

State Approaches to Managing the Medicaid Pharmacy Benefit

Insights from a National Survey for State Fiscal Years 2023 and 2024

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EXECUTIVE SUMMARY

Millions of Americans rely on Medicaid drug coverage to treat acute illnesses and manage chronic and disabling conditions. Though optional, all states cover pharmacy benefits under Medicaid but administer the benefit in different ways in accordance with federal guidelines. To better understand how states across the country administer the Medicaid pharmacy benefit, as well as states' planned priorities and anticipated future challenges, Health Management Associates (HMA) surveyed all 50 states and the District of Columbia (DC) in 2024. The survey instrument was designed, in part, to collect updated responses to a number of questions posed in the 2019 Medicaid pharmacy study of all 50 states and the District of Columbia, which HMA and the Kaiser Family Foundation (KFF) conducted. The counts of state policies or policy actions in this report include survey responses from 47 states (in this report, DC is identified as a state). Survey highlights follow.

Pharmacy Benefit Administration

Medicaid pharmacy benefit administration has evolved over time to include delivery of pharmacy benefits through managed care organizations (MCOs) in most states and the expanded use of fee-for-service (FFS) pharmacy benefit managers (PBMs) and other vendors to manage one or more pharmacy benefit functions.

Although pharmacy benefit carve ins remain the dominant approach, more states with MCOs are carving out pharmacy (outpatient drugs only) or implementing alternative approaches to administering the pharmacy benefit. Eight states carved the pharmacy benefit out of MCO contracts as of July 1, 2023, double the number of states with a carve out in 2019. A few states are using alternative approaches, such as directing their contracted MCOs to use a single, state-selected PBM. Many MCO states carve out select drugs or drug classes from MCO contracts. They also employ risk mitigation strategies, which may include select drug carve outs, to limit their MCOs' financial risk for high-cost drugs, including new medications with unpredictable costs due to a lack of historical experience.

States increasingly rely on PBMs to administer the FFS pharmacy benefit. As of July 1, 2023, 33 states reported contracting with a PBM such as Magellan, OptumRx, or Conduent. More than half of all states also outsource other functions, such as clinical activities, rate setting, and rebate reporting, to non-PBM vendors, including schools of pharmacy, accounting and consulting firms, fiscal agents, and actuarial firms.

More than half of MCO states that carve in pharmacy benefits (17 of 30 responding MCO states) reported having PBM transparency reporting requirements in place as of July 1, 2023, and 25 MCO states prohibit spread pricing in MCO PBM contracts altogether. This is more than double the number of states reporting prohibitions on spread pricing in 2019.



Most states (34 of the 47 responding states) use comparative effectiveness studies when making coverage decisions—most commonly studies from the Institute for Clinical Economic Review (ICER) and the Drug Effectiveness Review Project (DERP)—but also other drug effectiveness studies, compendia, and clinical trial information.

Cost Containment and Utilization Control Strategies

Because federal law requires states to cover all drugs from manufacturers that have entered into a National Drug Rebate Agreement, states have limited ability to control drug costs using formulary management. Instead, states apply a combination of payment strategies and utilization management protocols to manage pharmacy expenditures.

Nearly all responding states (44) reported having a preferred drug list (PDL) in place for FFS prescriptions as of July 1, 2023. A PDL is a list of "preferred" medications typically having a lower net cost to the state (after rebates) that providers are encouraged to select from when prescribing.

The number of MCO states adopting a uniform PDL that requires all MCOs to cover the same drugs as the state continues to grow. Nearly two-thirds of responding MCO states that do not carve out the pharmacy benefit (19 of 30 states) reported having a uniform PDL for some or all classes as of July 1, 2023. One state reported that it intends to implement a single PDL effective July 1, 2024, and two states reported plans to expand a uniform PDL to additional classes.

Though states commonly use prior authorization (PA) to manage drug utilization, more than three-fifths of responding states (29 of 46 states and DC) reported statutory limitation(s) on the ability of the Medicaid agency to apply utilization controls to certain drugs or drug classes in the FFS pharmacy benefit.

States also play an active role in managing MCO clinical protocols or medical necessity criteria, with 22 out of 30 responding MCO pharmacy carve-in states reporting that they require uniform clinical protocols for some or all drugs with clinical criteria. Approximately one-half of responding MCO carve-in states also require review and approval of MCOs' PA criteria (15 of 30 states) and step therapy criteria (14 of 30 states).

Most states have policies in place to manage drugs reimbursed through the medical benefit (i.e., physician administered outpatient drugs), and coverage criteria are similar when a drug is also reimbursable through the pharmacy benefit. Most prescription drugs that Medicaid covers are reimbursed through the pharmacy benefit, but some are reimbursed through the medical benefit, such as medications administered in an office-based setting, infusion facility, or hospital.

Payment, Supplemental Rebates and Rebate Management

States employ a variety of payment policies and strategies to reduce the net cost of pharmacy drugs to the state.



All states that reported having a PDL in place for FFS prescriptions (44 of 47) reported having supplemental rebate agreements in place for preferred agents. To leverage their negotiating power, three-quarters of these states participate in an interstate purchasing pool.

Fewer than half of the responding states (21 of 47) reported requiring FFS pharmacy copayments for non-exempt adults as of July 1, 2023, a notable decrease from 2019, although four states without copayments planned to resume copayment requirements that had been waived during the COVID-19 public health emergency in state fiscal year (FY) 2024 or FY 2025.

Nine states reported having a value-based arrangement (VBA) in place as of July 1, 2023, up from only two states in 2019. VBAs are contracting agreements between manufacturers and payers that tie reimbursement to specified outcomes.

A total of 34 states reported having a Medicaid policy in place to reimburse pharmacists for clinical services. Common clinical services reimbursed include vaccine administration, point-of-care testing, COVID-related services, prescribing under a collaborative practice agreement or statewide protocol, and counseling for smoking cessation.

State Policies for Selected Drugs/Drug Classes

More than half of responding states (23 of 43) reported that they were pursuing or exploring the potential for value-based arrangements to address coverage of new gene and cell therapies that come at a high cost to Medicaid and other payers but are often curative.

Almost all states (43 of 46) reported no prior authorization (PA) requirements as of July 1, 2023, for Truvada, an HIV pre-exposure prophylaxis (PrEP) medication used to prevent individuals from contracting HIV.

Almost all states (44 of 47) cover or intend to cover over the counter (OTC) Narcan, a lifesaving prescription drug that can reverse an opioid overdose. The Food and Drug Administration (FDA) first approved the OTC version of Narcan in May 2023. At the time of the survey (prior to market availability), nearly two-thirds of responding states (30 of 47) reported plans to cover Opill, the first OTC daily oral contraceptive pill, approved by the FDA in July 2023.

Challenges and Priorities in FY 2025 and Beyond

Nearly three-quarters of the responding states reported that managing the Medicaid pharmacy budget, including the development of policies and strategies for managing new high-cost therapies, was a top priority. Other top priorities cited by multiple states included: developing, negotiating, or implementing a value-based arrangement; PBM management or implementation of a single PBM for all MCOs; and considering coverage of GLP-1 anti-obesity medications.



INTRODUCTION

Millions of Americans rely on Medicaid drug coverage to treat acute illnesses and manage chronic and disabling conditions. (Beneficiaries dually eligible for Medicaid and Medicare, however, receive drug coverage through Medicare.) Though optional, all states cover pharmacy benefits under Medicaid but administer the benefit in different ways within federal guidelines. To better understand how states across the country administer the Medicaid pharmacy benefit, as well as states' planned priorities and anticipated future challenges, Health Management Associates (HMA) conducted a survey of all 50 states and the District of Columbia (DC) in 2024.

Overview of Survey Methods

Report findings are drawn from a survey of Medicaid officials in all 50 states and the District of Columbia that HMA conducted in December 2023 through April 2024. HMA sent the survey each state Medicaid director and Medicaid pharmacy director in December 2023. The survey instrument was designed in part to collect updated responses to a number of questions posed in the 2019 Medicaid pharmacy survey of all 50 states and the District of Columbia conducted by HMA and KFF.² The District of Columbia is counted as a state in this report, and the counts of state policies or policy actions throughout this report include survey responses from 46 states and DC for a total of 47. Florida, Kansas, Minnesota, and Ohio did not respond. This report examines Medicaid pharmacy policies in place or implemented as of July 1, 2023, and policy changes for which a definite decision has been made to implement in state fiscal year (FY) 2024, which for most states began on July 1, 2023). Policies adopted for the upcoming year are occasionally delayed or not implemented for reasons related to legal, fiscal, administrative, systems, or political considerations, or because of delays in approval from CMS.

PHARMACY BENEFIT ADMINISTRATION

States may administer the Medicaid pharmacy benefit on their own or through contracted external vendors, such as pharmacy benefit managers (PBMs), to carry out one or more functions. Pharmacy benefit administration also has evolved to include delivery through managed care organizations (MCOs) in most states. Drug utilization review (DUR) boards and pharmacy and therapeutics (P&T) committees also perform oversight and consultative roles. The decisions these vendors, MCOs, boards, and committees make have important implications for Medicaid pharmacy access, utilization management, and costs.



Managed Care's Role in Administering Pharmacy Benefits

In many states, managed care delivery systems play a major role in administering Medicaid benefits, including prescription drugs. As of July 1, 2023, 41 states had comprehensive, risk-based contracts with one or more MCO(s).³ States with MCOs may "carve in" the pharmacy benefit by including outpatient drugs as a covered benefit and placing MCOs at risk for their costs, "carve out" the pharmacy benefit by excluding outpatient drugs from the MCO contract and covering them in FFS or carve in some outpatient drugs and carve out others. A few states use alternative approaches, such as directing their contracted MCOs to use a single state-selected PBM (e.g., Kentucky)⁴ or carving out pharmacy to a prepaid ambulatory health plan or prepaid ambulatory health plan (PAHP) serving as a single PBM for all MCOs (e.g., Ohio and Tennessee).⁵

Carve In versus Carve Out of the Outpatient Pharmacy Benefit

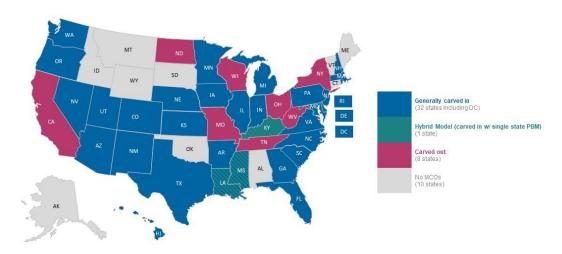
Changes made in the Affordable Care Act (ACA) encouraged more states to carve in the pharmacy benefit to their MCO contracts by allowing states to capture federal rebates for drugs covered under managed care. A total of 33 states carve pharmacy benefits into MCO contracts as of July 1, 2023 (see Figure 1). Oklahoma intends to carve a portion of the pharmacy benefit into MCO contracts beginning in 2024. When pharmacy is carved in, states often build administrative and clinical requirements into the MCO contract to manage and oversee the pharmacy benefit, as discussed in more detail later in this report.

Although pharmacy benefit carve ins remain the dominant approach, more states with MCOs are carving out pharmacy (outpatient drugs only) or implementing alternative approaches to administering the pharmacy benefit. There were eight carve-out states as of July 1, 2023 (California, Missouri, North Dakota, New York, Ohio⁸, Tennessee, Wisconsin, and West Virginia)—double the number in 2019,⁹ with California, New York, and Ohio most recently implementing a pharmacy carve out.¹⁰

One MCO state, Kentucky, has implemented a "hybrid" model for managing the prescription drug benefit and two MCO states—Louisiana and Mississippi—will be implementing a hybrid model after July 1, 2023. Under the hybrid model, pharmacy remains carved in but the state selects a single PBM that MCOs must use, and prescription drug claims are processed according to a uniform preferred drug list (PDL). When states move away from traditional pharmacy carve ins, they often are looking for opportunities to save costs by increasing supplemental rebates, improving transparency and oversight, and streamlining processes and prior authorization/step therapy policies across MCOs.¹¹



FIGURE 1
State Coverage of Outpatient Pharmacy Benefits in MCO Contracts, as of July 1, 2023



NOTE: ID's Medicaid-Medicare Coordinated Plan has been recategorized by CMS as an MCO but is not counted here as such since it is secondary to Medicare. Publicly available data used to document MCO coverage of outpatient pharmacy benefits in states that did not respond to the survey or this question (FL, KS, MN, OH). KY has implemented a "riybrid" model where MCOs remain at risk for the pharmacy benefit but contract with the state's PBM to process claims (according to uniform PDL). LA and MS will implement a hybrid model after July 1, 2023.

Many states carve out select drugs, or drug classes, from MCO contracts. We asked MCO states about their use of carve outs for certain drug products/classes, inclusive of physician-administered drugs¹² covered under the medical benefit. In all, 19 states reported carving out one or more drug classes or select agents within a drug class (see Table 1 and Appendix Table 1).¹³ Of those states, 13 reported using the carve-out as part of a risk mitigation strategy, as discussed in more detail below. ¹⁴ The drug classes and/or products most commonly carved out are hemophilia drugs, spinal muscular atrophy agents (e.g., Zolgensma, Spinraza), chimeric antigen receptor T-cell (CAR-T) therapies¹⁵, and mental health drugs. States also reported carving out gene and cell therapies in general, hepatitis C antivirals, HIV/AIDS antiretrovirals, medications for opioid use disorder (OUD), anticonvulsants, COVID vaccines, and other high-cost drugs.

Table 1: Drug Products or Classes Carved Out of MCO Benefit, July 1, 2023 (37 MCO States Responding)		
Drug Class	# of States	States
Hemophilia	10	AZ, CA, IN, MI, NH, NJ, TX, UT, WA, WV
Spinal Muscular Atrophy Agents	10	AZ, CO, HI, IA, IN, MI, NH, NV, TX, WA
Oncology/CAR T-Cell Therapies	8	AZ, CO, IN, MI, NY, SC, TX, WA
Mental Health	5	CA, MD, MI, OR, UT
Hepatitis C Antivirals	4	IN, MI, TX, WA
HIV/AIDS Antiretrovirals	4	CA, DC, MI, WA
Medications for OUD	4	CA, MD, MI, UT
Other	8	IA, IN, MI, NH, SC, TX, UT, WA



States reported few changes to drug product/class carve outs planned in FY 2024. Most MCO states reported no plans for full or partial drug carve out changes in FY 2024 (21 states). Three states (Delaware, Louisiana, and Washington) intend to expand the number of drugs carved out, and Texas reported plans to update its pharmacy carve-in and carve-out policies. New Hampshire is transitioning its MCO pharmacy risk mitigation strategy from a drug carve out to a high-cost pharmacy risk pool. The rationale for expanding the number of drugs carved out in FY 2024 varies. For example, Delaware's planned carve out is limited to high-cost medications that will be subject to future value-based arrangements (VBAs), such as gene therapies. Washington will be reviewing drugs against its state-established criteria, as it does biannually, to determine which new drugs will be subject to a carve out. Nine states reported that carve in or carve out changes for FY 2024 had yet to be determined. The states reported that carve in or carve out changes for FY 2024 had yet to be determined.

Risk Mitigation Strategies

Some specialty drugs, such as cell and gene therapies, can cost more than \$1 million dollars for a full course of treatment. MCO states may implement risk mitigation strategies to limit MCOs' financial risk and address the uncertainty associated with covering high-cost drugs, including new drugs with unpredictable costs due to a lack of historical experience, and drugs used to treat rare diseases. As of July 1, 2023, 27 states reported having at least one MCO risk mitigation strategy in place, with select drug carve outs and risk corridors being the most commonly reported approaches (see Table 2). 19

MCO risk mitigation strategies commonly apply to high-cost, specialty drugs. Drugs frequently reported as being the target of a risk mitigation strategy are spinal muscular atrophy drugs (8 states²⁰), hemophilia drugs (7 states²¹), hepatitis C drugs (6 states²²), CAR-T therapies (5 states²³), and Duchenne muscular dystrophy drugs (3 states²⁴). Some states identified specific drug products or drug classes for risk mitigation, whereas others reported using established criteria, such as costs in excess of an annual dollar threshold (e.g., \$300,000–\$500,000) and apply risk mitigation to any drug that meets those criteria.

Risk Mitigation Strategies

Drug Carve-out. Drug is carved out of MCO covered benefits and paid through the FFS delivery system, eliminating any MCO risk.

Risk Corridors. State and MCO share risk by limiting the amount of potential losses (and potential savings) beyond a set threshold.

Risk Pools. A portion of each MCO's capitation rates are paid into the pool, and pool funds are re-distributed based on utilization of the drug.

Reinsurance. The state protects MCOs from higher than expected costs, either for a single individual, in the aggregate, or both. The state pays all or a portion of the drug costs above an established threshold.

Kick Payments/Non-risk Arrangement. Drug is covered by MCOs, but MCOs are not at risk for the cost. State makes separate payment to reimburse MCOs the cost of the drug.

Four states are making changes to their risk mitigation strategies in FY 2024, including the establishment of a new risk pool (New Hampshire), a gene therapy carve out (Texas), and an increase in the annual cost threshold for drugs currently excluded from risk-based capitation payments (Maryland). Oregon and Texas reported that they will discontinue risk mitigation policies for hepatitis C drugs in FY 2024, with Oregon citing the reduction and stabilization of hepatitis C drug costs as the rationale for this modification.



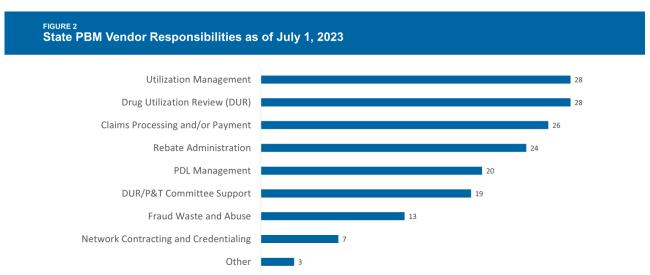
Table 2. Risk Mitigation Strategies Used in MCO Contracts, July 1, 2023		
Strategy	# of States	States (30 MCO Carve-in States Responding)
Drug Carve outs	13	CO, DC, HI, IA, IN, MI, NH, NV, OR, SC, TX, UT, WA
Risk Corridors	11	GA, HI, IN, LA, MA, MS, NC, NJ, NV, OR, RI
Risk Pools	5	DE, KY, LA, NE, UT
Reinsurance	3	AZ, RI, VA
Kick Payments	1	VA
Other	5	MA, MD, NV, OR, PA
None	3	AR, IL, NM
NOTE: IN and RI reported risk corridors that apply to all covered benefits, inclusive of pharmacy.		

The Role of PBMs and Other Vendors in Administering Pharmacy Benefits

States and MCOs may contract with external vendors like PBMs to manage or administer the pharmacy benefit. PBMs offer a variety of services, including claims adjudication, development and maintenance of PDLs, negotiated supplemental rebates and pharmacy reimbursement, contracts with and management of pharmacy networks, and DUR.²⁵

Pharmacy Benefit Managers and Other Vendors in FFS

States increasingly rely on pharmacy benefit managers (PBMs) to administer the FFS pharmacy benefit. As of July 1, 2023, 33 states reported contracting with a PBM such as Magellan, OptumRx, or Conduent. ²⁶ The most frequently reported functions that PBMs performed on behalf of state Medicaid agencies were utilization management, DUR, claims processing and/or payment, and rebate administration activities (see Figure 2 and Appendix Table 2).



Notes: States that reported utilizing PBMs for claims processing and review functions were counted in claims payment. Other functions reported by states include third party liability and coordination of benefits activities, maximum allowable cost (MAC) pricing, and help desk and call center operations.

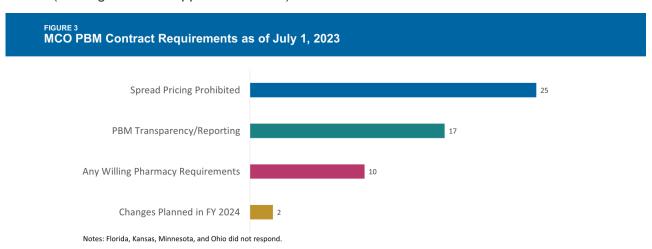


More than half of all states also outsource other functions to non-PBM vendors, including schools of pharmacy, accounting and consulting firms, fiscal agents, and actuarial firms. Functions fulfilled by these vendors include but are not limited to clinical activities, DUR, rate setting, P&T committee support, rebate reporting, and PDL management.

MCO Contracts with PBMs and State Requirements

As MCO/PBM contracting arrangements have become more common, so have concerns about transparency, access, and inflated Medicaid drug costs.²⁷ In particular, the practice of spread pricing—that is, when a PBM charges the MCO more for the drug than the amount the PBM pays to a pharmacy and retains the difference²⁸—has resulted in closer scrutiny of PBM arrangements and more state and federal oversight.²⁹ In the May 2023 Misclassification of Drugs proposed rule (not yet finalized at the time of this report), CMS sought to address select issues in support of PBM transparency. The proposed rule requires PBMs that contract with MCOs to separately report incurred claims for drugs, dispensing fees, and administrative fees to help MCOs capture information necessary for accurate medical loss ratio (MLR) calculations.

Meanwhile, many states have already sought to promote PBM transparency and/or prevent or monitor spread pricing within MCO/PBM contracts. Of the survey respondents, 30 MCO states that carve in pharmacy responded to survey questions about PBM transparency and spread pricing requirements.³⁰ Of these states, 17 (including DC) reported having PBM transparency reporting requirements in place as of July 1, 2023, and 25 states (including DC) prohibit spread pricing in MCO PBM contracts altogether—more than double the number of states reporting prohibitions on spread pricing in 2019³¹ (see Figure 3 and Appendix Table 3).



In addition, 10 MCO states with pharmacy carve ins reported having "any willing" pharmacy requirements in place for FY 2024.³² Any willing pharmacy provisions require MCOs and their contracted PBMs, if applicable, to permit any pharmacies willing to accept the contract's standard terms and conditions to participate in the network.



DUR Board and P&T Committee Policies

Federal DUR Board Requirements. Under federal Medicaid law, state DUR boards are responsible for ongoing review and evaluation of state DUR standards and activities, including both prospective DUR (ProDUR) and retrospective DUR (RetroDUR). They also help identify and develop educational topics for prescribers as needed to improve proscribing and dispensing practices.³³ According to federal fiscal year (FFY) 2022 data, DUR programs in 48 states also reviewed DUR program estimated cost savings or cost avoidance.³⁴

P&T Committees. Many states have P&T committees that review therapeutic drug classes for PDL placement and coverage decisions. Of the 47 responding states, 38 reported having a P&T committee as of July 1, 2023, including two states (Arkansas and Oregon) reporting a "combined" DUR board and P&T committee and two states (Texas and Vermont) reporting that their DUR boards perform the functions of a P&T committee. Take their own. FFY 2022 federal data indicates that at least one MCO in 27 MCO states (including Florida, Minnesota, and Ohio, which did not participate in this survey) had its own DUR board.

Conflict-of-Interest Policies. Federal regulations³⁷ require DUR boards to consist of pharmacists, physicians, and other healthcare professionals with applicable knowledge and expertise but otherwise leave states with flexibility for

ProDUR and RetroDUR Defined

ProDUR is performed at the point of sale (POS), prior to dispensing, using electronic monitoring systems to screen prescriptions for red flags, such as therapeutic duplication, drug-disease interactions and contraindications, incorrect dosage or duration of treatment, and clinical misuse or abuse.

RetroDUR occurs after a prescription has been dispensed and involves the ongoing and periodic review of claims data to identify patterns of fraud, abuse, gross overuse, and medically unnecessary care, as well as implementation of corrective actions.

determining board operations, including whether to adopt conflict-of-interest policies. Only four of 46 responding states reported having no conflict-of-interest policy in place for the DUR board as of July 1, 2023.³⁸ Similarly, only four of the 38 states that reported having a P&T committee reported having no conflict-of-interest policy in place.³⁹ Three states had no conflict-of-interest policy for either entity (Missouri, North Carolina, and Rhode Island).⁴⁰

Roles and Responsibilities. States vary in the roles and responsibilities they assign to their DUR boards and P&T committees, but often use them to establish or review pharmacy utilization management tools. Except for the review of new drugs for PDL placement carried out by a P&T committee in more than half the reporting states, other activities (i.e., review of prior authorization [PA] criteria, step therapy criteria, and orphan/expedited drugs) were more evenly divided among DUR boards, P&T committees, Medicaid agencies, and other entities (see Table 3 and Appendix Table 4). States reporting that "other" entities were responsible for at least one review activity usually have more than one entity that is responsible for reviews, sometimes including state contractors. However, Arizona reported that its PBM develops step therapy and PA criteria, Hawaii reported that it administers DUR functions only for a small transplant program and a dental drug program, and Louisiana reported that its DUR board reviews PA criteria that the University of Louisiana at Monroe has developed.



Table 3: Responsible Entity for Reviewing New PDL Drugs, Step Therapy Criteria, PA Criteria and Orphan/FDA Expedited Review Drugs, July 1, 2023
(47 States Responding)

Entity	New PDL Drugs	Step Therapy Criteria	PA Criteria	Orphan/ Expedited Review Drugs
DUR Board	6	11	13	9
P&T Committee	25	5	5	8
Medicaid Agency	6	18	18	20
Other	8	9	11	10
N/A	2*	4+	0	0
NOTES: *States that reported they had no PDL. +States that reported they had no step therapy.				

Most states use comparative effectiveness studies to make coverage decisions. Nearly three-quarters of the responding states (34 of 46⁴¹ states) report reviewing comparative effectiveness studies when determining coverage criteria, most commonly, studies from the Institute for Clinical Economic Review (ICER) and the Drug Effectiveness Review Project (DERP), but also other drug effectiveness studies, compendia, and clinical trial information in some states.

COST CONTAINMENT AND UTILIZATION CONTROL STRATEGIES

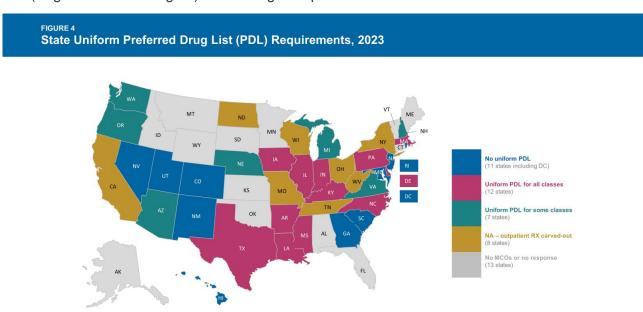
The federal Medicaid Drug Rebate Program requires state Medicaid program coverage of all drugs from manufacturers that have entered into a National Drug Rebate Agreement, a pricing agreement for the Section 340B Drug Pricing Program and an agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule. This requirement limits states ability to control drug costs using formulary management. Instead, states apply a combination of payment strategies and utilization management protocols to manage pharmacy expenditures.

Preferred Drug Lists

A PDL is a list of "preferred" medications, which typically have a lower net cost to the state (after rebates), that providers are encouraged to select from when prescribing. Though "non-preferred" drugs may be prescribed, the state may require providers to submit PA requests or impose a higher copayment on beneficiaries. **Nearly all responding states (44 of 47) reported having a PDL in place for FFS prescriptions as of July 1, 2023.** In most states (25 of 44 responding states with PDLs), P&T Committees are responsible for determining PDL placement for new drugs. A smaller number of states reported that the Medicaid agency (6 states), the DUR board (6 states), or a combination of entities (8 states) is responsible for the review of new drugs for inclusion on the PDL (see Table 3). Most states review their PDLs at least annually, including 21 states reporting annual reviews and 10 states reporting quarterly reviews (see Appendix 5).



The number of MCO states adopting a uniform PDL that requires all MCOs to cover the same drugs as the state continues to grow. In a previous survey of state Medicaid programs, 16 MCO states reported having a uniform PDL across FFS and managed care in FY 2019.⁴⁴ In this survey, nearly two-thirds of responding MCO states that do not carve out the pharmacy benefit (19 of 30 states) reported having a uniform PDL for some or all classes as of July 1, 2023; only 11 states reported no uniform PDL requirement (Figure 4). South Carolina is implementing a single PDL effective July 1, 2024, to promote use of the most cost-effective medications in a drug class, reduce administrative burden for providers, and improve continuity of care as Medicaid enrollees change MCOs.⁴⁵ Delaware, which currently has a uniform PDL for all classes, reported plans to apply utilization management to the top 25 prescribed oncology medications covered under both the pharmacy and medical benefit. Two states (Virginia and Washington) are looking to expand their uniform PDL to additional classes.



Note: Responses as of July 1, 2023. SC reported plans to implement a uniform PDL for all classes effective July 1, 2024. FL, KS, MN, OH did not respond to the survey. Publicly available data used to document outpatient Rx carve out in OH.

Though not all states utilize a uniform PDL, many states do review and approve MCOs' PDL changes. Half of the responding MCO states that do not carve out outpatient drugs (15 of 30 MCO states)⁴⁶ reported that the DUR board, P&T committee, or other state entity reviews and/or approves MCO PDL changes, and three states reported that review and approval requirements vary by drug class.⁴⁷



Prior Authorization and Step Therapy

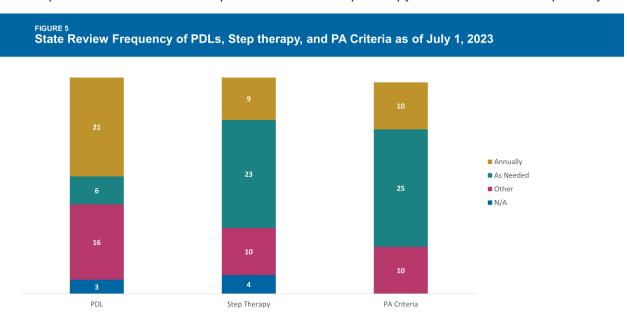
The entity responsible for developing PA or step therapy criteria varies across the states. States commonly use PA to manage drug utilization, requiring prescribers to obtain approval from the state Medicaid agency (or its contractor) before a particular drug can be dispensed. Many states also impose step therapy requirements. Most commonly, states (18) reported that the Medicaid agency is responsible for developing PA and step therapy criteria (see Table 3). Fewer states use their DUR board to fulfill this role (13 for PA and 11 for step therapy) or their P&T committee (5 for both PA and step therapy).⁴⁸

Step Therapy Defined

Step therapy is a utilizationmanagement strategy that uses tiered treatment pathways for defined conditions. Patients (and their physicians) who seek approval for restricted therapies must document unsuccessful attempts at treatment with less expensive therapies in earlier "steps."

Most states review PA and step therapy criteria less frequently than PDLs. Most responding states reported reviewing both step

therapy (23 states) and PA criteria (26 states) as needed (Figure 5 and Appendix Table 5). The most common response for other review frequencies for both step therapy and PA criteria was quarterly.



Notes: Three responding states do not have a PDL. Four responding states do not have step therapy. CA did not report PDL review frequency, GA did not report Step Therapy review frequency and GA and NM did not report PA criteria review frequency. FL, KS, MN, and OH did not respond.



Most states subject new drugs to PA prior to DUR board and/or P&T committee review.

California, Delaware, Georgia, South Dakota, Texas, and two other states without a PDL (Hawaii, and New Mexico) reported no PA requirement for new drugs, whereas all other responding states reported that PA was always (13 states) or sometimes (27 states) required. For states answering "sometimes," the most common reason cited for imposing PA (by 14 states) was if the new drug was in an existing PDL class (see Table 4). In this circumstance, failure to impose PA could have a detrimental impact on the supplemental rebates earned on existing PDL-preferred agents. A total of 10 states reported imposing PA on high-cost drugs or those exceeding a specified cost threshold, 10 states reported imposing PA to address clinical indications or to avoid abuse or misuse, and five states mentioned "other" reasons.

- Alaska places new drugs on its interim PA list for at least six months to allow time for review.
- New Hampshire imposes PA for all new drugs except for oncology and HIV drugs and narcotic reversal agents.
- Oregon imposes PA only drugs that are FDA-approved only to treat conditions that are unfunded on Oregon's prioritized list of health services (under the state's 1115 waiver).
- Pennsylvania imposes PA on new drugs approved by the FDA through the accelerated approval, priority review, breakthrough therapy, or fast track programs.

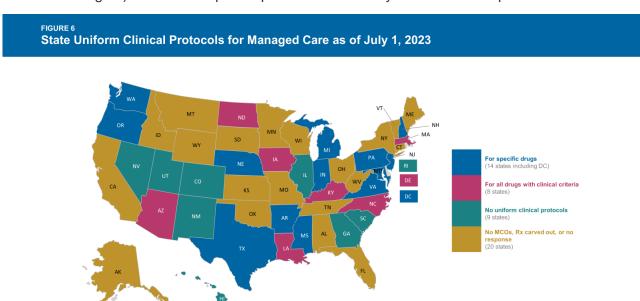
Table 4. New Drug PA Reasons, July 1, 2023		
Condition for PA	# of States	States
Drug is in a current PDL class	14	AL, AR, CO, DC, IA, ID, MI, MS, ND, NV, NY, OR, WI, WV
Cost threshold/high-cost drugs	10	AR, IN, MD, ND, NV, OR, RI, SC, UT, WV
Needed due to clinical indication or avoid abuse or misuse	10	ID, KY, MI, NC, NJ, RI, SC, UT, WV, WY
Orphan drugs for rare diseases	3	AR, PA, UT
Other	4	AK, NH, OR, PA
Note: Responses are from the 27 states that reported not automatically subjecting all drugs to PA before initial review, sometimes reporting more than one condition for PA.		

Though states often apply utilization management protocols like PA or step therapy to more costly, non-preferred drugs to help manage the overall cost of prescription drugs, a number of states have enacted statutory prohibitions on utilization management for select drug classes and/or diseases (see Table 5). Of the responding states, three-fifths (28 of 47) reported statutory limitation(s) on the ability of the Medicaid agency to apply utilization controls for certain drugs or drug classes in the FFS pharmacy benefit. Some states noted that the statutory limitation prevents specific drug classes from being included on the PDL or the selection of preferred drugs from within a class. In contrast, Georgia requires step therapy of one preferred drug before using a non-preferred drug for mental health conditions. More than half of the states with a statutory limitation on utilization controls also apply the limitation to MCOs.



Table 5: Statutory Prohibitions on Utilization Management, July 1, 2023		
Protected Drug Classes/ Disease States	# of States	States (47 States Responding)
HIV/AIDS	14	AL, CO, CT, HI, LA, MD, MI, NC, ND, NJ, NV, RI, TX, WA
Medication Assisted Treatment and/or Substance Use Disorder	11	AR, DC, IL, KY, MI, NJ, NM, NY, OR, TX, VT
Mental Health	10	CT, HI, IN, MI, MO, ND, NE, NM, OR, UT
Anticonvulsants	6	CT, IL, MI, ND, NE, TX
Immunosuppressants	6	HI, MI, ND, NV, RI, UT
Cancer	5	MI, NC, ND, TN, TX
Sickle Cell	3	NC, NV, TX
Other*	2	HI, NV
Note: Other drugs include drugs for the treatment of hepatitis C and hemophilia		

Many states actively manage MCO clinical protocols or medical necessity criteria: 21 of 30 responding MCO pharmacy carve-in states and North Dakota reported requiring uniform clinical protocols for some or all drugs with clinical criteria and nine states reported no uniform clinical criteria for MCOs (Figure 6). Two states reported plans to impose uniform protocols on at least one drug or drug class in FY 2024 (DC and Washington). No states reported plans to remove any uniform clinical protocols.



Note: Florida, Kansas, Minnesota, and Ohio did not respond.

Many states closely monitor MCO utilization management controls for prescription drugs. About half of responding MCO states that do not carve out outpatient drugs require review and approval of MCOs' PA criteria (15 of 30 states) ⁴⁹ and step therapy criteria (14 of 30 states), ⁵⁰ and three states report that review and approval requirements vary by drug class for step therapy criteria and PA criteria. ⁵¹



Most states have policies in place to manage drugs reimbursed through the medical benefit (i.e., physician-administered outpatient drugs), and coverage criteria are similar when the same drug can also be reimbursed through the pharmacy benefit. Most prescription drugs that Medicaid covers are dispensed by a retail pharmacy or other outpatient pharmacy and reimbursed through the pharmacy benefit. Other outpatient drugs, including many specialty drugs, are reimbursed through the medical benefit when administered by a health care provider in a physician's office or other outpatient clinical setting. These "physician-administered drugs" are typically drugs that are infused or injected.⁵²

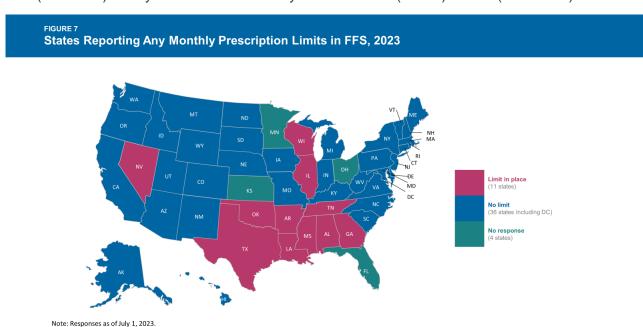
The vast majority of responding states (40 of 47) reported applying utilization controls like PA or step therapy to drugs reimbursed through the medical benefit. Depending on how the drug is dispensed and administered, the drug may be covered under the medical benefit, pharmacy benefit, or both. For drugs that can be reimbursed under both the pharmacy and medical benefits, 17 states reported that the coverage criteria sometimes vary depending on whether the drug is billed as a pharmacy or medical benefit (Table 6). States attributed variability in coverage criteria to various factors, including differences in the site of service, drug formulation, managed care oversight, PA processes, or claims processing system. Twenty states, however, reported that the coverage criteria were the same, and nine states reported that the coverage criteria were not the same. In 14 states, the DUR board or P&T committee always approves the coverage criteria for drugs paid through the medical benefit. Eleven states reported that DUR board or P&T committee approval is only sometimes required, with a few of these states noting that some drugs paid under the medical benefit are subject to approval by an internal committee other than the DUR board or P&T committee.

Table 6. Utilization Controls & Coverage Criteria for Medical Benefit Drugs, July 1, 2023		
Utilization Control/ Coverage Criteria	# of States	States
Utilization controls applied to drugs paid through the medical benefit	40	47 states responding: AK, AL, AR, AZ, CO, CT, DC, GA, IA, ID, IL, IN, KY, LA, MA, MD, ME, MI, MO, MS, MT, ND, NE, NH, NM, NV, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, WA, WI, WV, WY
Coverage criteria compared to pharmacy benefit		46 states responding:
Always the same	20	AK, AL, AZ, GA, HI, ID, IL, IN, LA, MA, MO, MS, NH, OK, PA, TN, UT, VT, WA, WY
Sometimes the same	17	CA, CO, CT, DC, KY, MD, ME, MT, ND, NY, OR, RI, SC, SD, TX, WI, WV
Not the same	9	AR, IA, MI, NC, NE, NJ, NM, NV, VA
Coverage criteria approved by DUR board/P&T Comm.		46 states responding:
Always approved	14	AK, GA, IN, MO, MT, NH, NV, OK, OR, PA, TN, UT, WV, WY
Sometimes approved	11	CO, DC, LA, MA, ME, NY, SD, TX, VA, VT, WA



Prescription Limits

Some states limit the number of total and/or brand prescriptions a beneficiary may access in a month without PA,⁵³ but prescribers and pharmacists may submit requests to override these limits when medically necessary. Approximately one-quarter of responding states (11 of 47 states) reported imposing a monthly limit on FFS prescriptions (see Figure 7 and Appendix Table 6). Two states reported applying monthly prescription limits only to narcotics or opioids, and seven of the remaining nine states with limits noted a number of excluded drugs or drug classes such as family planning products (5 states), cancer drugs (4 states), mental health drugs (4 states), tobacco cessation products (4 states), HIV antiretrovirals (3 states), vaccines (3 states), diabetic testing supplies (3 states), antivirals (2 states), and hemophilia clotting factor (2 states). Five of the 11 states reported applying the limits only to adults, and five states noted specific exemptions for people receiving long-term services and supports. Two states specifically reported higher limits for people enrolled in an assisted living waiver (Arkansas) or any home and community-based service (HCBS) waiver (Oklahoma).



States that impose monthly limits also were asked to indicate whether MCOs were required to apply the same limits, PA/appeals processes, and exemptions. Four of the 11 states with prescription limits had no MCOs as of July 1, 2023 (Alabama and Oklahoma) or did not include outpatient pharmacy as an MCO-covered benefit (Tennessee and Wisconsin). Of the remaining seven states, only two (Mississippi and Nevada) required MCOs to apply the same limits. No state reported a planned change for FY 2024.

Generic Drug Policies

Though every state (47 of 47) reported having policies or tools in place to promote generic drug utilization, several respondents said that their policies promote utilization of the drug with the

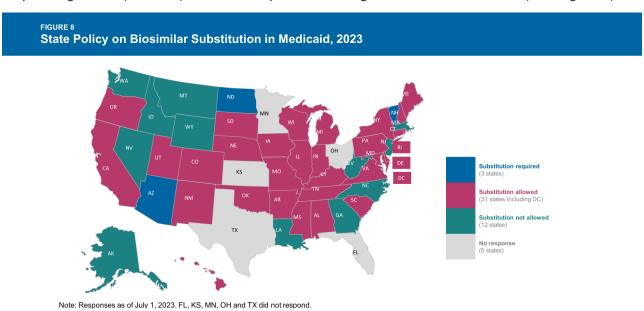


lowest net cost to the state, which could be either a brand name or generic drug. The most common policy reported was mandatory generics followed by lower copays for generics (Table 7 and Appendix Table 7). No state reported any generic drug policy changes planned for FY 2024.

Table 7: Policies or Tools in Place to Promote Generi (47 States Reporting)	c Utilization, July 1, 2023
Policy/Tool	# of States
Mandatory generics	39
Lower copays for generics	12
Provider education	6
Higher dispensing fee for generic substitution	1
Other*	12
No policies or tools	0
Notes: For other policies and tools reported, several states indicated the drug—either branded or generic—with the lowest net cost to the s	

More than three-quarters of the 30 responding MCO states that carve in pharmacy (19 states⁵⁴) require MCOs to follow the state's FFS generic drug policies and five states⁵⁵ require MCOs to follow their FFS generic drug policies in part.

Only three states reported a biosimilar (defined below) substitution requirement, with Arizona and North Dakota clarifying that substitution is required only if the biosimilar is more cost-effective. Most responding states (31 of 46), however, reported allowing biosimilar substitutions (see Figure 8).





Biosimilar Review Process

The vast majority of responding states (40 of 47) require biosimilar drugs to undergo the same DUR board/P&T committee review process as other drugs. Six states,⁵⁶ however, reported a different process.

- Arizona's Medicaid agency decides whether to prefer a biosimilar over the branded agent.
- Kentucky reported that the review process depends on whether the drug is classified as a new molecular entity.
- Missouri typically treats new biosimilars as generic launches, which are not subject to new drug review but are reviewed for net cost effectiveness before placement on the PDL relative to the original biologic.
- In Montana, the DUR board has recommended that the state treat biosimilars as generics.
- New Hampshire reported that biosimilars, like generics, follow the same clinical criteria as the brand. The DUR board reviews therapeutic classes to be placed on the PDL and the Medicaid agency determines PDL placements.
- New Mexico covers biosimilars based on FDA approval and a CMS rebate agreement.

Expenditure Reporting

Tracking Medicaid pharmacy expenditures across the states can be challenging. All states complete quarterly CMS Form 64 reports on Medicaid expenditures, but pharmacy expenditures can appear in more than one line/category of these reports. State survey responses indicate that states typically report FFS pharmacy expenditures on line 7 for prescribed drugs, but pharmacy expenditures can also be subsumed within line 5A for physician and surgical services and line 6A for outpatient hospital services. In addition, pharmacy expenditures under managed care arrangements are typically reported within line 18A for Medicaid health insurance payments.

Biosimilar Defined

An FDA-approved biosimilar has been compared with an FDA-approved biologic and determined to have no clinically meaningful difference in safety and effectiveness. Biologics are large and generally complex molecules produced from living organisms.

To gain a better understanding of the total cost of pharmacy products to state Medicaid programs, the survey asked that states indicate the approximate share of total Medicaid spending in FY 2023 that was attributable to pharmacy expenditures—net of rebates—under both the pharmacy benefit and the medical benefit. Because most responding states were unable to provide the approximate share, it is not possible to draw definitive conclusions. However, 19 states did provide an estimate, almost all of which reported that the approximate share was 15 percent or less and most reported an approximate share of 10 percent or less.



Prescription Drug Affordability Board (PDAB)

A small, but growing number of states are implementing state prescription drug affordability boards (PDABs) with the goal of lowering drug costs for all payers in their states. In general, PDABs are designed to regulate the prices of specifically identified drugs in the way that a public utility commission regulates rates for energy.⁵⁷ The authority granted to PDABs varies by state but may include the ability to set upper payment limits, negotiate supplemental rebates with manufacturers or recommend additional strategies to limit costs to the state legislature. Maryland was the first state to authorize a PDAB in 2019, and the number of states with PDABs had grown to 11 as of March 2024.⁵⁸ Of the 47 states responding to the survey, most (35) reported no plans to establish a PDAB, whereas 12 states reported that a PDAB was in place as of July 1, 2023 (Colorado, Maryland, Maine, New Hampshire, Oregon, and Washington) or under consideration (Illinois, Michigan, New Jersey, Pennsylvania, Virginia, and Vermont).

PAYMENT, SUPPLEMENTAL REBATES, AND REBATE MANAGEMENT

Payment for prescription drugs under Medicaid is determined by a complex set of federal and state laws, regulations, and policies. Though the Medicaid Drug Rebate Program dictates federal statutory rebates, most states also negotiate supplemental rebates with manufacturers by leveraging placement on their PDL. Many states have joined interstate purchasing pools to increase their supplemental rebate negotiating power, and a growing number of states are entering into VBAs with individual manufacturers that tie reimbursement to outcomes for specific high-cost drugs. To facilitate and ensure collection of rebates on single source and certain high-dollar/high-volume *outpatient physician administered drugs* (paid under the medical benefit rather than the pharmacy benefit), federal law also requires states to collect and submit utilization data and national drug codes (NDCs) for these drugs. A few states apply additional approaches to facilitate rebate claiming on physician administered drugs including use of an NDC/HCPCS crosswalk or vendor facilitated or assisted rebate claiming.

Supplemental Rebates

All states that reported having a PDL in place for FFS prescriptions (44 of 47 states⁶⁰) reported having supplemental rebate agreements in place for preferred agents (Appendix Table 8). To leverage their negotiating power, three-quarters of these states participate in an interstate purchasing pool. As of July 1, 2023, 33 states reported participation in three different interstate purchasing pools (Table 8). One state, Missouri, also reported participating in an intrastate purchasing pool, where multi-agency purchasing agreements are used as needed.



Table 8: Interstate Purchasing Pool Participation, July 1, 2023		
Pool	# of States	States (44 States with PDLs Responding)
National Medicaid Pooling Initiative (NMPI)	13	AK, AR, DC, KY, MI, MT, NC, NH, NV, NY, RI, SC, VA
Sovereign States Drug Consortium (SSDC)	13	DE, IA, ME, MS, ND, OK, OR, PA, SD, UT, VT, WV, WY
Top Dollar Program (TOP\$)	7	CT, ID, LA, MD, NE, WA, WI
Not part of an interstate pool	14	AL, AZ, CA, GA, HI, IL, IN, MA, MO, NJ, NM, TN, TX
Note: Kentucky moved to SSDC on January 1, 2024.		

About half the states with PDLs (23 of 44) rely on interstate purchasing pools to negotiate supplemental rebates (Table 9). A smaller number of states reported relying on more than one entity (7 states), a PBM, (7 states), or other vendor (3 states), and four states indicated the state Medicaid agency was responsible for these negotiations. Of the seven states that reported that more than one entity is involved, all but Pennsylvania reported that the state Medicaid agency works with their purchasing pools, PBMs, or other vendors to negotiate the supplemental rebates. A total of 31 states reported selecting the negotiating entity through a competitive procurement (Appendix Table 8).

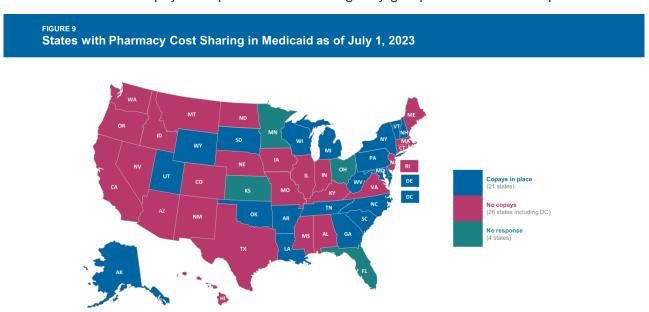
Table 9: Negotiating Supplemental Rebates, July 1, 2023		
Entity	# of States	States (44 States with PDLs Responding)
Purchasing pool	23	AR, CT, DC, DE, IA, ID, MD, ME, MI, MS, MT, NC, ND, NV, OK, OR, RI, SD, UT, VT, WI, WV, WY
More than one entity	7	AZ, KY, LA, NY, PA, TN, WA
PBM	7	AK, CO, IN, NE, NH, SC, VA
Medicaid agency	4	AL, CA, IL, MA
Other vendor*	3	GA, MO, TX
*Georgia and Texas both reported using Magellan and Missouri reported using Gainwell.		

Less than half of the states with managed care are allowing MCOs to negotiate supplemental rebates. Fourteen of 30 responding non-carve-out MCO states reported allowing MCOs to negotiate supplemental rebates. More than two-thirds of the MCO states that allow MCOs to negotiate supplemental rebates (10 of 14 reporting) require the MCOs' PBMs to pass through supplemental rebate collections to the MCO and all the reporting states required MCOs to report the aggregate supplemental rebate collections to the state Medicaid agency.



Pharmacy Copays

Fewer than half of responding states (21 of 47) reported requiring FFS pharmacy copayments for non-exempt adults as of July 1, 2023 (Figure 9 and Appendix Table 9), a notable decrease from the number of states reporting pharmacy copayment requirements in place as of July 1, 2019 (37 of 50 responding states). Four states without copayments, however, planned to resume copayment requirements that had been waived during the COVID-19 public health emergency in FY 2024 (Iowa and Nebraska) or FY 2025 (Indiana and Maine). Of the 21 states with pharmacy copayment requirements as of July 2023, nine structured their requirements to favor lower-cost generics (4 states) or lower cost generics and preferred brands (5 states); six states reported varying copayment amounts based on drug costs; and five states reported a monthly or quarterly cap on total Medicaid copayments. A few states also have copay exemptions for certain eligibility groups or selected therapeutic classes.



Note: States reported if they required pharmacy copayments for any adults in FFS as of July 1, 2023.

Almost all responding states that had copay requirements and had implemented the ACA Medicaid expansion as of July 1, 2023 (16 of 21 states) reported that copayment requirements for the expansion population were the same as for non-expansion adults. Michigan reported higher copay amounts for higher income expansion adult as of July 2023 but reported aligning copay requirements as of January 1, 2024. Iowa, which has copay requirements only for non-expansion adults, and Indiana will resume copay requirements in FY 2025 only for certain expansion adults. One other state reported copay changes in FY 2024: North Carolina reported plans to eliminate copays on Narcan and possibly nicotine replacement therapy and drugs used to treat substance use disorder.



Value-Based Arrangements

VBAs are contracting agreements between manufacturers and payers that tie reimbursement to specified outcomes. As of July 1, 2019, only two states, Oklahoma and Washington, had a VBA in place.⁶³ As of July 1, 2023, nine states reported having a VBA in place.⁶⁴ The most common arrangement reported was supplemental rebates. Four states with at least one VBA in place reported that their VBA arrangement(s) apply to the MCOs.⁶⁵

Of the nine states that reported having a VBA in place, six states⁶⁶ have a VBA in place for hepatitis C

drugs, and four states⁶⁷ have a VBA in place for drugs used to treat spinal muscular atrophy. Additional arrangements cover drugs used to treat acute hepatic porphyria, polyneuropathy in people with hereditary transthyretin-mediated amyloidosis, and beta thalassemia. Most states with VBAs reported that it was too soon to tell whether the arrangements have been successful, but two states, Michigan and Washington, reported savings and/or positive outcomes. Four states that have arrangements in place reported that they are already pursuing additional arrangements.⁶⁸

In addition to the nine states with a VBA in place, three states reported plans to implement a VBA in FY 2024.⁶⁹ Another ten states indicated that they are actively considering VBAs⁷⁰ and four states reported that they have submitted or plan to submit a state plan amendment (SPA) that includes VBAs.⁷¹ According to CMS, 25 states had an approved VBA (SPA) in place as of March 14, 2024 (Figure 10).

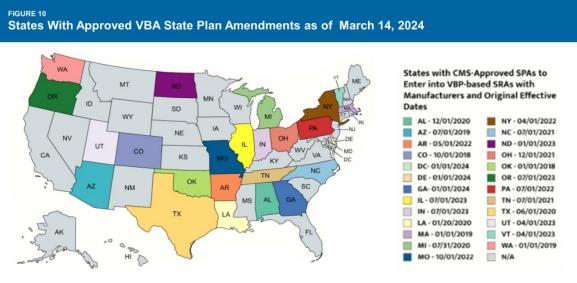
Though a growing number of states are entering into VBAs with manufacturers, states face a range of barriers and challenges when negotiating or

CMS CELL AND GENE THERAPY (CGT) ACCESS MODEL

In January 2024, the US Department of Health and Human Services (HHS) announced that sickle cell disease (SCD) would be the first focus of the CGT Access Model that is designed to increase affordable access to potentially lifesaving and life-changing treatments by testing outcomes-based agreements (OBAs). In 2024, CMS is partnering with participating states and manufacturers to create a framework for expanded access to SCD treatment. CMS will negotiate an OBA with participating manufacturers that will tie pricing to improved health outcomes for Medicaid enrollees with SCD. The CGT Access Model will begin in January 2025, and states may choose to begin participation between January 2025 and January 2026.

implementing a VBA. The most commonly cited barriers or challenges were a lack of willing manufacturers, the administrative burden of executing the agreements combined with existing resource constraints, lack of clinical and/or technical expertise within the agency, the overall complexity of the agreements, low return on investment, managed care carve-out requirements, 340B exclusion and data access, collection, and tracking.





Source: CMS Medicaid Prescription Drugs website; https://www.medicaid.gov/media/162941

Over the next few years, it will become increasingly important to tackle the various barriers and challenges that states face when implementing Medicaid VBAs. Nine states have at least one VBA in place, and 23 states reported that VBAs are among their solutions for addressing coverage of new cell and gene therapies when market entry of a large number of high-cost products is imminent.

Other Payment Initiatives

A few states use limited pharmacy networks for specialty drugs. Medicaid FFS programs typically enroll "any willing," qualified, and appropriately credentialed provider. However, five states reported having selective contracting or limited network arrangements for FFS specialty pharmacy drugs in place as of July 1, 2023.⁷² For example, Arkansas and Georgia allow use of limited pharmacy networks to obtain specialty drugs that are unavailable locally, such as certain oncology drugs and orphan drugs used to treat rare diseases. Arizona leverages a specialty network for high-cost drugs and medications with risk evaluation and mitigation strategies in place or other safety concerns.

Some states have mandated dispensing fees for MCOs. Of the 30 responding non-carve-out MCO states, 10 (Iowa, Illinois, Kentucky, Louisiana, Michigan, Mississippi, North Carolina, Nebraska, New Mexico, and Virginia) reported having have some form of mandated dispensing fee in place as of July 1, 2023 (Table 10). Four states reported minimum dispensing fees targeting local, independent pharmacies. New Mexico recently passed legislation that increases the dispensing fee MCOs pay to community-based pharmacies effective July 1, 2024, citing the important role community pharmacies play in maintaining access for older adults and people who live in rural areas.⁷³



Table 10: Mandated Dispensing Fees, July 1, 2023		
State	Description of Fee	
IA	Set dispensing fee established via statewide dispensing fee survey	
IL	Minimum dispensing fee required for Critical Access Pharmacies (located in county with less than 50,000 residents and owning fewer than 10 retail outlets) ⁷⁴	
KY	Dispensing fee of \$10.64 for all covered outpatient drugs	
LA	MCOs must pay independent pharmacies (local, non-chain) at least the FFS rate, which was increased from \$10.99 to \$11.81 effective October 1, 2023	
MI	Legislation requires MCOs pay a minimum dispensing fee in alignment with FFS to pharmacies with 7 or fewer retail outlets	
MS	MCOs must pay FFS rate	
NC	Set dispensing fee of \$10.24	
NE	Minimum dispensing fee applies to independent pharmacies (non-chain)	
NM	MCOs required to pay a minimum \$2.00 dispensing fee, increasing to \$10.30 for community-based pharmacies effective July 1, 2024	
VA	Minimum dispensing fee of \$10.65 required for OUD medications	

340B Management Strategies

In order to have their drugs covered under Medicaid, manufacturers must enter into a pricing agreement for the 340B Drug Pricing Program. The 340B program allows eligible healthcare organizations or covered entities to acquire outpatient drugs at significantly reduced prices. Because of a prohibition on duplicate discounts, manufacturers are not required to provide a Medicaid drug rebate and a discounted 340B price for the same drug. Though covered entities must have mechanisms in place to prevent duplicate discounts and ensure proper identification of 340B claims, it is also the Medicaid agency's responsibility to ensure they are not invoicing a manufacturer for a rebate for a drug obtained through the 340B program.

Most states reported using multiple strategies to avoid duplicate discounts on drugs dispensed by 340B covered entities. The most common strategies are use of the Medicaid exclusion file, a prohibition on the use of contract pharmacies in FFS, and the use of National Council for Prescription Drug Programs (NCPDP) fields to identify 340B claims (Table 11). Several states also prohibit the use of contract pharmacies in managed care or require the use of 340B modifiers on claims for prescription drugs paid through the medical benefit. In addition, most states have no specific requirements for MCO payment levels for 340B claims. Only 11 MCO states reported having a requirement that MCOs pay the same reimbursement to 340B covered entities as they do to other entities.⁷⁷



Table 11: 340B Strategies to Avoid Duplicate Discounts			
Strategy	# of States (46 States Responding ⁷⁸)		
Use Medicaid exclusion file1	31		
Prohibition on the use of contract pharmacies in FFS ²	29		
Use of NCPDP fields to identify 340B claims ²	29		
Prohibition on the use of contract pharmacies in managed care	13		
Use of claim modifiers	7		
340B entities carved out of FFS	3		

Notes: ¹The Health Resources and Services Administration publishes the Medicaid Exclusion File, which lists all of the covered entities that choose to bill Medicaid for the 340B drugs that Medicaid enrollees use. ² Contract pharmacies are those that have entered into an agreement with a covered entity to provide pharmacy services. ³ NCPDP fields are used by pharmacies on a claim to indicate that a drug was purchased through the 340B program.

Reimbursing Pharmacist Clinical Services

A 2022 study found that 48.1 percent of the US population lived within one mile of a community pharmacy, and 88.9 percent lived within five miles,⁷⁹ making pharmacists one of the most accessible healthcare providers. Subject to state scope of practice laws, an increasing number of states and other payers are taking advantage of this proximity to expand access to primary care by providing reimbursement for pharmacists to move beyond their traditional dispensing function and provide direct patient care services such as immunizations, wellness and prevention screening, medication therapy management, chronic condition management, and patient education and counseling. Pharmacists still are not recognized as healthcare providers at the federal level, and although at least 37 states recognize pharmacists as providers in state law, the designation does not always directly correlate with reimbursement for clinical services.⁸⁰

Medication Therapy Management

The American Pharmacists Association defines medication therapy management (MTM) as "a distinct service or group of services that optimize therapeutic outcomes for individual patients" and "are independent of, but can occur in conjunction with, the provision of a medication product." MTM traditionally includes a broad range of professional activities based on individual patient needs, including health status assessments, comprehensive medication reviews, identification and resolution of adverse drug events, evaluation of medication adherence, therapeutic response monitoring, creation of medication treatment plans, and patient education. Less than one-third of responding states (13 of 47) reported that they paid pharmacists to provide MTM services in the FFS program as of July 1, 2023 (Table 12).



Table 12: States Reporting FFS Medication Therapy Management Reimbursement, July 1, 2023				
State	Comments Including Condition-Specific or Other Restrictions	MCOs Required to Cover Same MTM services?		
California	Diabetes, asthma, COPD, severe mental disorders, HIV/AIDS, cancer, and blood disorders.	N/A – pharmacy carved out		
Idaho	Not restricted by condition.	N/A – no MCOs		
Massachusetts	Restricted to the community health center setting.	Yes		
Michigan	Limited to the treatment or prevention of state-specified chronic conditions.	No		
Missouri	Provided at pharmacist's discretion.	N/A – pharmacy carved out		
Mississippi	Includes diabetes, lipids, and asthma.	Yes		
Montana	Montana has an MTM program, but no pharmacists have enrolled. MT pays for clinical pharmacist practitioner (CPP) services for members who have one chronic disease state and take at least one maintenance medication for the chronic condition.	N/A – no MCOs		
North Dakota	Not restricted by condition.	Yes		
New Hampshire	Smoking cessation and oral contraception.	Yes		
New Mexico	Members with one or more chronic condition.	No		
Oklahoma	Chronic conditions. Yes			
Utah	Member must take at least three medications to treat or prevent at least one chronic condition.	Yes		
Vermont	Alcohol/substance use disorder and mental health disorders.	N/A – no MCOs		

Though most states reported restricting the provision of MTM services to certain chronic conditions like diabetes or asthma, two states reported no MTM coverage restrictions. Of the 13 states that pay pharmacists to provide MTM services in the FFS program, six require MCOs to cover the same MTM services. Three states (Delaware, Tennessee and Louisiana) reported that though the state does not pay pharmacists to provide MTM services within the FFS program, their MCOs do provide MTM. In addition, nine states reported MTM policy changes planned for FY 2024, including expansion of their existing program (California, Massachusetts, and Mississippi), plans to implement a MTM program (Alaska, DC, Maryland, Pennsylvania, and Wyoming) and a transition to the MCOs (Oklahoma).



Other Clinical Services

All responding states (4682) reported that their State Boards of Pharmacy allow pharmacists to provide clinical services within their scope of practice, but only 34 states reported having a Medicaid policy in place to reimburse pharmacists for clinical services. A number of states noted that it is the pharmacy that is reimbursed for these services rather than the pharmacist. Common clinical services reimbursed include vaccine administration, point-of-care testing, COVID-related services, prescribing under a collaborative practice agreement or statewide protocol and counseling for smoking cessation. Of the 34 states that have a Medicaid policy in place to reimburse clinical services provided by pharmacists, 21 states require MCOs to follow the same reimbursement policy, with two states noting that their MCOs have some flexibility, including developing their own clinical criteria, reimbursement rates, or vaccine coverage.

STATE POLICIES FOR SELECTED DRUGS/DRUG CLASSES

Coverage of New and Emerging Gene and Cell Therapies

Significant advancements in gene and cellular therapies in recent years that treat cancer and rare diseases, like hemophilia and sickle cell disease, come at a high cost to Medicaid and other payers but are often curative. Through July 2023, the FDA had approved 16 cell and gene therapies with list prices ranging from \$400,000 to \$3.5 million per course of treatment and more than 60 new approvals are projected by 2030. More recently, the FDA approved a new, single treatment stem cell gene therapy for children with metachromatic leukodystrophy, a rare and potentially fatal disease, in March 2024, with a list price of \$4.25 million making it the most expensive drug in the United States at that time. The single payers are supported by the single payers and potentially fatal disease, in March 2024, with a list price of \$4.25 million making it the most expensive drug in the United States at that time.

A total of 43 states responded to an open-ended question regarding initiatives or planning efforts under way to address coverage of new gene and cell therapies. More than half of the states (23) reported that they were pursuing or exploring the potential for value-based arrangements with manufacturers, the most common initiative or approach mentioned.⁸⁸ Other strategies reported included:

GENE AND CELL THERAPY

Gene therapy is the use of genetic material in the treatment or prevention of disease. The transferred genetic material changes how a single protein or group of proteins is produced by the cell.

Cell therapy is the transfer of intact, live cells into a patient to help lessen or cure a disease. The cells may originate from the patient (autologous cells) or a donor (allogeneic cells).

 American Society of Gene & Cell Therapy

- Hospital carve outs, add-on payments, single-case agreements, or separate diagnosis-related groups (Georgia, Indiana, Louisiana, Massachusetts, North Carolina, Texas, Vermont, and Wyoming)
- MCO risk mitigation strategies such as reinsurance, reimbursement, risk pools, risk corridors, and carve outs (Arizona, Kentucky, New Hampshire, New Jersey, Pennsylvania, South Carolina, and Washington)



- Setting clinical criteria and imposing PA (Alabama, North Carolina, Nebraska, Nevada, Utah, Vermont, and Washington)
- Negotiating additional supplemental rebates (Alaska, Massachusetts, and North Carolina)
- Reimbursement of actual invoice cost (North Carolina and Washington)

Other states commented that research or planning efforts were under way, and a few states mentioned tracking and monitoring efforts focused on product pipelines and health outcomes.

Coverage of HIV PrEP

Pre-Exposure Prophylaxis (PreEP) medications prevent individuals from contracting HIV. Two approved medications are available in pill form. Truvada is approved for both males and females at risk of HIV through sex or injection drug use. Descovy is for people at risk of HIV through sex but not for people assigned female at birth who are at risk for HIV through vaginal sex.⁸⁹ Generics are available for Truvada but not for Descovy. One long-acting injectable (Apretude) has also been approved for PrEP.⁹⁰ All states must cover PrEP medications but may apply utilization controls such as PA requirements. **Of the 46 responding states**, **43 reported no PA requirements for Truvada as of July 1, 2023**.⁹¹

Coverage of Recently Approved OTC Products

Unlike most prescription drugs, federal law does not require states to cover OTC drugs, except for nonprescription prenatal vitamins, fluoride preparations for pregnant people, and certain nonprescription tobacco cessation products. States have the option of covering other OTC drugs, but can only obtain federal Medicaid matching funds for OTC drugs prescribed by an authorized healthcare provider. This OTC prescription requirement imposes an extra, potentially burdensome step on Medicaid members who must see an authorized provider to obtain a prescription. Without Medicaid coverage, however, the OTC drug could be unaffordable for members. States that want to remove or mitigate this prescription barrier can provide coverage without a prescription using state-only funding or by expanding pharmacists' prescribing authority, for example, through standing orders, statewide protocols, or full prescriptive authority (Figure 11).



Figure 11: Mechanisms to Expand Pharmacists' Scope of Practice					
Collaborative Practice Agreement Voluntary agreements between a pharmacist and a prescriber (e.g., physician or nurse practitioner) authorizing the pharmacist to initiate, adjust, and/or discontinue medications and order laboratory tests.	Standing Order Often signed by a physician within a state agency or health department to authorize pharmacists to provide patient care when conditions set out in the standing order are met.				
Statewide Protocol Issued by a state board or agency to authorize pharmacists meeting requirements to autonomously prescribe certain medications under authority granted by the state through laws and regulations.	Prescriptive Authority State statutory authority granting pharmacists full autonomy to prescribe medications without the need for a protocol or agreement, based on clinical guidelines and professional judgment.				

Planned OTC Narcan Coverage

Naloxone is a lifesaving prescription drug that can reverse an opioid overdose. In May 2023, the FDA approved Narcan, the first OTC naloxone nasal spray, and it became available online and in stores in September 2023. The FDA approved a second OTC naloxone nasal spray in July 2023 (RiVive) that became available online and in stores in early 2024. Even before OTC Narcan became available, all 50 states and the District of Columbia had taken some action to allow individuals to obtain naloxone without a prescription through statewide standing orders (33 states), authority for prescribers and pharmacists to enter into standing order arrangements (14 states and DC), and direct authority for pharmacists to prescribe or dispense (3 states).⁹⁵

Almost every state now covers or plans to cover OTC Narcan. At the time of the survey, 44 of 47 states reported current coverage of OTC Narcan and two states reported plans to add coverage (see Table 13). Only one state, Rhode Island, reported no plans to cover OTC Narcan. Nearly two-thirds of responding states (30 of 47) reported facilitating coverage through a statewide standing order, 96 and nearly one-third (14 states) 7 reported that pharmacists had prescribing authority for OTC Narcan.

Table 13: OTC Narcan Coverage			
Coverage Status (at time of the survey)	# of States	States (47 States Responding)	
Currently cover	44	AK, AL, AZ, CA, CO, CT, DC, DE, GA, HI, IA, ID, IL, IN, KY, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	
Plan to cover	2	AR, LA	
No plans to cover	1	RI	
Undetermined	0		



Planned Opill Coverage

The FDA approved the first OTC daily oral contraceptive, Opill, in July 2023, and it became available online and in stores in March 2024. At the time of the survey (prior to market availability), nearly two-thirds of responding states (30 of 47) reported plans to cover Opill, four states reported no plans to cover Opill, and 13 states reported that Opill coverage remained undetermined (Table 14). Nine states⁹⁸ reported that pharmacists would have authority for prescribing Opill, but only five states⁹⁹ reported statewide standing orders would be in place to facilitate coverage.

Table 14: OTC Opill			
Coverage Status (at time of the survey)	# of States	States (47 States Responding)	
Plan to Cover	30	AL, CA, CO, CT, DC, DE, ID, IL, IN, MA, ME, MI, MO, MS, ND, NH, NJ, NM, NV, NY, OK, OR, PA, SC, TN, TX, UT, WA, WI, WY	
No plans to cover	4	LA, MT, RI, VA	
Undetermined	13	AK, AR, AZ, GA, HI, IA, KY, MD, NC, NE, SD, VT, WV	

CHALLENGES AND PRIORITIES IN FY 2025 AND BEYOND

States reported a range of challenges and priorities for CY 2024 and beyond.

Average Manufacturer Price Cap Removal

Starting in January 2024, the American Rescue Plan Act of 2021 (ARPA) lifted the federal Medicaid drug rebate cap that previously limited statutory rebates (but not supplemental rebates) on a drug to 100 percent of that drug's quarterly average manufacturer price (AMP). The AMP is the wholesale price charged by the manufacturer, and the statutory federal drug rebate formula has two components: 1) a base rebate equal to a percentage of AMP or the difference between AMP and the "best price," whichever is greater; and 2) an additional rebate based on a drug's inflationary increases over time. Until ARPA removed the AMP cap, total statutory rebates under both components were capped at 100 percent of AMP. Once a manufacturer reached the cap, additional price increases would not result in additional required statutory rebates. As a result of the AMP cap's removal, however, required federal statutory rebates could exceed a manufacturer's wholesale price for drugs with substantial price increases over time. To avoid this situation, some manufacturers are lowering drug prices and discontinuing products. For example, GlaxoSmithKline (GSK) announced the discontinuation, effective in 2024, of its popular asthma inhaler, Flovent, in favor of a new authorized generic inhaler, also manufactured by GSK.



More than one-third of responding states cited concerns arising from the AMP cap removal, noting that the resulting product discontinuations would result in drug shortages and access disruptions for Medicaid members and higher net spending for Medicaid programs because of lower rebate collections in the affected drug classes. One state also commented on the need for the Medicaid agency to constantly review the

state's PDL to ensure members have access to appropriate medications.

Inflation Reduction Act

The Inflation Reduction Act of 2022 (IRA) includes several provisions that affect Medicare prescription drug prices and coverage (Figure 12). The Congressional Budget Office (CBO) has predicted that the inflation rebate requirement will result in a net increase in Medicaid drug costs: 103

 For drugs currently on the market, CBO predicts that the inflation rebate requirement will reduce Medicaid statutory rebate collections, more than offsetting the benefit to Medicaid from reduced retail prices. Figure 12: Summary of Inflation Reduction Act Provisions That Lower Medicare Drug Costs

Requires the US Department of Health and Human Services (HHS) to negotiate prices for certain drugs with the highest total Medicare spending, beginning in 2026.

Imposes an inflation rebate that requires drug companies to pay Medicare back for any list price increases above inflation, beginning in 2023.

Caps out-of-pocket spending for Medicare Part D enrollees and makes other Part D benefit design changes, beginning in 2024.

Limits monthly cost sharing for insulin to \$35 for Medicare enrollees, beginning in 2023.

Eliminates cost sharing for adult vaccines beginning in 2023.

Expands Medicare Part D Low-Income Subsidy Program eligibility beginning in 2024.

Further delays implementation of the Trump Administration's drug rebate rule, beginning in 2027

 CBO also predicts that new drugs will launch at higher prices, increasing Medicaid spending, as manufacturers factor in both the new Medicare inflation rebate requirement and negotiated prices for certain drugs.

Forty-two states responded to an open-ended question asking for comments on any notable concerns they have regarding IRA Medicare drug policy changes. About one-quarter of responding states reported no current concerns or that they were monitoring for potential impacts. A somewhat smaller number of states, however, echoed CBO's predictions expressing concern that the IRA provisions would increase Medicaid net drug costs by lowering Medicaid rebate collections and incentivizing manufacturers to increase initial product launch prices. Other states commented, instead, on the ARPA AMP cap removal (described above).

Accelerated Approval Drugs

The FDA Accelerated Approval Program allows certain drugs that treat unmet medical needs to come to market sooner based on "surrogate endpoints" that can considerably shorten the time needed for



FDA approval.¹⁰⁴ States have expressed concern about the budget impacts of covering high-cost drugs approved through the accelerated approval pathway noting that, by definition, these drugs have yet to show a verified clinical benefit and typically do not have competition, limiting their ability to negotiate supplemental rebates to better manage their cost. ¹⁰⁵

The survey asked for feedback on the fiscal impact of accelerated approval drugs on the respondents' Medicaid pharmacy programs and their spending growth expectations for the year ahead. Responses from 38 states regarding the fiscal impact were mixed: more than one-quarter of responding states reported a significant or high fiscal impact, while nearly a quarter of responding states reported a modest effect. Approximately one-sixth of responding states reported a low fiscal impact. One state citing a modest impact indicated that most of these high-cost, innovative drugs had low utilization levels, whereas another state reporting a low impact commented that these drugs were managed through PA in both FFS and managed care.

Other State Priorities and Challenges in the Year Ahead

Nearly three-quarters of the responding states (33 of 46) reported that managing the Medicaid pharmacy budget, including the development of policies and strategies for managing new high-cost therapies, was a top priority and the most common priority area cited. The second most commonly cited priority, mentioned by 10 states, was making progress on the development, negotiation, or implementation of a value-based arrangement. Several states mentioned a top priority relating to PBM management or implementation of a single PBM for all MCOs and several mentioned plans to consider coverage of GLP-1 anti-obesity medications. Other top priorities and challenges mentioned by at least one state included:

- 340B
- IT projects (e.g., claims processing, e-prescribing, and interoperability)
- State staffing needs
- Improved management of physician administered drugs
- Federal and/or state PA policy changes and other state legislation
- The need for clinical programs to identify and address healthcare disparities
- Adoption of an FFS formulary or transition to a single PDL for all MCOs
- COVID-19 therapy commercialization

SURROGATE ENDPOINT

"A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit."

 FDA Accelerated Approval Program <u>Website</u>

STATE COMMENT ON ACCELERATED APPROVAL DRUGS

"Drugs are being approved that have no evidence of any clinical benefit and under Medicaid laws, states are required to cover them. Medicaid has a higher prevalence of patients with rare disease than the typical commercial health plan. Essentially the Medicaid program is now funding the post marketing studies the manufacturers are required to perform."



CONCLUSION

Managing the Medicaid pharmacy benefit has never been more challenging. In 2024 and beyond, states must quickly respond to an evolving marketplace that is producing innovative therapies that offer new hope to persons with chronic conditions and rare diseases but come at a high cost. States also must react to changing drug marketplace conditions driven, in part, by federal policy changes to the Medicaid drug rebate formula and changes designed to lower Medicare drug costs. Drug manufacturer responses to these changes have implications for Medicaid state budgets, but also for state PDL management decisions and beneficiary access to needed medications. At the same time, Medicaid pharmacy managers must meet the demands of state policymakers for cost-effective management of the pharmacy benefit while also meeting the access demands of beneficiaries and providers, sometimes with imperfect information and almost always within administrative resource constraints.

While states continue to rely on tried-and-true pharmacy management tools, such as PDLs, supplemental rebates, clinical protocols, and PA, a growing number of states are implementing or exploring value-based arrangements that link reimbursement to health outcomes. States with managed care arrangements also are increasingly reconsidering how the pharmacy benefit should be managed by MCOs or whether it should be carved out entirely. Yet, in this environment of constant change and ever-growing challenges, Medicaid officials in 47 states devoted time and expertise to participate in this Medicaid pharmacy survey, and for that, we express our sincere gratitude and appreciation.

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APPENDIX

Table 1: Drugs and Classes Carved Out of MCO Benefits

July 1, 2023

States	Hemophilia Factor	Hepatitis C Antivirals	HIV/AIDs Anti- retrovirals	Mental Health Drugs	Opioid Use Disorder Drugs	Oncology/ CAR-T Drugs	Spinal Muscular Atrophy Agents	Other Drugs/Classes Carved Out
Alabama		randivirdio	Totroviraio	Diago	Drugo	Drugo	rarophly rigorito	
Maska								
Arizona	Х					Χ	Х	
Arkansas	X					Α	, A	
California	Χ		X	V	Х			
	^		^	^	^	Х	Х	
Colorado						^	^	
Connecticut								
Delaware								
OC			Х					
lorida	NR	NR	NR	NR	NR	NR	NR	NR
Seorgia								
lawaii							Х	
daho								
linois								
ndiana	Х	X				Х	Х	COVID vaccines, CFTR potentiators, cell and gene therapies, non-hydroxyurea agents (sickle cell), non-corticosteroid agents (muscular distrophy)
owa							Х	Mepsevii
Kansas	NR	NR	NR	NR	NR	NR	NR	NR
Kentucky								
ouisiana.								
/laine								
Maryland				Х	Χ			
lassachusetts				7.				
lichigan	X	Х	Х	Х	Х	Х	Х	Anti-convulsants/epilepsy treatments, select high cost drugs
Minnesota	NR	NR	NR	NR	NR	NR	NR	NR
Mississippi								
Missouri								
Montana								
lebraska								
levada							Х	
	Х						X	COVID vaccines COVID tests Carbadly (and generic
New Hampshire	^						^	COVID vaccines, COVID tests, Carbaglu (and generic versions), Ravicti, Crysvita, Gattex, Procysbi, Vijoice, ge therapies
New Jersey	X							
New Mexico								
New York						Х		
lorth Carolina								
lorth Dakota								
Ohio	NR	NR	NR	NR	NR	NR	NR	NR
Oklahoma	1411	NK	NK	NK	1411	1411	IVIX	
Oregon				Х				
				^				
Pennsylvania								
Rhode Island								
South Carolina						X		High cost/no experience drugs
South Dakota								
Tennessee								
Texas	Х	Х				Х	Х	Besponsa, Crysvita, Amondys/ Exondys/ Vyondys/ Viltepso, Aduhelm, Luxturna, Skysona, Zynteglo, Tzield
Jtah	X			Х	Χ			Immunosuppresants (transplants), cell and gene therapi
/ermont								
/irginia								
Vashington	х	Х	Х			Χ	Х	Most cell and gene therapies, high cost/rare disease dru
Vest Virginia	X							
Visconsin								
Vyoming								
- y william								

*Notes: States that cover pharmacy through managed care were asked to report drug products or classes that were carved out as of July 1, 2023. "X" = the state carves out the entire drug class or one or more products within that class; "NR" = Not Reporting.



Table 2: Pharmacy Vendor Responsibilities July 1, 2023

States	Claims Process/ Payment	Utilization Management	DUR	PDL Management	Rebate Admin	Network Management	Fraud, Waste, Abuse	P&T Committee Support	Other
Alabama									
Alaska	X	X	Х	X	Х		X	X	
Arizona	X	X	Χ			Χ	X		
Arkansas		X	Χ	X	X		X	X	
California	X	X	Χ						Х
Colorado	X	X			Х			X	
Connecticut									
Delaware	X	X	Χ		Х	Х			
DC	X	X	Χ				X		
Florida	NR	NR	NR	NR	NR	NR	NR	NR	NR
Georgia	X	X	Χ	X			X	X	
Hawaii	Х	X	Х		Х				
Idaho	Χ	Χ	Χ	X	Х			Χ	
Illinois									
Indiana	Χ	X	Χ	X	Х		Χ	Χ	
lowa	X	X	X	X	Х			X	
Kansas	NR	NR	NR	NR	NR	NR	NR	NR	NR
Kentucky	X	X	Х	X	X		X	X	
Louisiana	X	-	X			Χ	-		
Maine	X	х	Х	х		X	х	х	
Maryland	X	X	X	7.	Х		X	7.	
Massachusetts	X	,			X	Х			
Michigan	X	X		Х	X	Α		X	
Minnesota	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mississippi	III	1417	1414	IVIX	1414	Turk	1410	1417	1411
Missouri		Х	Х	Χ				X	
Montana	X	^	^	^				^	
Nebraska	^	Х	Х	X	Х			Х	
Nevada	X	X	X	X	X			X	
New Hampshire	X	X	X	X	X			^	Х
	^	^	^	^	^				^
New Jersey	V		V		V	V	v		
New Mexico	Х	V	X	V	X	Х	Х		
New York		X	X	Χ	Х				
North Carolina									
North Dakota									
Ohio	NR	NR	NR	NR	NR	NR	NR	NR	NR
Oklahoma									
Oregon									
Pennsylvania			X	Х	Х			X	
Rhode Island									
South Carolina	X	X	X	Х	Х			X	
South Dakota		Х	Х					X	
Tennessee	X	X	Х	X	Х	X	X	X	X
Texas	X	X	Х		Х				
Utah	X								
Vermont		X	Х	X	Х		Х	X	
Virginia		X	X	X	Х			X	
Washington									
West Virginia									
Wisconsin									
Wyoming	Χ	Χ		X	Х		Χ		

*Notes: States that reported contracting with a vendor to administer the FFS pharmacy benefit were asked to report which services were provided by a vendor as of July 1, 2023. "NR" = Not Reporting.



Table 3: PBM Transparency Requirements in Place July 1, 2023

States	Spread Pricing Arrangements Prohibited as of 7/1/2023?	PBM Transparency/ Reporting Requirements in place FY 2024?	PBMs Required to Contract with "Any Willing Pharmacy" as of 7/1/2023?	FY 2024 Comments on PBM Transparency Requirements
Alabama	N/A	N/A	N/A	
Alaska	N/A	N/A	N/A	
Arizona	No	Yes	No	Annual reporting of rebates
Arkansas	Yes	Yes	Yes	MCOs subject to many Insurance Department guidelines per state PBM legislation/regulations
California	N/A	N/A	N/A	
Colorado	Yes	No	No	
Connecticut	N/A	N/A	N/A	
Delaware	Yes	Yes	Yes	Quarterly transparency reporting of drug costs
DC			No	
	Yes	Yes		Annual report format and submission guidelines under development
Florida	NR	NR No	NR No	
Georgia	Yes	No	No	
Hawaii	No	No	No	
Idaho	N/A	N/A	N/A	
Illinois	Yes	No	No	
Indiana	Yes	No	No	
Iowa	Yes	No	No	
Kansas	NR	NR	NR	
Kentucky	Yes	Yes	Yes	MCO contract with single PBM requires pricing transparency. The Commonwealth requires the single PBM to meet various reporting requirements
Louisiana	Yes	Yes	Yes	Annual transparency reporting required by the legislature
Maine	N/A	N/A	N/A	
Maryland	Yes	Yes	No	PBM transparency requirements set forth in MCO contract, including reporting amounts MCO pays to PBM and amounts PBM pays to pharmacy and disclosure of supplemental rebate allocation methodology and rebate revenue
Massachusetts	Yes	Yes	No	Reporting requirement
Michigan	Yes	Yes	No	State statute requires annual reporting of dispensed prescriptions, wholesale acquisition cost for each drug on formulary, rebates/discounts/price concessions, administrative fees PBM receives from drug manufacturers, and amounts retained by PBM.
Minnesota	NR	NR	NR	
Mississippi	Yes	No	Yes	
Missouri	N/A	N/A	N/A	
Montana	N/A	N/A	N/A	
Nebraska	Yes	No	No	
Nevada	Yes	Yes	No	Quarterly Pharmacy Supplemental Rebate Agreement and Rx Rebate Detail reports required. MCOs must hire an independent third party to complete an annual Service Organization Controls (SOC-1) report.
New Hampshire	Yes	No	No	
New Jersey	Yes	Yes	Yes	MCOs must submit the PBM Disclosure Reporting Template annually
New Mexico	Yes	Yes	No	Quarterly reporting required, including rebates, discounts, and price concessions (which must be passed through to the Human Services Department)
New York	N/A	N/A	N/A	
North Carolina	No	No	Yes	MCOs must not include PBM "spread" in MLR calculations. Public dashboards and legislative reporting of pharmacy claims.
North Dakota	N/A	N/A	N/A	
Ohio	NR	NR	NR	
Oklahoma	N/A	N/A	N/A	
Oregon	Yes	Yes	No	State Medicaid agency reviews and approves PBM contracts and performs annual market checks. If PBM operates under a P4P model, administrative costs reported quarterly; must be at or below the administrative costs of the Oregon Prescription Drug Program or renegotiation is required.
Pennsylvania	Yes	Yes	Yes	State Medicaid agency reviews and approves PBM contracts. Transparency reporting required, including all PBM fees charged to MCO and pharmacy providers, amount PBM receives for each drug encounter, and amount provider receives. Any difference between the amount the PBM receives and the amount paid by the PBM to the provider must be reported as "other" fee. State law provides audit rights.
Rhode Island	No	No	Yes	
South Carolina	No	Yes	No	State law requires biannual audits of MCO pharmacy pricing mechanisms effective January 1, 2024.
South Dakota	N/A	N/A	N/A	. , , , , , , , , , , , , , , , , , , ,
Tennessee	N/A	N/A	N/A	
Texas	Yes	Yes	Yes	Quarterly reporting of financial status
Utah	Yes	No	No	and the state of t
Vermont	N/A	N/A	N/A	
Virginia	Yes	No	No	No. 11 11 11 11 11 11 11 11 11 11 11 11 11
Washington	Yes	Yes	No	MCOs must demonstrate compliance with contract requirements related to PBMs
West Virginia	N/A	N/A	N/A	
		A1/A	A1/A	
Wisconsin	N/A	N/A	N/A	
Wisconsin Wyoming Totals	N/A N/A 25	N/A N/A 17	N/A N/A 10	

"Notes: States were asked to report if spread pricing arrangements in MCO subcontracts with PBMs were prohibited and if MCOs are subject to other PBM transparency requirements as of July 1, 2023. Spread pricing refers to the difference between the payment the PBM receives from the MCO and the reimbursement amount it pays to the pharmacy dispensing to the beneficiary. "N/A" = MCO states with a full pharmacy carve out and states that do not have comprehensive managed care; "NR" = Not Reporting.



Table 4: Responsible Entity for Reviewing New PDL Drugs, Step Therapy Criteria, PA Criteria and Orphan/FDA Expedited Review Drugs

July 1, 2023

States	New PDL Drugs	Step Therapy Criteria	PA Criteria	Orphan/ Expedited Review Drugs
Alabama	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Alaska	P&T Committee	DUR Board	DUR Board	Medicaid Agency
Arizona	P&T Committee	Other	Other	P&T Committee
Arkansas	Other	Medicaid Agency	Medicaid Agency	Medicaid Agency
California	Medicaid Agency	NA (No FFS step therapy)	Medicaid Agency	Medicaid Agency
Colorado	Medicaid Agency	Medicaid Agency	Medicaid Agency	Medicaid Agency
Connecticut	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Delaware	P&T Committee	DUR Board	DUR Board	DUR Board
DC	P&T Committee	DUR Board	DUR Board	Other
Florida	NR	NR	NR	NR
Georgia	DUR Board	Medicaid Agency	Medicaid Agency	DUR Board
Hawaii	Other	Other	Other	Other
Idaho	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Illinois	P&T Committee	Medicaid Agency	Medicaid Agency	Other
Indiana	P&T Committee	P&T Committee	P&T Committee	P&T Committee
lowa	P&T Committee	DUR Board	DUR Board	P&T Committee
Kansas	NR	NR	NR	NR
Kentucky	Medicaid Agency	Medicaid Agency	Medicaid Agency	Medicaid Agency
Louisiana	P&T Committee	Other	Other	P&T Committee
Maine	DUR Board	DUR Board	DUR Board	DUR Board
Maryland	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Massachusetts	Medicaid Agency	Medicaid Agency	Medicaid Agency	Medicaid Agency
Michigan	Other	Other	Other	Other
Minnesota	NR	NR	NR	NR
Mississippi	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Missouri	Medicaid Agency	Medicaid Agency	Medicaid Agency	Medicaid Agency
Montana	Other	DUR Board	DUR Board	DUR Board
Nebraska	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Nevada	P&T Committee	DUR Board	DUR Board	P&T Committee
New Hampshire	Other	Other	Other	Other
New Jersey	NA (No FFS PDL)	NA (No FFS step therapy)	DUR Board	DUR Board
New Mexico	NA (No FFS PDL)	NA (No FFS step therapy)	Other	Other
New York	DUR Board	DUR Board	DUR Board	Medicaid Agency
North Carolina	P&T Committee	P&T Committee	P&T Committee	P&T Committee
North Dakota	Other	Other	Other	Other
Ohio	NR	NR	NR	NR
Ohlo	DUR Board	DUR Board	DUR Board	DUR Board
Oregon	Other D&T Committee	Other	Other	Other
Pennsylvania	P&T Committee	Other	Other	Other
Rhode Island	P&T Committee	Other	Other	Other
South Carolina	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
South Dakota	P&T Committee	P&T Committee	P&T Committee	Medicaid Agency
Tennessee	P&T Committee	P&T Committee	P&T Committee	P&T Committee
Texas	DUR Board	NA (No FFS step therapy)	DUR Board	DUR Board
Utah	Medicaid Agency	Medicaid Agency	Medicaid Agency	Medicaid Agency
Vermont	DUR Board	DUR Board	DUR Board	DUR Board
Virginia	P&T Committee	Medicaid Agency	Other	Medicaid Agency
Washington	Other	Medicaid Agency	Medicaid Agency	Medicaid Agency
West Virginia	P&T Committee	DUR Board	DUR Board	DUR Board
Wisconsin	P&T Committee	Medicaid Agency	Medicaid Agency	Medicaid Agency
Wyoming	P&T Committee	P&T Committee	P&T Committee	P&T Committee

^{*}Notes: States were asked to indicate the entity responsible for new drugs for PDL placement, step therapy criteria, PA criteria and orphan/expedited review drugs as of July 1, 2023. Pharmacy and therapeutics (P&T) committees or drug utilization review (DUR) board are committees of physicians and pharmacists that help inform the development of the PDL, review drugs, and develop coverage decisions. "NR" = Not Reporting.



Table 5: Frequency of Reviews

States	New PDL Drugs	Step Therapy Criteria	PA Criteria	Comments
Alabama	Other	As needed	As needed	Quarterly PDL review
Alaska	Other	As needed	As needed	Quarterly PDL meetings
Arizona	As needed	As needed	Other	PA criteria, which is updated monthly, is not developed by the P&T Committee.
Arkansas	As needed	Other	As needed	Agency does not refer to any prior authorizations or criteria as actual step therapy, rather if clinical guidelines refer to drugs in a procession from an agent or class to another, our agency would follow that in our clinical PA criteria or PDL.
California	NR	NA no step therapy	As needed	CA has a Contract Drug List (CDL) that functions like a PDL. CDL not reviewed by the DUR Boar
Colorado	Annually	Annually	As needed	
Connecticut	Annually	As needed	As needed	
Delaware	Other	Other	Other	At quarterly meetings, review all new medications and PDL change recommendations from supplemental rebate vendor
DC	Annually	As needed	As needed	
Florida	NR	NR	NR	
Georgia	As needed	NR	NR	Step therapy and PA criteria not reviewed by the DUR Board or the P&T Committee.
Hawaii	NA no FFS PDL	As needed	As needed	PDL reported for dental drug program only
Idaho	Other	Other	As needed	PA Criteria do not require P&T or DUR review or approval. When drug classes on the PDL are reviewed biannually, P&T Committee is asked if they have any suggested changes to criteria or additional adds.
Illinois	Other	As needed	As needed	Quarterly PDL review
Indiana	Other	Other	Other	Therapeutics Committee reviews twice annually
lowa	Other	Annually	Annually	PDL reviewed 3 times a year
Kansas	NR	NR	NR	
Kentucky	Other	Other	Other	P&T Committee reviews PDL drug classes quarterly using class review schedule based on recommendations from the Commonwealth
Louisiana	Annually	As needed	As needed	
Maine	Annually	As needed	As needed	
Maryland	Annually	As needed	As needed	Only drugs from classes that are on the PDL are taken to the P&T Committee for review. For review of clinical criteria, there is an internal agency process for most drugs. The internal agency committee is composed of physicians and pharmacists.
Massachusetts	As needed	As needed	As needed	Therapeutic classes reviewed when new drugs enter the class or as needed (at least annually).
Michigan	Other	Other	Other	All PDL drug classes and PA criteria are reviewed at least once annually broken out across quarterly meetings. Additionally, adhoc step therapy, PA criteria, or PDL coverage changes may take place in cases of product availability or other market changes.
Minnesota	NR	NR	NR	
Mississippi	Other	As needed	As needed	Quarterly PDL reviews
Missouri	Annually	Annually	Annually	
Montana	Annually	As needed	As needed	
Nebraska	Annually	As needed	Annually	PA criteria reviewed annually and as needed
Nevada	Other	Other	Other	Quarterly reviews
New Hampshire	As needed	Annually	Annually	
New Jersey	NA no FFS PDL	NA no step therapy	As needed	
New Mexico	NA no FFS PDL	NA no step therapy	NR	
New York	Annually	As needed	As needed	
North Carolina	Other	Other	Other	PDL review is quarterly; PA and policy are reviewed every 3 years
North Dakota	Annually	Annually	Annually	
Ohio	NR	NR	NR	
Oklahoma	Annually	Annually	Annually	
Oregon	As needed	As needed	As needed	
Pennsylvania	Annually	Annually	Annually	
Rhode Island	Annually	As needed	As needed	
South Carolina	Other	As needed	As needed	PDL reviewed every 6 months (Jan. 1 and July 1)
South Dakota	Annually	Annually	Annually	
Tennessee	Other	Other	Other	The P&T Committee meets once per quarter to address PDL, Step therapy, and/or PA criteria for established classes and new drugs to market.
Texas	Other	NA no step therapy	Other	PA criteria and PDL classes are reviewed at least once annually. The DUR Board meets quarterly to perform these functions. There are no additional step therapies imposed.
Utah	Annually	Annually	Annually	
Vermont	Other	Other	Other	The DUR Board meets 7 times per year. Agendas include New Drug Reviews and Thearpeutic class reviews for addition and changes to the PDL, including PA criteria/step therapy where applicable.
Virginia	Annually	As needed	Annually	
Washington	Annually	As needed	As needed	
West Virginia	Annually	As needed	As needed	
Wisconsin	Other	As needed	As needed	PDL meetings are held twice per year with each PDL drug class being reviewed annually.
Wyoming	Annually	As needed	As needed	

*Notes: States were asked how often PDLs, step therapy criteria and PA criteria are reviewed by DUR boards and/or P&T committees. Pharmacy and therapeutics (P&T) committees or drug utilization review (DUR) board are committees of physicians and pharmacists that help inform the development of the PDL, review drugs, and develop coverage decisions. "NR" = Not Reporting.



Table 6: States Limiting the Number of FFS Prescriptions July 1, 2023

States	Description of Limit	Drugs/Drug Classes or Individuals Exempted
Alabama	Limit of 5 prescriptions per month for adults (excluding nursing home residents), including up to 4 brand name drugs	Antipsychotic, antiepileptic, antiviral, and three-month maintenance supply drugs
Arkansas	Limit of 6 prescriptions per month for non- expansion adults (excluding long term care). Assisted Living HCBS waiver adults allowed 9 prescriptions per month.	Selected maintenance classes including drugs for diabetes, hypertension, cholesterol, breathing disorders (asthma/COPD), family planning, tobacco cessation, bleeding disorders (warfarin), and drugs for MAT/AUD.
Georgia	Limit of 5 narcotic prescriptions per month	Cancer and hospice patients
Illinois	Limit of 4 prescriptions per month, including a 3 brand limit	Oncolytics, Antiretrovirals, Contraceptives, Immunosuppressants, OTCs, Test Strips & Monitors
Louisiana	Limit of 4 prescriptions per month	None
Mississippi	Limit of 6 prescriptions per month for adults with no more than 2 brand-name drugs	Preferred brands on the PDL do not count toward the 2 brand limit
Nevada	OTC drugs are limited to two prescription requests for medications in the same therapeutic class	None
Oklahoma	Limit of 6 prescriptions per month with no more than 2 brand-name drugs. For HCBS waiver enrollees, a limit of 13 prescriptions per month.	Contraceptives, smoking cessation, anti-neoplastics, MAT, naloxone, HIV, hemophilia, diabetic testing supplies, vaccines
Tennessee	Limit of 5 prescriptions per month with no more than 2 brand-name drugs for adults 21 and over who are not in an institution or HCBS waiver.	Including, but not limited to: MAT therapy, Narcan, antitubercular agents, antibiotics, antifungals, anti-infectives, antivirals, cardiovascular agents, central nervous system agents, topical antivirals, antipsoriatrics and antineoplastics, diabetic supplies, endocrine and metabolic agents (including oral contraceptives and diabetes agents), immunologic agents, oncology agents, clotting factor, COVID-19 and flu vaccines, respiratory agents, and smoking cessation
Texas	Limit of 3 prescriptions per month for adults (excluding HCBS waiver enrollees)	Family planning products, home health supplies, mosquito repellent, flu vaccines, smoking cessation products, vitamins and minerals, COVID 19 at home test kits
Wisconsin	Limit of 5 opioid prescription fills per month excluding nursing home residents	Buprenorphine products used for opioid use disorder, liquid antitussive products containing opioids and methadone products used for opioid use disorder

^{*}Notes: States were asked if there is a monthly or other limit on the number of FFS prescriptions an enrollee may receive as of July 1, 2023. "HCBS waiver" = Section 1915(c) Home and Community-Based Services waiver.



Table 7: FFS Policies and Tools to Promote Generic Utilization July 1, 2023

States	Mandatory Generics	Lower Copays for Generics	Higher Dispensing Fee for Generic Substitution	Tiered Dispensing Fee Based on Pharmacy's Generic Drug Utilization Rate	Provider Education	Other	No Policies or Tools
Alabama	Х						
Alaska	X						
Arizona	X						
Arkansas	X	X	X				
California	X						
Colorado	X					X	
Connecticut	X				Х		
Delaware	X						
DC	X				Х		
Florida	NR	NR	NR	NR	NR	NR	NR
Georgia	Х	X					
Hawaii	X						
Idaho						X	
Illinois	X						
Indiana	X						
Iowa						Х	
Kansas	NR	NR	NR	NR	NR	NR	NR
Kentucky						Х	
Louisiana	Х						
Maine	X						
Maryland	Х	X					
Massachusetts	Х	Х				Х	
Michigan		X				Χ	
Minnesota	NR	NR	NR	NR	NR	NR	NR
Mississippi	Х				Х		
Missouri	Х						
Montana	X						
Nebraska		Х					
Nevada	X					Х	
New Hampshire	X						
New Jersey	X						
New Mexico	Х						
New York	Х	X			Х	Χ	
North Carolina	Х						
North Dakota	Х						
Ohio	NR	NR	NR	NR	NR	NR	NR
Oklahoma	Х						
Oregon	X				Х		
Pennsylvania	Х	X					
Rhode Island						Х	
South Carolina						Х	
South Dakota	Х	х					
Tennessee	Х	X			Х		
Texas	х					Х	
Utah	Х						
Vermont	Х						
Virginia	Х						
Washington	Х					Х	
West Virginia	X						
Wisconsin		х					
Wyoming	Х	X					
Totals	39	12	1	0	6	12	0



Table 8: Supplemental Rebate Programs July 1, 2023

States	Supplemental Rebate Program in Place?	Negotiator(s)	Negotiator Competitively Procured?
Alabama	Yes	Medicaid agency	No
Alaska	Yes	PBM	Yes
Arizona	Yes	More than one of the above	Yes
Arkansas	Yes	Purchasing pool	Yes
California	Yes	Medicaid agency	No
Colorado	Yes	PBM	Yes
Connecticut	Yes	Purchasing pool	Yes
Delaware	Yes	Purchasing pool	Yes
DC	Yes	Purchasing pool	Yes
Florida	NR	NR	NR
Georgia	Yes	Other vendor	Yes
Hawaii	No	NR	NR
Idaho	Yes	Purchasing pool	Yes
Illinois	Yes	Medicaid agency	No
Indiana	Yes	PBM	Yes
Iowa	Yes	Purchasing pool	Yes
Kansas	NR	NR NR	NR
Kentucky	Yes	More than one of the above	No
Louisiana	Yes	More than one of the above	Yes
Maine	Yes	Purchasing pool	Yes
Maryland	Yes	Purchasing pool	No
Massachusetts	Yes	Medicaid agency	No
Michigan	Yes	Purchasing pool	Yes
Minnesota	NR	NR	NR
Mississippi	Yes	Purchasing pool	Yes
Missouri	Yes	Other vendor	Yes
Montana	Yes	Purchasing pool	Yes
Nebraska	Yes	PBM	Yes
Nevada	Yes	Purchasing pool	Yes
New Hampshire	Yes	PBM	Yes
New Jersey	No	NR	NR NR
New Mexico	No	NR	NR
New York	Yes	More than one of the above	Yes
North Carolina	Yes	Purchasing pool	Yes
North Dakota	Yes	Purchasing pool	No
Ohio	NR	NR	NR
Oklahoma	Yes	Purchasing pool	No
Oregon	Yes	Purchasing pool	No
Pennsylvania	Yes	More than one of the above	Yes
Rhode Island	Yes	Purchasing pool	No
South Carolina	Yes	Purchasing poor PBM	Yes
South Dakota	Yes	Purchasing pool	NR
		• •	
Tennessee	Yes Yes	More than one of the above Other Vendor	Yes Yes
Texas			
Utah	Yes	Purchasing pool	Yes
Vermont	Yes	Purchasing pool	Yes
Virginia	Yes	PBM	Yes
Washington	Yes	More than one of the above	Yes
West Virginia	Yes	Purchasing pool	No
Wisconsin	Yes	Purchasing pool	Yes
Wyoming	Yes asked if they have supplemental rebate agreements in	Purchasing pool	No

^{*}Notes: States were asked if they have supplemental rebate agreements in place, what entity negotiates supplemental rebates and if the state's negotiator is selected through competitive procurement as of July 1, 2023. "NR" = Not Reporting.



Table 9: FFS Pharmacy Copayment Requirements for Non-Exempt Adults July 1, 2023

	Required for	Copay Required				
States	Non-Exempt Adults	Non-Expansion Adults	Expansion Adults	FY 2024 Copay Changes		
Alabama	No	N/A	Non-expansion state			
Alaska	Yes	\$0.50/\$3.50 for under/over \$50 drug cost	Same			
Arizona	No	N/A	N/A			
Arkansas	Yes	\$4.70 generics and preferred brands; \$9.40 other specialty medications; quarterly cap on total copays per member. Copays applicable to small subset of Working Disabled and Transitional Medicaid enrollees.	Same for some expansion adults depending on income.			
California	No	N/A	N/A			
Colorado	No	N/A	N/A			
Connecticut	No	N/A	N/A			
Delaware	Yes	\$0.50-\$3.00 based on drug cost; \$15 monthly copay cap	Same			
DC	Yes	\$1.00 brand and generic	Same			
Florida	NR	NR	Non-expansion state			
Georgia	Yes	0.50 for preferred; $0.50\$ for non-preferred based on drug cost.	Non-expansion state			
Hawaii	No	N/A	N/A			
ldaho	No	N/A	N/A			
Illinois	No	N/A	N/A			
Indiana	No	N/A	N/A			
lowa	No	N/A	N/A	*Copays resume 6/1/2024 (\$1 generics an preferred brands; \$2-\$3 non-preferred brands based on drug cost)		
Kansas	NR	NR	Non-expansion state			
Kentucky	No	N/A	N/A			
Louisiana	Yes	\$0.50-\$3.00 based on drug cost.	Same			
Maine	No	N/A	N/A			
Maryland	Yes	\$1.00 generic/preferred brand; \$3.00 non-preferred brand	Same			
Massachusetts	No	N/A	N/A			
Michigan	Yes	\$1.00 generic/preferred brand; \$3.00 other brand	Same for expansion adults up to 100% FPL; \$4.00 generic/preferred brand and \$8.00 other brand for those with higher income	Copays for all expansion adults aligned with non-expansion adults 1/1/2024		
Minnesota	NR	NR	NR			
Mississippi	No	N/A	Non-expansion state			
Missouri	No	N/A	N/A			
Montana	No	N/A	N/A			
Nebraska	No	N/A	N/A	*Copays resume 6/1/2024 (\$2.00 generic/\$3.00 brand)		
Nevada	No	N/A	N/A			
New Hampshire	Yes	\$1.00 brand and generic	Same			
New Jersey	No	N/A	N/A			
New Mexico	No	N/A	N/A			
New York North Carolina	Yes	\$1 generic, preferred brand, and brand less than generic; \$3 non-preferred brand; \$0.50 OTC; \$1 medical supplies	Same	Eliminating consus on Narcon and naccit		
North Carollia	162	\$4.00 brand and generic	Same	Eliminating copays on Narcan and possil nicotine replacement therapy and drugs used to treat substance use disorder		
North Dakota	No	N/A	N/A			
Ohio	NR	NR	NR			
Oklahoma	Yes	\$4.00 brand and generic	Same			
Oregon	No	N/A	N/A			
Pennsylvania	Yes	\$1.00 generics, \$3.00 brands	Same			
Rhode Island	No	N/A	N/A			
South Carolina	Yes	\$3.40 brand and generic	Non-expansion state			
South Dakota	Yes	\$1.00 Generics, \$3.30 Brand	Same			
Tennessee	Yes	\$1.50 for generics and preferred brands; \$3.00 for other brands	Non-expansion state			
Texas	No	N/A	Non-expansion state			
Jtah	Yes	\$4.00 brand and generic; \$20 monthly copay cap	Same			
Vermont	Yes	\$1.00 -\$3.00 depending on drug cost	Same			
Virginia	No	N/A	N/A			
Washington	No	N/A	N/A			
West Virginia	Yes	\$0 -\$3.00 based on drug cost; out of pocket maximum based on household income	Same			
Wisconsin	Yes	\$1.00 generic, \$3.00 brand copay; \$12.00 per member, per provider, per calendar month maximum. \$0.50 copay for OTC drugs and diabetic supplies with no maximum limitation per month.	Non-expansion state			
Wyoming	Yes	\$0.65 generics; \$3.65 brands	Non-expansion state			

^{*}Notes: States were asked to report if pharmacy copayments were required for adults and any differences for adults covered by the Medicaid expansion as of July 1, 2023. "Non-expansion state" = state has not implemented ACA Medicaid expansion as of July 1, 2023; "NR" = not reporting; "OTC" = over the counter drug.

^{*}Copays requirements waived during the COVID-19 Public Health Emergency resume in FY 2024.



ENDNOTES

- ¹ Gifford K, Winter A, Wiant L, Dolan R, Tian M, and Garfield R, How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020. KFF, April 29, 2020. Available at: https://www.kff.org/medicaid/report/how-state-medicaid-programs-are-managing-prescription-drug-costs-results-from-a-state-medicaid-pharmacy-survey-for-state-fiscal-years-2019-and-2020/. Hereinafter referred to as 2019 KFF Medicaid Pharmacy Survey.

 ² Ibid.
- ³ Hinton E, Williams E, Raphael J, Mudumala A, et al. Amid Unwinding of Pandemic-Era Policies, Medicaid Programs Continue to Focus on Delivery Systems, Benefits, and Reimbursement Rates: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2023 and 2024. KFF, November 14, 2023. Available at: https://www.kff.org/medicaid/report/50-state-medicaid-budget-survey-fy-2023-2024/.
- ⁴ Judy-Cecil V, Bechtel S. Single Pharmacy Benefit Manager. Kentucky Cabinet for Health and Family Services. Prepared for the Interim Joint Committee on Health Services, September 27, 2023. Available at: https://ncpa.org/sites/default/files/2023-11/KY Single PBM PPT Oct 23.pdf.
- ⁵ Ohio contracts with a single PBM to administer pharmacy benefits for MCO enrollees according to a uniform PDL and single set of prior authorization policies and claims processes. The single PBM meets requirements to be a prepaid ambulatory health plan (PAHP) under federal Medicaid managed care rules, providing "managed care tools and flexibilities for advancing policy and cost effectiveness of services". Ohio separately contracts with a Pharmacy Pricing and Audit Consultant to develop reimbursement methodologies and oversee and audit the single PBM. Source: The Ohio Department of Medicaid. About the SPBM and PPAC. Available at: https://managedcare.medicaid.ohio.gov/managed-care/single-pharmacy-benefit-manager/odm-spbm-ppac.
- ⁶ The ACA extended federal statutory rebates to prescription drugs provided under Medicaid managed care arrangements. Prior to the ACA, manufacturers only had to pay rebates for outpatient drugs purchased on a feefor-service basis, not those purchased through managed care.
- ⁷ Twenty-nine states reported carving pharmacy benefits into MCO contracts (with possible exceptions) as of July 1, 2023, and one additional state reported carving the pharmacy benefit into MCO contracts but uses a single state PBM (KY). Publicly available data was used to document MCO coverage of outpatient pharmacy benefits in three (FL, KS, and MN) of the four states that did not respond to the survey.
- ⁸ Ohio was the fourth state that did not respond to the Medicaid Pharmacy Survey. Publicly available Medicaid MCO model contracts confirm pharmacy services and benefits (with exception of provider-administered drugs) are carved out of MCO contracts and covered by the state's contracted PBM as of July 1, 2023. See Medicaid Managed Care Provider Agreement (Amended effective 9/1/2023), available at
- https://medicaid.ohio.gov/resources-for-providers/managed-care/mc-policy/managed-care-agreements/managed-care-agreements.
- ⁹ 2019 KFF Medicaid Pharmacy Survey.
- ¹⁰ California and Ohio carved out pharmacy from managed care in 2022. California Department of Health Care Services. Medi-Cal Rx Overview. Available at https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx. Ohio Department of Medicaid. Single Pharmacy Benefit Manager and Pharmacy Pricing and Audit Consultant. Available at: https://managedcare.medicaid.ohio.gov/managed-care/single-pharmacy-benefit-manager. New York's pharmacy carve out was effective April 1, 2023. New York State Department of Health. Transition of the Pharmacy Benefit from Managed Care (MC) to Medicaid NYRx Pharmacy Program Frequently Asked Questions (FAQs). Updated April 10, 2024. Available at:

https://www.health.ny.gov/health care/medicaid/redesign/mrt2/pharmacy transition/pharmacy transition fag.htm.



- ¹¹ California Department of Health Care Services. Medi-Cal Rx Overview. Available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx. Louisiana Department of Health, Request for Proposals for Pharmacy Benefit Management Services for Louisiana Medicaid Managed Care Organizations (RFP #: 3000018331). Mississippi Division of Medicaid. Medicaid to Implement Single Pharmacy Benefit Administrator for All Pharmacy Claims on July 1. *MS Medicaid Provider Bulletin*. April 2024. Available at: https://medicaid.ms.gov/wp-content/uploads/2024/05/April-2024-Provider-Bulletin.pdf.
- ¹² Physician-administered drugs are typically dispensed by a provider in clinical setting and covered under the medical benefit. Medicaid and CHIP Payment and Access Commission. Medicaid Coverage of Physician-Administered Drugs. Available at: https://www.macpac.gov/wp-content/uploads/2024/03/05_March-Slides Themes-from-Expert-Roundtable-on-Physician-administered-Drugs-PAD-2.pdf.
- 13 AZ, CA, CO, DC, HI, IA, IN, MD, MI, NH, NJ, NV, NY, OR, SC, TX, UT, WA, and WV.
- 14 CO, DC, HI, IA, IN, MI, NH, NV, OR, SC, TX, UT, and WA.
- ¹⁵ Chimeric antigen receptor T-cell (CAR-T) therapy is a type of immunotherapy that uses a patient's own genetically modified T-cells to find and kill cancer.
- 16 DC, GA, HI, IA, IL, IN, KY, MA, MD, MS, NC, ND, NE, NJ, NM, OR, PA, RI, UT, WI, and WV.
- ¹⁷ AR, AZ, CA, CO, MI, NV, NY, SC, and VA.
- ¹⁸ Medicaid and CHIP Payment and Access Commission. High-Cost Drugs and the Medicaid Program. *Policy in Brief.* February 2024. Available at: https://www.macpac.gov/wp-content/uploads/2024/02/Policy-in-Brief-High-Cost-Drugs-FINAL-2.pdf.
- ¹⁹ AZ, CO, DC, DE, GA, HI, IA, IN, KY, LA, MA, MD, MI, MS, NC, NE, NH, NJ, NV, OR, PA, RI, SC, TX, UT, VA, and WA.
- ²⁰ AZ, CO, HI, IA, MI, NV, TX, and WA.
- ²¹ AZ, DE, MI, NH, PA, TX, and WA.
- ²² LA, MD, MI, OR, TX, and WA.
- ²³ AZ, CO, MI, TX, and WA.
- ²⁴ CO, PA, and TX.
- ²⁵ Amid Unwinding of Pandemic-Era Policies, Medicaid Programs Continue to Focus on Delivery Systems, Benefits, and Reimbursement Rates: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2023 and 2024.
- ²⁶ AK, AR, AZ, CA, CO, DC, DE, GA, HI, IA, ID, IN, KY, LA, MA, MD, ME, MI, MO, MT, NE, NH, NM, NV, NY, PA, SC, TN, TX, UT, VA, VT, and WY.
- ²⁷ In December 2023, CMS expressed concerns about PBM practices negatively affecting access, including inadequate payment for vaccine administration and potentially anticompetitive behaviors as the result of vertical integration. Centers for Medicare & Medicaid Services. 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.
- ²⁸ Office of Inspector General. Medicaid Managed Care: States Do Not Consistently Define or Validate Paid Amount Data for Drug Claims. May 2024. Available at: https://oig.hhs.gov/documents/evaluation/9898/OEI-03-20-00560.pdf.
- ²⁹ Since 2017, states have passed over 170 laws regulating PBMs in Medicaid and other markets. National Academy for State Health Policy, State Laws Passed to Lower Prescription Drug Costs: 2017-2024. Updated July 19, 2024. Available at https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/.



- ³⁰ Florida, Kansas, and Minnesota did not respond.
- ³¹ 2019 KFF Medicaid Pharmacy Survey.
- ³² Florida, Kansas, and Minnesota did not respond.
- ³³ Centers for Medicare & Medicaid Services. National Medicaid Fee-for-Service (FFS) FFY 2022 Drug Utilization Review (DUR) Annual Report.2022. Available at: https://www.medicaid.gov/media/171456.
- 34 Ibid.
- ³⁵ Washington reported having both a DUR board and P&T committee but noted that both entities have the same members. States reporting no P&T committee as of July 1, 2023, were California, Georgia, Hawaii, Maine, North Dakota, New Hampshire, New Jersey, New York, and Oklahoma.
- ³⁶ Centers for Medicare & Medicaid Services. National Medicaid Managed Care Organization (MCO) 2022 FFY Drug Utilization Review (DUR) Annual Report. 2022. Available at: https://www.medicaid.gov/media/171796.
- ³⁷ 42 CFR Section 456.716.
- ³⁸ States that reported having no DUR board conflict of interest policy: Hawaii, Missouri, North Carolina, and Rhode Island. South Dakota skipped this question, and Florida, Kansas, Minnesota, and Ohio did not respond to the survey.
- ³⁹ Responding states with P&T Committees that reported having no P&T committee conflict of interest policy were Missouri, North Carolina, New Mexico, and Rhode Island.
- ⁴⁰ Hawaii reported that its DUR board had no conflict of interest policy and that it did not have a P&T committee.
- ⁴¹ Non-responding states for this portion of the survey were FL, KS, MN, NC, and OH.
- ⁴² Centers for Medicare & Medicaid Services. Medicaid Drug Rebate Program (MDRP). Available at: https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.
- ⁴³ New Jersey and New Mexico reported having no PDL in place for FFS prescriptions as of July 1, 2023, and Hawaii reported having a FFS PDL limited to only its dental drug program. California is counted as having a PDL because the state has a contract drug list (CDL) that functions like a PDL by giving preference to drugs on the CDL over drugs not on the list to treat the same medical condition.
- ⁴⁴ 2019 KFF Medicaid Pharmacy Survey.
- ⁴⁵ South Carolina Department of Health and Human Services. Implementation of a Single Preferred Drug List. May 8, 2024, Available at: https://www.scdhhs.gov/communications/implementation-single-preferred-drug-list#:~:text=Effective%20July%201%2C%202024%2C%20the,the%20Healthy%20Connections%20Medicaid%20 program.
- ⁴⁶ AR, DC, GA, IL, KY, LA, MA, MI, NC, NJ, NM, PA, SC, TX, and VA.
- ⁴⁷ AZ, IN, and NH.
- ⁴⁸ Arkansas reported that the Medicaid agency does not refer to any PAs or criteria as actual step therapy; rather if clinical guidelines refer to drugs in a procession from an agent or class to another, the Medicaid agency would follow that in its clinical PA criteria or PDL.
- ⁴⁹ AR, DC, GA, IL, KY, LA, MA, MI, MS, NC, NH, NJ, NM, PA, and TX.
- ⁵⁰ AR, DC, IL, KY, LA, MA, MI, MS, NC, NH, NJ, NM, PA, and VA.



- ⁵¹ Arizona and Indiana reported review and approval requirements varied by drug class for both PA criteria and step therapy criteria, and Virginia reported that MCOs must follow that state's PA criteria for "closed classes."
- ⁵² Medicaid and CHIP Payment and Access Commission, Physician-administered drugs. Available at: https://www.macpac.gov/physician-administered-
- <u>drugs/#:~:text=A%20physician%2Dadministered%20drug%20is,are%20typically%20physician%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%20drug%2Dadministered%2Dadministered%20drug%2Dadministered%2D</u>
- ⁵³ 42 U.S.C. §1396r-8 (d) (5).
- ⁵⁴ AR, AZ, DC, DE, HI, IA, IL, IN, KY, MA, MS, NC, NH, NJ, NM, PA, RI, TX and WA.
- 55 LA, MI, NE, NV and VA.
- ⁵⁶ Hawaii reported that its dental drug program formulary does not have biosimilars and that each MCO has its own process for biosimilars. If patients enter the FFS transplant program with an MCO approved biosimilar, it is maintained
- ⁵⁷ Becker C, Digging Into Prescription Drug Data: Affordability Boards and Transparency. National Conference of State Legislatures., Updated October 26, 2022. Available at: https://www.ncsl.org/health/digging-into-prescription-drug-data-affordability-boards-and-transparency.
- ⁵⁸ LexisNexis. Potentially Big Year for Prescription Drug Affordability Boards. State Net Insights. March 25, 2024. Available at: https://www.lexisnexis.com/community/insights/legal/capitol-journal/b/state-net/posts/potentially-big-year-for-prescription-drug-affordability-boards. According to this source, the 11 states are Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Oregon, and Washington.
 ⁵⁹ Centers for Medicare & Medicaid Services. Physician Administered Drugs (PADs). Updated October 20, 2022. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/physician-administered-drugs-pad/index.html.
- 60 New Jersey and New Mexico do not have a PDL and Hawaii has no PDL except for a small dental program formulary.
- ⁶¹ AZ, DC, HI, MD, MI, NH, NJ, NM, NV, OR, SC, UT, VA, and WA. Non-responding, non-carve-out MCO states are Florida, Kansas, and Minnesota.
- 62 2019 KFF Medicaid Pharmacy Survey.
- 63 Ibid.
- ⁶⁴ AL, AZ, CO, MA, MI, ND, OK, TX and WA.
- 65 AZ, MA, OK and TX.
- 66 MA, MI, ND, OK, TX and WA.
- 67 CO, MA, MI and OK.
- 68 AZ, MA, MI and ND.
- ⁶⁹ GA, TN and NY.
- ⁷⁰ AR, DC, DE, ID, IL, IN, MO, PA, SD and VA.
- 71 CA, MS, SC and WV.
- ⁷² AR, AZ, DC, GA, and PA.
- ⁷³ New Mexico Legislature. HB 165 Fiscal Impact Report. Updated February 12, 2024. Available at: https://www.nmlegis.gov/Sessions/24%20Regular/firs/HB0165.PDF.
- ⁷⁴ 305 ILCS 5/5-5.12b(a)
- ⁷⁵ Medicaid Drug Rebate Program (MDRP).



- ⁷⁶ Health Resources & Services Administration. 340B Drug Pricing Program. Last reviewed July 2024. Available at: https://www.hrsa.gov/opa.
- ⁷⁷ DC, DE, IA, IL, IN, KY, MA, NV, OK, RI and VA.
- ⁷⁸ Non-responding states were CA, FL, KS, MN, and OH.
- ⁷⁹ Berenbrok LA, Tang S, Gabriel N, et al. Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis, *Journal of the American Pharmacists Association*. 2022;62(6):1816–1822.e2.
- ⁸⁰ Weaver K. Provider Status in the States. *Pharmacy Times*. December 10, 2014. Available at: https://www.pharmacytimes.com/view/provider-status-in-the-states.
- ⁸¹ APhA Foundation. Medication Therapy Management (MTM). Available at: https://www.aphafoundation.org/medication-therapy-management#:~:text=care%20delivery%20system-, Definition.provision%20of%20a%20medication%20product.
- 82 Non-responding states were FL, KS, MN, OH, and SD.
- ⁸³ AK, AL, AR, CA, CO, DC, HI, IA, ID, IL, IN, LA, MA, MD, MI, MO, MS, MT, NC, ND, NE, NH, NM, NV, OK, OR, PA, TX, UT, VA, VT, WA, WV and WY.
- 84 AR, DC, HI, IA, IL, IN, LA, MA, MD, MI, MS, NC, ND, NH, NM, OK, PA, TX, UT, VA, and WA.
- 85 MD and MI.
- ⁸⁶ Horrow C, Kesselheim AS. Confronting High Costs And Clinical Uncertainty: Innovative Payment Models For Gene Therapies. *Health Affairs*. 2023;42(11); and Ofengeym Y, Dworkowitz A, Fiori A. Accessing Cell and Gene Therapies Insights on Coverage, Reimbursement and Emerging Models. Manatt Health. July 2023.
- ⁸⁷ Drugs.com. 10 of the Most Expensive Drugs in the U.S. Updated April 1, 2024. Available at: https://www.drugs.com/article/top-10-most-expensive-drugs.html.
- 88 ÅK, AL, AZ, CA, DC, DE, IL, IN, MA, MI, MO, NJ, NM, NY, OK, OR, SC, SD, UT, VT, WI, WV, and WY.
- ⁸⁹ Centers for Disease Control and Prevention. Preventing HIV with PrEP. January 18, 2024. Available at: https://www.cdc.gov/hiv/prevention/prep.html?CDC_AAref_Val=https://www.cdc.gov/hiv/basics/prep/about-prep.html.
- ⁹⁰ Apretude is given every other month by a healthcare provider after initiation injections have been given one month apart for two consecutive months. Apretude patient information is available at: https://apretude.com/?qclid=a7814356c97c1d8a1ef62140b1d57e53&qclsrc=3p.ds&.
- ⁹¹ Includes Maine and Maryland who reported that while the brand version of Truvada was subject to PA, the generic version was not.
- 92 Social Security Act Sec. 1927(d)(2).
- ⁹³ Centers for Medicare & Medicaid Services. Medicaid Drug Rebate Program Notice: Defining a "Prescribed Drug" and a "Covered Outpatient Drug," October 5, 2016, Release No. 178. Available at: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-178.pdf.
- ⁹⁴ Long M, Diep K, Sobel L, Salganicoff A, Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field. KFF. September 14, 2023. Available at: https://www.kff.org/affordable-care-act/report/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field/.



- ⁹⁵ Legislative Analysis and Public Policy Association. Naloxone Access: Summary of State Laws. January 2023. Available at: https://legislativeanalysis.org/wp-content/uploads/2023/02/Naloxone-Access-Summary-of-State-Laws.pdf.
- ⁹⁶ AZ, DC, GA, HI, IL, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NH, NM, NY, OK, PA, SC, TN, TX, UT, VA, VT, WA, WI, and WV. One additional state, Oregon, reported that a statewide standing order was being pursued.
- ⁹⁷ AK, AR, CO, CT, DC, DE, ID, ND, NM, NV, UT, VA, VT, and WY.
- ⁹⁸ CA, CO, DC, DE, ID, ND, NV, OR, and UT. Also, New York reported that pharmacy dispensing legislation had been enacted and is pending enabling regulation.
- ⁹⁹ IL, ME, NM, OK and SC. Also, Massachusetts and Wisconsin reported plans to implement a standing order in the future.
- ¹⁰⁰ Public Law 117-2, 2021, Section 9816.
- ¹⁰¹ Williams E. What Are the Implications of the Recent Elimination of the Medicaid Prescription Drug Rebate Cap? KFF. January 16, 2024. Available at: https://www.kff.org/policy-watch/what-are-the-implications-of-the-recent-elimination-of-the-medicaid-prescription-drug-rebate-cap/.
- ¹⁰² Lupkin S. A popular asthma inhaler is leaving pharmacy shelves. Here's what you need to know. NPR. December 30, 2023. Available at: https://www.npr.org/sections/health-shots/2023/12/30/1222224197/a-popular-asthma-inhaler-is-leaving-pharmacy-shelves-heres-what-you-need-to-know.
- ¹⁰³ Congressional Budget Office. How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. February 2023. Available at: https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.
- ¹⁰⁴ US Food and Drug Administration. Accelerated Approval Program. Available at: https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program.
- ¹⁰⁵ National Association of Medicaid Directors. Letter of Support for MACPAC's Accelerated Approval Pathway Drug Rebate Proposal, April 1, 2021. Available at: https://medicaiddirectors.org/wp-content/uploads/2022/02/NAMD-Sends-Letter-of-Support-for-MACPACs-Accelerated-Approval-Pathway-Drug-Rebate-Proposal-updated.pdf.

