NCSL | Health

Part 2 –NCSL Toolkit: External Experts and Opinions on High Costs in Medicaid drugs

UPDATED: August 2018 for the Utah Legislature *

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*- This is a prepublication draft of third-party material already available in diverse sources, combined for policymaker convenience.

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May 2018 | Issue Brief

How Does the Trump Administration Drug Pricing Blueprint Affect Medicaid?

Katherine Young

The cost of prescription drugs continues to be a policy issue for the U.S. health system and for state Medicaid programs. Recent news stories have highlighted the high costs of life-saving drugs such as Sovaldi, EpiPen, Daraprim, insulin, and oncology drugs; the American public[1] reports concern over high out-of-pocket spending for prescriptions; and many states are pursuing actions to try to lower drug costs.[2] President Trump campaigned on the issue and has since repeatedly commented that lowering the cost of prescription drugs is one of his greatest priorities. On May 11th, 2018, the Trump Administration released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" ("the Blueprint"), which reviews the issue of high cost drugs, presents actions the Administration has already taken, lists actions that the Administration may undertake or promote going forward, and seeks feedback on potential actions. The Blueprint includes provisions across the U.S. healthcare system; this issue brief focuses on how the Blueprint's proposals could affect Medicaid drug spending.

New Medicaid Proposals

The only new, Medicaid-specific proposal in the Blueprint is a technical provision related to the Medicaid Drug Rebate Program (MDRP). The Blueprint suggests that "HHS may [...] [d]evelop proposals related to the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of the Average Manufacturer Price." This proposal is referring to the MDRP, which stipulates that in return for state Medicaid agency coverage of nearly all drugs produced by the manufacturer, the manufacturer must provide a rebate as described in federal Medicaid law. The amount of the federal rebate is based on both a non-inflationary component (based on whether the drug is a brand or a generic) and an inflationary component that accounts for the increase in the drug's price relative to inflation. Currently, the total rebate is capped at 100% of Average Manufacturer Price (AMP).

The Blueprint provision is based on the idea that removing or significantly increasing the rebate cap would be a disincentive for a manufacturer to increase its list price for any drug for which Medicaid collects rebates.[3] However, it would not directly affect drugs for which Medicaid does not collect rebates, such as physician-administered drugs provided on an inpatient basis. In addition, the rebate cap is currently secured in Medicaid statute[4] and would require Congressional action to be modified.

Other Proposals

The Blueprint also includes two proposals related to Medicaid drug spending that the Administration first proposed in the FY 2019 White House Budget[5]: removing ambiguity over how drugs are reported in Medicaid and calling for a new Medicaid demonstration authority for states to implement their own formularies instead of participating in the MDRP. The first proposal stems from the idea that, because the federal Medicaid rebates vary based on whether the drug is a brand or a generic, in addition to some other distinctions amongst brand drugs, for Medicaid to recoup the appropriate amount of money, the prescription drugs being provided need to be correctly categorized.[6] The second proposal calls for a new Medicaid demonstration authority limited to five states and would allow for state Medicaid agencies to create their own Medicaid formularies. The proposal is based in the idea that, in contrast to the open formulary essentially created by the MDRP, allowing states to utilize their own formularies would enable them to negotiate directly with manufacturers.[7] However, opponents worry that states would use this authority to limit or deny coverage of high-priced drugs.

Non-Medicaid Proposals

The Blueprint proposes a number of actions to address high drug costs that are broader in scope, affecting all payers including Medicaid. Over the past year, the FDA has taken a variety of actions to encourage generic competition to ease the high cost of prescription drugs. The Blueprint proposes continuing a number of ongoing FDA initiatives. It also proposes that HHS direct CMS to develop demonstration projects to encourage value-based care[8] and to make prices more transparent to the public[9].

Looking Ahead

The Trump Administration is seeking comment on the Blueprint through July 16, 2018, and the Blueprint includes many questions for policymakers and stakeholders to consider as they develop actions based on the Blueprint. These questions include direct questions about the likely effect of proposed Medicaid policies (e.g., removing the rebate cap). Notably, the questions also ask if and how low prices in Medicaid (and other government programs) may incentivize manufacturers to increase prices for drugs overall to recoup perceived lost profits. The Blueprint also asks about pricing transparency and potential alternative prescription drug payment structures in Medicaid (and Medicare) including: pricing curative drugs to account for the fact that current payers may not realize long-term cost savings from lower treatment costs; pricing drugs based on the indication they are used for and how effective the drug is for that specific indication; and pricing drugs to remove disincentives to provide a drug in a particular setting (e.g., inpatient versus outpatient).

It is unclear what policy actions will ultimately emerge from the Blueprint, and not all proposals in the Blueprint can be implemented through administrative (versus Congressional) action. However, the document provides insight into the Administration's areas of interest for lowering drug costs overall. While Medicaid-specific provisions focus on increasing manufacturer rebates, other discussion in the Blueprint suggests concern over Medicaid rebates leading to higher prices system-wide. The question of which provisions are priorities will be shaped by ongoing policy debate, politics, and stakeholder responses to the ideas in the Blueprint.

ENDNOTES

[1] "Public Opinion on Prescription Drugs and Their Prices," Kaiser Family Foundation, https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/.

[2] K Young and R Garfield, *Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control*, Kaiser Family Foundation, February 2018, https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/.

[3] Secretary Azar presented this position in his comments at the White House Press Briefing Friday, May 11th, 2018.

[4] 42 U.S.C. 1396r-8(c)

[5] FY 2019 HHS Budget in Brief, "Putting America's Health First, FY 2019 President's Budget for HHS," https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

[6] In August 2017, Mylan settled with the Department of Justice to resolve claims that they had intentionally classified the EpiPen product incorrectly as a generic drug to pay less money in rebates to Medicaid. *See* "Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates," Department of Justice, August 17, 2017, https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates. Additionally, a 2017 OIG report found that Medicaid lost over a billion dollars in rebates between 2012 and 2016 due to misclassification of drugs. *See* "Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates," HHS, Office of Inspector General, December 2017, https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf.

[7] For more information on formularies in Medicaid, *see* Young and Garfield, *op. cit.*

[8] The Blueprint strongly favors value-based pricing, at one point saying "[v]alue-based transformation of our entire healthcare system is a top HHS priority." Value-based pricing is a popular idea, and one that requires reconciling with the best price aspect of the MDRP.

[9] On May 15th 2018, CMS unveiled its "enhanced drug dashboard."

Health Affairs

PRESCRIPTION DRUG PRICING

HEALTH POLICY BRIEF SERIES
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MEDICAID BEST PRICE

The Medicaid best price policy requires drug manufacturers to give Medicaid programs the best price among nearly all purchasers.

Medicaid "best price" was a legislated policy solution enacted over twenty-five years ago to address high drug costs and make Medicaid drug spending more manageable for states. Under this policy, a drug manufacturer must offer state Medicaid programs the best price given to any other purchaser (with a few exceptions) with a mandatory rebate of 23.1 percent off the list price. Medicaid programs must, in turn, cover all of the manufacturer's prescription drugs, with few exceptions. States, payers, and manufacturers are considering whether the Medicaid rebate and best price system is still effective policy or whether the arrangement unintentionally inhibits new ways to lower drug costs and improve access to therapies.

Background

In 1989 the Senate Special Committee on Aging issued a milestone report on prescription drug prices. The report stated, "Rising drug prices, particularly the high prices of new drugs, are driving State Medicaid program costs and projected Medicare drug benefit expenditures to unsustainable levels, causing the Congress to consider reducing benefits to the elderly and poor, and forcing State legislatures to choose between funding drug benefits or other health care needs of the elderly and poor." The committee investigation was one of several efforts that led to enactment of the Medicaid drug rebate program as part of the Omnibus Budget Reconciliation Act of 1990.

The Medicaid drug rebate program requires a drug manufacturer to enter into a national agreement with the Department of Health and Human Services whereby states get the so-called best price offered to any purchaser (there are exceptions) in exchange for Medicaid coverage of essentially all of the manufacturer's drugs. Manufacturers must also provide rebates to certain safety-net providers under the federal 340B drug pricing program and to the Department of Veterans Affairs as part of the agreement.

Program participation by drug manufacturers is essentially mandatory; companies declining to participate are excluded from all federal programs, including Medicare. Approximately 600 manufacturers have entered into rebate agreements. Medicaid beneficiaries have broad access to medications with minimal out-of-pocket expenses, and states have recouped financial returns in the form

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of rebate streams from manufacturers. The federal government shares in the Medicaid rebates as well. The weakness of the program, however, has been its failure to lower the growth rate of Medicaid drug spending over time, given that manufacturers control launch prices of new drugs and can account for rebates in the prices of new products.

> "Companies declining to participate are excluded from all federal programs."

The combination of Medicaid expansion under the Affordable Care Act (ACA) and a recent increase in new drug approvals, many of which have high launch prices, have coalesced to increase overall Medicaid prescription drug spending. Medicaid spent approximately $57 billion on prescription drugs in 2015 (the most recent year for which there are full data), compared to $42 billion in 2014.

The issue was brought to a head with the market entry of high-cost curative hepatitis C drugs in 2014. With large numbers of Medicaid recipients eligible for these medications and state requirements to cover the drugs as part of the drug rebate program, the high prices put many state budgets in crisis. Given the requirement for most states to balance budgets annually, some states had to choose between treating all eligible patients with a curative therapy or funding other fundamental state programs outside of health care.

Medicaid Best Price: What You Need To Know

Certain features of the Medicaid best price policy are critical to understanding its impact on prices in Medicaid and elsewhere.

THE REBATE FORMULA

The "best price" rebate formula applies to sole-source innovator drugs distributed to Medicaid beneficiaries. The best price must be reported to the Centers for Medicare and Medicaid Services. The statutory rebate formula takes into account three factors: (1) the Average Manufacturer Price (AMP), or list price, of the drug, which is intended to account for different discounts and price concessions for other purchasers; (2) either a minimum rebate of 23.1 percent off of AMP or the "best price" offered to any other private or public purchaser (with a few exceptions—see below) if such a purchaser receives more than the minimum discount; and (3) an adjustment if the drug price rises faster than inflation. For older drugs, the inflation component is often a significant factor in the size of the rebate.

There are different minimum rebates for certain drug categories. For example, blood clotting factors and drugs approved exclusively for pediatric populations use a minimum rebate of 17.1 percent off AMP per unit. Generic drugs have a separate rebate formula, including a minimum rebate of 13 percent and an inflation adjustment similar to the one noted above, but no "best price" component.

Each state Medicaid program tracks drugs purchased for recipients and submits quarterly invoices to manufacturers for rebates. Manufacturers must update AMP and inflation calculations and ensure that they pay the correct rebate. That builds in some lag time between actual market prices and Medicaid rebates.

EXEMPTIONS FROM BEST PRICE

There are several excluded programs that do not trigger the "best price" guarantee for Medicaid. These include federal health systems such as the Department of Veterans Affairs and the Department of Defense and also prices negotiated by private plans operating Medicare Part D plans. Such programs can receive a lower price than Medicaid for a given drug.

ACA CHANGES TO MEDICAID REBATE

The ACA made several changes to the Medicaid rebate program. The biggest impact was the change in the minimum rebate from 15.1 percent to 23.1 percent. The law also defined the AMP more broadly, leading to some adjustments in the baseline price from which rebate percentages are calculated. A new rebate was added for product-line extensions, defined in the law and by clarifying regulation. In addi-

tion, the law capped rebates at 100 percent of AMP. Unlike other statutory changes, this change reduced manufacturer rebates, as some products with significant price increases over time actually owed a rebate of more than 100 percent, because of the inflation adjustment built into the rebate formula. In other words, states were ultimately recouping more than the cost of the medicine in the form of a rebate.

REBATES AS A REVENUE STREAM FOR STATES

The time lag built into the program tends to encourage states to treat rebates as a stand-alone income line in the budget, instead of looking at total Medicaid drug spending. The amount is significant: In fiscal year 2014, Medicaid programs spent $42 billion on prescription drugs and collected about $20 billion in rebates.

THE "BEST PRICE" FLOOR

One ripple effect of guaranteeing the best price for Medicaid is that it weakens the leverage of private commercial payers and pharmacy benefit managers (PBMs) in negotiations with manufacturers, in effect setting a floor under prices. Private payers argue that they would be able to negotiate even lower prices for patients if manufacturers were not obliged to offer the same price to all fifty state Medicaid programs. Best price is also confidential by law, so manufacturers could use that argument to deny a discount below the 23.1 percent minimum, even if they did in fact provide better pricing to other customers (although misreporting best price or otherwise violating the rules for calculating Medicaid rebates can be prosecuted as a violation of the False Claims Act).

The Future Of Medicaid Rebates And Best Price

Several important issues will play into the future impact of rebates and best price on Medicaid drug spending.

IMPACT ON OUTCOMES-BASED PURCHASING

Policy experts, lawmakers, drug developers, and payers are generally united in their desire to explore the potential of outcomes-based drug purchasing models (also called "value-based" purchasing models). Under such models, the payer and manufacturer agree upon assumptions about a drug's expected improvement in outcomes for the population. If the drug fails to perform as expected, the manufacturer must pay a rebate to the purchaser. However, according to a July 2016 policy notice from CMS, manufacturers' concerns over compliance with best price provisions have made some wary of entering into those agreements, which might ultimately lower the best price. In that memo, CMS says that value-based purchasing contract questions, as they relate to the best price requirement, should be taken case by case and that manufacturers should seek guidance from the agency when seeking to enter into these agreements. One interpretation of the policy notice is that manufacturers are encouraged to experiment with outcomes- or value-based models in Medicaid first, as opposed to attempting to employ the agreements in the private sector.

AN OPT-OUT FOR STATES

Some state program administrators and Medicaid managed care organizations have explored the potential benefits of a state opt-out from the Medicaid rebate program. The driving factor is the requirement that essentially all outpatient drugs from a given manufacturer must be covered by the state in exchange for the best price guarantee and rebates. For some states, the financial risk of covering all drugs, including new high-cost therapies, is not worth the benefit of the rebate. Eliminating that requirement and moving to more aggressive formulary management tools could give Medicaid programs more latitude for responding to high-price new therapies entering the market.

OTHER OPTIONS FOR STATE SAVINGS

Instead of significantly altering the best price paradigm, policy makers could dial up the minimum rebate further. The sole-source brand rebate was originally phased in from 12.5 percent in 1990, to 15.1 percent in 1995, to its current 23.1 percent. There is, in principle, no reason the minimum rebate could not be adjusted higher again.

Alternatively, policy makers could align the rebate program with potential caps on Medicaid spending, in

the context of either federal reforms to the program or states' initiatives to contain their share of costs. Some states have considered instituting a cap on Medicaid drug spending. New York, for example, recently passed legislation (Senate Bill S2007B) that sets a target cap on drug spending growth at 5 percent above inflation. If the target growth rate is exceeded, the breach triggers reviews by a drug utilization review board "for a recommendation as to whether a target supplemental Medicaid rebate should be paid by the manufacturer."

Key Terms

- **Best price:** According to statute, "The term 'best price' means, with respect to a single-source drug or innovator multiple-source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States."
- **Outcomes-based or value-based drug purchasing:** Linking the purchase price of a medicine to a given clinical outcome or measure. If the drug fails to deliver on efficacy or safety metrics demonstrated in trials or other forms of real-world evidence, the manufacturer pays a rebate or other concession to the purchaser.
- **Average Manufacturer Price:** The AMP provides the baseline to determine Medicaid's federal upper limit on prices paid to pharmacies for generics. In addition, the new AMP calculation may also serve as the baseline for calculations states use to reimburse Medicaid drugs more broadly. Therefore, the rule impacts which drugs are new or exempted from a higher rebate, the calculation of prices, and the rebate amount. The January 2016 Medicaid Covered Outpatient Drug final rule revised the long-standing definition of AMP to "now mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer."

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February 2018 | Issue Brief

Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control

Katherine Young and Rachel Garfield

After several years of spending growth below five percent, Medicaid spending on outpatient drugs increased 25 percent from $22.4 billion in 2013 to $28 billion in 2014 and another 13 percent in 2015 to $31.7 billion (Figure 1).[1] This spike in 2014-2015 is in large part attributed to Sovaldi, Harvoni, and Viekira Pak[2], the breakthrough hepatitis C Direct Acting Antivirals that came to market in 2013 and 2014. The high cost of specialty drugs and certain classes of drugs, the rapid rise in generic drug prices from some manufacturers in 2015, and the price hikes of Mylan's EpiPen in 2016, fueled concern among policymakers and the public about rising drug costs.[3] However, reflecting system-wide trends, Medicaid drug spending growth slowed in 2016, though recent rates of prescription drug spending growth in Medicaid are still higher than other payers. Although drug spending constitutes only 6% of Medicaid total spending,[4] the high cost of specialty drugs continues to be a concern among Medicaid policy directors looking to control future spending.[5]

Figure 1

Annual Growth in Medicaid Spending on Prescription Drugs, 2008-2016

Source: CMS National Health Expenditure Accounts, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

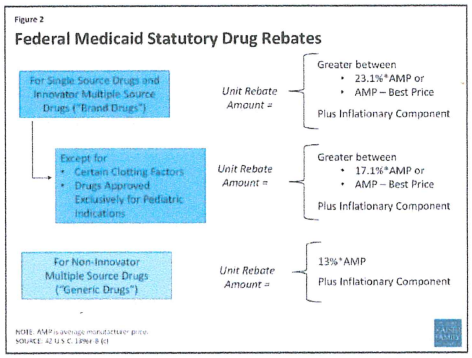
Due to the structure of Medicaid's rebate program, states are generally obligated to provide a drug to their beneficiaries when it comes on the market and currently cannot exclude high cost drugs from their programs. In the early 2000s, prescription management programs, which included preferred drug lists, supplemental rebates, and script limits, were implemented and expanded by states in an effort to control costs.[6] However, these programs have reached maturity, and states, facing the prospect of more new and costly drugs coming to market, are now looking to develop new ways to achieve savings in the prescription drug program. This issue brief provides a snapshot of current state initiatives aimed at addressing the cost of prescription drugs in Medicaid.

Background: How does Medicaid pay for prescription drugs?

States' methods of paying for outpatient prescription drugs in Medicaid vary but are bound by federal requirements regarding the federal rebate program and allowable schedules for reimbursement. Under federal law, in order for a drug to qualify for federal statutory Medicaid matching funds, manufacturers must sign an agreement with the Secretary of Health and Human Services stating that they will rebate a specified portion of the Medicaid payment for the drug to the states, which in turn share the rebates with the federal government. In return, Medicaid must cover almost all FDA-approved drugs that those manufacturers produce. The formula for the amount of the rebate is set in statute[7] and varies by type of drug (brand or generic) (Figure 2). Rebates apply regardless of whether a state pays for prescription drugs on a fee-for-service basis or includes them in capitation payments to managed care plans. As discussed in detail below, most states also negotiate supplemental rebates with manufacturers.[8]

Figure 2

Federal Medicaid Statutory Drug Rebates



NOTE: AMP is average manufacturer price.
SOURCE: 42 U.S.C. 1396r-8 (k)

For Medicaid drugs provided on a fee-for-service basis, state payment includes both a dispensing fee (amount paid to the pharmacy for the work of filling the prescription) and payment for the ingredient cost (amount paid to the pharmacy for the cost of the drug). States have flexibility to set professional dispensing fees. In setting the ingredient cost, states now have to base payment on the Actual Acquisition Cost (AAC) for a drug.[9] The federal Center for Medicare & Medicaid Services (CMS) allows states to use certain schedules as AAC and encourages states to use the National Average Drug Acquisition Cost (NADAC).[10] The NADAC is intended to be a national average of the prices at which pharmacies purchase a prescription drug, including some rebates. These federal rules regarding allowable schedules do not apply to Medicaid drugs provided through managed care.[11]

Many states also use pharmacy benefit managers (PBMs) in their Medicaid prescription drug programs. PBMs perform financial and clinical services for the program, administering rebates, monitoring utilization, and overseeing preferred drug lists.[12] PBMs may be used regardless of whether the state administers the benefit through managed care or on a fee-for-service basis.

What policy levers have states traditionally used to control Medicaid drug spending?

Within federal rules regarding the federal rebate agreement and medical necessity requirements, states have flexibility in administering their Medicaid prescription drug programs. States have used a variety of strategies to contain pharmacy costs and have done so for many years. Common strategies include implementing prescription limits, negotiating supplemental rebates, requiring prior authorizations, and using state Maximum Allowable Cost (MAC)[13] programs. States also have joined multi-state purchasing pools when

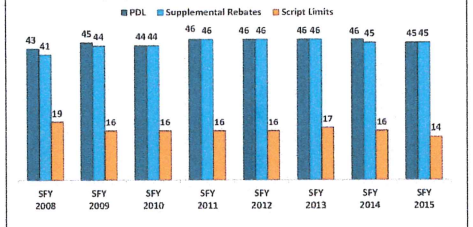
negotiating supplemental Medicaid rebates to increase their negotiating power, and states have switched ingredient cost methodologies.[14] Most state Medicaid programs also maintain a preferred drug list (PDL) of outpatient prescription drugs,[15] which is a list of drugs states encourage providers to prescribe over other drugs. A state may require a prior authorization for a drug not on a preferred drug list. PDLs create incentives for a provider to prescribe a drug on the PDL if possible. Often, drugs on PDLs are cheaper or include drugs for which a manufacturer has provided supplemental rebates. While states may require prior authorization, restrict access to drugs only being used for medically accepted indications, or not cover certain specific drugs that are listed in the statute, outside of these allowances, they are required to provide nearly all prescribed drugs made by manufacturers that have entered into a rebate agreement. [16] This requirement holds regardless of whether the beneficiary receives prescriptions in a managed care or fee-for-service setting.

States have used these strategies in Medicaid for many years (Figure 3). However, such actions have slowed in recent years as economic conditions have improved and states reach the limits of utilization controls allowed under federal law (Figure 4).

Figure 3

Many of the traditional pharmacy cost containment tools have been in place for a number of years.

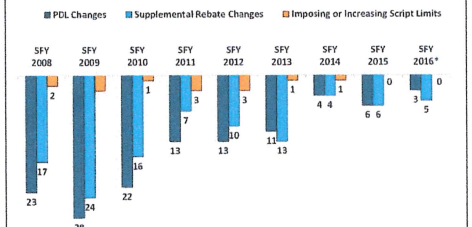
# of states with select pharmacy management policies in place



SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, 2007-2015.

Figure 4

Over time, changes to the traditional pharmacy cost containment tools have decreased as such programs have matured.



NOTE: No changes in script limits were reported for SFY 2015 and SFY 2016. Changes reported for SFY 2016 reflect what states planned to do at the start of SFY 2016. Illinois did not provide a response for any FY 2016 rates as a budget for FY 2016 had not been enacted at the time of the survey.
SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, 2008-2015.

High-Cost Specialty Drugs & Limits on Traditional Pharmacy Management Controls

FDA approval of Sovaldi in December 2013 created a fiscal challenge to states' Medicaid drug programs. Sovaldi, a direct acting antiviral (DAA), was a major advance in the treatment of hepatitis C (HCV) in that it essentially cures the disease in most people while causing minimal side effects. Previous treatments had been much less successful and had debilitating side effects. However, the list price of Sovaldi was $84,000 for a typical course of treatment. Even with the federally-required Medicaid rebate, Sovaldi remained expensive to Medicaid, and limited competition in the drug class made it difficult for states to initially use PDLs to obtain supplemental rebates. Because a disproportionate number of people with HCV are enrolled in public programs, Medicaid financed a large share of DAA treatment.[17]

Many state Medicaid programs implemented utilization controls for Sovaldi: in 2014 and 2015, over half of the state Medicaid programs had implemented prior authorization restrictions for DAAs, and nearly all of those

based the prior authorization on the degree of the patient's liver damage.[18] In addition to restrictions based on the extent of liver damage, some states also required that a patient meet with a specialist, as well as drug counseling, drug testing, and periods of abstinence from drugs and alcohol. However, these restrictions were inconsistent with treatment recommendations and with federal law about drug utilization control. Class actions were filed in federal courts in a number of states, and in May 2016, a federal court issued a preliminary injunction ordering Washington State to provide DAAs to all Medicaid beneficiaries with the virus.[19] Following these legal actions, many states loosened restrictions on DAAs, and some now provide DAAs to all Medicaid beneficiaries. Despite increased competition,[20] DAAs remain expensive, and states continue to grapple with the high cost of specialty drugs. In addition, although states have placed particular focus on DAAs, they remain vigilant about other high cost drugs as well, such as hemophilia, oncology, and diabetes classes of drugs.[21] Most states have been looking for new ways to control drug spending.

What new Medicaid strategies are states trying to control drug spending?

Some new strategies that states are trying aim to expand the scope of efforts already underway in Medicaid or implement new Medicaid policies not previously allowed under federal law. In general, these efforts share a goal of obtaining greater supplemental rebates from manufacturers. Currently, states use placement on their PDL as a means to negotiate supplemental rebates. States often join in multi-state pools to have greater leverage to obtain supplemental rebates.[22] New strategies include state spending caps for Medicaid prescription drugs and a proposal of a closed formulary in Medicaid.

Drug Growth Caps

One idea currently being tested is use of a spending growth cap for Medicaid prescription drugs. If spending is above the cap, the state undertakes close review of drug spending and targets certain drugs for additional utilization review.

New York is currently implementing such a process. The state has had a spending cap on its Medicaid program since 2011.[23] However, drug expenditures have continually grown faster than other cost components under the cap.[24] As a result, in April 2017, the governor signed into law[25] the addition of a drug cap as a separate component of the spending cap. Under this drug cap, if total Medicaid drug spending in a year is projected to exceed the growth target, the state Commissioner of Health may identify specific drugs for referral to a Drug Utilization Review Board (DUR Board)[26] and reach out to the manufacturer to see if they can agree on a satisfactory rebate for the specified drugs. If the Department of Health and the manufacturer cannot reach an agreement, the Commissioner may refer the drug to the DUR Board, which considers a variety of factors about the specified drugs, such as the cost of the drug including rebates, its impact on the drug spending growth target, and its value to Medicaid beneficiaries. After considering these factors, the DUR Board may seek additional supplemental rebates with the manufacturers. If the department is unable to obtain the desired additional supplementary rebates, the manufacturer must provide information to the department on the drug in question including the cost of development and manufacturing, R&D costs, advertising costs, utilization, prices charged outside the U.S., average rebates, and average profit margin. This information is not provided to the public. Ultimately, if Medicaid drug spending is greater than the annual growth rate, the Commissioner can further limit access to the drug through existing utilization controls allowed under current law.

Good morning folks. The attached press release may be of interest in follow-up to discussion at the December 2017 Health Innovations Task Force Meeting.

CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers

Date: 2018-06-27

Title: CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers
Contact press@cms.hhs.gov

CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers

First-of-its-kind approval for Oklahoma Medicaid will drive value

Today, the Centers for Medicare & Medicaid Services (CMS) issued the first-ever approval of a state plan amendment proposal to allow the state of Oklahoma to negotiate supplemental rebate agreements involving value-based purchasing arrangements with drug manufacturers that could produce extra rebates for the state if clinical outcomes are not achieved. The state plan amendment proposal submitted by Oklahoma will be the first state plan amendment permitting a state to pursue CMS-authorized supplemental rebate agreements involving value-based purchasing arrangements with manufacturers.

"Oklahoma's plan for value-based drug contracts is an important example of how states can innovate to bring down drug costs," Secretary Alex Azar said, "The Trump Administration is committed to giving states the flexibility they need to make healthcare more affordable, and strongly supports innovations like value-based purchasing for prescription drugs."

Value-based purchasing can link the payment of a drug to its effectiveness and the outcomes it achieves. Promoting value-based payment is one many initiatives outlined in the Administration's American Patients First Blueprint, which President Trump's sweeping plan to address the high drug prices facing Americans. Oklahoma submitted to CMS an amendment that added value-based supplemental rebate agreement (SRA) language to their state Medicaid plan. Today, CMS approved the state plan amendment Oklahoma proposed, permitting the state to enter into tailored agreements with manufacturers on a voluntary basis. The state and each manufacturer can now jointly agree on benchmarks based on health outcomes and the specific populations for which these outcomes-based benchmarks will be measured and evaluated.

"President Trump is committed to lowering prescription drug prices and working with states in their pursuit towards innovative state health plans. We want to ensure we are giving states all the tools they need to better negotiate with manufacturers," said CMS Administrator Seema Verma. "We applaud Oklahoma's proposal for a state-plan amendment, which is an innovative approach to reform how we pay for prescription drugs and will lead to better deals for our beneficiaries and our program."

About supplemental rebate agreements

Almost every state Medicaid plan includes the authority of the state to negotiate supplemental rebate agreements (SRAs) with drug manufacturers that provide rebates at least as large as those set forth in the Medicaid national drug rebate agreement. Since Medicaid is a federal and state partnership, CMS reviews all state plan amendments, including SRAs. Consistent with regulations at 42 CFR 447.505(c)(7), SRAs are exempt from the Medicaid "best price" rule that requires drug manufacturers to extend the lowest price for a drug they negotiate with any other buyer to all states in the Medicaid program.

For more information, visit the following links:

State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf.

State Plan Amendment: https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/OK/OK-18-08.pdf.

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THE NEW YORK TIMES

Oklahoma Medicaid Approved for Drug Pricing Experiment

By The Associated Press

- July 13, 2018

OKLAHOMA CITY — The federal Centers for Medicare and Medicaid Services has approved Oklahoma's Medicaid program for a first-in-the-nation drug pricing experiment that supporters say could save taxpayer dollars and provide patients with the most effective medications for their ailments.

Under the "value-based purchasing" program approved in late June, the state and a pharmaceutical company would agree to a set payment if its medication works as advertised, but only a fraction of that if the drug is not as effective as promised.

"When a company signs an agreement, we hope that they're going to agree to only have us pay for the therapy that works .... and if it doesn't work we should get a rebate on it," said Nancy Nesser, pharmacy director for the Oklahoma Health Care Authority, which administers the Medicaid program in the state.

"One thing we've learned is that some companies don't really stand behind their drugs, and it's kind of scary," Nesser said. "We're paying a premium for them and they're not willing to say that they will work."

The companies are not required to take part, but Nesser said several, which she declined to identify, have shown interest and discussions are underway with three. She said she hopes the program can begin by Aug. 1.

"This is a good thing," said Matt Salo, executive director of the nonpartisan National Medicaid Directors Association, which represents state programs. "It paves the way for states and other payers to start really thinking about how to do value-based purchasing for prescription drugs."

The federal waiver would allow Oklahoma to get around a potential obstacle to value-based contracts.

A possible pitfall is Medicaid's "best price" requirement, which says if any purchaser gets a really good deal on a drug, then Medicaid has to get that lower price too.

Some interpret that to apply to value-based deals as well, Salo said. That means that if a drug didn't work too well, and a state paid only 10 percent of the original price, then every other Medicaid program could get the drug for that rock-bottom price, too.

"This seems to allow for paying less for a failed treatment without triggering the 'best price' requirement," Salo said.

Oklahoma spent about $650 million on prescription drugs in the fiscal year that ended June 30, Nesser said, and the change could save "a couple of million, maybe."

Medicaid patients, primarily children who do not pay for prescriptions and the elderly, whose costs are fixed, would see no pocketbook impact, according to Oklahoma Health Care Authority spokeswoman Jo Stainsby.

"The change we're looking for is improved health outcomes," Stainsby said.

Oklahoma is "taking the lead" in working to bring down the cost of medications, the AARP director for the state, Sean Voskuhl, said.

"It is a great example of how states can implement change in the absence of reform at the federal level," Voskuhl said.

Alonso-Zaldivar reported from Washington.

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CMS Denied MassHealth Drug Proposal

Jul 9, 2018

In a highly anticipated decision that suggests the limitations of the Trump administration's willingness to let states control their own destiny, CMS on June 27 said it would not allow Massachusetts to establish a closed drug formulary and negotiate directly with manufacturers for rebates. But on the very same day, CMS approved a state plan amendment (SPA) proposed by Oklahoma to advance specific Medicaid value-based purchasing arrangements with drugmakers — a move that puzzled some industry experts.

Jeff Myers, president and CEO of Medicaid Health Plans of America (MHPA), says CMS's decision wasn't surprising, but it was "interesting" that CMS simultaneously approved the Oklahoma SPA. And because Oklahoma is one of the few fee-for-service Medicaid states and supplemental rebates don't count against drug companies' "best price" calculations, he doesn't see that test in value-based purchasing as having a widespread impact.

Jerry Vitti, president and CEO of Healthcare Financial, Inc., calls the Massachusetts rejection "a win for pharma and a loss for low-income people," and says he finds it puzzling that the Oklahoma waiver was approved on the same day.

If the federal government wants states to employ private sector practices, MHPA has long maintained that formulary design should be left to the managed care companies that are taking full risk for about 75% of Medicaid enrollees, as opposed to about 8% when the Medicaid Drug Rebate Program was established in 1990.

"I think [the Massachusetts rejection] signals that CMS has very limited options when it comes to the statute of outpatient drug pricing," Myers says. "Sixty-eight percent of the managed Medicaid market is in the top 20 companies…and those companies have enormous ability to negotiate drug pricing in a way that will save the taxpayers money. So my takeaway is CMS is coming to the understanding that short of a statutory change, it's going to be very hard if not impossible to significantly change the way Medicaid drugs get purchased."

Abstract
Medicare and Medicaid

Medicaid Prescription Drug Update:
Massachusetts Health Can't Close Formulary, Oklahoma Can Negotiate Rebates

CMS on June 27 denied a waiver request by **Massachusetts** to allow its Medicaid program, Mass-Health, to use a closed formulary, excluding certain drugs. But the agency left the door open on the state's pursuit of tighter drug controls.

"The **Massachusetts** proposal brought to the table a new approach to increase its leverage to get lower drug prices, but an approach that left many unanswered questions," says Jack Hoadley, Ph.D., a research professor emeritus in Georgetown University's Health Policy Institute. "Its rejection by CMS should not stop states from continuing to seek new ways to achieve lower prices. The key is how to balance maintaining access to needed drugs with tools to get lower prices."

MassHealth's pharmacy spending has doubled from $1.1 billion to $2.2 billion over the past five years, twice as fast as spending growth for other program components, state officials say. "While it is disappointing that our request to more effectively control rising pharmacy costs was not approved at this time, we remain committed to finding more innovative state-based solutions to reduce the growth in drug spending while maintaining access to necessary medications," says spokesperson Elissa Snook of the Massachusetts Executive Office of Health and Human Services, which oversees MassHealth. CMS approved other requested amendments to Mass-Health, including the extension of Medicaid benefits to certain veterans and their families.

Separately on that same day, CMS approved **Oklahoma**'s request to amend its Medicaid state plan, allowing it to negotiate supplemental rebate agreements for drugs as part of value-based purchasing deals with pharmaceutical manufacturers.

"By approving Oklahoma's proposal for value-based purchasing, the state has a chance to try new ideas," Hoadley adds. "But it will be important to see if they move forward in a way that protects patient access."

Also on June 27, CMS sent a **letter to states** clarifying its guidance that drugs given the go-ahead under FDA's accelerated approval pathway—for drugs treating a serious condition and filling an unmet medical need —are considered to be covered outpatient drugs. Thus, they must be covered by states consistent with the Medicaid Drug Rebate Program, agency officials explained.

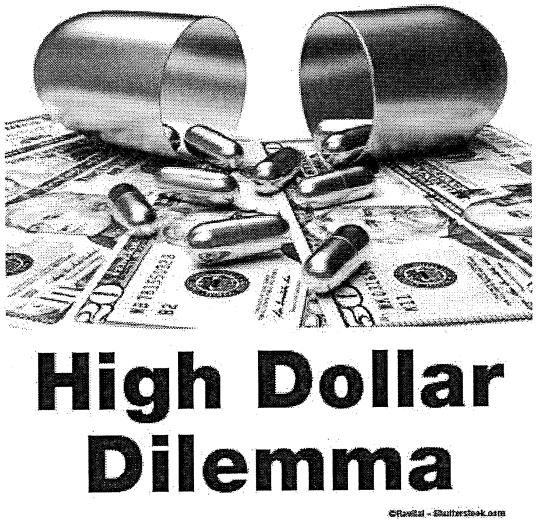
Read CMS's Massachusetts letter at https://tinyurl.com/ydguejmy ,
its Oklahoma letter at https://tinyurl.com/y86scncq , and
its letter to all states at https://tinyurl.com/ybv4drzb . Contact Snook at elissa.snook@state.ma.us
by Judy Packer-Tursman

Includes information extracted from NCSL subscription only: AIS Health Plan Weekly, 7/2/2018
https://pubs.aishealth.com/sites/all/files/latest-issue-pdf/jun. 29 2018/hpw070218.pdf. *Not a public website.*

State Net Capitol Journal

States Looking for Cure to High Drug Prices

During his State of the Union speech in February, President Donald Trump declared his intention to address what he called "the injustice of high drug prices." He repeated the promise last month in New Hampshire during a press conference on opioids, vowing we would "be seeing drug prices falling very substantially in the not-so-distant future, and it's going to be beautiful."



But the particulars of his plan remain a mystery. Trump has promised those details are soon forthcoming, but states are not waiting around holding their breath. As prescription drug prices have continued to climb, over the last three years all but a handful have adopted their own laws aimed at bringing those costs down.

According to the **National Conference of State Legislatures**, 44 states have adopted a total of 135 prescription drug pricing bills since 2015. States have introduced another 361 bills across 47 states this year alone. Those measures cover a wide spectrum of efforts, from requiring drug makers to justify price increases to removing so-called "gag orders" from pharmacy benefits managers (PBMs) that bar druggists from telling consumers about cheaper options for their medications.

Of the latter, NCSL Health Program Director Richard Cauchi notes that since Minnesota became the first in 2004, 14 states have adopted gag order provisions, including eight so far in 2018: Kansas, Mississippi, South Dakota, Virginia, Utah, Florida, Indiana and West Virginia. A bill awaiting gubernatorial action in New York (AB 8781) is also expected to be signed into law. According to the LexisNexis State Net database, similar bills are also currently still working their way through multiple statehouses (see *Bird's Eye View* in this issue). Those include Hawaii (SB 3104), Louisiana (SB 241), New Hampshire (SB 354) and South Carolina (SB 815), where bills have all passed the Senate. Bills have also cleared the House and are awaiting Senate action in three states: Kentucky (HB 463), Maryland (HB 736) and Arizona (HB 2107). Legislation in Washington (HB 2296) received unanimous approval in the Evergreen State House in February, but died in committee in the Senate last month.

Legislation pioneered in Vermont in 2016 is also sparking a growing number of transparency bills, which require drug manufacturers to offer justifications for significant price increases. That measure, signed into law by then-Gov. Pete Shumlin (D), requires state officials to annually identify 15 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." From there, drug makers must provide the state attorney general's office with acceptable reasons for those price hikes, with the information then being posted online for public viewing.

California and Nevada followed suit in 2017 with their own versions of the law. California's measure (SB 17 2017) applies to brand name and generic drugs with a wholesale cost of at least $40 that have risen in cost by at least 12 percent in the preceding year, or by 32 percent in the last two years. It also requires drug makers to give at least 90 days advance notice of that increase. The bill Nevada Gov. Brian Sandoval (R) signed (SB 539 2017) applies strictly to diabetes medications.

After the failure of a price control bill last year that included mandated rebates and caps on drug co-pays, Oregon Gov. Kate Brown (D) signed legislation (HB 4005) in March of this year that requires pharmaceutical companies in the Beaver State to justify price hikes on drugs that cost $100 or more a month, or that have gone up more than 10 percent in the last 12 months. According to the LexisNexis State Net database, at least 15 other states introduced some form of transparency bill this session. But states are exploring even more creative methods for keeping drug prices under control.

Eight have weighed or are still pondering bills that would bar so-called "non-medical switching," where a health plan forces a patient to stop taking the medication prescribed by their doctor in favor of a less expensive option. While that in theory would seem to lead to lower overall drug costs, a report from the Institute for Patient Access contends that forcing patients to use medications with potentially less efficacy than those prescribed by their doctor could lead to even more medical care and additional prescriptions.

At least 13 states have introduced or carried over measures this year similar to so-called "price gouging" legislation signed into law in Maryland in 2017. That bill (HB 631 2017) empowers the Old Line State to take legal action to block what it deems to be an excessive prescription drug price increase. And at least 10 more states have weighed bills to seek permission to contract with wholesale pharmacies in Canada, where drug prices are substantially lower than in the States.

Accessing Canadian pharmacies is hardly a new idea. Federal law has allowed it since 2003, with the caveat that states first receive permission from the U.S. Secretary of Health. Therein lies the rub: amidst fierce opposition to such imports by U.S. pharmaceutical companies, permission has never been granted even once, and current HHS Secretary Alex Azar – a former executive at Eli Lilly and company – has yet to indicate any willingness to be the first.

States are also not the only ones looking north for price relief. American consumers buy Canadian prescription medications online every day. But it is a process fraught with risk. According to the U.S Food and Drug Administration, only about 3 percent of online pharmacies meet U.S. safety standards, and many alleged Canadian pharmacy sites are actually located in countries like China, Russia and India. Many sell meds that are unapproved or even counterfeit.

None of this was a deterrent for Utah Rep. Norm Thurston (R), a self-described "free market guy" who authored his state's measure (HB 163) earlier this year. He said escalating drug prices are not a result of good free market practices and that combatting them should not be a partisan issue.

"We would be bringing in drugs intended for the Canadian market, and therefore at Canadian pricing," Thurston told *Kaiser Health News* in February. "One would assume if we could come up with a program that meets the recommendations of federal law, what justification would the [Health and Human Services] secretary have for saying no?" Azar, however, won't get the chance to decide, at least in regard to Utah. Thurston's measure cleared the House but died in committee in the Senate

Big Pharma has spared little cost battling these and other measures at both the state and federal levels, and the industry is suing to block new laws in California, Nevada and Maryland.

Even so, states remain more than willing to continue devising solutions of their own. Anthony Wright, executive director of the advocacy group Health Access California, says there is a good reason for that. "The federal level is even worse," he says. "The president talks a good game, but his solutions so far have been to just give the drug companies anything they want, including having a former Eli Lilly executive running HHS."

But as NCSL's Cauchi notes, we are probably a fair distance out from knowing which, if any, of these new state laws will produce the kind of results Wright and others are looking for either. "All of these laws are definitely interesting, and other states are definitely watching to see what happens," he says. "But it does seem to be on the early side to have enough data to know how the implementation is going."

If, as the president says, the looming specter of a federal overhaul does become reality this year, the biggest question of all might be whether they will get that chance.

March 30, 2018 – Cited/linked in NCSL TODAY, April 2, 2018

https://www.lexisnexis.com/communities/state-net/b/capitol-journal/archive/2018/03/30/states-looking-for-cure-to-high-drug-prices.aspx Live links are included in the electronic version

Bloomberg

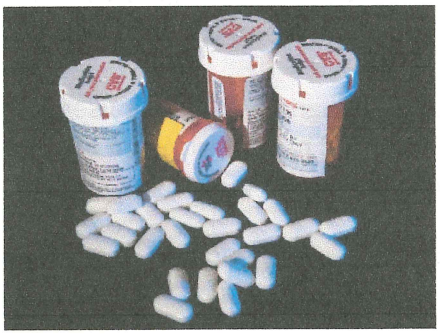
Prognosis
https://www.bloomberg.com/news/articles/2017-10-09/california-drug-price-bill-becomes-law-as-legal-fight-looms

Drugmakers Cancel Price Hikes After California Law Takes Effect

By Ben Elgin , Cynthia Koons, and Robert Langreth
July 10, 2018, 2:46 PM EDT

- Roche, Novo Nordisk, Novartis reduce or cancel some increases
- State law signed amid ongoing pressure on U.S. drug prices

Trump vs. Big Pharma: Can He Bring Drug Prices Down?



A handful of the world's biggest drugmakers are canceling or reducing planned price increases in the U.S., following a new California drug pricing transparency law and continued political pressure over pharmaceutical costs.

The California law, which began to take effect earlier this year, requires drugmakers to give insurers, governments and drug purchasers advance notice of large price increases, as a way of publicly pressuring pharmaceutical companies to keep prices down. In the past three weeks, Novartis AG, Gilead Sciences Inc., Roche Holding AG and Novo Nordisk A/S sent notices to California health plans rescinding or reducing previously announced price hikes on at least 10 drugs.

The drugs include everything from multibillion-dollar blockbusters like Novartis's psoriasis drug Cosentyx to smaller products, such as Entresto for heart failure and Gilead's drugs Letairis for pulmonary hypertension and Ranexa for angina. The changes were described by a health plan official who spoke on condition of anonymity because the information isn't yet public. Drugmakers confirmed most of the pricing decisions.

"Many factors influence our decisions to change product prices for our U.S. portfolio and it is not uncommon for us to adjust plans for price changes," Novartis spokesman Eric Althoff said in an email. Novartis said it notified some health plans of potential price increases but later decided against implementing them.

Transparency Law

The **California** measure, signed in October by Governor Jerry Brown, is among the most aggressive efforts by states to peel back the secretive process of setting drug prices. The law requires pharmaceutical companies to notify insurers and government health plans at least 60 days before planned price increases of more than 16 percent during a two-year period.

It also provides a rare window into the complex U.S. pharmaceutical market, where drugmakers sometimes raise list prices multiple times a year, then negotiate discounts and rebates with insurers and drug plans.

The law is being challenged in court by the drug industry's lobbying group Pharmaceutical Research and Manufacturers of America. Many drugmakers have been complying in the interim, sending out notices to health plans.

The law's implementation comes as President Donald Trump, who has accused drugmakers of "getting away with murder," promised on May 30th that drug companies will voluntarily reduce the price of drugs.

Real Moves?

What seems like transparency or falling prices forced by the new law may not actually be so, said Richard Evans, an health and pharmaceutical analyst at SSR in Montclair, New Jersey.

Pharmaceutical companies are likely "throwing up a smokescreen" to conceal the timing and magnitude of their actual price increases from competitors, or from purchasers who might then stock up in advance of an increase, said Evans. He predicted that the law won't slow the actual rate of actual price increases.

"If what you are trying to do is limit price inflation, this is not the way to go about it," said Evans, whose company provides drug investment research. "This is not going to change mainstream list price behavior at all."

Other drugmakers have raised prices around the same time. Earlier this month, the Financial Times reported that Pfizer had raised prices on about 100 drugs, following a pattern of regular increases that the company takes each year.

Swiss drugmaker Roche confirmed that it was canceling a proposed 4 percent price increase for Cathflo Activase, a clot treatment.

Roche has gone ahead with price increases on some of its top-selling cancer drugs. In July it raised the price of a single-use vial of Herceptin, a breast cancer drug, by 3 percent to $1,558.42. Avastin, another cancer drug, went up 2.5 percent to $3,187.76 for a 16-milliliter vial, according to price data compiled by Bloomberg Intelligence and First Databank. The changes follow increases for both drugs in January.

The price hikes were small enough that Roche wasn't required to send a notification, a spokeswoman for the company said.

Novo Nordisk told California drug purchasers it was also reducing a previously announced price increase, said company spokesman Ken Inchausti. Inchausti declined to name the drug or drugs, and wouldn't provide details on the price changes.

In early July, Novo Nordisk raised the price of its Victoza diabetes injection by 7.9 percent, and its diabetes drugs Levemir and Novolog by 5 percent, according to data compiled by First Databank and Bloomberg Intelligence. The new price is $293.75 for a 10 milliliter vial of Levemir and $289.36 for a 10 milliliter vial of Novolog. Patients can use more than one vial per month.

According to the health plan official, Gilead canceled planned price increases for four drugs, none among its biggest blockbusters. The company had given notice in May that it would be increasing prices roughly 7 percent on July 1.

Gilead didn't respond to multiple requests for comment.