The California Insulin Crisis Explained: A Primer on Insulin Pricing, Past Legislative Action, and the Path Forward.

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ABSTRACT

With both manufacturer-set list prices for insulin and median out-of-pocket cost per insulin vial nearly tripling over the past two decades, insulin has become less affordable over time for all Californians at an alarming rate.5,9 Through comprehensive policy efforts that address every level of the insulin supply chain, from manufacturer set list-prices to out-of-pocket costs faced by patients, California can be a leading example of how state policy can promote insulin affordability.

This policy brief provides an overview of the market and policy forces that have driven California’s insulin affordability crisis. It also provides a set of policy recommendations that will lead to a healthier California, such as caps on insulin cost-sharing for all Californians regardless of insurance status, year-to-year limits on insulin list price increases, and legislation that calls for rebates to be passed through to patients at the point-of-sale.

INTRODUCTION

In 2017 alone, direct medical costs from diabetes mellitus totaled to $237 billion, not including the costs from reduced productivity. Approximately one in every seven dollars spent in health care (14%) was due to diabetes.3 Medications accounted for a little less than a half of those costs (43%), and insulin alone accounted for the majority of the economic toll, totaling to $15 billion.3 Between 2012 and 2017, the inflation-adjusted cost of insulin increased by 110%.3

Despite a decrease in incidence in diagnosed diabetes, the prevalence of diabetes mellitus (Type I and Type II) in the United States has increased from 3.7% in 1980 to 8.5% in 2017.4 In particular, minority groups experienced a higher prevalence of diabetes compared to non-Hispanic Whites (7.4%). Between 2013 and 2015, the prevalence of diabetes was highest among communities that identified as American Indian/Alaska Native (15.1%), followed by non-Hispanic Black (12.7%), Hispanic (12.1%), and Asian (8.0%)2

With more than half of California’s 40 million population living with prediabetes or undiagnosed diabetes and over 10% of the population diagnosed with either Type 1 or Type 2 diabetes, there is an urgent need for California’s legislature and state agencies to take bold policy to relieve the burden of the out-of-pocket insulin costs for California’s diabetic population, which is the focus of this policy brief.
INSULIN PRICING AND THE COST CONUNDRUM

Out-of-pocket costs of insulin for Californians have skyrocketed over the past twenty years leading to barriers to insulin access and affordability.\textsuperscript{5,6,7}

A key and growing barrier to insulin access and affordability has been the rising list price of insulin over the past two decades. Between 2002 and 2013, for example, list prices for insulin nearly tripled. This pricing trend continued from 2012 to 2016, driven by the average U.S. list price (wholesale acquisition cost) of the four insulin categories increasing by 15\% to 17\% per year when the median household income in California increased by 11\% percent ($62,389 to $69,196) over that same four year period in total.\textsuperscript{5,9}

Patient out-of-pocket costs followed suit as from 2006 and 2013 alone, the average out-of-pocket costs for insulin among Medicare Part D users doubled for all insulin types [$27 per month in 2006 to $65 per month in 2013].\textsuperscript{1} Among the commercially insured, the median out-of-pocket costs for patients skyrocketed from $10 per vial of insulin in 2000 to $36 per vial in 2010.\textsuperscript{5} \textbf{This data underscores how insulin has become less affordable over time for all Californians at an alarming rate.}

To understand how insulin prices have risen dramatically over the past two decades, one must analyze how the shifts in the pharmaceutical supply chain, and subsequent changes in price and rebate negotiating power among key stakeholders (namely manufacturers, wholesalers, pharmacy benefit managers, health plans, and pharmacies), have led to \textbf{price escalation that has ultimately been passed through to patients, with a disproportionate burden falling upon the uninsured, low income, and often minority patients.\textsuperscript{5,10,11}}

\textbf{THE INSULIN SUPPLY CHAIN}

While a detailed discussion of the insulin supply chain is beyond the scope of this policy brief, it is important to highlight how the major stakeholders in the supply chain have differential degrees of negotiating power to determine the price of insulin (See Figure 1).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{insulin_supply_chain.png}
\caption{The Insulin Supply Chain (Cal-IHEA, 2020)}
\end{figure}
PHARMACEUTICAL MANUFACTURERS are the source of insulin in the supply chain and manage the distribution of insulin from manufacturer facilities to insulin wholesalers. While insulin manufacturers can distribute directly to purchasers such as the Veterans Administration and other government entities, very few drugs are distributed directly to patients and consumers. In the United States, three pharmaceutical companies, Eli Lilly, Sanofi, and Novo Nordisk, control 90% of the insulin market by value.11

WHOLESALE DISTRIBUTORS purchase insulin from manufacturers and distribute the drug to pharmacies, hospitals, long-term care facilities, and other medical facilities. Wholesalers purchase insulin from manufacturers at a price called the Wholesale Acquisition Cost (WAC), which is often referred to as insulin’s List Price. For their distribution services, Wholesale Distributors are paid a fee from Manufacturers, which is typically a negotiated percent of the WAC. Three drug wholesalers, AmerisourceBergen Co., Cardinal Health, and McKesson Corp., receive 90% of revenue from pharmaceutical distribution.12

PHARMACIES purchase insulin from Wholesale Distributors at the WAC minus a negotiated discount and are charged with storing insulin safely before dispensing to customers. Pharmacies collect any cost-sharing amounts (i.e. co-insurance, co-payment, full-price) for insulin specified in a patient’s health plan and are reimbursed by Pharmacy Benefit Managers (PBMs) the Average Wholesale Price [average cost of insulin to Wholesale Distributors] plus a dispensing fee minus a negotiated discount and any cost-sharing collected from the patient. In particular, since the implementation of Medicare Part D in 2006 through the Medicare Prescription Drug Improvement, and Modernization Act and the “patent cliff” of 2012, the specialty pharmacies market have grown considerably (note: Medicare defines specialty drugs as those that cost more than $670 per month).13,14 The 4 major specialty pharmacy chains [CVS Health- 25%, Cigna/Express Scripts -21%, Walgreens Boots Alliance-13%, United/OptumRx Scripts- 11% ] make-up over 70% of the Pharmacy Market Share.15

PHARMACY BENEFIT MANAGERS (PBMs) are contracted with health plans to manage the outpatient pharmaceutical benefits for their clients, including what drugs will be covered (formulary development), how much designated pharmacies will receive in dispensing fees and reimbursement, and how much patients must pay in cost-sharing. In addition, PBMs also negotiate discounts and rebates with Pharmaceutical Manufacturers and subsequently negotiate with health plans how much of rebates received will be passed along to health plans. The Big Three PBMs [Caremark (CVS Health)/ Aetna- 30%, ExpressScripts- 23%, OptumRx (United Health)- 23%] control over 75% of the PBM market share.15

RAMIFICATIONS OF PERVERSE INCENTIVES

Discounts on list prices, rebates, and reimbursements along the insulin supply chain are ultimately determined by the ability of PBMs and payers (i.e. health plans, self-insured employers) to leverage market forces in negotiations with manufacturers.9,16,17 For example, Pharmacy Benefit Managers that have a large share of the market (thus contracting with a large percentage of health plans or health plans with a large patient population) are able to demand larger rebates from Pharmaceutical Manufacturers in return for placing their drugs on a lower cost-sharing tier on a health plan’s formulary.

Over the past 20 years, the largest PBMs and health plans, recognizing their unique role and value in the supply chain and ability to capitalize off exponentially growing specialty drug markets, set off a wave of consolidation and vertical...
integration to command greater market power. Particularly, vertical integration arrangements between health plans, PBMs, and specialty pharmacies (see Figure 5) have allowed for PBM’s to demand larger rebates from pharmaceutical manufacturers on specialty therapeutics and drugs like insulin. Because rebates are often given on a percent-of-list-price basis, there is often little incentive for PBMs and health plans to demand lower drug prices when they can often simply pass on the cost of higher list prices to patients through cost-sharing (co-payment, co-insurance, high deductibles) and premiums while collecting and retaining larger rebates.

As a result of these perverse incentives, insulin list prices on brand name insulins soared upwards of 250% between 2007 and 2016, while the net price of insulin, which does not account for the contribution of rebates and other discounts, rose between 3-57% (See Figure 3). Thus, while pharmaceutical manufacturers of insulin, namely the big three in Eli Lily, Sanofi, and NovoNordisk, are in part responsible for spikes in insulin prices over the past decade, Pharmaceutical Benefit Managers (the largest of which are able to demand and retain larger rebates through monopsony power derived from integration with large health plans and specialty pharmacies, See Figure 2) are also responsible for the insulin affordability crisis across California and the United States more broadly.
At the end of the insulin supply chain resides millions of patients who bear the burden of the soaring list prices for drugs like insulin through high out-of-pocket costs, with **unaffordable insulin prices disproportionately impacting low-income, often minority Californians.** The result is poor diabetes management and ultimately higher healthcare costs due to preventable outcomes such as lower limb amputations, retinopathy, neuropathy, kidney disease and emergency room utilization.

**FEDERAL AND STATE LEGISLATIVE ACTION**

Federal and state legislation bodies have begun to address pharmacy benefit managers and rising insulin prices, with both protective and dismantling proposals. On one hand, the Health and Human Services Department put forward a proposal to protect the point-of-sale rebates from laws that discouraged kickbacks in Medicare Part D and Medicaid programs. Their justification was that partial point-of-sale rebates will shift the burden away from consumers.

Nancy Pelosi, on the other hand, drafted a house bill (H.R.3 Drug Price Negotiation) granting the HHS Secretary the authority to negotiate directly with manufacturers on the pricing of 250 of the most widely used drug. In addition, drug companies that raise drug prices in Medicare Part B and D above the inflation rate since 2016 would be subject to either lower their prices or pay the residual price above the inflation to the US Department of the Treasury. Prices are also capped to comparable prices used in other countries by utilizing an International Price Index during negotiations. These new prices would be available to all purchasers, not strictly Medicare beneficiaries, as an attempt to maximize savings for the most Americans. The House of Representative will be voting on the bill; however, it is not expected to pass the Senate.

Similarly, a bipartisan Senate bill introduced to the Committee on Finance in September 2019 addressed drug pricing with similar proposals. The Prescription Drug Price Reduction Act of 2019 (S. 2543) proposed amending the Social Security Act to facilitate transparency around drug prices and transactions, lower pharmaceutical drug prices in Medicare and Medicaid, and

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Figure 3: Gross-to-Net Bubble: How Lantus (Sanofi) List Prices and Net Prices (price after rebates and other reductions) changed from 2007-2016. Sources: Truven Health Analytics (list prices) and Bernstein (net price estimates) (Adapted from ADA Workgroup 2018 reprint via Wall Street Journal)
reduce out-of-pocket expenditures. The bill is expected to have more success because of its bipartisanship.

Several states have passed legislation to address increasing wholesale acquisition costs (WAC). Much of the enacted legislation since 2017 has mandated transparent reporting requirements regarding payments to healthcare providers and organizations and reporting requirements of state prices. Colorado recently passed legislation in May 2019 to reduce the economic burden of an insured person by basing the price for insulin they pay by the rebates the carrier receive, and have capped the maximum out-of-pocket fees to $100 for one-month’s supply of insulin. The bill mandates an investigation of insulin pricing and a report sent to the governor, the commissioner of insurance, and the judiciary committees of the senate and house of representatives. Other states that have proposed and passed similar legislation include Illinois, Louisiana, Maine, Maryland, and Missouri.

In California, there have been recent proposals and passed legislation focused on increased transparency and reporting as a means of stemming the rise in medication prices, but price increases for many brand-name drugs and therapeutics remain problematic.

The upturn in legislation promoting pharmaceutical regulation among federal and state legislative bodies has indicated a conducive political climate. Within California, the majority of Health Committee Members in the Assembly and Senate supported these bills, further indicating a political window for proposed legislation. However, Senator McGuire’s SB 790 was a clear example of the difficulty in passing legislation of this nature.

THE WAY FORWARD: POLICY RECOMMENDATIONS

As of January 2020, there has been a lack of California state legislation specifically addressing the rise in insulin pricing. It may be more feasible to pass bills regulating pharmaceutical manufacturers and health insurers for specific medications documented to be underused due to financial barriers.

While the broad based national and state policy is necessary to control prices across all pharmaceutical classes, policy that addresses insulin pricing is an immediate concern for the health of California’s diabetic population. Thus, comprehensive short and long-term state policy action is necessary to relieve the financial burden of insulin on patients, while ensuring the highest level of health for all Californians battling diabetes. We provide our policy recommendations below:

1. **Eliminate or cap cost-sharing on insulin for Medi-Cal and commercial plans.** While there is some evidence that health plans’ overall prescription drug benefit cost-sharing can result in increased premiums, this does not generalize to cost-sharing caps for individual drugs, e.g., insulin. Given the narrow scope of reduced cost sharing for insulin through out of pocket caps or caps on price increases is unlikely to have an impact on premiums overall. Importantly, a Milliman report points out that even when small premium increases occur due to increased cost sharing, “members who use high-cost drugs may see a large reduction in out-of-pocket spending.” For members with high medical and pharmacy expenses that are expected to hit the annual out-of-pocket maximum, patients’ out-of-pocket costs may be spread more evenly throughout the year instead of concentrated in the first few months.” This is a key point because evidence indicates that cost-related barriers to insulin access reduce adherence, increase adverse medical events and result in preventable hospitalizations. Colorado’s HB19-1296 capped
caps the cost sharing a covered person is required to pay for prescription insulin drugs at $100 per 30-day supply of insulin, effective January 1, 2020.\textsuperscript{32} Similarly, New Mexico’s House Bill 292 caps co-payments for insulin at $25 per month and Virginia’s House Bill 66 will cap insulin co-payments at $50 effective July 1, 2020.

2. **Extend point-of-sale price caps to all Californians regardless of insurance status.**
Uninsured patients in California, a majority of which are undocumented immigrants, must pay the manufacturer-set list price of insulin at the point-of-sale (pharmacies), making insulin extremely unaffordable. This price can exceed $450 for a 30-day supply of brand-name insulins.\textsuperscript{33}

3. **Mandate that a majority of rebates (51%) received by PBMs and health plans from pharmaceutical manufacturers for insulin sales must be passed through to patients to reduce cost-sharing requirements at the point of sale.**
Such legislation would ensure that rebates that PBMs and health plans receive from insulin manufacturers are used to reduce out-of-pocket costs for patients at the point-of-sale. Colorado, through HB19-1296, requires a carrier to reduce the cost sharing a covered person is required to pay for prescription drugs by an amount equal to the greater of 51% of the average aggregate rebates received by the carrier for all prescription drugs, including price protection rebates, or an amount that ensures cost sharing will not exceed 125% of the carrier’s cost for the prescription drug.\textsuperscript{32}

4. **Exempt the cost of insulin from patient deductibles on all Medi-Cal and commercial health plans.**
Patients who must meet a yearly deductible, which average $1,402 in California for all plans, must pay the full list price of insulin before cost-sharing provisions (i.e. only a co-payment, co-insurance) kick in.\textsuperscript{34} By excluding insulin from patients’ deductibles, cost-sharing would immediately protect patients from unaffordable insulin list prices before their deductible is met in the early part of the year. Through this protection, poor health outcomes such as preventable hospitalizations, lower limb amputations, retinopathy, neuropathy, and kidney disease would be mitigated as a result of deterring unfilled insulin prescriptions and insulin rationing.\textsuperscript{21}

5. **Institute caps on insulin list prices increases set by manufacturers, i.e. no more than 3% price increase per year.**
Caps on co-payments alone will not address the problem of exorbitant insulin prices because mark-ups are primarily due factors upstream in the pharmaceutical supply chain such as list prices set by manufacturers (Eli Lilly, Novo Nordisk, and Sanofi) and the negotiation power of Pharmacy Benefit Managers.\textsuperscript{5, 17} Policies that limit insulin price increases over time, e.g., no more than 3% per year, would have more impact on making insulin affordable than co-payment caps.
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