NCSL Toolkit and Resources on High Costs in Medicaid Drugs (Part A)
UPDATED: August 2018 for the Utah Legislature *
Compiled by Richard Cauchi, NCSL Health Program, Denver, Colorado

With Medicaid prescription drug expenditures reaching more than $57.3 billion nationwide (2015,) state legislators and state policymakers nationwide are actively seeking a fuller understanding of the costs, the structures and requirements and promising practices already implemented or being tried in selected states. **

With hundreds of reports and thousands of pages of facts and ideas, this NCSL report seeks to distill practical, state-related information into a single easy-to-use document. Rather than reinvent the research, this Toolkit offers key summaries, excerpts and brief examples, all specific or related to state Medicaid programs. Sources include federal agencies, state agencies and offices, as well as academic and commercial research and publications. Some formats are captured in original design, thus the varied styles and readability. All NCSL-published material may be referenced online or reproduced with attribution. All copyrighted material remains the property of the authors or publishers.

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Part B – External Recent News and Data

* - This is a prepublication draft of NCSL and third-party material already available in diverse sources, combined for policymaker convenience. The included links and citations provide additional details and attribution.

** - Cumulative expenditures were $42 billion with rebates reported at $22 billion for 2014 (MACPAC).
1- Introduction and overview

Prescription drugs play a central role in improving the health of tens of millions of Americans, including most Medicaid enrollees. For those with life-threatening diseases, particularly those who are now too ill or disabled to work or otherwise qualify for Medicaid, prescription drugs are a lifeline. Millions more gain a better quality of life, so they can return to work or care for their family. For most patients, one or more prescriptions are a lower-cost and less disruptive treatment option than hospitalization, emergency rooms visits or a long-term-care facility.

At the same time, it is widely known that prescription drug costs are the fastest growing segment of U.S. health care spending, especially over the past three years (2015-2017). “With the continued release of new and innovative therapies, state Medicaid programs are under increasing pressure to provide access to these drugs, while managing competing priorities and program budgets. As states’ recent experiences with new hepatitis C drugs illustrate, soaring costs of specialty drugs have exceeded Medicaid budgets, forcing state agencies to request additional funding from their legislatures, straining allocation of public resources, and putting other programs at risk.” Faced with this challenge, state Medicaid programs need policy options to manage costs and ensure beneficiary access to effective and safe specialty medications.

Under the federal Medicaid Drug Rebate Program (MDRP), states have access to rebates that have historically helped to control outpatient prescription drug spending. In exchange, however, state Medicaid programs must cover all drugs produced by manufacturers who have signed federal rebate agreements. “For new, high-cost specialty therapies with few or no competitors, states have raised concern that federal rebate requirements hinder states’ ability to negotiate drug pricing and coverage”.

Source: NCSL, with statistics from National Association of Medicaid Directors [NAMD], 2016; and the Oregon Center for Evidence-Based Policy
2- Prescription drug high costs – overview statistics

- “Specialty drug spending is projected to increase at an even faster rate with estimates of 11.8%, 13.7%, and 15.4% growth in 2016, 2017, and 2018, respectively (Express Scripts, 2016). Some estimates place the projected specialty drug cost growth rate at upwards of 19% per year (Segal Consulting, 2016).”

- In 2016, there were 300 specialty drugs on the market, and nearly 700 specialty drugs under development. By 2020, some estimates project that specialty drug spending will comprise more than half of all drug expenditures, and 9.1% ($400 billion) of total national health spending (PEW Charitable Trusts).

- Within Medicaid programs, states are experiencing an increase in the cost and utilization of prescription drugs, with a particularly sharp increase in specialty drug expenditures. Some estimates place overall Medicaid drug spending growth at over 24% per year.

- Medicaid Specialty drugs are a key driver in this spending growth. In 2014, high-cost drugs (defined as over $1,000 per claim) accounted for 0.9% of pharmacy claims, but 32% of total Medicaid drug spending “

Sources: MACPAC, 2016; Oregon Center Report, 2016

3- Medicaid Rx Purchasing Structure & History

The federal statutory structure appears very complex, although most provisions have been in place since the 1990’s. This is the CMS description for states:

The Medicaid Drug Rebate Program is a program that includes CMS, State Medicaid Agencies, and participating drug manufacturers that helps to offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients. Approximately 600 drug manufacturers currently participate in this program. All fifty States and the District of Columbia cover prescription drugs under the Medicaid Drug Rebate Program. The amount of rebate due for each unit of a drug is based on statutory formulas as follows:

- **Innovator Drugs** – the greater of 23.1% of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.

- **Drugs Approved by FDA Exclusively for Pediatric Indications + Blood Clotting Factors** – the larger of 17.1% of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.

- **Line Extensions** – For a drug that is a new formulation (line extension) of a brand name drug that is an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:
  - the AMP for the line extension drug,
  - the highest additional rebate for any strength of the original brand name drug, and
  - the total number of units of each dosage form and strength of the line extension drug (section 1206 of HCERA, which replaced section 1927(c)(2)(C) as added by section 2501(d) of PPACA).

- **Cap on Total Rebate Amount for Innovator Drugs** – The limit on the total rebate amount for each innovator drug is at 100 percent of the AMP.

- **Generic or Non-Innovator Drugs** – 13% of the AMP per unit.

- **Orphan drugs --- exceptions**

(Source: CMS website)
4-State Medicaid Supplemental Rebates & Negotiations

Unlike the 1990 federal laws, Supplemental rebate were initiated and urged by states, and finally approved as an option by CMS on a case by case basis in 2003. This was approved in conjunction with Medicaid Preferred Drug Lists.

- **Multistate Medicaid Purchasing** – 25 states divided into 4 groups; (NCSL map)
  
  The Sovereign States Drug Consortium (SSDC) was founded as a non-profit structure in October 2005 by three states for Medicaid purchases. **Now 12 states:** Delaware, Iowa, Maine, Mississippi, North Dakota, Ohio (joined 2017), Oklahoma, Oregon, Utah, Vermont, West Virginia and Wyoming are operational members as of June 2018.

- **Managed Care Organizations (MCOs)** CMS reports that only 18 states are set up to include MCO Supplemental Rebate Collections for Utilization, as of March 2018. (See 5B below)

340B, the HHS/HRSA Drug Discount Program – “State Medicaid programs may seek to maximize drug savings through 340B drug prices, although limited access to the federally determined 340B ceiling prices makes 340B policy implementation administratively burdensome to implement. Most states expect entities participating in the 340B program to bill the state at the AAC for 340B drugs, which is generally lower than Medicaid drug prices. However, because 340B ceiling and sub-ceiling prices are proprietary, states must rely on post-payment reviews to determine payment accuracy. To avoid duplicate discounts, states may forgo submitting 340B drug claims for federal Medicaid rebates. Some states have developed programs to take advantage of drug pricing offered through 340B Hemophilia Treatment Centers, requiring Medicaid beneficiaries with hemophilia to receive care through these providers.”

  o Source: [Oregon: SMART-D report](#)

Medicaid State Supplemental Pharmaceutical Rebates (Discounts)

Compiled by NCSL. Updated 6/1/2018
See online Report for details and status


“Forty-Eight States reported $2 billion in ACA offset rebates for 2011 and 2012, and 44 States reported collecting $1.7 billion in supplemental Medicaid rebates during the same period. We also found that the method most States used to calculate supplemental rebates may reduce rebate amounts. Finally, we found that six States reported making changes to their SRAs because of changes related to the ACA.”

States use prior authorization as a primary tool to manage high-cost specialty drugs, focusing on criteria to encourage appropriate use of the drugs, patient adherence, and discouraging waste. For newly released drugs, some states require prior authorization for an initial period to allow time to determine whether ongoing prior authorization or other tracking is needed. Some states have limited the number of brand prescriptions that beneficiaries may fill. States’ ability to prior authorize certain specialty drug classes may also be limited by state law protecting conditions such as oncology, human immunodeficiency virus (HIV), hepatitis C, from coverage restrictions.

In recent months, CMS issued guidance raising concerns that state prior authorization criteria in the case of hepatitis C drugs were more restrictive than allowed by federal law (CMS, 2015b). Federal law allows states to limit coverage of drugs to treatment of “medically accepted indications,” defined as Food and Drug Administration (FDA)-approved indications and off-label uses supported by certain drug compendia (Social Security Act, §1927(k)(6)). States underscored concern that the recent CMS guidance undermines state authority and well-established processes through state advisory committees and drug utilization review (DUR) boards to review evidence and make these determinations. In the case of hepatitis C drugs, states were also forced to create narrow coverage requirements based on the available medical evidence and impact of the drugs’ costs on state budgets.

**Care management** involving close monitoring

*Enrollee Co-Payments:* “Medicaid members are required to pay a portion of the cost for some of the services they receive. For example, members pay up to $3 per prescription with a maximum of $15 per month.”


### Ingredient and Pharmacy dispensing fees

Each state may set its own “Ingredient cost basis” and retail pharmacy dispensing fee. The comparative list for the 50 states is available online from NCSL.

<table>
<thead>
<tr>
<th>State</th>
<th>Ingredient cost is the lesser of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utah</td>
<td>• Utah Estimated Acquisition Cost (UEAC),</td>
</tr>
<tr>
<td></td>
<td>• FUL,</td>
</tr>
<tr>
<td></td>
<td>• Utah Maximum Allowable Cost (NADAC), or</td>
</tr>
<tr>
<td></td>
<td>• Submitted Ingredient Cost</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Professional Dispensing fee is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• $9.99 (urban) located in Utah;</td>
</tr>
<tr>
<td>• $10.15 (rural) located in Utah.</td>
</tr>
<tr>
<td>• $9.99 for out of state pharmacies</td>
</tr>
<tr>
<td>• $716.54 for hemophilia clotting factor dispensed by the contracted pharmacy and in accordance with the hemophilia disease management program</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State Maximum Allowance Cost (MAC)</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
</tr>
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</table>

### Medicaid Managed Care:

States have made a significant shift of prescription drug coverage into Medicaid managed care since 2011. Managed care prescription drug spending grew from 14% of overall prescription drug spending in 2011 to 47% of overall drug spending in 2014 (Medicaid and CHIP Payment and Access Commission [MACPAC], 2016).

Medicaid managed care plans generally contract with pharmacy benefit managers to manage drug benefits and negotiate prices with manufacturers and pharmacies.

- The final Medicaid managed care rules released in April 2016 reinforce CMS expectations that Medicaid managed care plans are subject to the same prescription drug coverage requirements of Section 1927 of the Social Security Act (i.e., the MDRP and prior authorization processes) as state fee-for-service (FFS) programs [42 CFR § 438.3(s); 81 Fed. Reg. 27544 (2016)]. In addition, managed care coverage requirements cannot be more stringent than state FFS standards. However, managed care plan preferred drug lists (PDL) and prior authorization clinical criteria and review requirements do not have to be identical to state FFS standards.
- States have allowed plans varied levels of control over preferred drug lists. Most states allow plans to develop independent PDLs, although some states have retained control over PDLs for some or all drug classes. A few states manage a single state PDL that plans are required to follow.

(2017 Annual Report excerpt p. 50)

Utah Medicaid Report Excerpts – (For reference only – See Agency for full facts and publications)

“PHARMACY SERVICES

The Division of Medicaid and Health Financing provides coverage for nearly all available prescription drugs approved by the Food and Drug Administration (FDA).
To manage the costs of prescription drugs, the Division of Medicaid and Health Financing has a **generic-first requirement**. If a generic product is available in a drug class and it is not more expensive than the brand name product, then the pharmacy must dispense the generic.

The Division also employs a **Preferred Drug List (PDL) program with prior authorization**. Following a determination of safety and efficacy by the Pharmacy and Therapeutics Committee, preferred drugs are selected based upon recommendations by the Committee and the net cost of the drugs. In many cases, the manufacturers of these products provide a secondary rebate to Medicaid."


**CO-PAYMENTS**

Medicaid members are required to pay a portion of the cost for some of the services they receive. For example, members pay up to $3 per prescription with a maximum of $15 per month."

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**6-Expanded Sources for Medicaid Costs and Use**

**CMS Dashboard: Example of top-10 drugs from Medicaid Dashboard (released 5/15/2018)**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Annual Growth Rate (2012-2016)</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Lantus</td>
<td>Insulin Glargine, Hum.Rec.Anlog</td>
<td>18.7% ($13 to $25)</td>
<td>Sanofi-Aventis</td>
</tr>
<tr>
<td>2 Latuda</td>
<td>Lurasidone HCl</td>
<td>18.6% ($17 to $33)</td>
<td>Sunovion Pharma</td>
</tr>
<tr>
<td>3 Lyrica</td>
<td>Pregabalin</td>
<td>17.9% ($3 to $6)</td>
<td>Pfizer US Pharm</td>
</tr>
<tr>
<td>4 Enbrel</td>
<td>Etanercept</td>
<td>17.6% ($487 to $933)</td>
<td>Amgen</td>
</tr>
<tr>
<td>5 Humira Pen</td>
<td>Adalimumab</td>
<td>17.5% ($1,007 to $1,919)</td>
<td>Abbvie US LLC</td>
</tr>
<tr>
<td>6 Lantus Solostar</td>
<td>Insulin Glargine, Hum.Rec.Anlog</td>
<td>14.3% ($15 to $25)</td>
<td>Sanofi-Aventis</td>
</tr>
<tr>
<td>7 Abilify</td>
<td>Aripiprazole</td>
<td>11.4% ($21 to $32)</td>
<td>Otsuka America</td>
</tr>
<tr>
<td>8 Vyvanse</td>
<td>Lisdexamfetamine Dimesylate</td>
<td>11.0% ($5 to $8)</td>
<td>Shire US Inc.</td>
</tr>
</tbody>
</table>

This federal report is available online at https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html

It contains very detailed use and cost data, with an average of 17,000 lines of data for each state and each year. It is invaluable to academic researchers. It can be used by an individual state to seek out highest spending on individual drugs using the annual “Medicaid Reimbursement Amount” by drug product name. Excerpt example: https://data.medicaid.gov/State-Drug-Utilization/Drug-Utilization-2018-Utah/j9yc-5qbg
State Enacted Provisions; Outcomes to Be Determined or Not Yet Tested

During the past two to three years, several states have enacted laws with novel or alternative approaches to state regulation related to prescription drug costs and prices. The laws described below are examples from Arizona, California, Connecticut, Louisiana, Maine, Maryland, Massachusetts, Nevada, Oregon, Tennessee and Vermont. The list does not include pending legislation or laws from earlier years. NCSL’s Prescription Drug Database provides additional details and further examples of non-enacted measures, covering 2015 to 2018.

Drug Cost Transparency

California law (SB 17), enacted Oct. 19, 2017 as Chapter 603. Lead sponsor: Senator Ed Hernandez (D); Passed Senate (28y-10n) and Assembly (66y-9n).

This price transparency law applies to all drugs (brand-name and generic) with a wholesale acquisition cost of at least $40 when the price of these drugs increases more than 16 percent in the prior 12 months or 32 percent in the preceding 24 months. Requires pharmaceutical manufacturers to submit to public and private purchasers (including state agencies, health insurers and pharmacy benefit managers) 90-day advance notification of price increases for prescription drugs currently on the market, including detailed information regarding the reasons and justification for such increases, aggregating and summarizing public information. It also requires justification of launch prices for new drugs. Requires health insurers that file rate information to report specified cost information regarding covered prescription drugs, including generic, brand-name and specialty drugs. Requires reporting the percentage of the insurance premium attributable to prescription drugs.

Vermont enacted two related state laws, first in 2016, than in 2018, modifying and expanding the earlier law. Review both to obtain the full effect of the changes:

- **Vermont 2016**: (S 216), enacted in June 6, 2016 as Act 165; lead sponsor: Senator Kevin Mullin (R)
  Provides for pharmaceutical cost transparency, requiring the state to annually identify up to 15 state-purchased prescription drugs "on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing." The state attorney general "shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug" in an understandable and appropriate format. Requires that rules be adopted requiring certain insurers to provide information about the State Health Benefit Exchange plan’s drug formularies; also provides for drug dispensing fees, reimbursement, and out-of-pocket drug limits.

- **Vermont 2018**: (S 92); signed May 30, 2018 as Act No. 193; lead sponsor: Sen. Virginia Ginny Lyons (D)
  Revises provisions relating to prescription drug price transparency and cost containment. 1) It expands the provisions of Vermont’s 2016 Rx transparency law to require the Department of Vermont Health Access and health insurers with more than 5,000 covered lives to create lists of 10 prescription drugs for which the payer’s net cost has increased by 50 percent or more over the past five years or 15+ percent annually. The Office of the Attorney General will identify 15 drugs for which the drugs’ manufacturers must provide a justification for the price increase or increases. Each manufacturer must also provide a separate version of its justification that will be made public.
  2) It prohibits pharmacy benefit managers from prohibiting or penalizing a pharmacy or pharmacist for providing information to an insured about a cost-sharing amount for a prescription drug, disclosing to an insured the cash price of a prescription drug, or selling a lower-cost drug to an insured if one is available.
  3) It requires prior authorization to refill a prescription with a drug or biological product different than the originally filled prescription; requires electronic notification from the pharmacy to the provider after dispensing biological products. Requires a pharmacist to select the lowest priced drug or interchangeable biological product.

- **Vermont Attorney General implementation report, February 2018** [Full text, PDF]

Nevada law (SB 539), enacted June 15, 2017 as Chapter 509; Lead sponsor: Senator Michael Roberson (R),

This law has several provisions to contain drug costs. The law requires the state to post a list of all essential anti-diabetes medicines, and the drugs’ makers also must report annually the costs of manufacturing and marketing each product, in addition to other details. Additionally, each year the state will identify products with price increases exceeding the medical consumer price index in the past 12 months or twice the increase in the previous 24 months. Makers of those drugs must report additional information that justifies or explains their price increases. Nevada’s law makes all manufacturer-supplied information public. The law also requires:
• Reporting free goods or compensation provided by each sales representative to Nevada-licensed health care providers.

• Pharmacy benefit managers to report the dollar value of manufacturer drug rebates collected.

• All non-profit patient groups that are active in Nevada to publicly report all sources of financial support. The intent is to make it more transparent when patient groups have financial interests in aligning with and lobbying on behalf of the pharmaceutical industry.

Connecticut law (H 5384) Enrolled as Public Act No.18-41, May 17, 2018. Requires manufacturers to disclose net drug cost after rebates and to inform the state Office of Health Strategy when a company has submitted a drug approval application to the US Food and Drug Administration; requires disclosing price increase justifications to the Office, where it must be posted on the state website. Requires the Office of Health Strategy to annually list 10 drugs whose wholesale acquisition cost has increased by 25 percent and that represents substantial state spending.


Oregon law (H 4005), enacted March 12, 2018. Lead sponsor: Representative Robert Nosse (D) Requires prescription drug manufacturers to report annually to the Department of Consumer and Business Services prices of prescription drugs and costs associated with developing and marketing prescription drugs. This includes drugs for which the price was $100 or more for a one-month supply or for a course of treatment lasting less than one month, and there was a net increase of 10 percent or more in the price of these drugs over the course of the previous calendar year. Also requires drug manufacturers to report the reasons behind significant drug price increases, and authorizes the state to impose civil penalties on a manufacturer for failing to comply with reporting requirements. Requires health insurers that offer a prescription drug benefit to report to the department the most frequently prescribed and higher-priced drugs, including those whose prices have increased dramatically. The law requires insurers to detail the impact of these costs on insurance premium rates.

Louisiana law (H 436) Enacted as Act No. 220 of 2017, June 14, 2017. Sponsors: Representatives Kirk Talbot (R); H. Bernard LeBas (D); Major Thibaut (D); Helena Moreno (D); Paul Hollis (R) and Dustin Miller (D). Requires drug manufacturers to provide transparency of information regarding prescription drug prices. Each manufacturer or pharmaceutical marketer "who engages in any form of prescription drug marketing" to a physician, prescriber or any member of his or her staff must provide to the Louisiana Board of Pharmacy the current wholesale acquisition cost (WAC) of each of the drugs approved by the U.S. Food and Drug Administration and marketed in the state by that manufacturer.

Free Speech for Off-Label Pharmaceutical Use

Arizona law (H 2382), enacted March 21, 2017. Lead sponsor: Representative Lovas (R). Creates a "Free Speech in Medicine Act." Relates to pharmaceuticals, allowing drug makers to promote and market drugs off label if the information consists of "truthful promotion" of a drug, biological product or device. Prohibits the state or any medical board or subdivision from enforcing any federal or state restriction on manufacturers, health care institutions or a physician from such "truthful promotion." Does not require a health care insurer, other third-party payer or other health plan sponsor to provide coverage for the cost of any off-label use of a drug, biological product or device as a treatment. The law conflicts with current federal law, 21 USC Sec. 331, restricting drug manufacturers from promoting off-label uses.

♦ Tennessee law (H 2220) 2nd law, enacted and signed May 3, 2018

Drug Anti-Price Gouging

Maryland law (H 631), enacted May 2017. This law prohibits makers of "essential drugs" from raising prices to "unconscionable" levels. The law applies to generic and off-patent drugs on the World Health Organization’s list of "essential medicines"—considered to be the minimum pharmaceutical treatments needed for a basic health care system. Three manufacturers would be affected. Allows the state’s Medicaid agency to inform the attorney general about drugs that cost at least $80 and have a wholesale cost increase of 50 percent or more in 12 months. The attorney general can use the agency information, or it can independently identify essential generic and off-patent drugs that undergo an "unconscionable" price increase. An "unconscionable" price increase is defined as an excessive price hike that is not justified by changes in production and for which consumers have no meaningful treatment alternative. If the attorney general does not find an adequate explanation for the price increase, the issue can be referred to the state court, which can decide if penalties should be imposed on a manufacturer. The law specifies three specific remedies that a state court could apply to manufacturers: They can lower the price to an earlier, lower level; compensate all Maryland purchasers and insurance companies that paid the "unconscionable" price for the drugs; or impose civil penalties of up to $10,000 for each violation.

Prescription Drugs Covered by Health Insurance
Nevada law (A 381) of 2017, enacted June 1, 2017, as Act No. 281. Lead sponsor: Assembly member Spiegel (D) 
Relates to health insurance, prohibiting an insurer from taking certain actions concerning prescription drugs covered by individual and small group health insurance policies. Restricts increasing co-payments to a higher cost tier from original coverage for a prescription drug pursuant to a formulary with more than one cost tier. The insurer may move the prescription drug from a lower cost tier to a higher cost tier only on Jan. 1, 2018, at the annual start of the policy or when a new generic drug is approved by the FDA and is added to the lower cost tier list. Does not alter the ability of a pharmacist to substitute a generic or interchangeable biologic when it is available.

Prohibiting PBM “Gag Clauses” to Lower Prices to Consumers

Recently enacted laws in at least 24 states block commercial PBM or health insurer contracts that may prohibit pharmacies from informing customers about available alternative pricing for medications, including paying out-of-pocket, or including generics or brand products that may be less costly, or comparatively more suitable for a patient. Many bills also address the "co-pay clawback" situation. Typical state language includes, "A pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing any information described in this section or for selling a lower priced drug to the insured if one is available."

- Read Full NCSL report online | Updated July 5, 2018

Requires Brand Manufacturers to sell an already-marketed drug to a developer of a generic version of that drug

Maine law (S 432), enacted July 4, 2018

The new law "ensures increased competition in the market for drugs and biological products, which will lower the cost of prescription drugs for Maine residents and for the State." Amends the Maine Pharmacy Act to require that a drug distributed in this state must be made available for sale in this state to a person seeking to develop an application for the approval of the drug under the Federal Food, Drug, and Cosmetic Act or the licensing of a biological product under the federal Public Health Service Act; establishes disciplinary actions for noncompliance. (updated 7/20/2018)

Prescription Drug Wholesale Importation

Vermont Enacted Legislation (S 175) passed House (141v-2n) and Senate (29y-0n) May 7, 2018; signed into law May 16, 2018. Creates a wholesale importation program to purchase high-cost drugs through authorized wholesalers, who will purchase the drugs in Canada and make them available to Vermonters through an existing supply chain that includes local pharmacies. The new law requires Vermont’s Agency for Human Services, in consultation with stakeholders and the federal government, to design and submit an importation proposal to the state legislature on or before Jan. 1, 2019 and further requires the agency to submit its proposal to the federal government on or before July 1, 2019, for final approval. The importation program must be operational within six months of approval of the financing strategy, certification, and federal government sign-off.

- Read Vermont Legislature First to Approve Rx Drug Importation | Is It Safe and Cost-Effective to Import Drugs from Canada? | View an infographic on wholesale importation | posted by NASHP.

Medicaid Rx Coverage Based on Negotiation and Cost Effectiveness - Executive Order

Massachusetts, by agency executive action, requested a Section 1115 Medicaid waiver that would allow the state to choose which prescription drugs to cover based on the majority of beneficiaries’ needs and which medicines prove to be the most cost effective. The state wants the power to negotiate discounts for the drugs it purchases and to exclude drugs with limited treatment value. According to the most recent data, Medicaid spending on prescription drugs increased about 25 percent in 2014 and nearly 14 percent in 2015. If the Department of Health and Human Services approves the Bay State’s plan, it is speculated that others may take similar action.

- States want control over drug prices. Will feds give it to them? - by Governing Magazine, 5/7/2018 - “To lower health-care costs, Massachusetts is seeking to exclude certain drugs from its Medicaid program.”

Legal Analyses for State Drug Laws

Legal Resources for Drug Cost Containment Legal Challenges of Rx Drug Laws Passed in 2017 Will Shape States’ Future Cost Containment Legislation: Analysis of 2018 cases with links to individual cases, posted 2018 by the National Academy for State Health Policy.

Opposing Views: The Pharmaceutical Research and Manufacturers of America (PhRMA) argues that state legislation (like California’s SB 17) “attempts to dictate national health care policy related to drug prices in violation of the United States Constitution, singles out drug manufacturers as the sole determinant of drug costs despite the significant role many other entities play in the costs patients pay, and will cause market distortions such as drug stockpiling and reduced competition.” They note that the mandatory
transparency bills don't fully consider the costs of drug development and post-market surveillance, and the value and savings drugs bring to society. "None of these bills get at the affordability question for patients. It's a huge oversight."

**Rx Ballot Questions- Rejected in 4 states by judges and voters**

A **South Dakota** judge has blocked a ballot measure intended to limit how much state agencies could pay for prescription drugs. In July 2018 the circuit court judge ruled in favor of a group opposing the measure, which had challenged the validity of the signatures used to get the initiative on the ballot. The measure would have prevented the state from paying more than the VA pays for drugs. It’s the second time this year a court fight has kept a drug pricing initiative off the ballot — a nearly identical measure didn’t make the cut in the **District of Columbia** — and similar initiatives have failed in **Ohio** and **California** in 2016.

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**NEW YORK – ENACTED LAW**

**NY S 2007 of 2017**

**Health and Mental Health Budget: Establishes a Medicaid drug cap**

**Status:** Enacted - Act No. 57

**Date of Last Action:** 04/20/2017 - Enacted

**Author:** Office of the Governor

**Topics:** Pricing and Payment - Industry, Medicaid Use and Cost - Rx Drugs

**Associated Bills:** NY A 3007 - Same as

**Summary:** Relates to drug costs, Medicaid, pharmacy copayments, and other matters. Establishes a Medicaid drug cap. "The legislature hereby finds and declares that there is a significant public interest for the Medicaid program to manage drug costs in a manner that ensures patient access while providing financial stability for the state and participating providers. Since 2011, the state has taken significant steps to contain costs in the Medicaid program by imposing a statutory limit on annual growth. Drug expenditures, however, continually outpace other cost components... Therefore, the department will "establish a Medicaid drug cap as a separate component within the Medicaid global cap as part of a focused and sustained effort to balance the growth of drug expenditures with the growth of total Medicaid expenditures." Provides for Medicaid DUR board to follow "a recommendation for a target supplemental Medicaid rebate to be paid by the manufacturer of the drug to the department and the target amount of the rebate." If the state is unsuccessful in entering into a satisfactory rebate agreement, non-cooperating manufacturers will be required to file a detailed financial report including “actual cost of developing, manufacturing, producing... administrative, marketing, and advertising costs, including but not limited to prescriber detailing, copayment discount programs, and direct-to-consumer marketing, pricing used outside the U.S. and other specific statistics. Provides for budget implementation. [Updated 5/30/17]

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**Value-Based Purchasing and Contracting**

NCSL has held two recent (2017) meeting sessions specific to Medicaid and Prescription drugs, plus an authoritative presentation in 2016 by the Michigan Medicaid expert:


**Drug Effectiveness and SMART-D Alternative Payments**

Innovative drugs are being introduced at an accelerating pace. At the same time, the high prices of the new therapies pose a challenge for all healthcare payers’ budgets, especially state Medicaid programs. Explore alternative payment models for drug purchasing in Medicaid. **Panelists:**

- **Rhonda Driver Anderson**, Director of Pharmacy, Center for Evidence-Based Policy, Oregon
- **Peter Juhn, M.D.,** vice-president for Value and Access, Amgen Inc., California

**Respondent:**

- **Lindsey Browning**, Program Director for Medicaid Operations, National Association of Medicaid Directors, Washington, D.C.

  - [Drug_Effectiveness_Review_Project](#) | PDF |
  - [Presentation_by_P_Juhn](#) | PDF |
  - [Presentation_by_R_Anderson](#) | PDF |
  - [SMART-D_FactSheet_Jan_2017](#) | PDF |
  - [Value-Based-Innovation](#) | PDF |

- **Biotechnology and State Roles - NCSL live session** at Summit in Boston - August 8, 2017.
Biotech research is growing fast. In Massachusetts, more than 63,000 biopharma employees are working on more than 1,600 potential new medicines. Learn how new models for pricing and research are hoping to bring down the cost.

- **Video of session** - on demand
- **Moderator & Panelists:**
  - Susan Dentzer, Network for Excellence in Health Innovation, Massachusetts
  - Robert Coughlin, Massachusetts Biotechnology Council
  - Alice Moore, (Mass. Medicaid) Executive Office of Health & Human Services, Massachusetts
  - Dr. Michael Sherman, Harvard Pilgrim Health Care, Massachusetts
  - Dr. Martin Zagari, Amgen, California
  - **Additional Resources:** Moderator and Panelist Biographies | State Laws Related to Biologic Medications and Substitution of Biosimilars (NCSL report)

- **Moving Forward on Value-Based Contracting for Biopharmaceuticals** (an academic and pro-industry analysis by S. Dentzer)

- **Steve Fitton,** former Michigan Medicaid director; principal at Health Management Associates; slides 8-9-2016

8- External resources from NCSL’s online “Medicaid Rx” compendium listing

- **Medicaid: State Managed Care Pharmacy Uniform Prior Authorization Requirements** (2015-2016 State Data)  
  Prior authorization (PA) is a technique for controlling costs that requires specific drugs or services to be pre-approved by an individual’s insurance company in order to be covered by the insurer. Uniform PA requirements are state prescribed requirements for adjudicating prior authorization requests - Published by Kaiser State Health Facts 11/2016
- **Medicaid: State Managed Care Pharmacy Uniform Preferred Drug List (PDL) Requirements** (2015-2016 State Data)  
  A preferred drug list (PDL) is a list of medications that are covered without the need to obtain prior authorization. Uniform PDL requirements are state prescribed requirements for designating a specified drug product as either preferred or non-preferred.
- **Medicaid: State Managed Care Pharmacy Uniform Clinical Protocols** (New 2015-2016 State Data)  
  Uniform Clinical Protocols are state prescribed medical necessity criteria for a specified drug product.
- **Gaining Coverage Through Medicaid Or Private Insurance Increased Prescription Use And Lowered Out-Of-Pocket Spending.** Uninsured people who gained private coverage filled, on average, 28 percent more prescriptions and had 29 percent less out-of-pocket spending per prescription in 2014 compared to 2013. [Read abstract or request text] A Health Affairs study, Aug. 18, 2016.

(These are an excerpt from NCSL's "RECENT MEDICAID PRESCRIPTION DRUG LAWS AND STRATEGIES http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx

9-The New Trump Administration Plan - May 2018

The Trump administration announced on May 11 a “Blueprint to Lower Prices and Reduce Out-of-Pocket Costs.” (live link) The plan included more than 25 strategies grouped into four categories: improved competition, better negotiation, incentives to lower list prices and lower out-of-pocket costs. (Read NCSL’s analysis, posted July 2, 2018)

Mr. Trump said his administration will begin work immediately, describing it this way: "Everyone involved in the broken system -- the drug makers, insurance companies, distributors, pharmacy benefit managers, and many others -- contribute to the problem," Mr. Trump said. "Government has also been part of the problem because previous leaders turned a blind eye to this incredible abuse. But under this administration, we are putting American patients first. ... I've instructed Secretary Azar to begin moving forward on reforms that will bring soaring drug prices back down to Earth."

The blueprint strongly favors value-based pricing, with the Department of Health and Human Services calling value-based transformation of the entire health care system a top priority. The same week the 21st state enacted a no gag-clause law, President Donald Trump said “Our plan will end the dishonest double dealing that allows the middleman to pocket rebates and discounts that should be passed on to consumers and patients. Our plan bans the pharmacist gag rule which punishes pharmacists for telling patients how to save money. This is a total rip off, and we are ending it.” This federal action will affect Medicare transactions; however, only state regulators have jurisdiction over commercial and private market coverage
Appendix:
10-Step therapy for prescription drugs in Medicaid – NCSL Information and notes on a state ban

The following are a collection of facts and explanations related to the use or application of step therapy or “fail-first” policies. Sources are noted at the bottom where appropriate. Items specific to a ban will be bold in this space.

Most state Medicaid programs have adopted preferred drug lists (PDL, also called formularies), making any medication not deemed “preferred” subject to prior authorization. States use prior authorization, in conjunction with a PDL, to encourage the prescribing of the most clinically appropriate and cost-effective drug within a specific therapeutic drug category. Under federal law, non-preferred products must be made available through a review process that must provide a response within 24 hours and allow for a 72-hour supply of the drug in emergency situations. The complexity of the prior authorization process determines the extent to which it encourages trials of preferred medications first (i.e., step therapy).

Step therapy requirements under Medicaid programs vary by state and by the prescribed drug or medical condition. Some states have broad step therapy requirements for program participants; other states have narrower requirements (see IN, MI).

Among the states that have adopted legislation on step therapy are Florida, Louisiana, New York, and Vermont; while Indiana and Michigan restrict the use of prior authorization for prescription drugs.

Legislation limiting step therapy requirements was recently passed but vetoed in Maine. There is pending legislation in California that would authorize the use of step therapy, but restricts its use (a 2012 bill was passed but vetoed).

The recent legislation in Florida, Indiana, Michigan, and New York applies to Medicaid programs.

A 2011 literature review of studies of the impact of step therapy (seven commercial insurance programs and seven Medicaid programs) found that step therapy programs for drugs other than antipsychotics can provide significant savings through the greater use of lower-cost alternatives and, to a lesser extent, reduced drug utilization. On the other hand, the review found that the savings and clinical impact of step therapy for antipsychotics are unclear given the research conducted to date.

A 2013 analysis of the pending California legislation by the California Health Benefits Review Program (a University of California office that conducts analyses for the legislature) found that while step therapy does not have the goal of preventing persons from receiving prescription medications, the preponderance of evidence suggests that this may occur for some persons. It also found that there is insufficient evidence to determine whether step therapy protocols directly affect health outcomes.

For example,

- **California.** Authorizes the Department of Health Services (DHS) to establish step therapies for drugs and other items. (AB 1762 Passed Assembly and Senate, 7/03; signed by governor 8/9/03)

- **Connecticut.** § 17b-274f. Step therapy program for Medicaid prescription drugs
  - o (a) The Commissioner of Social Services may establish a step therapy program for prescription drugs in the Medicaid program. The commissioner may condition payment for such drugs on a requirement that the drug prescribed be from the preferred drug list established pursuant to section 17b-274d prior to any other drug being prescribed, provided any step therapy program shall: (1) Require that the patient try and fail on only one prescribed drug on the preferred drug list before another drug can be prescribed and eligible for payment; (2) not apply to any mental health–related drugs; and (3) require that the prescribing practitioner, when medications for the treatment of any medical condition are restricted due to the step therapy program, has access to a clear and convenient process to expeditiously request an override of such restriction from the Department of Social Services.
  - Step Therapy Prior Authorization Form Step Therapy required for the following drug classes: Acne Agents (Topical), Antimigraine Triptans, Cytokine and CAM Antagonists, Proton Pump Inhibitors, and Statins (note)

- **Georgia.** Requires insureds to fail on two older forms of antipsychotic medications before receiving newer antipsychotic agents such as clozapine, risperidone, or olanzapine. **
  - o A 2008 survey found about $7 million in drug cost savings for Georgia Medicaid after implementing ST for atypical antipsychotic medications compared with a state Medicaid program without ST. (Farley et al, 2008)

- **Florida.** The law requires the state Medicaid agency to implement a step therapy prior authorization approval process for medications excluded from its PDL. Medications listed on the PDL must be used within the previous 12 months before the alternative medications that are not listed (Fla. Rev. Stat. § 409.912 ). **
  - o The step therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling, with the trial period between the specified steps varying according to the medical indication.
A drug may be approved without meeting the step-therapy criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

1. there is not a drug on the PDL to treat the disease or medical condition that is an acceptable clinical alternative;
2. the alternatives have been ineffective in treating the beneficiary’s disease; or
3. based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The Medicaid agency has established step therapy requirements for certain drugs. For example, before an insured can be covered for Celebrex (used to treat rheumatoid arthritis) he or she must have first failed two preferred NSAIDs.

Indiana has a step therapy requirement for anti-hypertensives (i.e., drugs used to address high blood pressure). With certain exceptions, Indiana law prohibits prior authorization requirements under the state’s Medicaid program for mental health drugs, such as antianxiety, antidepressant, or antipsychotic drugs. On the other hand, prior authorization is required for a brand name drug that a prescriber determines to be “medically necessary” when there is a generic equivalent (Ind. Code § 12-15-35.5-3).

Michigan. Michigan law restricts the use of prior authorization under Medicaid. These restrictions do not apply to drugs being provided under a contract between the Department of Community Health and a health maintenance organization (Mich. Comp. Laws § 400.109h).

STEP THERAPY coverage requires that a trial of another drug be used before the medication is covered. The Pharmacy Benefits Manager (PBM) logs all prescribed medication and can track medications that qualify for Step-Therapy.

The law prohibits a prior authorization requirement for the following types of prescription drugs:

1. anticonvulsants, antidepressants, antipsychotics, or an antianxiety drug in a generally accepted standard medical reference that is not a controlled substance;
2. a prescription drug that is cross-induced for any of these drugs in a generally accepted standard medical reference;
3. under most circumstances, a prescription drug that is recognized in a generally accepted standard medical reference as effective in the treatment of conditions specified in the most recent diagnostic and statistical manual of mental disorders; and
4. a prescription drug that is recognized in a generally accepted standard medical reference for the treatment of and is being prescribed to a patient to treat HIV, AIDS, cancer, epilepsy or seizure disorder or as part of organ replacement therapy.

New York. Historically, New York’s Medicaid program generally did not cover brand name drugs that have a federal Food and Drug Administration approved A-rated generic equivalent, unless a prior authorization was obtained. This provision did not apply to drugs covered by the Preferred Drug, Clinical Drug Review Program, and the Brand Less Than Generic programs. However, legislation passed as part of the FY 14 budget establishes a “prescriber prevails” provision in the state’s Medicaid Managed Care program. The provision applies to medically necessary prescription drugs in the anti-depressant, antiretroviral, anti-rejection, seizure, epilepsy, endocrine, hematologic, and immunologic therapeutic classes, including non-formulary drugs. It requires insurers to cover those drugs that are medically necessary and warranted in the prescriber’s reasonable professional judgment. The prescriber must consult with the managed care provider in making this decision.

Medicaid plans will continue to develop formularies and may also administer prior authorization programs for these drug classes. Prescribers will still be required to supply plans with requested information and clinical documentation or both. As they do currently, plans will be able to provide a three-day supply of medication when necessary.

Pursuant to federal and contractual provisions, the plans will continue to be required to meet specified turnaround times (e.g., a 24-hour review of urgent requests under Medicaid). Additionally, notices will be sent to insureds and prescribers for prior authorization requests where the plan cannot make a determination (1) due to missing information or (2) if the prescriber’s reasonable professional judgment has not been adequately demonstrated. In these cases, members’ rights regarding appeals and fair hearings will continue to apply. This is consistent with plans' current processes for member and provider notification.
Ohio uses step therapy, as described in the Medicaid PDL -
http://www.molinahealthcare.com/providers/oh/medicaid/drug/Pages/formulary.aspx

Pennsylvania has step therapy requirements for a wide variety of drugs, including NSAIDS, protein pump inhibitors, anticonvulsants, anti-depressants, and others.

Tennessee - Smalley et al. (1995) found a decrease of 53% in expenditures for NSAIDs after implementation of ST for brand NSAIDs without grandfathering in Tennessee Medicaid.24

Texas. The Medicaid program initiated the "Texas Medication Algorithm Project", a type of "step therapy" to bring greater consistency (and greater quality) to medication treatment of mental health conditions, based on guidelines stating, "most efficacious, safest treatment should be used first" and "simpler interventions should proceed more complex ones." The project was launched in 1996 and expanded in 2001. Requires trial of preferred agent before coverage of brand clozapine, fluoxetine-olanzapine, or olanzapine (Texas study by Harvard Medical School)

West Virginia 14-day trial of preferred agent before coverage of aripiprazole, brand clozapine, fluoxetineolanzapine, or olanzapine. Market share of nonpreferred antipsychotics decreased 3.5% immediately and 13.9% after 2 years in West Virginia. (study by Harvard Medical School)


[non-binding] Item 128 directs the state to convene an ad hoc advisory committee by July 1, 2002 to advise the legislature regarding options to improve access to pharmaceuticals for seniors, people with disabilities, Medicaid recipients and the uninsured. Includes the option of a Medicaid waiver or demonstration project; an initial report is due by 11/30/02 and recommendations on possible legislation or waiver by 6/30/03. (Signed by governor as Chapter 277, 3/26/02)

Requires the Department of Health to reimburse for the use of generic drugs when generics are available unless the treating physician demonstrates medical necessity for a brand name drug. States that except as provided, the Department "may not maintain a restrictive drug formulary that restricts a physician’s ability to treat a patient..." Also provides for redistribution of unused drugs under controlled circumstances. (Signed by governor as Chapter 18, 7/23/02)

Spending reduction law, facilitates a reduction in the Medicaid pharmacy dispensing fee, from $3.90 ~$4.40 downward; effective January 1, 2003. (passed in 6th special session, 12/20/02; partial veto by governor, 1/4/03)

Authorizes the Department of Health to study a revised Medicaid drug program that shall "be based on clinical and cost-related factors which include medical necessity." It requires legislative oversight before a new drug program is implemented. The act clarifies that the department must submit a proposed administrative rule that would modify Medicaid benefits, services, or reimbursement methodologies to a legislative committee before adopting the rule. (Passed by House and Senate 3/03; signed by governor, 3/24/03)

Amends the Pharmacy Practice Act to permit the state's Medicaid program to reimburse for nongeneric drugs when the brand name drug is cheaper to the state than the generic form of the drug. (Filed and referred to committee 1/16/06; passed House 72y-0n, 2/1/06; passed Senate 27y-0n, 2/14/06; signed into law by governor 3/10/06 as Ch. 90)

Allows use of a Preferred Prescription Drug List in Medicaid, which "may include placing some drugs on a preferred drug list to the extent determined appropriate by the department" and repeals 2003 language restricting PDLs. Final version provides a blanket exemption for psychotropic or anti-psychotic drugs and allows prescribers to override restrictions in cases of "medical necessity" when documented in the patient’s medical file and by handwriting on the prescription. (Filed 12/26/06; passed Senate 28y-10n, 1/26/07; passed House 70y-1n, 2/6/07; signed into law by governor 3/20/07)

Requires the Department of Health and Human Services to explore the feasibility of expanding the use of 340B drug pricing programs in the state Medicaid program, which limits the cost of covered outpatient drugs to federally qualified health centers including consolidated health centers, migrant health centers, health care for the homeless, Healthy Schools/Healthy Communities and Tribal Programs. (Prefiled 12/14/07; passed House 1/23/08; passed Senate 2/7/08; signed into law by governor 3/14/08)

Removes the automatic override to the preferred drug list in the state Medicaid program; requires the Drug Utilization Review Board to implement prior authorization requirements for a non-preferred drug that is in the same therapeutic class as a drug that is on the list; requires a health care provider requesting an override to provide documentation of the medical need for the preferred drug list override. A preferred drug list developed under the provisions of this section must exclude psychotropic or anti-psychotic drug and immunosuppressive drug for organ transplants. (Filed 1/26/09; passed Senate; passed House; signed into law by governor, 3/25/09)

Source: NCSL archive Medicaid data online

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