers that participate in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for uninsured and low-income patients.

SB 94 aims to incentivize providers to fully comply with the federal law as well as protect consumers from being subject to collections by providers that are out of compliance with federal requirements. Sen. Sylvia Santana (D-Detroit) who voted no on the bill, said SB 94 "fails to address the real concerns about transparency, accountability and, most critically, ensuring that this program serves the patients that need it most."

"I hope that this bill moves forward and my colleagues in the House will take a serious look at these concerns and work to strengthen this legislation," Santana said. "If we are serious about addressing systemic inequities, then we will need to ensure that programs like 340B are working as they are intended to work, not as a revenue stream, but as a lifeline to patients who need the help the most."

Brian Peters, CEO of the Michigan Health and Hospital Association, in a statement, thanked the Senate for its votes and urged the House to do the same. "This bill prevents drug manufacturers from continuing to issue arbitrary restrictions on 340B eligible Federally Qualified Health Centers and hospitals," Peters said. "We continue to be grateful for the Senate's leadership and collaboration in recognizing the need for strong, quality health care providers over out-of-state prescription drug interest groups."

MPA and its members continue to push grassroots advocacy efforts encouraging legislators to advance this legislation, which would prohibit a manufacturer, wholesaler, or distributor from "denying, restricting, prohibiting, conditioning, discriminating against, or otherwise limiting the acquisition of a 340B drug by, or the delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a 340B entity to receive a 340B drug on behalf of the 340B entity."

The <u>MPA Advocacy Action Center</u> has been updated to facilitate messages directly to Michigan House members. Please take the time to click the <u>link</u> and tell your elected official about the important efforts funded by the 340B program in your community.

Coverage of Immunizations and Test-to-Treat Programs under Pharmacist Authority

Senate Bill (SB) <u>107</u>, sponsored by Sen. Santana, passed out of the Senate on April 22, 2025, by a vote of 34-2. The bill requires insurers to cover immunization and test-to-treat services rendered under a pharmacist's independent authority to be covered by insurers contracted with that pharmacy. The bill now moves to the House of Representatives and will likely be referred to the committee on Health Policy chaired by Rep. Curtis Vander Wall.

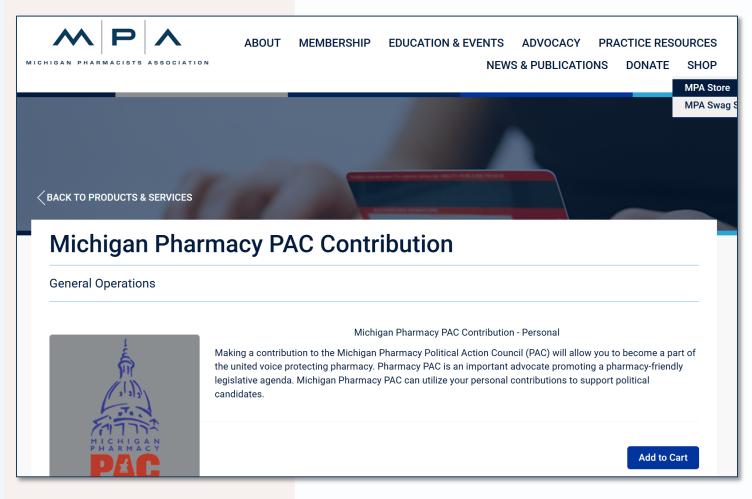
The bill's advancement comes at a critical time with the progression of the required amendments to the Pharmacy General Ruleset. On April 16, 2025, the Board of Pharmacy voted to advance the proposed rule changes along the promulgation process. The draft rules, which contain proposed training requirements for immunization, test-to-treat and hormonal contraception services, are expected to be available for public comment sometime this summer.

MPA's <u>Advocacy Action Center</u> has been updated to allow you to send letters to your state representatives encouraging action on this important issue. We cannot express strongly enough how much you taking a few minutes to send a form letter to your legislator helps representative today.

Donating to Pharmacy PAC is Easier than Ever

MPA strives to represent your voice when working with elected officials, but we can't advance our mission without your support. Donating to Pharmacy PAC allows us to build relationships and support legislators who advance good public health policy. Your donations make all that we do possible.

To donate to Pharmacy PAC, visit the MPA Online Store and search "PAC." Select the "Michigan Pharmacy PAC Contribution – Personal" option as a product and proceed to checkout. It's that simple.



If every MPA member donated \$25, we would meet our fundraising goal for the year. Donate today to ensure that your voice continues to be heard.

Questions? Please contact Eric Roath, MPA Director of Government Affairs at eroath@michiganpharmacists.org