2024 Legislative Update

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OHIO PHARMACISTS ASSOCIATION

OPA Annual Conference & Trade Show
April 5-7, 2024

1 VOICE VISION TEAM

Disclosure Statement

Michelle Fitzgibbon and Michael Murphy have no relevant financial relationship(s) with ineligible companies to disclose.

and

None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. discuss current legislative and policy changes at both the state and federal level that will impact the practice of pharmacy;
2. explain how to effectively advocate for OPA supported legislative changes with state legislators and federal elected officials; and
3. identify issues on OPA's legislative agenda for 2024-25 and what they may mean for pharmacy practice.

Congress
Federal Agencies
National trends in the states

FEDERAL UPDATE

The political landscape – What can we expect?

- Time is limited in the current Congressional session
- November elections on the horizon
- Continuing resolution (CR)
- Lame duck legislation
- Health care packages and legislative vehicles
- A change in leadership?
  - United State House of Representatives
  - United States Senate

Payment for pharmacist-provided patient care services

- The Equitable Community Access to Pharmacist Services Act (ECAPS) (S. 2477), (H.R. 1770)
- The Pharmacy and Medically Underserved Areas Enhancement Act (MUA) (S. 1491)
- ECAPS introduced in the Senate
- Potential introduction of MUA in the House
- CBO Score
- Broad support in the House and Senate
- What is next?

Appropriations language requests

- Pharmacists and Patient Care Services Recognition Under Medicare Part B
- Pharmacist-Provided Incident to Services and Telehealth Codes
- Virtual Supervision of Clinical Staff
- HIV Preventative Services Guidance to Plans on U.S. Preventive Services Task Force (USPSTF) Recommended Initiation of PrEP and HIV Screening
- Health Resources and Services Administration (HRSA) Faculty Loan Repayment Program
- National Health Service Corps (NHSC) - State Loan Repayment Program
- Bureau of Labor Statistics, HRSA to work with APhA and American Association of Colleges of Pharmacy (AACP) to Account for the Complete Pharmacy Labor Force

PBM reform legislation

- **House**

Lower Costs, More Transparency Act (H.R. 5378)-Passed House on 12/23! 320-71

  - Prohibits PBM spread pricing in Medicaid Managed Care and moves to a market-based reimbursement model (national average drug acquisition cost/NADAC), increases PBM transparency for employers & prohibits all PBM “gag clauses”

- **Senate**

Pharmacy Benefit Manager Transparency Act (S. 127)-Passed Commerce Committee

  - Prohibits PBMs spread pricing and clawbacks and increases PBM transparency
  - Protects stronger state PBM laws & more oversight to FTC & states
  - Pharmacy Benefit Manager Reform Act (S. 1339)-Passed HELP Committee
  - Prohibits PBM spread pricing for employer health plans & PBM transparency
  - Requires PBMs pass rebates onto plans/employers
  - Does not protect stronger state PBM laws

PBM reform legislation

- **Senate**

Modernizing and Ensuring PBM Accountability Act (S. 2973)-Passed Finance Committee

- Delinks PBM compensation from Medicare Part D drug prices and increases PBM transparency
- Requires PBMs to provide pharmacies information on all components to price a Medicare Part D claim
- Requires HHS to establish standardized pharmacy quality and performance measures under Medicare Part D
- Prohibits PBM spread pricing in Medicaid/ managed care plans and includes survey of drug prices (NADAC)

PBM reform legislation

- **Senate**
- The Better Mental Health Care, Lower-Cost Drugs, and Extenders Act – Passed Finance Committee (S. 2430) – target for full Senate vote potentially 3/23
  - Requires that an “essential” independent community pharmacy cannot be reimbursed by PBMs or health plans lower than the average NADAC- takes effect beginning in 2028
  - Pharmacist organizations secured the following key amendments:
  - Ensuring pharmacy reimbursements include professional dispensing fees
  - Expanding the definition of essential independent pharmacies
  - Increasing the number of reasonable and relevant contract term violations that pharmacists can report to CMS
  - Ensuring pharmacies are not underpaid for dispensing certain discount-eligible drugs under net prices
  - Increasing congressional oversight of CMS’ implementation of the final rule on Medicare Part D reimbursements and DIR fees (e.g., DIR cliff)

DIR Cliff/Hangover

- Pharmacies are receiving the “lowest possible reimbursement” for Medicare Part D claims in 2024
- PBMs continue to collect pharmacy DIR fees from 2023 (likely April/March) = significant cash flow issues
- “Performance-Based Payment Arrangement”

CMS acknowledges the “possibility that changes in cash flow may cause some already struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks.”

DIR Cliff/Hangover

Example of how Part D plans and PBMs report costs/DIR in 2024:

- Assuming a Part D plan and a network pharmacy have a performance-based payment arrangement to: 1) recoup 5% of its total Part D-related payments to the pharmacy for not meeting performance standards, 2) recoup no payments for average performance, or 3) provide a bonus equal to 1% of total payments to the pharmacy for high performance.
- For a drug that the Part D plan has agreed to pay the pharmacy $100 at the point of sale, the pharmacy's final reimbursement under this arrangement would be: 1) $95 for poor performance, 2) $100 for average performance, or 3) $101 for high performance.
- The "negotiated price" reported to CMS on the prescription drug event record at the point of sale for this drug would be $95, or the "lowest possible reimbursement" under the arrangement.

DIR Cliff/Hangover

Example of how Part D plans and PBMs will report costs/DIR in 2024:

- If a Part D plan were required to pay 25% coinsurance for this drug, then the patient's costs under this scenario would be 25% of $95, or $23.75, which is less than the $25 the enrollee would pay today (when the negotiated price is likely to be reported as $100).
- Any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR. Under this requirement, the Part D plan would report $0 as DIR under the poor performance scenario ($95 minus $95), -$5 as DIR under the average performance scenario ($95 minus $100), and -$6 as DIR under the high-performance scenario ($95 minus $101) for every covered claim for this drug purchased at this pharmacy.

DIR Cliff – Iceberg ahead for Part D Plans!

- **Pharmacy Network Adequacy?** "At least 70 percent of Medicare beneficiaries, on average, in **rural areas** served by the Part D sponsor [must] live within 15 miles of a network pharmacy that is a retail pharmacy." 90 percent, on average, within 2 miles of a network pharmacy for **urban areas** and 90 percent, on average, within 5 miles for **suburban areas**.
- **Underwater Reimbursement Rates 2024 PBM contracts.**
- **Part D Plans out of compliance?** If pharmacies continue closing, Part D plans are likely out of compliance with pharmacy access standards and many Part D plans are, noncompliant, which means **not only will seniors lose access to their necessary pharmacies, they will also lose access to their Part D plans.**

Which PBM business practices is CMS looking for?

- **DO SEND:**
  - **Examples of patient access problems**
  - **Examples of patient harm and confusion**
  - **Examples of patient steering**
- **DO NOT SEND:**
  - **Financial prescription drug claims**

TO: partd_monitoring@cms.hhs.gov
CC: APhA aphagovernmentaffairsteam@aphanet.org

DSCSA

Authorized Trading Partner	• Buy only from authorized trading partners with valid registration or licensure	Required now
Product Tracing	• Exchange transaction documentation	Required now, but must be electronic by 11/27/24
Product Verification	• Quarantine and investigate • Respond if receive notification of illegitimate product • Notify FDA if illegitimate product found • Recordkeeping	Required now
Serialization	• Product identifier in human readable and 2D bar code on all covered products • Only purchase serialized product	Required now

DSCSA

- “Stabilization period” until November 27, 2024
  - Per FDA: This is not a delay
- Entire supply chain needs more time to stabilize connections, interoperability, systems, and processes
- Role of state boards of pharmacy

APhA's DSCSA survey

Q: Are you familiar with DSCSA requirements that went into effect in November 2023?

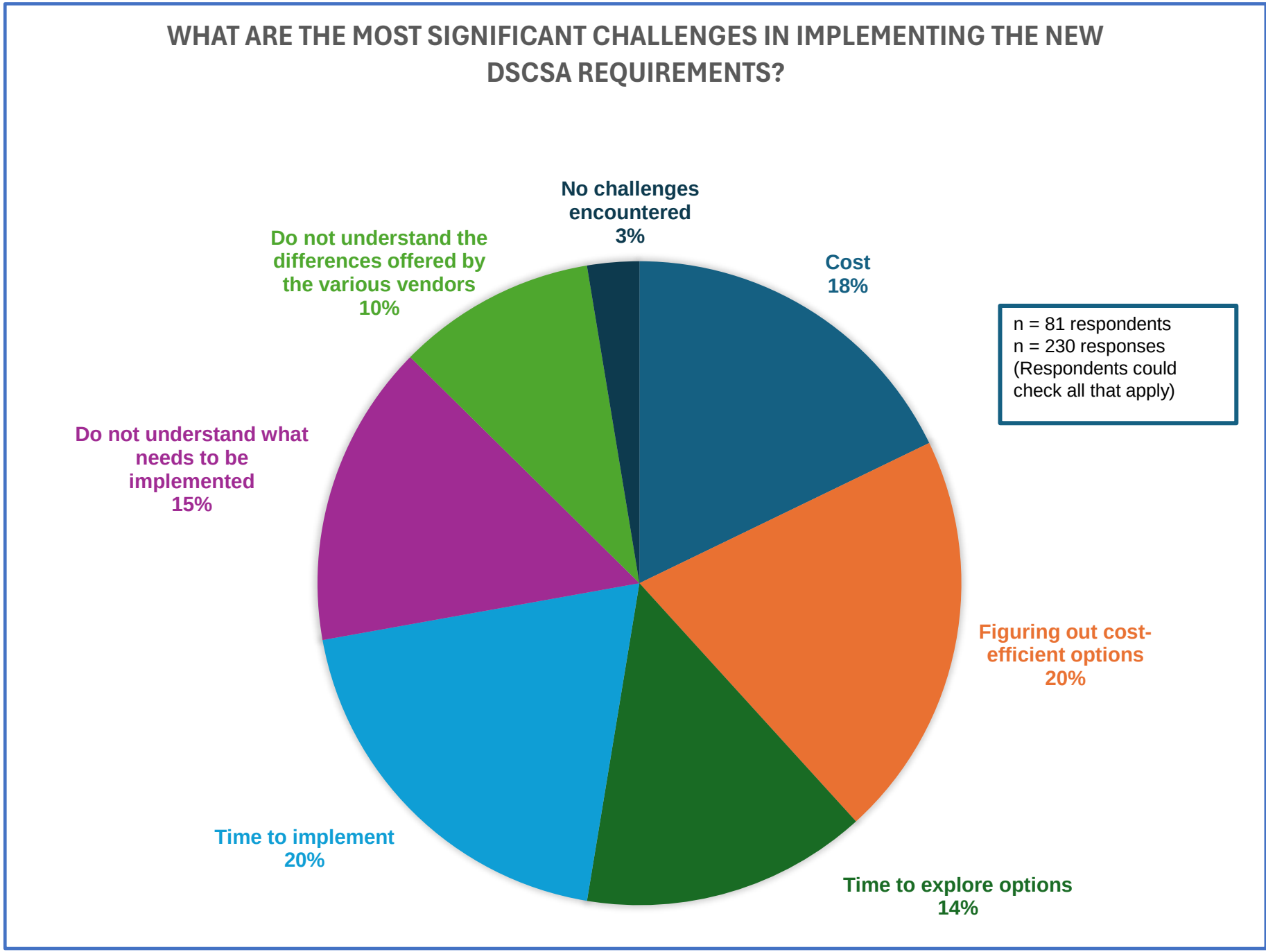
- Yes: 86.4%
- No: 13.6%

81 respondents
Fielded Jan/Feb 2024

Q2 - How are you using the stabilization period to troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with your trading partners?

1	My pharmacy has not yet looked into implementing new systems and processes for the new requirements.	19.75%
2	My pharmacy is exploring different vendors or options with my wholesalers to implement the new systems and processes for the new requirements.	13.58%
3	My pharmacy is using a vendor and we are currently working on implementation.	24.69%
4	My pharmacy is using a vendor and our systems are implemented and stabilized.	7.41%
5	My pharmacy is relying on our wholesaler and we are currently working on implementation.	23.46%
6	My pharmacy is relying on our wholesaler and our systems are implemented and stabilized.	6.17%
7	Other (Please, explain.)	4.94%
	Total	100%

APhA's DSCSA survey



Fielded Jan/Feb 2024

dscsa.pharmacy

Threat to FDA approvals

FDA U.S. FOOD & DRUG ADMINISTRATION

For approval, FDA experts review:

- Evidence from tests proves the drug is safe and effective for its intended use.
- Data that shows the drug provides benefits that outweigh its known and potential risks for the intended population.

FDA NEWS RELEASE

FDA Authorizes Florida's Drug Importation Program

For Immediate Release: January 05, 2024

Español Français

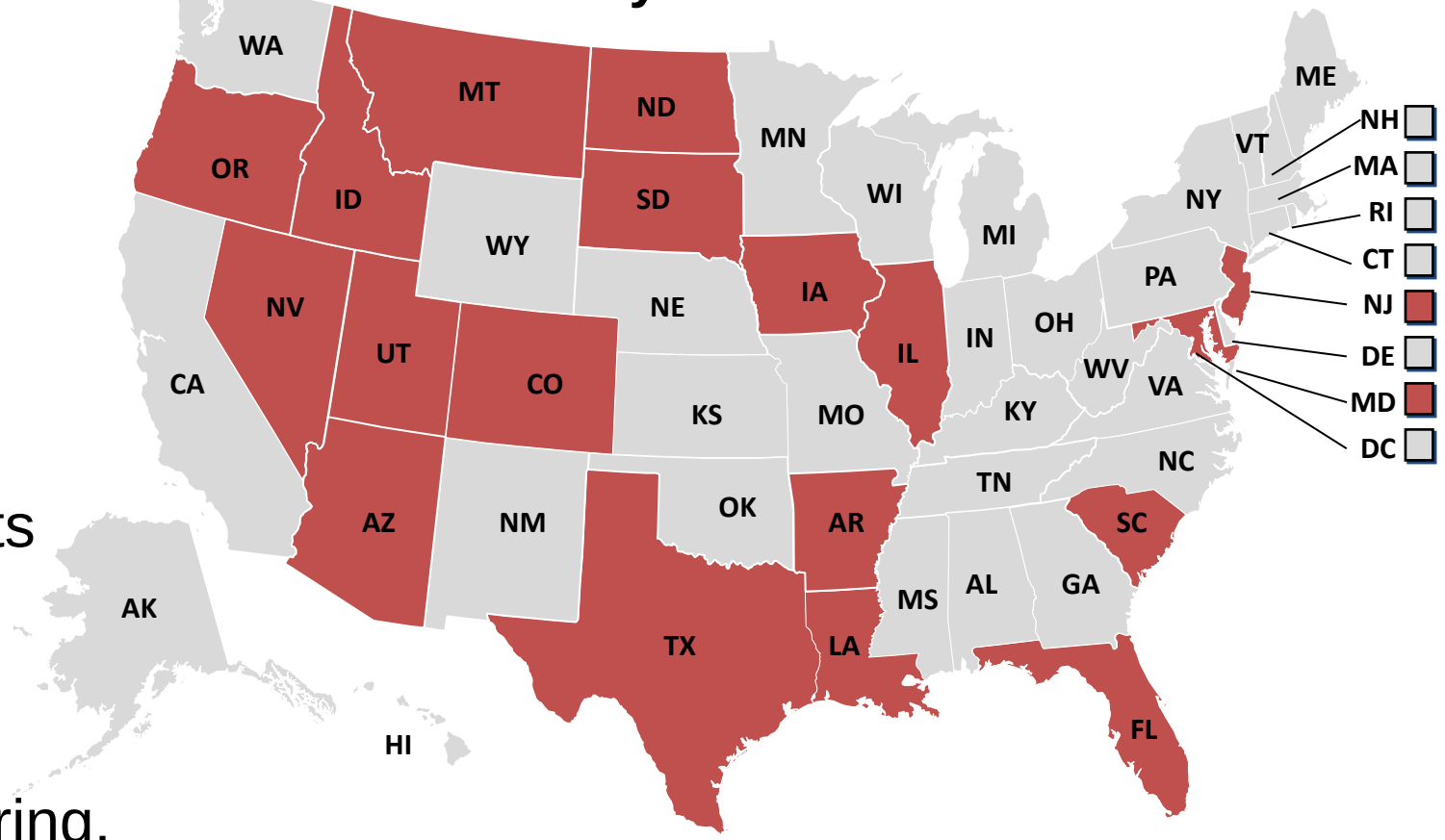
Today, the U.S. Food and Drug Administration authorized Florida's Agency for Health Care Administration's drug importation program under section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This is the first step on this pathway toward Florida facilitating importation of certain prescription drugs from Canada.

Through this pathway, the FDA may authorize section 804 importation program (SIP) proposals from states or Indian tribes to import certain prescription drugs from Canada if the SIP will significantly reduce the cost to the American consumer without imposing additional risk to public health and safety. President Biden's *Executive Order on Promoting Competition in the American Economy* directed the FDA to work with states and Indian tribes on these plans to reduce costs to American consumers while supporting

State trends: PBM reform*

- **Licensure & Registration**
- **Enforceability**
  - Fines
  - Commissioner oversight
- **Transparency**
  - Audit processes
- **Appeals**
- **Reimbursement Rates**
  - Preferential reimbursements
  - Standardized rates
- **Prohibition on specific PBM activities**
  - Mandatory mail order, steering, fees, etc.

Examples of 2023 Policy Advancements



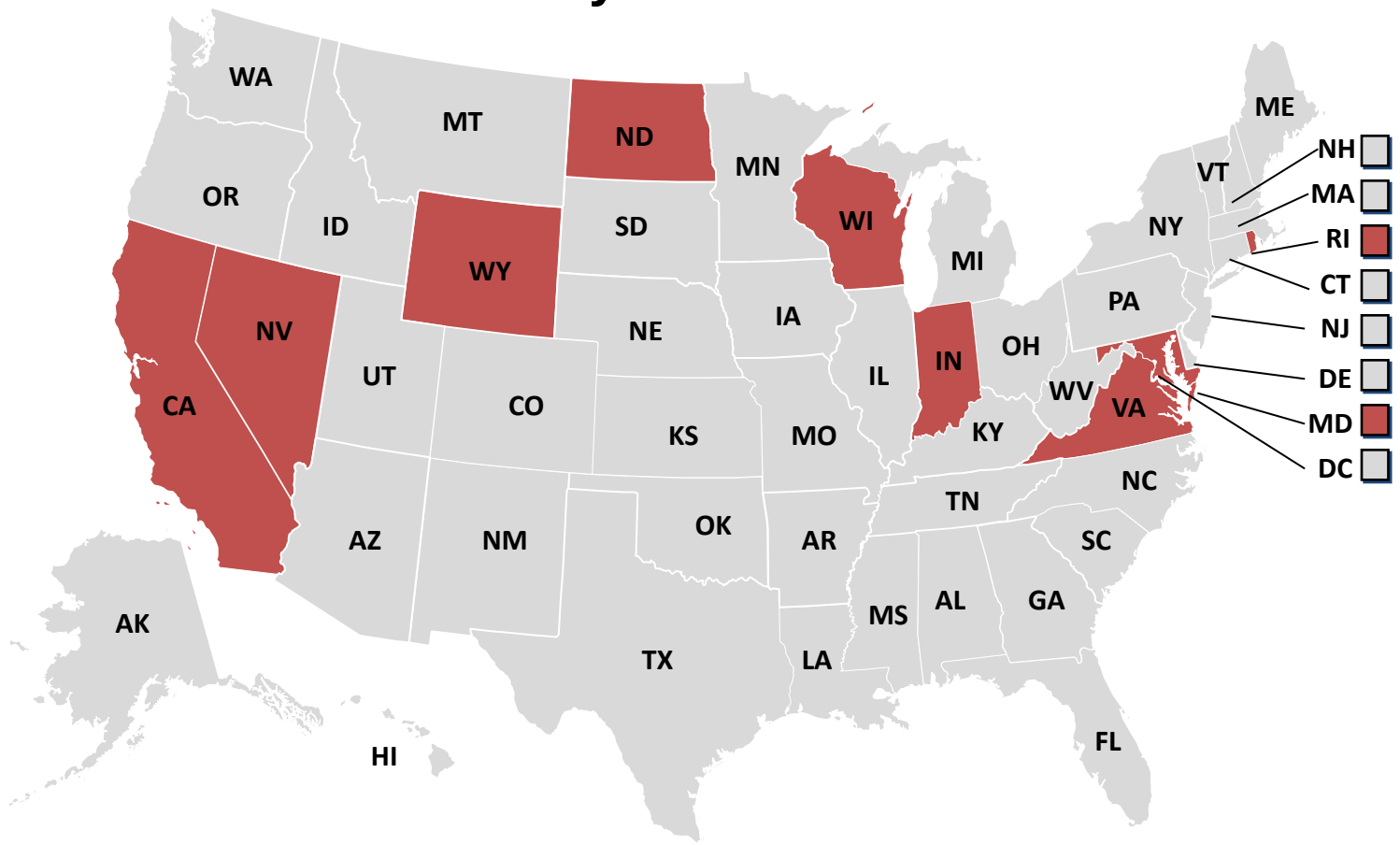
*Examples of legislative, regulatory, or policy advancements and not intended to be a comprehensive representation

Source: APhA Analysis of State Policies

State trends: Payment for services*

- **Reimbursement under the medical benefit**
- **Reimbursement under Medicaid approved by CMS**
- **Reimbursement under commercial health plans**
  - Public policy change not required
- **Reimbursable codes**
  - Office or Other Outpatient Services Codes – 99202-99205 & 99211-99215
- **Reimbursable services**
  - Narrow vs. broad

Examples of 2023 Policy Advancements



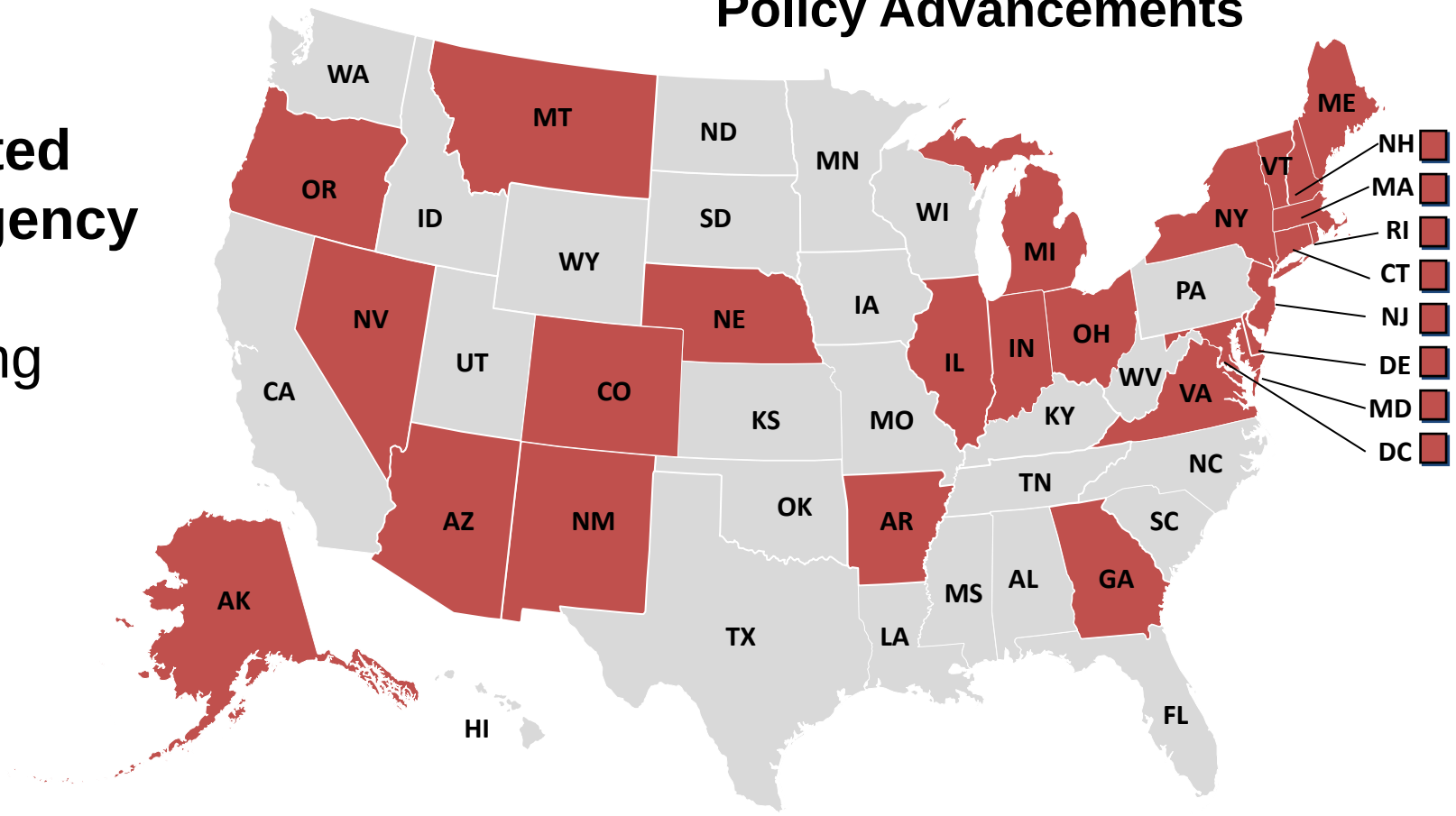
*Examples of legislative, regulatory, or policy advancements and not intended to be a comprehensive representation

Source: APhA Analysis of State Policies

State trends: Scope of practice alignment with education and training*

- **Codifying authorities granted during public health emergency for pharmacy personnel**
  - Vaccination age & ordering
  - Test and treat
- **Public health needs**
  - Hormonal contraceptives
  - HIV PrEP/PEP
  - Tobacco cessation
  - Substance use disorder

Examples of 2023 Policy Advancements

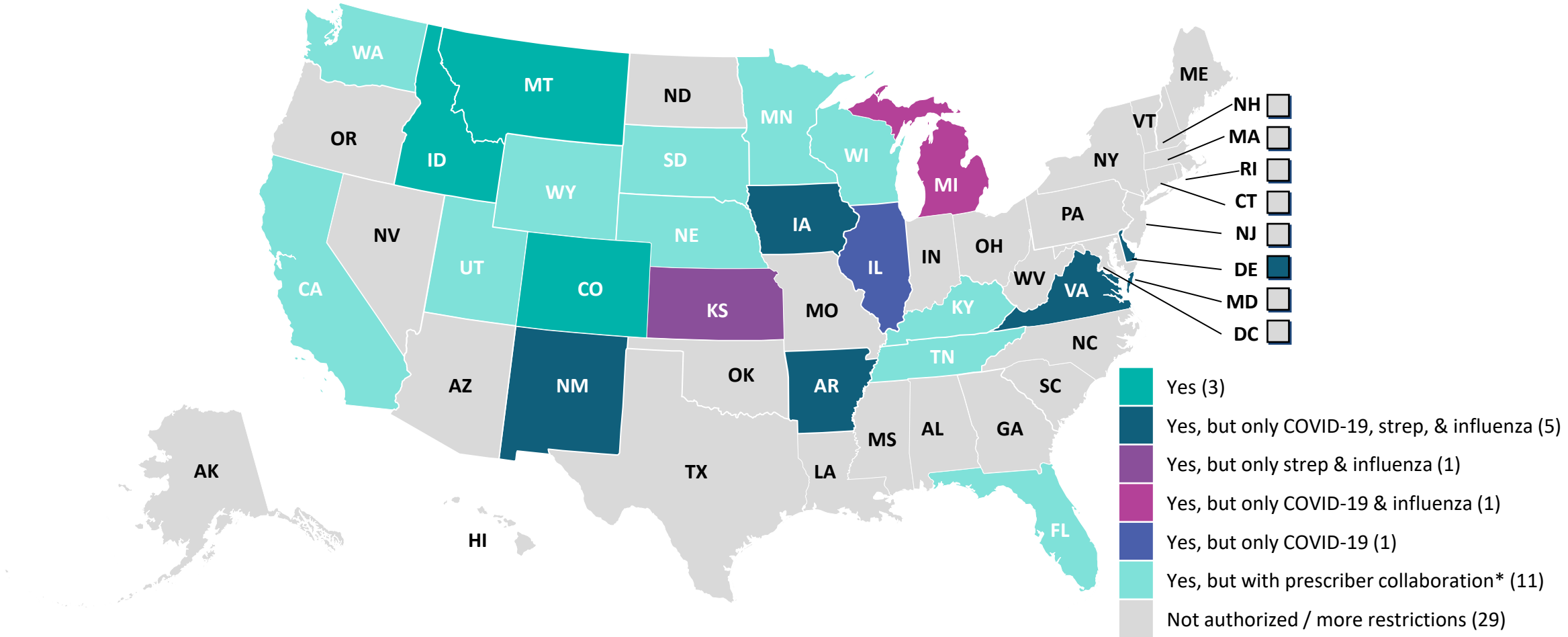


- **Collaborative practice agreements now in all ***50 states*****!

*Examples of legislative, regulatory, or policy advancements and not intended to be a comprehensive representation

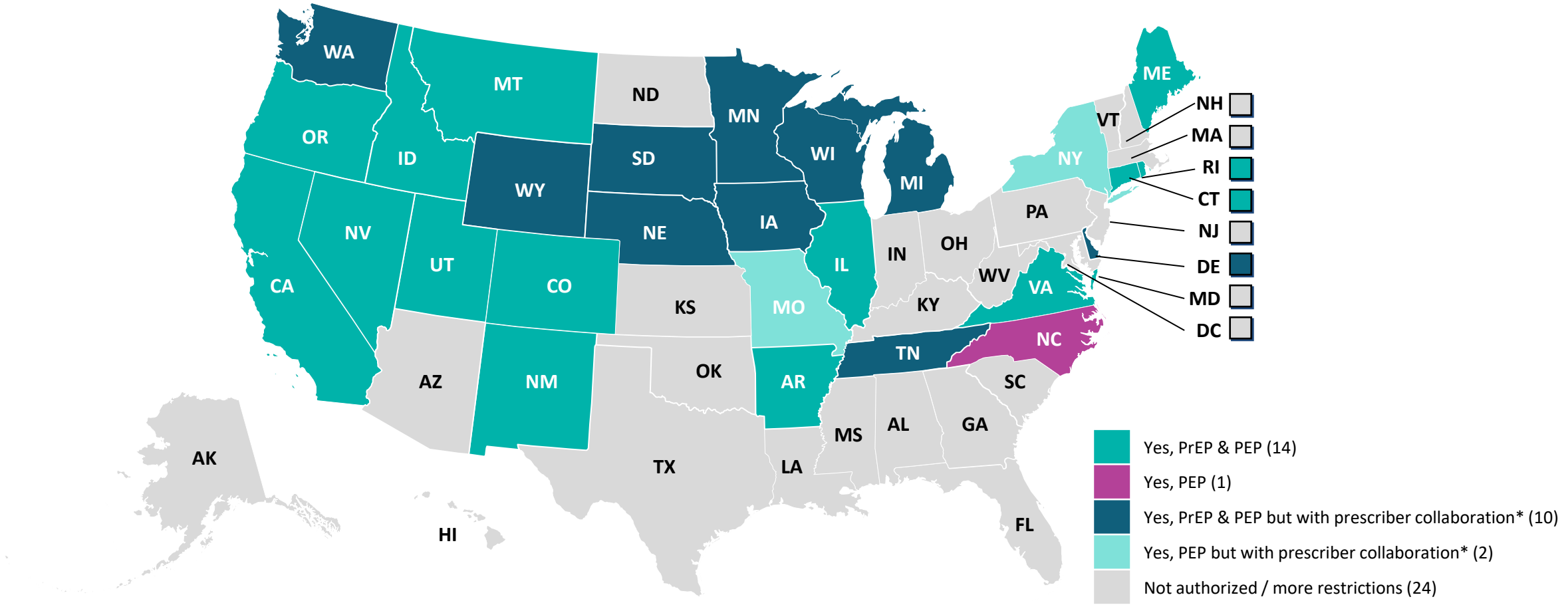
Source: APhA Analysis of State Policies

Can pharmacists test and treat for COVID–19, influenza, respiratory syncytial virus, or streptococcal pharyngitis via prescriptive authority, statewide protocol, or other means?*



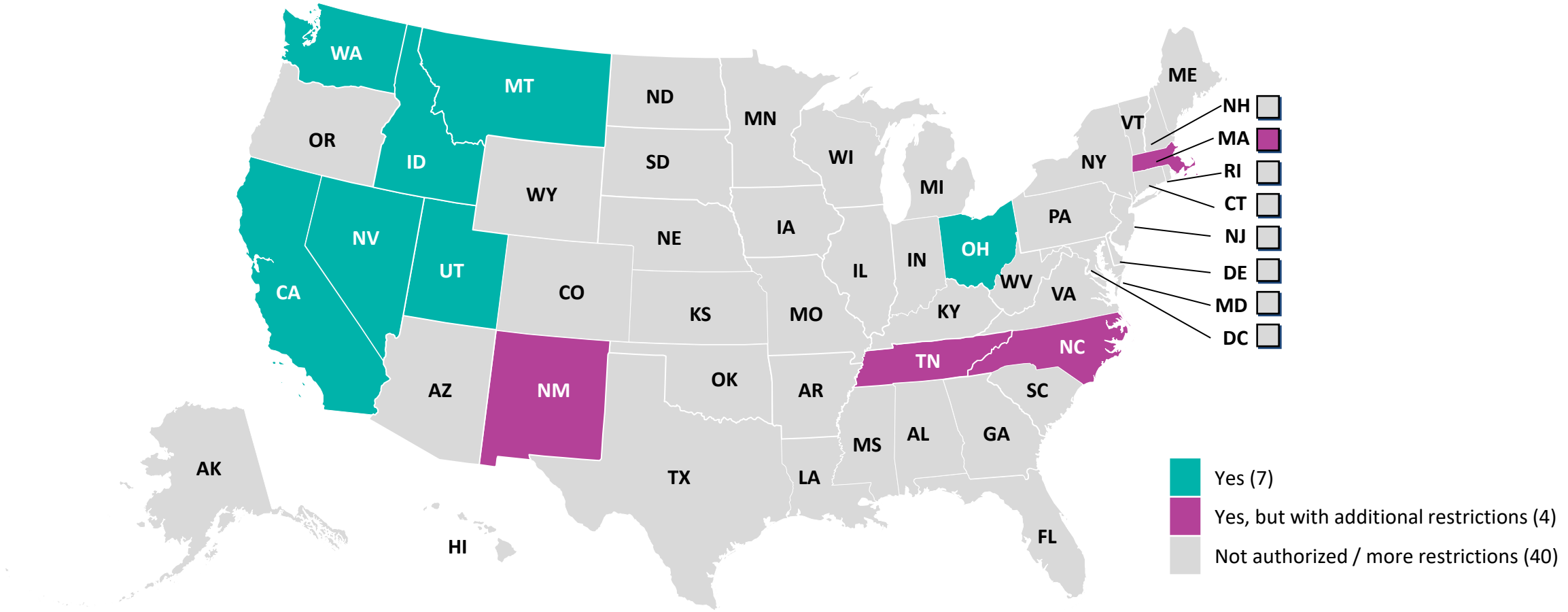
*Limited to collaborative practice agreements or prescriber protocols that allow multiple patients and do not require past prescriber-patient relationship

Can pharmacists furnish HIV PrEP/PEP via prescriptive authority, statewide protocol, or other means?



*Limited to collaborative practice agreements or prescriber protocols that allow multiple patients and do not require past prescriber-patient relationship

Can pharmacists furnish medications for opioid use disorder (MOUD) via prescriptive authority, statewide protocol, or collaborative arrangement?



135th General Assembly Priorities
Ohio Department of Medicaid Update
Ohio Board of Pharmacy Update

STATE UPDATE

135th Ohio General Assembly (2023 – 2024)

705 bills have been introduced

18 bills have been enacted

Less than 3% of bills have been signed into law.

2023 was least productive lawmaking year in Ohio since at least 1955

Updated: Jan. 05, 2024, 11:49 a.m. | Published: Jan. 05, 2024, 11:12 a.m.

135th Ohio General Assembly Schedule (2023 – 2024)

Session Dates:

April 10th and 24th
May 8th and 22nd
June 12th and 26th

General Election on November 7th

Schedule after November 7th = ????

135th Ohio General Assembly (2023 – 2024)

1. **House Bill 33** – State Biennial Operating Bill
2. **House Bill 73 –** Authorize Prescribing of Off-Label Drugs
3. **House Bill 80** – Test And Treat Legislation
4. **House Bill 92** – Canadian Importation Program
5. **House Bill 136/ Senate Bill 95** – Remote Dispensing Pharmacies
6. **House Bill 156 -** White Bagging
7. **House Bill 177** - Co-Pay Accumulators
8. **House Bill 291** – Nonmedical Switching
9. **House Bill 382** – Prescription Drug Readers
10. **House Bill 383** – Cap Cost Sharing of Insulin
11. **Senate Bill 144** – Immunization Administration

House Bill 33: State Biennial Operating Budget

On September 1, 2023, the Ohio Department of Medicaid increased pharmacists dispensing fee by 5.7% over the most recent cost of dispensing survey results.

All other fee increases went into effect on January 1, 2024, or later.

House Bill 73

Authorize Prescribing Off-Label Drugs

Sponsor:

Reps. Jennifer Gross (R-West Chester) and Mike Loychik (R-Cortland)

OPA position:

Oppose

Status:

Passed out of the House; Referred to the Senate Health Committee

House Bill 73

Authorize Prescribing Off-Label Drugs

Authorizes the prescribing of off-label drugs and requires a pharmacist to dispense, except for the following:

- The pharmacist has a moral, ethical, or religious belief or conviction that conflicts with the drug's dispensing;
- The pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the drug or there is a life-threatening contraindication.

The prescriber or pharmacist is NOT required to obtain a test result before issuing the off-label drug's prescription or dispensing the drug for the patient's use at home or for other outpatient treatment.

House Bill 73

Authorize Prescribing Off-Label Drugs

The patient is **NOT REQUIRED** by the bill **to have had a positive screen for a particular disease, illness, or infection** before the prescriber issues the prescription or the pharmacist dispenses the off-label drug.

The patient is **NOT REQUIRED to have been exposed to a disease, illness, or infection** before a prescriber may issue a prescription for the patient's prophylactic use of the off-label drug or a pharmacist dispenses the drug for such use.

Where an in-house treating prescriber issues for a hospital or inpatient facility patient a prescription for an off-label drug and the **drug is neither in stock nor listed on the hospital's or facility's formulary, the hospital or facility pharmacist MUST document in the patient's medical record that a good faith effort was made to find out if the drug is available from another hospital, facility, or distributor.**

House Bill 73

Authorize Prescribing Off-Label Drugs

Next Steps:

The bill was scheduled for a hearing in January. However, our members voiced STRONG opposition to the bill and Chairman Huffman removed the bill from the agenda.

An interested party meeting was held at the end of February, where OPA and other opponents weighed in on the issues with the bill.

House Bill 80

Test and Treat Legislation

Sponsor:

Representative Scott Lipps (R-Franklin)

OPA position:

Support

Committee:

House Provider Services Committee

Status:

Referred to House Health Provider Services Committee

House Bill 80:

Test and Treat Legislation

Would allow pharmacists, in accordance with a statewide protocol, to conduct screenings and tests, and treat for flu, COVID-19 and strep.

We are working on a companion bill in the Senate and will be looking to amend this language to mirror the Senate, which will include RSV and clarification on payment for services.

House Bill 92

Canadian Importation Program

Sponsor:

Representatives Tom Young (R-Dayton) and Nick Santucci (R-Warren)

Committee:

House Public Health Policy Committee

Status:

One hearing on May 3, 2023

House Bill 92

Canadian Importation Program

- Requires the State Board of Pharmacy to develop a program for the importation of prescription drugs from Canada.
- Requires the Board to contract with a third-party entity to establish and administer the program.
- Authorizes the third-party entity to negotiate process and directly purchase from drug manufacturers any prescription drugs, on behalf of the state agencies.

House Bill 136/ Senate Bill 95

Remote Dispensing Pharmacies

Sponsor:

Representatives Brian Miller (R-Ashville) and Adam Holmes (R-Nashport)

Senator Michelle Reynolds (R-Columbus)

Committee:

HB136: House Health Provider Services Committee; SB95: Senate Health Committee

Status:

HB136 – Fourth Hearing on April 2, 2024

SB95 – Four Hearings

House Bill 136/Senate Bill 95

Remote Dispensing Pharmacies

Authorizes the operation of remote dispensing pharmacies and requires the State Board of Pharmacy to regulate them.

Requires a remote dispensing pharmacy to be staffed by two or more pharmacy interns or certified pharmacy technicians and overseen and operated by both a supervising pharmacy and pharmacist through the use of a telepharmacy system.

Requires the Board to adopt rules governing the operation of remote dispensing pharmacies within 18 months of the bill's effective date and, if the Board fails to do so, authorizes the Ohio Attorney General or a county prosecuting attorney to apply for a court order requiring their adoption.

HB 136/SB 95

Remote Dispensing Pharmacies

Language Requests:

1. Allow pharmacists to mail prescriptions to their patients.

2. Allows the Board of Pharmacy to establish a process for providing a waiver for a remote dispensing pharmacy.

3. Allows the Board of Pharmacy, in consultation with the Ohio State Medical Board, to add additional long-acting injectables to the list of LAI's that can be administered by a pharmacist.

4. Add language to ensure that FQHC and FQHC look-alike entities participation in tele pharmacy services are limited to pharmacies attached to their facility properties.

House Bill 156
White Bagging

Sponsor:

Representatives Gayle Manning (R-North Ridgeville) and Scott Oelslager (R-North Canton)

Committee:

House Insurance Committee

Status:

1st Hearing was held on December 6, 2023.

Summary:

The bill would amend the law related to the practice of white bagging.

House Bill 156
White Bagging

White bagging requires a drug to be purchased through the insurers' exclusive specialty pharmacy of choice and then shipped to the patient's physician's office or hospital facility for administration to that specific patient.

This complex requirement interrupts the normal course of treatment and interferes with the physician's ability to provide the best possible care and service to the patient.

House Bill 177

Copay Accumulators

Sponsor:

Representative Susan Manchester (R-Waynesfield)

OPA position:

Support

Committee:

House Public Health Policy Committee

Status:

Voted out of committee on November 15, 2023. Awaiting a floor vote.

Summary:

Bans the practice of Copay Accumulators

House Bill 177
Copay Accumulators

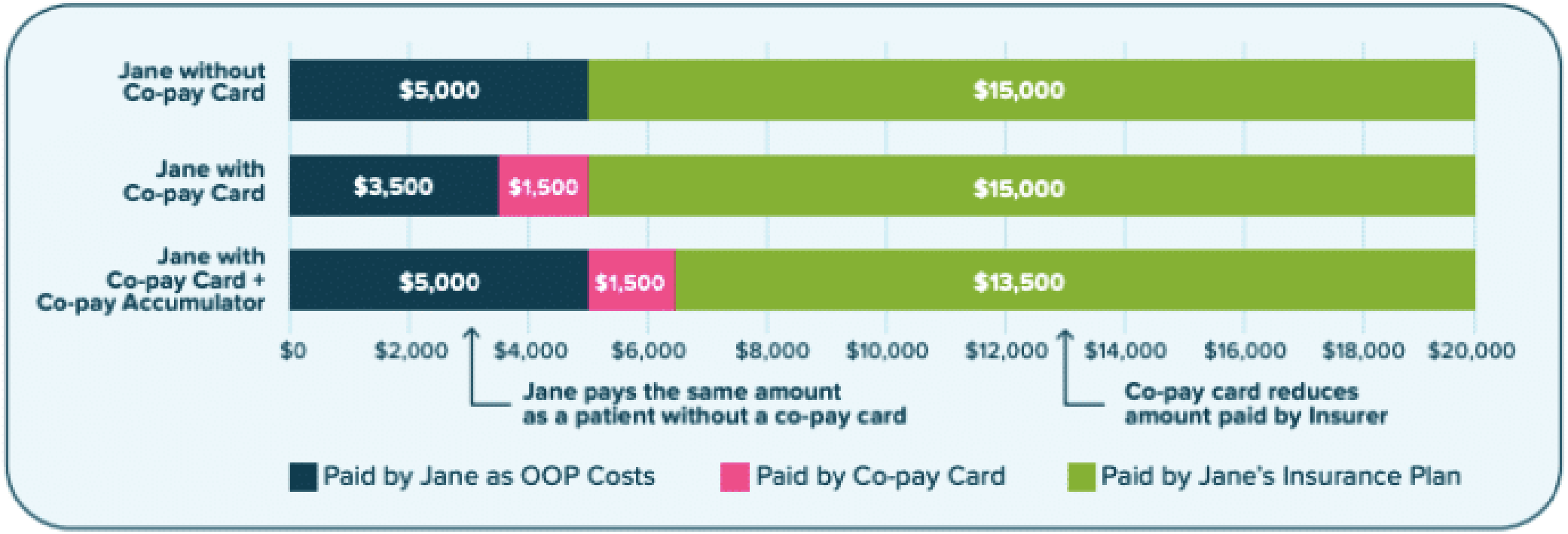
Copay accumulator adjustment policies are schemes from insurers and pharmacy benefit managers (PBMs) that **prevent patient assistance funds from counting toward a patient's out-of-pocket maximums, or deductibles**. Those funds are diverted to the insurer and PBMs pockets.

These policies undermine patient access to life-saving prescription drugs, making it more difficult for people living with serious, complex, chronic illnesses to adhere to a treatment plan. This increases the burden on the entire healthcare system.

House Bill 177

Copay Accumulators

This regulation was adopted during the Trump Administration, and it made copay accumulators legal unless state bans the practice. 16 states have already enacted a ban on this practice.



House Bill 291

Nonmedical Switching

Sponsor:

Representatives Beth Liston (D-Dublin) and Sarah Carruthers (R-Hamilton)

Committee:

House Insurance Committee

Status:

Three Hearings in the House Insurance Committee

House Bill 291

Nonmedical Switching

Prohibits health insurers from taking certain action with respect to prescriptions during a health plan year, including:

- Increasing cost sharing
- Reducing coverage
- Removing drugs from plan formularies

House Bill 382

Prescription Drug Readers

Sponsor:

Representative Richard Brown (D-Canal Winchester)

Committee:

House Insurance Committee

Status:

No hearings.

House Bill 382

Prescription Drug Readers

This is the third introduction of this bill.

The bill requires health benefit plans to coverage prescription drug readers.

Requires that the pharmacy notify the purchaser of the drug notice that a prescription drug reader is available if the pharmacy believes the patient is blind or visually impaired.

House Bill 384

Cap Cost Sharing for Insulin

Sponsor:

Representatives Munira Abdullahi (D-Columbus) and Thomas Hall (R-Middletown)

Committee:

House Insurance Committee

Status:

No hearings.

House Bill 384

Cap Cost Sharing for Insulin

This is the third introduction of this bill.

Sets cost sharing caps for insulin and devices:

- $35 for a thirty-day supply of insulin
- $100 for a thirty-day supply of diabetes care devices

This is regardless of any deductible, copayment, coinsurance or any other cost-sharing requirement under the health benefit plan.

Additionally, an insurer is able to offer a lower cost-sharing requirement.

Senate Bill 144

Immunization Administration

Sponsor:

Senator Mark Romanchuk (R-Ontario)

OPA position:

Support

Committee:

House Health Provider Services

Status:

Passed out of the Senate on December 6, 2023. Referred to the House Health Provider Services Committee. First hearing on April 2, 2024.

Senate Bill 144:

Immunization Administration

The bill authorizes certified pharmacy technicians and registered pharmacy technicians to administer immunizations in the same manners that are pharmacy interns are authorized to practice under current law.

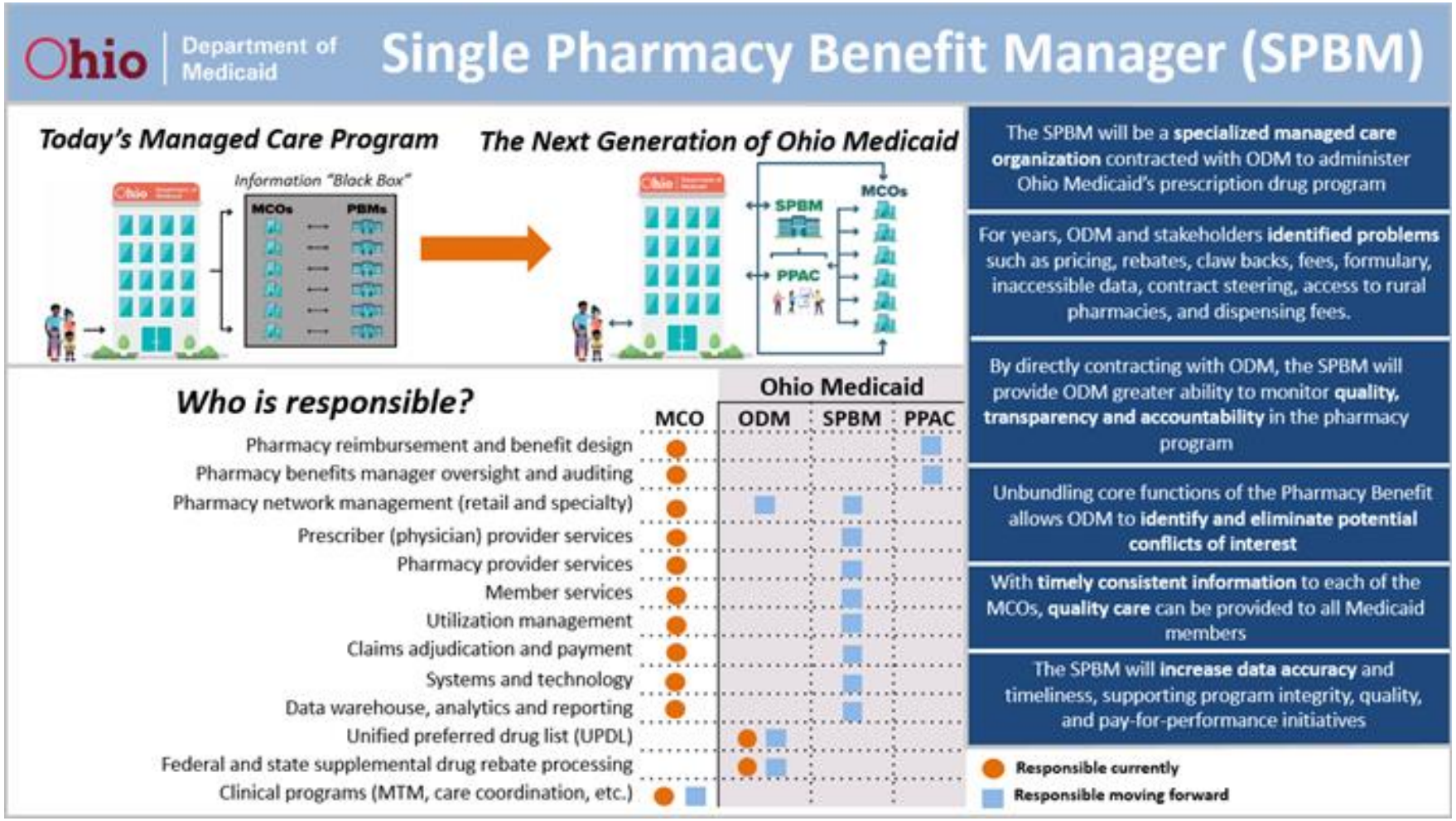
The bill also authorizes pharmacists, interns, and technicians to administer immunizations beginning when a child is five.

Ohio Department of Medicaid Update

- **Next Generation Medicaid Managed Care**
- **Provider Status**

Ohio Department of Medicaid Update

Next Generation Medicaid Managed Care



Ohio Department of Medicaid Update

Provider Status

- Discussions with ODM about ongoing concerns with the Ohio Administrative Rules that were passed to implement provider status, specifically around the challenges with the consult agreement provision.

- May pursue legislation to clarify that a consult agreement is not necessary for pharmacists to be reimbursed for managing drug therapy.

References

CMS. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare. Final Rule. May 9, 2022. Available at: https://public-inspection.federalregister.gov/2022-09375.pdf
Code of Federal Regulations 42 CFR 423.120. Last amended February 12, 2024. Available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-C/section-423.120
CMS. CMS Letter to Plans and Pharmacy Benefit Managers. December 14, 2023. Available at: https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers
APhA Analysis of State Policies

Need More Information?

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