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Newsom Wants To Create State-Run Generic Drug Label

Strategy Expected to Cut Costs of Many Drugs

By Elizabeth Aguilera

In a bold strategy to drive down prescription drug prices, Gov. **Gavin Newsom** is proposing that California become the first state in the nation to establish its own generic drug label, making those medications available at an affordable price to the state's 40 million residents.

The proposal, part of the new state budget Newsom sent to the Legislature last week, would authorize the state to negotiate contracts with drugmakers to manufacture selected prescriptions on behalf of California. Such a disruption of the pharmaceutical industry, proponents say, would leverage the state's massive market to increase competition and lower generic drug prices nationally.

The strategy is one of several the Democratic governor plans to recommend to lower the cost of healthcare for Californians. The administration released only a summary of the proposal on Thursday without the projected price tag, but indicated it's part of a multi-prong effort that includes strengthening the state's public option for health insurance and increasing drug pricing transparency.

Newsom will also continue last year's push to establish a single market for drug pricing, direct the state to ask for more rebates from drug manufacturers, and open a new healthcare affordability office sometime this spring.

"The cost of healthcare is just too damn high, and California is fighting back," Newsom said in a statement. "These nation-leading reforms seek to put consumers back in the driver seat and lower healthcare costs for every Californian."

Drug costs have become a persistent and increasing worry, both nationally and in California. Six in 10 Americans take a prescription and 79% say the cost is unreasonable, according to a recent survey by Kaiser Family Foundation.

And prices can affect whether people take their pills. The same Kaiser survey found three in 10 Americans reported not taking their medicine as prescribed due to the cost of the prescription.

Governmentally, healthcare also consumes a sizable portion of the state budget. California's Medicaid program for the poor, known as Medi-Cal, now tops $100 billion a year in state and federal spending.

One way to contain costs is to encourage the use of generic drugs instead of brand name medications, whose prices are often elevated by patent protections — necessary, drug companies say, to underwrite the high financial risks of pharmaceutical research and innovation.

The price protections have their own risks, underscored in recent years by high-profile cases of price gouging. In 2015, for instance, Martin Shkreli made national headlines for hiking the price of Daraprim, used to treat parasitic diseases such as malaria, by 5,000%. And in 2017, state attorneys general in New Mexico and Washington opened investigations into whether Eli Lilly conspired with other companies to drive up the price of insulin, a drug that is nearly a century old.

But generic drug prices also have risen, state health officials say — faster than brand name ones in California. According to the Office of Statewide Health Planning and Development, from January 2017 to June 2019, generic drug prices increased 37.6%, while brand name drugs rose by 25.8%.

Those increases in recent years have prompted allegations of price-fixing in the generics industry and federal antitrust lawsuits. Last year, Newsom signed a first-in-the-nation bill deterring "pay-to-delay" agreements in which drug companies pay manufacturers of competing generics to delay the release of less expensive off-brand drugs.

"A trip to the doctor's office, pharmacy or hospital shouldn't cost a month's pay," Newsom said.

The notion of a government getting into the business of manufacturing drugs is untested, though it has garnered attention among progressive politicians.

Massachusetts Sen. **Elizabeth Warren**, a Democratic presidential candidate, has proposed legislation to allow the federal government to manufacture prescription drugs when the market fails or prices become too high. Though Warren incorporated that proposal in her presidential platform, pharmaceutical companies have argued that government shouldn't be in the complex business of developing, manufacturing and distributing medicine, and free-market advocates have contended that the public sector shouldn't be competing with private companies.

(continued on next page)

In Brief

St. Vincent Medical Center Winding Down Operations

Operations of 366-bed **St. Vincent Medical Center** near downtown Los Angeles are winding down and the facility will close entirely in the coming days.

Its current owner, **Verity Health**, asked U.S. Bankruptcy Judge **Ernest Robles** for approval to close the facility. Robles granted the approval on Jan. 9.

"The absence of any serious purchaser willing to acquire St. Vincent as a going-concern has placed all constituencies in this case in a difficult position," Robles' decision said in part. "However, forcing the debtors to keep St. Vincent open when there is insufficient money to operate it would only make the situation far worse for St. Vincent and for the patients of the debtor's other hospitals."

Verity filed for chapter 11 bankruptcy protection in September 2018. Although its controlling company, **Integrity Healthcare**, is owned by Los Angeles billionaire **Patrick Soon-Shiong**, M.D., he has been selective in how Verity manages its properties. They include **St. Francis Medical Center** in Lynwood and **Seton Medical Center** and **Seton Coastside Hospital** in the Bay Area.

The original iteration of the hospital originally opened before the Civil War, when L.A. was a dusty frontier outpost with a population of less than 5,000. It has been dogged for decades by financial woes.

"We are deeply saddened to announce the planned closure of St. Vincent Medical Center. This decision has not been taken lightly and comes only after exhausting every option to keep this hospital open," said Verity Chief Executive Officer **Rich Adcock** in a statement. "St. Vincent and its caregivers have had the distinct privilege of providing care to patients in this community. We appreciate both the opportunity to serve and the caregivers who have made a difference in ensuring that patients received the highest quality care. While we regret the closure of St. Vincent, we know that this community will continue to be well-served by nearby hospitals."

(continued on next page)

Newsom Wants To Create State-Run Generic Drug Label *...continued*

Nor is it clear how substantial a dent a state-manufactured generic program would make in healthcare costs in California. Generic drugs make up 90% of all prescriptions but account for a fraction of drug spending because they're so much cheaper than brand-name prescriptions.

Brand-name drugs make up the remaining 10% but account for 70% of all drug spending, according to IQVIA Institute, a health data research firm. So while buying generic drugs can significantly reduce drug costs, Newsom's approach may not reduce the state's health spending that dramatically overall.

Generic drug makers said that while Newsom's approach to create a state label is noble, it's the wrong strategy. Costs are being driven up by brand name drugs, they said, not generics, which, by their calculation, have saved Californians have saved $26 billion.

"If California enters the market itself," the **Association for Accessible Medicines** said in a statement, "it will face the same market dynamics that have led to generic prescription drug price deflation in the past three years, as well as certain cases of patent abuse that have led to longer monopolies by select brand-name drugs."

Representatives for the broader pharmaceutical industry had no immediate comment, though political pushback would be expected. In 2016, drug companies spent more than $100 million to stop a ballot measure that would have barred the state from paying more for prescription drugs than the **U.S. Department of Veterans Affairs**, which pays the nation's lowest prices.

Consumer advocates, meanwhile, welcomed the idea.

"This is a potential game changer," said **Anthony Wright**, executive director of **Health Access California**, a statewide healthcare consumer advocacy coalition. "California has the capacity and the smarts and the scale to actually do it."

Wright said patient advocates have for years viewed this type of branding as a way to reduce healthcare costs and put the pharmaceutical industry on notice that California is paying attention.

Peter Maybarduk, who directs the Global Access to Medicines Program at **Public Citizen**, a progressive, nonprofit consumer advocacy organization, agreed that California's powerful economies of scale make the proposal worth trying, even though the federal government's broad jurisdiction on drug laws might pose a challenge.

"It's much better than not doing it," he said. "[The state] can offer a very large market that is an inducement to offer better prices and it can offer this contracting system to both inspire new competition and help select the best offers."

He noted that the public generic manufacturing idea is one of several policy innovations percolating at the state level. Louisiana, for example, is in the process of setting up a "Netflix model" for pricey Hepatitis C treatments by paying a set sum of money to the drug maker for all the state's needs, versus paying per prescription.

"Those are states taking matters into their own hands because the federal government has not solved the problem," Maybarduk said.

Health plans were receptive.

"We share the governor's concerns about tackling the high cost of prescription drugs," said **Mary Ellen Grant**, a spokesperson for the **California Association of Health Plans**, a trade group that represents health insurers. "If this idea can address that issue, then there's a lot of potential there."

Since taking office a little over a year ago, Newsom has made healthcare a priority by expanding Medi-Cal to undocumented young adults and continuing to champion Obamacare where the federal government has pulled back by requiring all residents to have health insurance. In the new budget, he's expected to propose extending Medi-Cal to seniors in the country illegally in another step toward healthcare for all.

His first executive order called for creating a bulk drug purchasing program across state departments to maximize purchasing power and negotiate better rates from pharmaceutical companies.

That meant the state **Department of Health Care Services** would begin negotiating the purchase of prescription drugs for all 13 million Medi-Cal recipients, or one in three Californians. Prior to that, the state only represented 2 million Medi-Cal recipients, while the rest were placed in managed care health plans that negotiate their own drug rates.

State officials have estimated the change will save California taxpayers $393 million by 2021.

But the plan has created tension between the state and nonprofit healthcare providers who care for California's poorest patients. The takeover of the pharmacy benefit in Medi-Cal removes a nonprofit clinic's ability to buy drugs at reduced costs through a separate federal program. Undeterred, the Newsom administration is pushing ahead and awarded a contract last month to a firm to manage the new pharmacy benefits.

Jim Mangia, president and CEO of **St. John Well Child and Family Center** in South Los Angeles, which serves more than 100,000 mostly Med-Cal patients — and which is standing to lose from the pharmacy benefits takeover — called Newsom's generics idea "interesting and creative," but cautioned it would be essential to couple it with a proposal to make sure poorer patients can get those low-cost medications.

"The drugs could be cheap," he said, "but that doesn't mean there are going to be pharmacies in reach."

A version of this article was originally published by CalMatters.

In Brief

St. Vincent Medical Center Winding Down Operations (continued)

St. Vincent began diverting ambulances to other hospitals, including **Good Samaritan Medical Center**, shortly after Robles issued his decision. Patients are also being transferred to other nearby facilities. Verity said it will provide some assistance, including a job fair, to St. Vincent's roughly 1,000 employees.

Molina Could Hit Rough Earnings Patch

Long Beach-based **Molina Healthcare**, which has expanded dramatically since the Affordable Care dramatically expanded Medicaid coverage and the purchase of health insurance coverage by individuals on state exchanges, may hit a rough patch with the release of its first quarter 2020 earnings.

Company CEO **Joseph Zubretsky** announced at this week's **J.P. Morgan Healthcare Conference** in San Francisco that Molina's ACA exchange enrollment may only reach 350,000 during the first quarter, down significantly from analyst projections of 407,000. Molina, which specializes in Medicaid managed care, often provides one of the lowest-priced options on the exchanges where it does business.

On Monday, an analyst with **SunTrust Banks** cut Molina's earnings per share projection to $3.31 for the first quarter, down from $3.41. The analyst projects second-quarter earnings per share will be even lower, at $3.13 per share.

Molina's stock dropped more than 6% on Monday but rebounded later in the week. It is currently trading at around $139 per share.

Medi-Cal's Decade-Long Growth Spurt

Spurred by The ACA, Enrollment Grew 78%

By Harriet Blair Rowan

Medi-Cal had a big decade.

The number of Californians enrolled in the state's health insurance program for low-income residents swelled by 5.5 million from 2010 to 2019. It now covers 1 in 3 Californians and 40% of children.

The program's annual budget — a combination of state and federal money — tops $100 billion, more than the entire state budget of Florida.

"Medi-Cal is the largest Medicaid program among all of the states," said **Andrew Bindman** M.D., a professor of medicine at **UC San Francisco** who helped implement the Affordable Care Act as part of the Obama administration.

It's most likely going to get bigger. On Friday, California Gov. **Gavin Newsom** released his 2020-21 state budget blueprint, which would boost Medi-Cal's annual budget to more than $107 billion and expand coverage to even more people.

Medi-Cal, California's version of the federal Medicaid program, was transformed in the past decade by federal and state laws — especially the federal Affordable Care Act — and by the ups and downs in California's economy.

In early 2010, Medi-Cal covered 7.2 million people. Enrollment peaked at 13.7 million in March 2016, and slowly but steadily decreased to 12.8 million people in August 2019, according to the most recent enrollment data from the state **Department of Health Care Services**. About 4.9 million of them were under age 19.

In 2018, half of enrollees identified as Hispanic, 18% as white, 10% as Asian or Pacific Islander and 8% as black, according to the department. Thirteen percent of enrollees did not report their race/ethnicity.

The federal Affordable Care Act spurred the most significant changes to Medi-Cal since 2010, largely because it allowed states to broaden eligibility for their Medicaid programs to low-income people who had not previously qualified. Thirty-six states plus Washington, D.C., have adopted Medicaid expansions.

In California, Medi-Cal enrollment grew 78% from January 2010 to August 2019, primarily due to the expansion, which began in 2014.

"California went all-in on that," Bindman said, and reduced its uninsured rate from 18.5% in 2010 to 7.2% in 2018.

Before the change, adults usually didn't qualify unless they were parents with dependent children, pregnant or had certain conditions or disabilities.

Under the expansion, any adult who met the income guidelines could enroll, which represented a "radical shift" in the way the program operates, said **Jen Flory**, a policy advocate at the **Western Center on Law & Poverty.**

It transformed Medi-Cal "to more general low-income coverage," she said.

The number of adults enrolled through the expansion has hovered around 3.7 million since mid-2016, while the rest of the Medi-Cal population dropped from 10 million to 9 million during the same period. Flory credited a strong economy and low unemployment in part, as more people got jobs that offered employer-based insurance and others surpassed the income limits to qualify.

But Flory and Bindman said other factors might be contributing.

They pointed to fears within immigrant communities over increased immigration enforcement, and policies such as the Trump administration's "public charge" rule. The rule would allow immigration officials to more easily deny permanent residency status to those who depend on certain public benefits such as Medicaid.

Federal judges temporarily blocked the rule from taking effect in mid-October, but the Trump administration on Monday the **U.S. Supreme Court** to allow it to implement the rule while the legal battles continue.

As a result of such policies and proposals, they said, some immigrants may not be enrolling in Medicaid and other government programs, even if they are eligible.

In the past decade, Medi-Cal has also changed how it delivers care. In January 2010, roughly half of Medi-Cal enrollees participated in the traditional "fee-for-service" model, in which patients can see any doctor who accepts them, and providers are reimbursed for each medical service or visit.

The other half received care from managed-care plans. Under managed care, the state contracts with health plans to deliver benefits to enrollees and pays them a fixed monthly rate to cover the expense of doing so — a payment system known as "capitation."

The percentage of enrollees served by managed care climbed to 82% by July 2019 as California, like many other states, looked to that model to save money.

The Trump administration and Republicans in Congress have weakened Obamacare and called for limits on federal spending on Medicaid. Such proposals may accelerate if Republicans retain the White House and regain control of the U.S. House of Representatives this year.

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Less Status Quo And More IHOP In Hospitals

The Chain Restaurant Training Approach Could Cut Healthcare Costs

The New York Times had an article that surprised me: Current Job: Award Winning Chef. Education: IHOP. The article, by food writer **Priya Krishna**, profiled how many high-end chefs credit their training in — gasp! — chain restaurants, such as **IHOP**, as being invaluable for their success.

I immediately thought of **Atul Gawande**'s 2012 article in *The New Yorker*: What Big Medicine Can Learn From the Cheesecake Factory.

Ms. Krishna mentions several well-known chefs "who prize the lessons they learned — many as teenagers — in the scaled-up, streamlined world of chain restaurants.

Some of the lessons learned are instructive. "It was pretty much that the customer is always right," one chef mentioned. Another said she learned "how to be quick, have a good memory, and know the timing of everything." A third spoke to the focus that was drilled into all employees: "Hot food hot. Cold food cold. Money to the bank. Clean restrooms,"

Oh, gosh, where are the healthcare equivalents of those?

I particularly was struck by three other quotes that could, and should, apply to healthcare:

- "There is this understanding that every person is important to making the restaurant run smoothly. Nobody thought the dishwasher was a lower status than them."
- "You spend a week on the grill, a week waitressing, a week in financials. You know every aspect of that restaurant."
- Chain restaurants have a playbook for every position. There is no guesswork."

By Kim Bellard

In healthcare, physicians usually get their training in academic medical centers, which is sort of like training chefs in culinary schools or five-star restaurants.

However, physicians are not trained on how the entire system works — no equivalent of working as a server or in the kitchen first — and without learning how much things cost. They tend to develop idiosyncratic approaches that may or may not be based on the latest research/best practices; even if they are, there's no mechanism to ensure that those approaches stay current. All this while too often tending to see themselves as more important than other healthcare workers.

No wonder Dr. Gawande was impressed by The Cheesecake **Factory** almost a decade ago.

He marveled at the size of their menu, the quality of the food, and the affordable prices — all delivered uniformly to tens of millions of customers in two hundred restaurants worldwide. As he noted:

Some of the things that impressed Dr. Gawande about the kitchens in The Cheesecake Factory:

- "the instructions [recipes] were precise about the ingredients and the objectives…but not about how to get there."
- "a kitchen manager is stationed at the counter where the food comes off the line, and he rates the food on a scale of one to ten."
- The chain-restaurant industry has produced a field of computer analytics known as "guest forecasting."

Dr. Gawande admitted: "As a doctor, I found such control alien—possibly from a hostile planet."

He went on to discuss the experience his mother had with a knee replacement; he deliberately steered her to an orthopedic surgeon who had led the charge to standardize such operations at **Brigham & Women's Hospital**: "they studied what the best people were doing, figured out how to standardize it, and then tried to get everyone to follow suit."

Most physicians I know recoil at "cookbook medicine." Most physicians believe their patients are unique. But, as Dr. Gawande pointed out: "we're moving from a Jeffersonian ideal of small guilds and independent craftsmen to a Hamiltonian recognition of the advantages that size and centralized control can bring."

Many of the chefs Ms. Krishna talked to reported there is still a stigma in high-end restaurants of having trained in chain restaurants, and that that culinary schools were still sending most of their graduates to independent restaurants, not chains (even though one such graduate complained: "when you graduate and work for that Michelin-star chef, you aren't going to make enough to be able to pay your loans."

But "the more casual, business-minded approach of chains is the future of dining," just as the future of healthcare is more patient-centered and business-minded. Healthcare may be consolidating, but it is far from replicating the business practices that have made chain restaurant successful.

We are, in essence, training physicians in expensive culinary schools, to work in high-end restaurants. That may be good for some of them, and for some of us, but it is not good for all of them or for most of us. The future is going to require that more of them get healthcare's version of a chain restaurant experience.

Kim Bellard edits the Tincture blog. A version of this article originally appeared at The Health Care Blog.

United Healthcare of California
Enrollment and Utilization Table as of 9/30/2019

QUARTERLY STATEMENT AS OF September 30, 2019 - UHC of California dba UnitedHealthcare of California

ENROLLMENT AND UTILIZATION TABLE

	1	2	3	4	5	6	7	8	9	10	11	12	13
	Source of Enr	Total Enrollees At End of Previous Period	Additions During Period	Terminations During Period	Total Enrollees at End of Period	Grandfathered Enrollees (also included in Column 5)	Cumulative Enrollee Months for Period	Total Member Ambulatory Encounters for Period - Physicians	Total Member Ambulatory Encounters for Period - Non-Physicians	Total Member Ambulatory Encounters for Period	Total Patient Days Incurred	Annualized Hospital Days/1000	Average Length of Stay
1.	Large Group (	344,603	6,106	8,111	342,598		1,031,394	179,268		179,268	16,172	188	4.05
2.	Medicare Risk	365,023	11,004	9,587	366,440		1,098,346	420,151		420,151	90,298	987	4.74
3.	Medicare Supplement				0					0		0	
4.	Medi-Cal Risk				0					0		0	
5.	Individual	2	0	0	2		6	0		0	0	0	0.00
6.	Point of Service - Individual				0					0		0	
7.	Point of Service - Small Group				0					0		0	
8.	Point of Service - Large Group				0					0		0	
9.	Small Group (	71,244	3,928	5,136	70,036		211,357	15,513		15,513	2,961	168	4.68
10.	Healthy Families				0					0		0	
11.	AIM				0					0		0	
12.	Medicare Cost				0					0		0	
13.	ASO				0		N/A	N/A	N/A	0	N/A	N/A	N/A
14.	PPO Individual				0					0		0	
15.	PPO Small Group				0					0		0	
16.	PPO Large Group				0					0		0	
17.	Aggregate Contracted from Other Plans	0	0	0	0		0	0	0	0	0	N/A	N/A
18.	Aggregate Other Source of Enrollment	0	0	0	0		0	0	0	0	0	N/A	N/A
19.	Total Member	780,872	21,038	22,834	779,076	0	2,341,103	614,932	0	614,932	109,431	N/A	N/A

Source: Quarterly Statement 9/30/2019 United Healthcare of California, Enrollment and Utilization Table

Medi-Cal's Decade-Long Growth Spurt ...*continued from page 3*

While the federal government moves to restrict funding and enrollment, California lawmakers continue to expand eligibility for Medi-Cal.

Starting this year, low-income young adults up to age 26 became eligible for full Medi-Cal benefits regardless of their immigration status, joining unauthorized immigrant children, who became eligible in 2016.

On Friday, Newsom proposed expanding full Medi-Cal benefits to eligible undocumented immigrant adults ages 65 and over as part of his state budget proposal.

California's policies offer "a striking contrast to the policies of the current federal administration," Bindman said.

This story was produced by Kaiser Health News, which publishes California Healthline, an editorially independent service of the California Health Care Foundation.

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