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The Cost of Cures

Analyzing the Surge in New York's Medicaid Spending

by Bill Hammond

A surge in overall spending on prescription drugs in recent years, coupled with high prices for new medications and rising prices for many existing ones, has caused widespread concern among insurers, consumers and government officials.

Among those raising an alarm is Governor Andrew Cuomo. In his January 2017 executive budget, Cuomo lamented a 38 percent increase in Medicaid drug spending over the previous three years and faulted "abusive" behavior by manufacturers.

A review of publicly available data, however, suggests that prices played relatively little role in the recent rise of New York's Medicaid drug costs. The far more important factor was enrollment, which surged at almost the same rate as spending.

When adjusted for enrollment and utilization, the program's drug costs over the past decade have been relatively well controlled compared to both national averages and recent history. New York's gross per-prescription spending was lower in 2017 than in 2008, and it has been lower than the national average since 2012.

At the same time, Medicaid's drug costs are disproportionately driven by a small number of high-priced, brandname medications. This leaves the state vulnerable to spending volatility when costly new drugs arrive on the market, as happened in 2013 with breakthrough treatments for hepatitis C.



This report explores recent trends in New York's Medicaid drug spending, the forces behind them, and how they fit into the national context. Its key findings include:

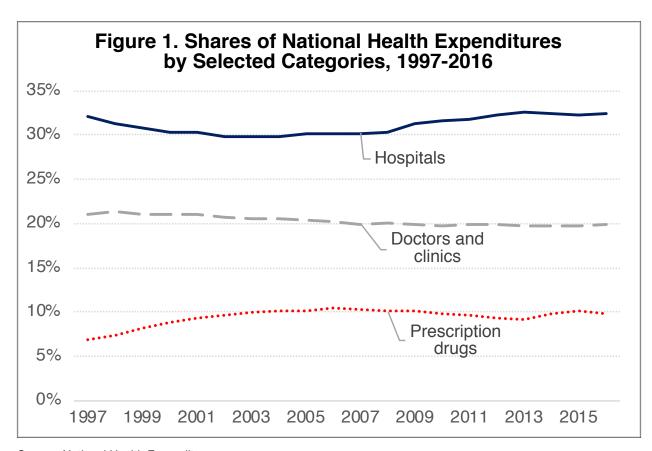
- The rate of increase in Medicaid drug spending from 2014 to 2016, net of manufacturer rebates, was largely driven by enrollment growth due to the Affordable Care Act.
- Between 2011 and 2013, Medicaid's cost per prescription dropped by 22 percent and dipped below the national average. Although costs per prescription have trended up since then, they remained lower in 2017 than when Cuomo took office.
- The share of overall Medicaid spending devoted to retail drugs in New York has held roughly steady around 5 percent.
- The top 10 costliest medications, out of more than 3,000 purchased, have accounted for 17 percent to 24 percent of total Medicaid drug costs in recent years.

 Among the state's biggest expenses since 2013 have been newly introduced hepatitis C treatments that cost tens of thousands of dollars per patient. In their first year of availability, New York spent three times more on hepatitis C drugs than any other state—in part because officials were slow to restrict coverage.

Background

Nationwide concern about rising pharmaceutical prices was spurred by a 12 percent jump in drug expenditures in 2014, followed by another 9 percent increase in 2015. These rates outpaced the growth of overall health care spending, which was 5 percent in 2014 and 6 percent in 2015.¹

The two-year surge in drug costs may have been a short-term phenomenon. It was preceded by a four-year period when the growth rate for drug spending was less than 3 percent,



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Source: National Health Expenditures

and it was followed by growth of 1.3 percent in 2016. The share of total health spending devoted to retail drugs is currently about 10 percent, consistent with the norm of more than a decade.² (See Figure 1.)

One factor behind the two-year surge was the advent of newly approved, patent-protected medications, which generally are more expensive than generic drugs.

Among the products hitting the market during that period were breakthrough drugs for hep-

atitis—which cure the potentially fatal liver disease in most cases, but cost tens of thousands of dollars per patient in the U.S. market. The first of these drugs, Sovaldi, received final ap-

proval from the Food and Drug Administration in late 2013,³ and was soon followed by several other hepatitis C medications that were similarly costly.

Also during that period, many manufacturers raised the prices of existing drugs—often for reasons that were unrelated to production costs.

Turing Pharmaceuticals and its then-CEO Martin Shkreli made headlines in 2015, for instance, when they acquired the rights to the anti-parasite drug Daraprim and raised its price from \$13.50 to \$750 per pill, a more than 5,000 percent increase.⁴

Another much-publicized example was the EpiPen, a long-standing emergency treatment for allergic reactions. Although its self-injection technology dates back to the 1970s, the price of a double-pack rose from \$265 in 2013 to \$609 in 2016.⁵

The impact of rising prices was cushioned to some degree by manufacturer rebates. This is especially true in the case of Medicaid, to which manufacturers are required to rebate the amount of price increases that exceed the inflation rate.

But consumers with high-deductible insurance plans, which have become more common, are sometimes responsible for paying the full cost of prescriptions, leaving them vulnerable to price swings.

Another force influencing government drug spending, in New York and most other states, was a major expansion of Medicaid under President Obama's health reform law, the Afford-

able Care Act.

Price accounted for about one-fifth of the spending surge, while enrollment accounted for four-fifths.

The ACA further broadened New York's already expansive Medicaid eligibility guidelines, financed the hiring of "navigators"

to help people to sign up, threatened a tax penalty on those who failed to do so, included significant marketing and generated intense media attention. After the ACA took full effect in 2014, New York's Medicaid enrollment jumped by 1.3 million, or 28 percent.⁶

How Medicaid is different

Medicaid is a health plan for the low-income and disabled, jointly financed and managed by the federal and state governments (including, in New York's case, contributions from New York City and the 57 counties). It covers medical care, including prescription drugs, for some 74 million Americans.⁷

New York's version covers 6.2 million people, or one-third of the state's population.⁸

By law, Medicaid must pay for all drugs approved by the FDA and offered by companies that agree to pay rebates—though certain usage restrictions are permitted. This sets Medicaid apart from private insurance, which has the option of not covering certain drugs when similarly effective alternatives are available.

At the same time, Medicaid plans are legally entitled to minimum rebates of 23.1 percent for most brand-name drugs and 13 percent for generics.¹⁰ Most states use their leverage as high-volume purchasers to negotiate additional rebates from manufacturers.

In addition, federal law also mandates that the amount of any higher-than-inflation price increase on an existing drug must be rebated in full to Medicaid programs.¹¹ This largely insulates Medicaid from hikes on products such as EpiPen.

In the aggregate, rebates have amounted to roughly half of New York Medicaid's gross drug spending in recent years. However, states are barred from disclosing details of rebates they negotiate, which hides the bottom-line cost of individual drugs from public view.

Another difference is that Medicaid covers non-prescription drugs, such as over-thecounter pain relievers and antacids.

Cuomo's diagnosis

Governor Cuomo's executive budget for 2017-18 warned that "gross prescription drug costs have grown by \$1.7 billion or approximately 38 percent" during the fiscal years 2014 through 2016.¹³

In his January 2017 budget address, the governor called such increases "abusive": "You have many pharmaceutical companies that are raising costs exponentially, and it has a devastating cost to the health care market as well as families themselves."¹⁴

In the final 2017-18 budget, Cuomo and the Legislature imposed a growth cap on Medicaid drug spending that empowers the Health Department to press for additional rebates on certain high-cost drugs. A statement of legislative intent accompanying the measure said that drug expenditures "continually outpace other cost components" of the Medicaid program.¹⁵

As this report will discuss in detail, these statements paint a misleading picture.

The impact of rebates reduced both the size and rate of the increase from 2014 to 2016; price hikes played a relatively small role in the trend; and drug costs have generally grown no faster than other Medicaid expenses over the past decade.

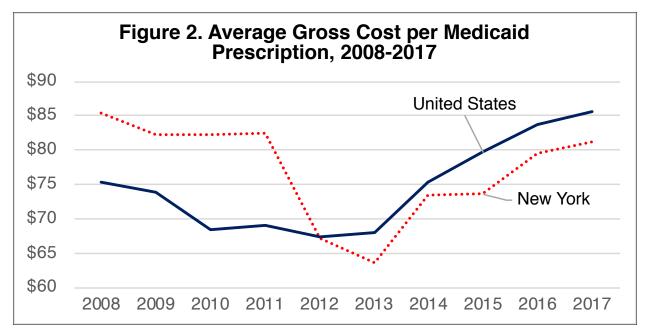
Understanding the surge

To understand the forces driving New York's Medicaid drug spending, it's necessary to consider not just total expenditures, but also rebates, enrollment, prescriptions and volatility related to high-cost, brand-name medications.

Chart 1. Medicaid Drug Spending in New York State, 2014-2016

Fiscal Year	Gross Spending*	Net Spending (After Rebates)	Enrollment†	Prescriptions [†]	Net Cost per Prescription
2014	\$4.5 billion	\$2.2 billion	5.1 million	65 million	\$35.84
2015	\$5.3 billion	\$2.8 billion	6.2 million	72 million	\$38.30
2016	\$6.2 billion	\$3.3 billion	6.1 million	76 million	\$38.50
Change	38%	25%	19%	17%	7%

Sources: *NYS Division of the Budget, †U.S. Center for Medicare and Medicaid Services



Source: CMS Medicaid State Drug Utilization Data. (Data for each state omits drugs prescribed to fewer than 11 individuals or in quantities smaller than 11 units.)

Although rebate payments to the state are not always readily available to the public, officials provided a summary for state fiscal years 2014 through 2016, the period referenced by the governor in his executive budget. (See Chart 1.)

The overall share of Medicaid drug spending rebated to the state grew from 49 percent in 2014 to 53 percent in 2016. With those payments factored in, the *gross* spending increase of \$1.7 billion or 38 percent was thus reduced to a *net* increase of \$600 million or 25 percent.¹⁶

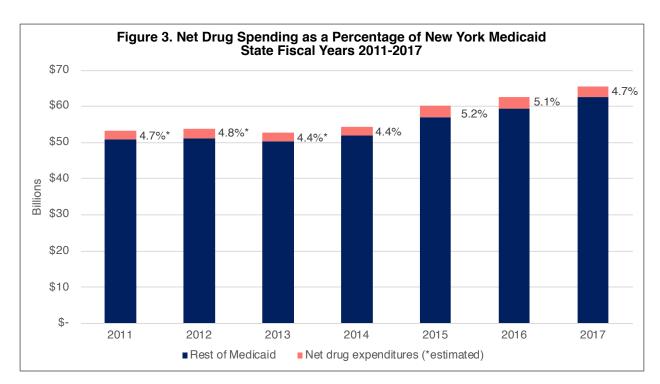
That same period saw a 19 percent rise in enrollment and a 17 percent increase in prescriptions filled. As a result, drug spending per recipient rose 5 percent, and spending per prescription grew 7 percent.¹⁷

This analysis confirms that New York State saw an increase in the average price of drugs during the three-year period, but that increase was not the primary factor behind rising Medicaid drugs costs. Price accounted for about one-fifth of the spending surge, while enrollment accounted for four-fifths. Comparable net spending numbers for earlier years were not readily available. But New York Medicaid's gross per-prescription costs had trended downward for several years preceding 2014. Indeed, they remained lower in 2017 than they were in 2008. (See Figure 2.)

They saw an especially steep drop between 2011 and 2013, paralleling a national trend as popular high-priced brand-name drugs lost their patent protection and generic alternatives became available. However, New York's decline outpaced the national rate; its per-prescription cost went from being higher than the U.S. average in 2011 to lower than the average in 2013.¹⁹

This is likely related to changes implemented during that period by the Cuomo administration. Among other steps, the governor's Medicaid Redesign Team, appointed in 2011, shifted a larger share of enrollees into managed care plans that steer patients to generic drugs where possible.

The growth of drug costs has outpaced overall Medicaid spending in some years, but lagged in



Sources: CMS Drug Data, NYS Division of the Budget Financial Plans

others. The share of Medicaid spent on drugs in fiscal year 2017, 4.7 percent, was approximately the same as in 2011. In between, it dipped as low as 4.4 percent and rose no higher than 5.2 percent.²⁰ (*See Figure 3*.)

A relative handful of brand-name drugs account for a disproportionate share of Medicaid spending. In calendar year 2016, just 10 medications out of more than 3,000 covered by New York's program accounted for 19 percent of gross costs. The comparable figures were 23 percent in 2015, 24 percent in 2014, 17 percent in 2013, and 21 percent in both 2012 and 2011.²¹

Some drugs reached the top 10 in 2016 because they were widely prescribed, such as Lantus for diabetes and Flovent for asthma. Others are used by relatively few patients, but cost thousands of dollars per prescription. Among these are Humira, which treats auto-inflammatory diseases, and Stribild, which controls HIV.²² (See Chart 2.)

The costliest drug of all for New York Medicaid in 2016 was Harvoni, one of a wave of break-

through treatments for hepatitis C that have played an outsized role in drug spending the past five years.²³

Curing hepatitis C

Hepatitis C is a virus of the liver that becomes chronic in most patients. It may cause no visible symptoms for decades but, if left untreated, typically leads to liver damage and failure. Before the adoption of routine blood screening in the 1990s, hepatitis C was commonly spread by transfusions. Now, the leading route of transmission in the U.S. is the sharing of needles by users of injectable drugs.²⁴

As many as 3.9 million Americans have the virus,²⁵ and almost 20,000 died from it in 2014, more than any other infectious disease.²⁶ The incidence rate in New York is estimated at 1.5 percent, just below the national average of 1.7 percent.²⁷ That suggests some 300,000 New Yorkers are living with the disease, many of whom are undiagnosed and unaware of their status.

Chart 2. Top 10 Drugs by Gross NY Medicaid Spending, Calendar Year 2016

Dru	g Name	Gross* Medicaid Reimbursements	Number of Prescriptions	Gross* Cost per Prescription	Maker	Disease	_
Н	arvoni	\$243 million	8,260	\$29,395	Gilead	Hepatitis C	
Н	umira	\$141 million	32,566	\$4,317	Abbott	Arthritis, IBD, Psoriasis, etc.	
Tr	uvada	\$126 million	87,214	\$1,439	Gilead	HIV Prophylaxis	
Lan	tus 3ML	\$122 million	347,083	\$351	Sanofi	Diabetes	
S	tribild	\$105 million	38,058	\$2,748	Gilead	HIV	
Syr	mbicort	\$89 million	317,840	\$280	AstraZeneca	Asthma, COPD	
٧	/iread	\$83 million	84,795	\$979	Gilead	Hepatitis B	
Triu	meq 50	\$81 million	33,895	\$2,393	Viiv	HIV	
Д	tripla	\$79 million	33,265	\$2,367	Gilead	HIV	
Flo	vent HF	\$72 million	340,071	\$211	GlaxoSmithKline	Asthma	

Source: CMS Medicaid State Drug Utilization Data. *Before rebates.

Because it is an infectious disease, treatment is important not just for individual patients, but also for public health.

In December 2013, the FDA approved a breakthrough hepatitis C drug called Sovaldi, which was significantly more effective, safer and easier to take than previous treatments. The manufacturer, Gilead Sciences, set the list price at \$84,000 for a 12-week course of treatment.²⁸ Assuming a minimum rebate of 23 percent, the cost to Medicaid started at \$65,000.

Sovaldi was the start of a wave of new hepatitis C drugs that arrived every few months over the next several years. Among them was Harvoni, also from Gilead, which combined the active ingredient of Sovaldi with a second medication to reduce the number of pills a patient would have to take. Other products were formulated to be more effective against different variants of the virus. All were priced at tens of thousands of dollars for a course of treatment.

The newest hepatitis C drug on the market is Mavyret, approved by the FDA in 2017,²⁹ which comes with a list price of \$26,400 for a shorter,

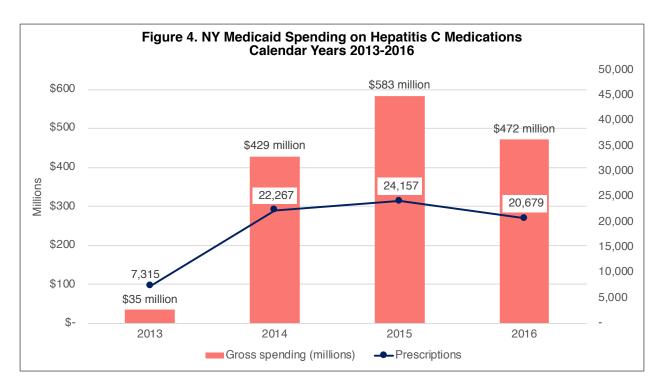
eight-week course of treatment.³⁰ The net prices of older drugs have also gotten lower as manufacturers have increased rebates in the face of market competition.

As often happens with brand-name drugs, the prices of hepatitis C treatments were determined more by the unusual workings of the American market than the underlying costs of their production.

In the name of fostering investment and innovation in the pharmaceutical industry, the U.S. does not directly regulate drugs prices, nor does the largest federal health plan, Medicare, have authority to negotiate prices. Manufacturers also have a practice of paying rebates to their U.S. distributors and buyers, which creates an incentive for setting list prices artificially high.

As a result, drugs often cost much more in the U.S. than elsewhere in the world. A course of treatment with Gilead's Harvoni, for example, carries a list price of more than \$90,000 in the U.S.³¹ Comparable drugs manufactured in Egypt, under license with Gilead, sell for \$80.³²





Source: CMS Medicaid State Drug Utilization Data (before rebates)

The impact of newly introduced hepatitis C drugs on New York's Medicaid program was particularly significant. In 2014—the first full year the new drugs were available—New York Medicaid spent \$429 million on the new hepatitis C medications, before rebates. That was about 8 percent of gross drug expenses for that year.³³ (See Figure 4.)

New York's spending on hepatitis C was also an outlier nationally. It was three times higher than in any other state in 2014, and accounted for 25 percent of the U.S. total.³⁴ (See Figure 5.)

This was partly the result of policy decisions. Most health plans, including most other Medicaid programs, imposed restrictions on coverage for the high-cost hepatitis C drugs, such as providing it only to patients who showed a certain level of liver damage or who had stopped abusing injectable drugs.³⁵

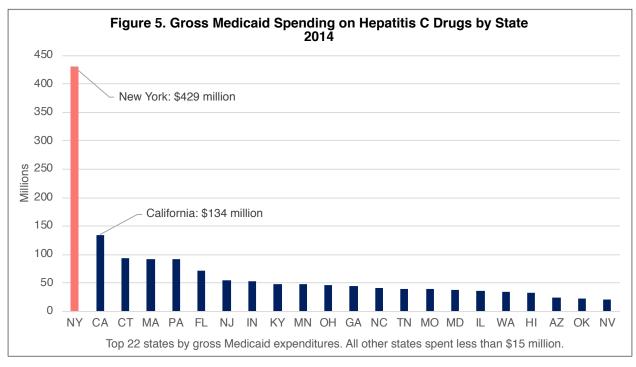
New York's Health Department did not impose any such restrictions until autumn 2014,

after the drug had been on the market for almost a year.³⁶ The department later dropped those limits in April 2016, after lobbying by patient advocates who saw them as unreasonably denying care to patients suffering a serious disease.³⁷ That same month, several of the state's private health insurers dropped their own coverage restrictions in a settlement with Attorney General Eric Schneiderman.³⁸

The state's gross spending on hepatitis C drugs has stayed high, at \$538 million in 2015 and \$471 million in 2016. California—which has almost twice the population—surpassed New York in 2016 with gross spending of \$732 million.³⁹

Cuomo's prescription

As part of the 2017-18 state budget, Governor Cuomo and the Legislature imposed a two-year statutory cap on the growth of the state's portion of Medicaid drug spending.⁴⁰



Source: CMS Medicaid State Drug Utilization Data (before rebates)

If spending is projected to exceed the cap, the Health Department and its Drug Utilization Review Board are instructed to review the pricing of high-cost drugs, identify products that are excessively expensive and seek additional rebates from their manufacturers. If a company balks, the department is empowered to demand detailed records of its expenses for research, manufacturing and marketing.

For the first year, the cap was set at the 10-year rolling average of the medical inflation rate, plus 5 percentage points, minus \$55 million. For fiscal year 2019, it was set at the rolling average of medical inflation, plus four points, minus \$85 million. For fiscal year 2020, Cuomo has proposed extending the cap at the 2019 rate.

The cap is tighter than it first appears. Although the formula for fiscal year 2018 starts with the medical inflation rate and adds five points, the subtraction of \$55 million reduces the final growth rate to 2.4 percent—a third less than the inflation rate. The second year's formula,

at current spending levels, would mandate a 2 percent *cut* to the state share of Medicaid drug spending.

The Health Department projected in August that drug spending in the 2017-18 fiscal year was on track to increase by 15 percent,⁴¹ which is more than in any recent year and higher than projected in an industry-sponsored analysis.⁴²

Based on its 15 percent projection, the department determined that it needed to reduce spending by \$119 million, or 12 percent.⁴³ The department has since signaled that its negotiations with manufacturers are on track to meet that target.⁴⁴

The department has not revealed which drugs or companies it has targeted for savings, and it is legally barred from sharing certain details about rebates. It is thus unclear how much, if any, of the anticipated savings came from hepatitis C drugs and their manufacturers.

Conclusion

The recent surge in New York's Medicaid drug spending was driven more by enrollment than price, and does not necessarily reflect a broad, long-term trend.

Costly new treatments for hepatitis C—which cure a deadly disease and control a significant public health threat—likely account for most or all of the recent uptick in per-prescription costs.

Over the longer term, the state's Medicaid drug spending has been well controlled compared to past patterns and national averages.

Unlike private health plans, the state is insulated from price increases on existing drugs—

because federal law entitles Medicaid to rebates offsetting any higher-than-inflation hikes.

Because it is obliged to cover all medications, regardless of price, the state's Medicaid program is vulnerable to hard-to-control costs when new products are approved for sale.

The recently imposed cap on Medicaid drug spending gives the state a potential tool for reducing excessive expense associated with certain pharmaceuticals. However, due to a lack of transparency, partly imposed by federal law, the effectiveness and fairness of its implementation will be hard to assess.



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