



**Memo: NCSL overview on high cost of Medicaid drugs
December 28, 2017**

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:

- (At Capitol Forum, Dec. 10, 2017)

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)

- (from 2016 Legislative Summit) [Steve Fitton, former Michigan Medicaid director; principal at Health Management Associates: slides 8-9-2016](#)

- **States' collection of offset and supplemental Medicaid rebates.** Office of the Inspector General (OIG), U.S. Department of Health and Human Services. 2014.

"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 time 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 as a result of changes related to the ACA."

Report No. OEI-03-12-00520. Washington, DC: OIG. <https://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf>.

These five resources are prominent on our online "Medicaid Rx" compendium listing

- [Moving Medicaid Data Forward, Part 3: A Guide to Medicaid Utilization Data -Mathematica August 2017](#)
- **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 (for a specified drug product subject to prior authorization). - 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. Those who gained Medicaid coverage had larger increases in fill rates (79 percent) and reductions in out-of-pocket spending per prescription (58 percent)." Diabetes shows the largest increased prescribing. [[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>)

Information and notes on a state ban on the use of Step therapy for prescription drugs in Medicaid

The following are a collection of facts and explanations related to this question. Sources are noted at the bottom where appropriate.

Items specific to a **ban** will be **bold / highlighted** 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.

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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

- (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. **
 - 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](#)). **
 - 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 anti-anxiety, 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](#)).
 - Under the law, prior authorization is a departmental process that conditions, delays, or denies the delivery of pharmaceutical services, using predetermined criteria, to Medicaid beneficiaries it covers on a fee-for-service basis or under a contract. The process may require a prescriber to (1) verify with the department that the proposed use of a prescription drug meets the criteria for a prescription drug that is otherwise covered or (2) obtain its authorization before prescribing or dispensing a prescription drug that is not included on a PDL or that is subject to special access or reimbursement restrictions.
 - **STEP THERAPY (ST)** 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 anti-anxiety drug in a generally accepted standard medical reference that is not a controlled substance;
- 2. a prescription drug that is cross-indicated 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.
 - Further information about these provisions is available at <https://www.cdphp.com/~media/files/pharmacy/mcicaid-fhp-step-therapy.ashx> -May 2015
<http://www.newyorkhealthworks.com/wp-content/uploads/2013/06/Expand-Prescriber-Prevails-6-4-13.pdf>.
- **Ohio** uses step therapy, as described in the Medicaid PDL - <http://www.molinahealthcare.com/providers/oh/mcicaid/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)
- **Wisconsin.** Medicaid [Formulary Step Therapy Criteria](#) Posted by Care Wisconsin –Jan. 2016

** Step Therapy Questions, Kevin E. McCarthy, Principal Analyst Connecticut OLR,

<https://www.cga.ct.gov/2013/rpt/2013-R-0308.htm>

<https://www.ctdssmap.com/CTPortal/PharmacyInformation/tabid/65/Default.aspx>

*** Law et al. (2008) Law MR, Ross-Degnan D, Soumerai SB. Effect of prior authorization of second-generation antipsychotic agents on pharmacy utilization and reimbursements. *Psychiatr Serv.* 2008;59(5):540-46. Available at: <http://ps.psychiatryonline.org/cgi/reprint/59/5/540> . Accessed February 9, 2011.

<http://www.amcp.org/data/jmcp/143-155.pdf>

Other resources from NCSL (sent via email to legislative staff on December 28, 2017):

1. (An excellent policy overview, a highly reliable professional source:) [Medicaid Payment for Outpatient Prescription Drugs](#), a 2017 updated report that summarizes Medicaid's role as the major source of outpatient pharmacy services for low-income Americans. "Medicaid prescription drug spending increased 23 percent in 2014, reaching its highest rate of growth since 1990 according to projections from the CMS. This large increase is driven by increased enrollment due to coverage expansions under the ACA, (P.L. 111-148, as amended) as well as new specialty drugs." Published by MACPAC, Medicaid and CHIP Payment and Access Commission, a federal agency. 17 pp, PDF
2. A "think outside the box" approach: ["Massachusetts Grabs Spotlight by Proposing New Twist on Medicaid Drug Coverage"](#) - A Kaiser Health News feature from 11/21/17.
3. ["Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State Quarter Ending September 2017"](#)* This little-known CMS 50-state, 16-page table provides an easy-to-use comparison
4. NCSL resources on pharmacy rebate programs in Medicaid-Dec.-2017.DOC (included below)



Summary and resources on pharmacy rebate programs in Medicaid.

December 1, 2017

Compiled NCSL Health Program

This is an informal compilation of material describing Medicaid rebates. The source for the many of the items and links are two NCSL web reports listed in Sources below.

- 1) **Federally established required rebates**, which increased through the ACA.

Federal Health Reform: Requirements Change for Medicaid Drug Rebates. The Affordable Care Act includes significant changes to the Medicaid prescription drug program. These changes include:

- **revising the definition of average manufacturer price (AMP),**
- **establishing a new formula for calculating Federal upper limit (FUL),**
- **increasing the rebate percentages for covered outpatient drugs dispensed to Medicaid patients and including the rebate offset associated with the increase in the rebate percentages.**

The ACA health law increased the rebates that drugmakers must offer state Medicaid programs from 15.1 percent to 23.1 percent for most brand name drugs, and by smaller amounts for other drugs and generics. In the past, states and federal Medicaid shared those savings. But under the new law, the federal government will keep all rebates within that 8-percentage-point range. State officials already negotiated "many drug discounts that exceed 15.1 percent so they will lose that money under the new federal rules.

- **extending the prescription drug rebates to covered outpatient drugs dispensed to enrollees of Medicaid managed care organizations (MCOs).**
- **Providing 50 percent discounts for Medicare Part D brand prescriptions drugs in the "donut hole" or coverage gap.** (This provision applies only to dual-eligible Medicare-Medicaid enrollees above a specific low-income eligibility level)

To explain the impact of these provisions on the Medicaid prescription drug program, CMS/HHS has provided guidance to stakeholders. Highlights and links include:

- **Maximum Nominal Out of Pocket Costs in Medicaid.** HHS/CMS describes federal requirements as follows: "Cost sharing for most Medicaid services is limited to nominal or minimal amounts. The maximum copayment that Medicaid may charge is based on what the state pays for that service, as described in the following table. These amounts are updated annually to account for increasing medical care costs." - [CMS Published Notice and Data](#). [Accessed 10/10/2015]

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.
- **[Medicaid Payment for Outpatient Prescription Drugs](#)**, a **2017** updated report that summarizes Medicaid’s role as the major source of outpatient pharmacy services for low-income Americans. "Medicaid prescription drug spending increased 23 percent in 2014, reaching its highest rate of growth since 1990 according to projections from the CMS. This large increase is driven by increased enrollment due to coverage expansions under the ACA, (P.L. 111-148, as amended) as well as new specialty drugs." Published by MACPAC, Medicaid and CHIP Payment and Access Commission, a federal agency. **(An excellent policy overview)**

2) Medicaid and Managed Care – analyses

- a. [Moving Medicaid Data Forward, Part 3: A Guide to Medicaid Utilization Data -Mathematica August 2017](#)
- b. **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.
- c. **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.

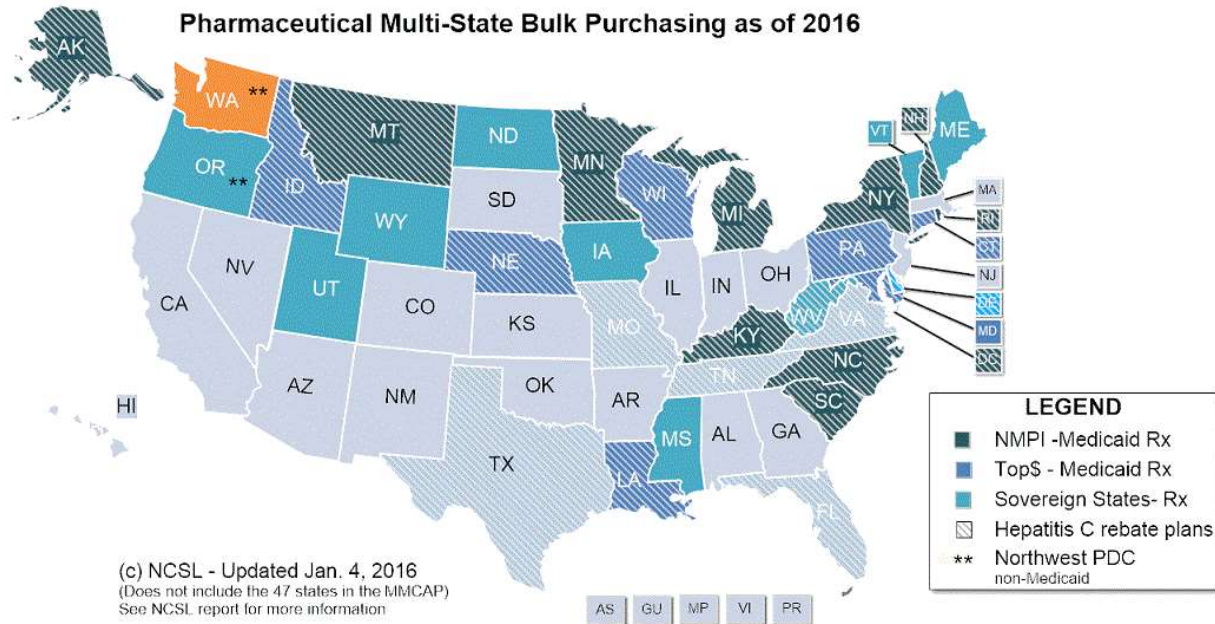
3) State supplemental rebates – initiated by states, with CMS approval with pricing usually proprietary and confidential

- **[Bulk Purchasing of Prescription Drugs - NCSL](#)**. Research shows as of early 2017, there were three operating multi-state bulk buying pools, not counting several additional variations and single state-initiatives.
 - 1) The "**National Medicaid Pooling Initiative**" (**NMPI** or **NMBP**) was first announced in early 2003 with four states. As of December 2015 the total number of pooled states is ten plus D.C. The states are **Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island, and South Carolina** as well as the **District of Columbia**. Previously, Arkansas, Georgia, Hawaii, Nevada,

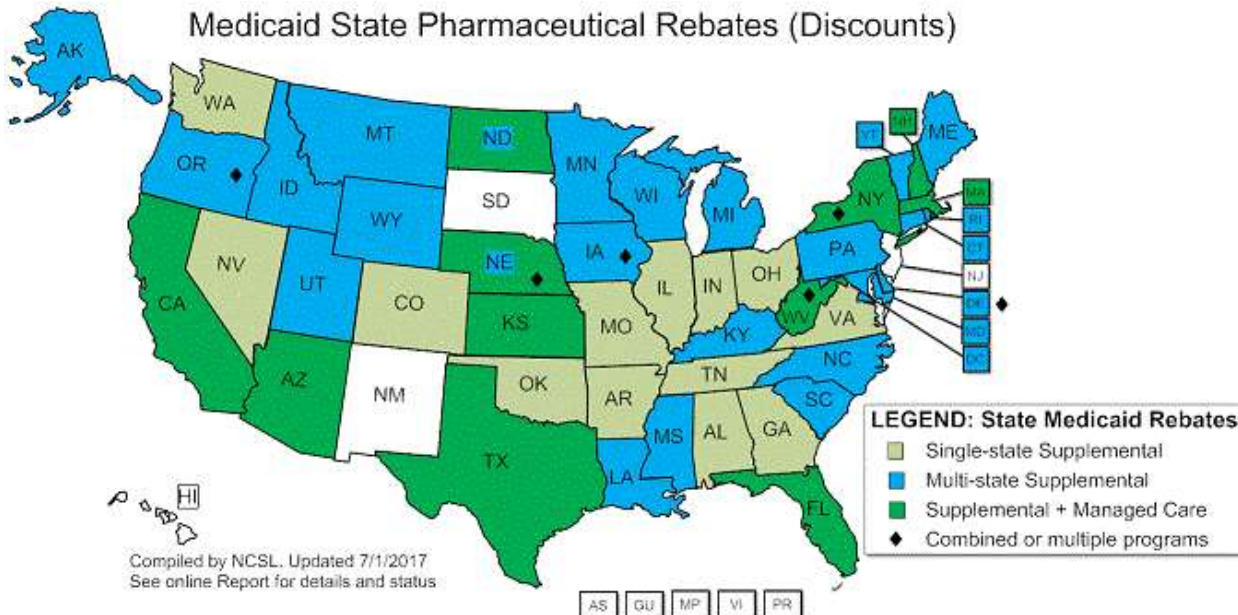
Tennessee, and Vermont were members.

2) **Top Dollar Program (TOP\$)**SM is the State Medicaid Pharmaceutical Purchasing Pool started by Provider Synergies, for Louisiana and Maryland in 2005. There are eight member states: **Connecticut, Delaware, Idaho, Louisiana, Maryland, Nebraska, Pennsylvania** and **Wisconsin**, as of December 2015.

3) **The Sovereign States Drug Consortium (SSDC)** was founded as a non-profit structure by the states of Iowa, Maine, and Vermont for Medicaid in October 2005. **Delaware, Iowa, Maine, Mississippi, North Dakota, Oklahoma, Oregon, Utah, Vermont, West Virginia** and **Wyoming** are operational members as of January 2016. In 2016, the state of Oklahoma joined the SSDC and they will be seeking CMS approval as well



- **Supplemental Rebates by State:** NCSL's April 2017 State Legislatures Magazine featured an article "Increases in Drug Spending Slow" that included a description of Medicaid rebates and an updated map of the state-initiated supplemental rebates, reproduced below:



State Supplemental Drug Rebate Agreements (2017). Many States have received CMS approval on their State Plan Amendments to enter into single-State and multi-State supplemental drug rebate pools that generate rebates that are at least as large as the rebates set forth in the national rebate agreement with drug manufacturers. This table shows the 45 states [with Medicaid Pharmacy Supplemental Rebate Agreements \(SRA\) \[PDF\]](#). NOTE that **16 states so far have expanded rebates to include managed care.**

NCSL SOURCES:

1. [Medicaid Prescription Drug Laws and Strategies](#). NCSL overview and state examples. Updated for 2017 - A top-10 popular health resource-
2. [Bulk Purchasing of Prescription Drugs - NCSL](#). Research shows as of early 2017, there were three operating multi-state bulk buying pools, not counting several additional variations and single state-initiatives.

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