White Paper

The Cost of the 340B Program Part 1: Self-Insured Employers

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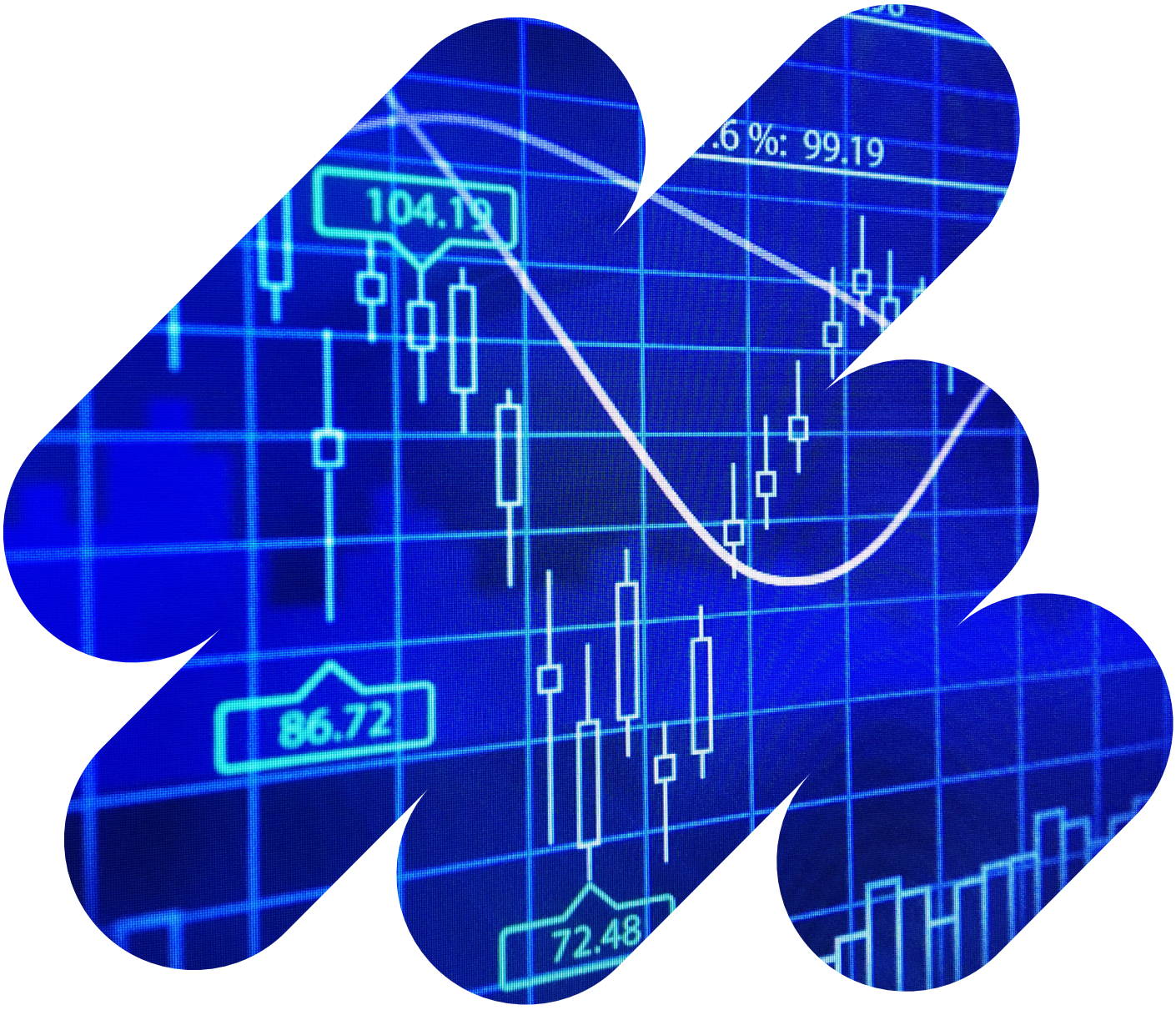

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Abstract

The 340B Drug Discount Program (“340B program”) is a federal program in which manufacturers provide discounted outpatient drugs to participating 340B hospitals and clinics. At first glance, the financial behavior of the program appears to be simple: 340B hospitals and clinics benefit, manufacturers pay, and the narrative is the program does not cost taxpayers anything.

To test these assumptions, IQVIA created a model to quantify the financial impact of the 340B program on drug and total healthcare costs. The model included factors such as 340B eligibility, manufacturer rebates, and lost rebates due to product purchased at the 340B discount price, and model parameters were estimated using national samples of consumers, payers, products, and providers. The model revealed drug costs for self-insured employers and their workers were 4.2% higher than they otherwise would have been if the program did not exist due to the loss of manufacturer rebates for drugs purchased through the 340B program. This corresponds to an annual increase of $5.2B in the cost of healthcare for self-insured employers and their workers.

In light of these findings, the narrative that “the 340B program costs taxpayers nothing” should be reconsidered. In addition, if the same dynamic with lost rebates were true for Medicare and Medicaid, the 340B program may also be increasing costs for state and federal programs.

Introduction

The 340B program has evolved rapidly in the last few years, including legislative changes driven by the 2022 Inflation Reduction Act[1] such as the use of 340B modifiers, changes in pharmaceutical industry practice such as restrictions on the usage of contract pharmacies[2], and judicial decisions that could impact how the program is implemented as in the Genesis case[3] for 340B eligibility.

At first glance, the way the 340B program works appears to be simple. 340B hospitals and clinics buy drugs at low prices, sell them at regular prices to patients and other payers, and the price differential generates 340B revenue for the hospital. Drug manufacturers have to sell product at lower prices, which negatively impacts their bottom line. And the narrative from hospitals and clinics is the program does not cost taxpayers anything[4-7].

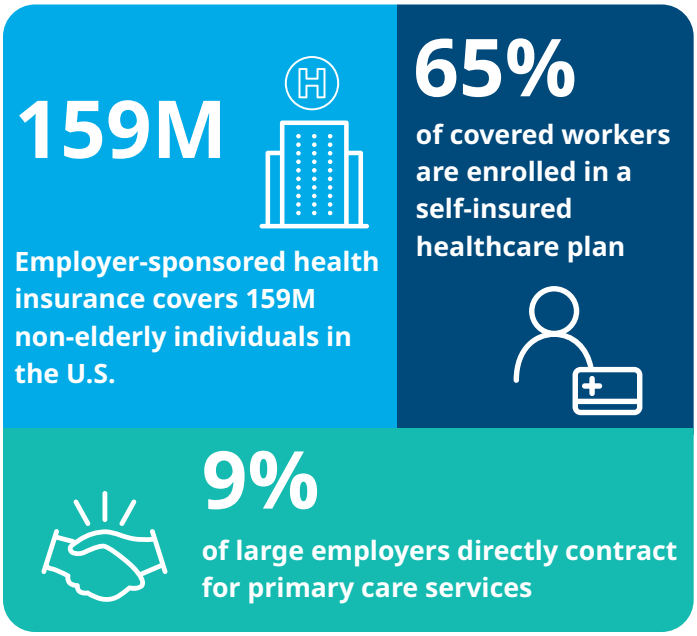
In the United States, individuals normally obtain health insurance either through a federal program such as Medicare, Medicaid, and the Veterans Health Administration, or through their employer as a benefit known as employer-sponsored plans. According to the most recent update in 2022 of an annual survey of private and non-federal employers[8], employer-sponsored insurance covered 159M non-elderly individuals in the U.S.. And 65% of covered workers were enrolled in a self-insured (self-funded) plan (discussed in detail below), up from 60% approximately 10 years ago[8]. Rebates paid by manufacturers to pharmacy benefit managers (PBMs) and passed through to employers are used to lower the net cost of drugs.

According to a recent study of the non-elderly individuals who were uninsured in 2022, 25% were eligible for Medicaid, 35% were eligible for the premium tax credit, and 20% were eligible for affordable coverage through an employer or the Marketplace[9].

Although the 340B program is often summarized as though it were a separate payer channel alongside commercial, Medicare, and Medicaid, in actuality, it relies on commercial and Medicare Part B and Part D payers to reimburse claims in order to generate revenue for 340B providers via arbitrage (i.e., buying low and selling high). This creates a potential problem for a self-insured employer if a 340B discount and a rebate apply to the same drugs — a situation known as a "duplicate discount" — because the 340B discount can displace the rebate, resulting in benefit only for the hospital or clinic and a loss for the employer.

IQVIA's study sought to answer the following question: How much is the 340B program costing self-insured employers and their workers in lost rebates?

Figure 1. Fast facts for employer-sponsored health insurance.



Self-insured employers

Self-insured employers pay for claims out of pocket versus fully insured employers which pay a fixed premium to a health insurer. Self-funding offers employers certain advantages. For example, not having to pre-pay for coverage improves cash flow although it requires adequate cash flow to pay claims, which can be difficult for small firms. Also, self-insured plans can be tailored to the employer's workforce instead of using a pre-packaged, national plan. Finally, the Employee Retirement Income Security Act of 1974 (ERISA)[10] exempts self-insured employers from taxes on insurance premiums, which are typically 2-3%[11], and exempts them from state health insurance mandates, which vary by state and can be an administrative burden for companies doing business across different geographies[12]. Self-funding offers more benefits and less risk for larger employers, which is why although self-insured plans cover 82% of workers in large firms, this falls to only 20% at small employers[8].

Self-insured plans normally cover both pharmacy benefits and medical benefits, and due to the complexities of pricing and formularies for self-administered drugs, self-insured employers often contract with PBMs to administer pharmacy benefits. PBMs consolidate the demand of their members to negotiate discounts which lower the net price paid by the employer. Those discounts are normally paid as rebates and are applied after the point of sale to the patient. Two large PBMs recently claimed that they pass through 95-98% of manufacturer rebates to their clients[13-15], and employers use rebates to lower the cost of healthcare benefits for themselves and their workers.

A critical challenge for a self-insured employer is the interaction between manufacturer rebates and 340B discounts.

The conflict between rebates and 340B discounts

PBMs contract with manufacturers to obtain rebates to lower the net cost of prescription drugs. The 340B discount and the rebates can both be substantial in size and are not intended to be paid on the same prescriptions, although this scenario — known as a duplicate discount — can happen. The act that created the 340B program[16] contains provisions to prevent drugs purchased at a 340B discount from claiming Medicaid rebates. However, no such safeguards exist for managed care rebates; and while manufacturers' contracts exclude rebates on drugs purchased at 340B pricing, these duplicate discounts can be difficult to detect, and the burden of proof lies with the manufacturer.

340B discounts and rebates are applied at different points in the supply chain: 340B discounts are reflected in wholesalers' invoice prices for drugs sold to their customers, including hospitals, clinics, and pharmacies, while rebates are applied after the point of sale to the patient. In part, because 340B discounts are applied earlier, when a duplicate discount arises and is detected by the manufacturer, rebates are lost to the employer, but the hospitals retain the 340B discount.

A graphic illustrating lost rebates is shown in Figure 2. The drug is assumed to be self-administered and costs $100 at wholesale acquisition cost (WAC). For simplicity, not all costs or stakeholders are shown. If the drug was not purchased through the 340B program (left-hand side), the self-insured employer reimburses the pharmacy at approximately WAC plus a dispensing fee. Assuming the drug is contracted, the manufacturer pays the PBM a rebate, most of which is passed through to the employer, reducing its costs to $75.30. If the drug was a 340B purchase (right-hand side), the rebate is no longer available and the employer pays close to full cost for the drug, around $105. In the 340B scenario, costs have increased or revenue has decreased for all stakeholders other than the 340B provider.

Figure 2. Employers and workers pay more for drugs when 340B is used, but hospitals profit. A self-administered drug costing $100 at WAC is purchased without the 340B program (left-hand side) and using the 340B program (right-hand side).

Methods

Rebate estimates

The contracts between manufacturers and payers that determine product formulary position and rebates are confidential, and we are unaware of any published, comprehensive study of rebates. A full treatment of the topic is beyond the scope of the current study, but given these limitations, rebates were estimated as follows. Drugs were divided into four segments — brands versus generics and self-administered versus physician-administered — to allow for different rebate behavior in each group.

For branded self-administered products, IQVIA estimated commercial rebates using manufacturers' annual financial statements for 14 products spanning four therapeutic areas: diabetes, HIV, immunology, and oncology (data on file). These areas were chosen to represent different mixes of product types and different degrees of competition. We weighted rebate values by commercial gross revenue, and the weighted mean rebate was 33.4%. Other approaches using net revenue were taken and gave similar results (data not shown). To reflect uncertainty in how representative this sample of disease areas was, we also tested values at 5% on either side of this mean (i.e., 28.4% and 38.4%).

Rebates are not used for generic self-administered products.

Many physician-administered branded products do not use rebates, an exception being drugs with biosimilar competitors. Rebates were approximated by calculating the difference between WAC and average sales price (ASP), and the mean rebate weighted by WAC sales was 13.3%. We tested points at 5% on either side of this mean.

For physician-administered generic products, the mean rebate weighted by WAC sales was 29.4%. Points were tested at 5% on either side of this mean.

Other data

Annual healthcare costs and premiums were estimated using 2021 data from the Medical Expenditure Panel Survey (MEPS)[17,18], the most recent period available at the time of the study. The mean annual total healthcare cost per patient was $6,142 which was the sum of insurer costs and patient costs, including deductibles, copays, and coinsurance. MEPS data captures healthcare costs before manufacturer rebates are applied. Self-administered products accounted for $1,224 (19.9%) of the total. Costs for physician-administered drugs were calculated from MEPS using product mix estimates (see below), which yielded an estimated cost per patient per year for physician-administered products of $306 (5.0% of total costs). Total annual healthcare premiums (employer and employee contributions) were $7,380 for a single employee and double this for an employee plus one additional beneficiary[18].

Estimates of product mix and 340B discounts were sourced at the NDC level from IQVIA's DDD Subnational Sales database, which measures wholesaler sell-in to pharmacies, clinics, hospitals, and nursing homes. Sales were dollarized using WAC pricing or invoice pricing, which reflects cost rather than utilization. WAC is the manufacturer's list price for a product for wholesalers or direct purchasers, not including discounts or rebates[19]. Invoice price is the price reported by wholesalers for product sold to their customers, and the type and magnitude of discount depends on the customer type. For outpatient sales to 340B hospitals and clinics, it must reflect the 340B discount or a greater negotiated discount. Product mix was based on WAC pricing. 80% of sales at WAC were generated by self-administered products while the remaining 20% was from physician-administered products. Drug reimbursement data was not available, so WAC pricing was used instead. 340B drug revenue was estimated as the product of the 340B discount and pre-rebate drug costs estimated from MEPS. The study period used was 2021 to align with MEPS.

340B eligibility based on the 1996 patient definition[20] was estimated using the method described elsewhere[21], which translates the patient definition into claims-level based on where patient care was delivered and where the prescription was filled or drug administered. We also considered scenarios involving expanded 340B eligibility[22].

340B conversion rates for branded and generic products were based on a recent study of 340B conversion behavior[22]. Branded self-administered products were assumed to have a 75% likelihood of conversion, while the rate for generics was 20%.

PBM pass-through of rebates was estimated to be 90%, based on self-reported data from PBMs[14,15] and on survey data[23].

The baseline 340B eligibility was assumed to be 20%, based on estimates of % 340B sales[24] and 340B conversion[22].

Parameters are summarized in Figure 3 (see page 7).

Model

A financial model was built to describe self-insured employer plans. Factors in the model included 340B eligibility, manufacturer rebates for self-administered and physician-administered products, and rebates lost due to product purchased at a 340B discount price. Parameters in the model were estimated as described above in Methods, and were the same across scenarios. We assumed manufacturer rebates were paid on non-340B-eligible drugs only (i.e., no duplicate discounts).

Three scenarios were studied.

Scenario 1: *No 340B*. This is a counterfactual scenario where no drugs were 340B-eligible. It was used as a benchmark for scenario 2, and to estimate the maximum amount of rebates that could be generated for the self-insured plan. It describes a population that has no 340B exposure.

Scenario 2: *340B Status Quo*. This describes the status quo assuming some workers received care from 340B providers. 340B eligibility was defined by the 1996 patient definition.

Scenario 3: *Expanded 340B Eligibility*. We assumed an expansion in 340B eligibility beyond the 1996 patient definition[22] in which 340B providers could generate 340B revenue from all of the drugs dispensed to their patients, regardless of where care was delivered. That is, there was no shift in the site of care, but the rules for determining 340B eligibility expanded.

The scenarios are also summarized in Figure 3.

Figure 3. Summary of scenarios and model parameters. "Rx": self-administered drugs. "Mx-drug": physician-administered drugs. "Mx": physician-administered drugs and other medical services.

SCENARIOS & VARIABLE PARAMETERS			
INPUT PARAMETER	**1: NO 340B**	**2: 340B STATUS QUO**	**3: EXPANDED 340B ELIGIBILITY**
340B Eligible Workers	0.0%	20.0%	40.0%

FIXED PARAMETERES

PRODUCT MIX (WAC $)			
DRUG TYPE	**BRANDED**	**GENERIC**	**TOTAL**
Rx	63.6%	16.4%	80.0%
Mx	18.0%	2.0%	20.0%
Rx & Mx	81.6%	18.4%	100.0%

340B CLAIM CONVERSION		
DRUG TYPE	**BRANDED**	**GENERIC**
Rx	75.0%	25.0%
Mx	75.0%	75.0%

ANNUAL COST PER WORKER	
TYPE	**TOTAL**
Rx	$1,224
Mx Drug	$306
Mx Non-Drug	$4,612
Total	$6,142

OTHER VARIABLES
PBM PASSTHROUGH
90%

MANUFACTURER REBATES		
DRUG TYPE	**BRANDED**	**GENERIC**
Rx	33.4%	0.0%
Mx	13.3%	29.4%

Limitations

Manufacturers' contract pharmacy restriction policies were not taken into account, however, given the study period, we believe there were fewer manufacturers with policies in place.

Duplicate discounts were assumed to be absent for self-insured plans. This is an approximation, and there is no public data to determine how often these types of duplicate discounts occur at present.

The model did not take into account the plan's benefit design, plan member demographics, or any change in behavior in reaction to any scenarios. For instance, the contribution of plan members was held constant for all scenarios. This was done for simplicity.

340B discounts were based on the difference between WAC pricing and invoice price. This approach is likely to be conservative for physician-administered drugs.

Findings

In scenario 1: *No 340B*, the total cost of drugs to the employer and workers before rebates was $1,530, $333 in manufacturer rebates were paid, and the cost of drugs after rebates was $1,197.

In scenario 2: *340B Status Quo*, $50 (15.0%) of manufacturer rebates paid to PBMs and employers were lost due to an average of 20% 340B eligibility compared to its benchmark in scenario 1. This is a hidden cost of the 340B program: some rebate-eligible drugs lose rebates because they were purchased through the program. Overall, drug costs for the employer and the worker increased by 4.2% compared to scenario 1. When drug rebates were 5% lower (as described in Methods above) than the estimates, the increase in costs was 3.3%, while when rebates were 5% higher, the increase was 5.1%.

In scenario 3: *Expanded 340B Eligibility*, it was assumed the 340B hospital was able to convert all prescriptions for its patients regardless of whether the prescriptions were written at the 340B hospital or not. Under this expansion in 340B eligibility, drug costs for the employer and the worker increased by 8.4% compared to scenario 1, falling to 6.6% if rebates were 5% lower than the mean and rising to 10.3% if rebates were 5% higher.

The findings are summarized in Figure 4.

Figure 4. Cost estimates by scenario. Rx: self-administered drugs. Mx: physician-administered drugs.

	SCENARIO		
ITEM	**1: NO 340B**	**2: 340B STATUS QUO**	**3: EXPANDED 340B ELIGIBILITY**
Drug Cost before Rebates	$1,530	$1,530	$1,530
Rx Drug Rebates	($292)	($248)	($204)
Mx Drug Rebates	($41)	($35)	($29)
Drug Cost after Rebates	$1,197	$1,247	$1,297

Discussion

This study found that the 340B program increases drug costs for self-insured employers and their workers by 4.2% due to the manufacturer rebates that are lost when drugs are purchased at the 340B discount price. This corresponds to a $5.2B increase in healthcare costs for self-insured employers and the 103.4M workers they employ. In light of this finding, the narrative that "the 340B program costs taxpayers nothing" should be reconsidered.

If the 340B program is increasing healthcare costs for employers and their workers, the same dynamic is likely occurring for Medicaid and Medicare. This warrants further study, since if true, the 340B program could be generating hidden costs for state and federal programs.

According to the Bureau of Labor Statistics, of the 37.9M people who lived below the official poverty level in 2021, 6.4M were "working poor"[25]. If the 340B program is increasing healthcare costs and financial stress for these vulnerable individuals, as our findings suggest, it questions whether the program is meeting its objectives in an efficient manner. Also, if the program is inadvertently raising costs for other parts of the healthcare system, there might be a need for greater transparency in how 340B savings are being used by 340B providers. This could include mandatory reporting on the utilization of 340B savings to ensure they are being used to support patient care and services as intended.

Our findings might encourage increased dialogue between hospitals, employers, PBMs, drug manufacturers, and the Federal Government to reevaluate the program and restructure it to minimize its negative aspects. Employers might want to reexamine the design of their health plans to consider ways of mitigating the impact of lost rebates due to 340B pricing, including seeking opportunities to learn more about the 340B program and how it operates.

Part of the narrative that the 340B program is "free" is it is paid for by manufacturers. Indeed, when examined in isolation, it is a transfer from manufacturers to 340B hospitals and clinics. However, the resulting erosion of manufacturers' gross to net could have unintended consequences, including cost increases for non-340B drugs, a phenomenon sometimes called cost-shifting, and decreased innovation of new products due to reduced budgets.

References

1. Yarmuth J. Actions - H.R.5376 - 117th Congress (2021-2022): Inflation Reduction Act of 2022.
2. 340B Manufacturer Updates. AmerisourceBergen. Accessed December 2023.
3. Genesis HealthCare, Inc. v. Becerra, No. 20-1701 (4th Cir. 2022), https://law.justia.com/cases/federal/appellate-courts/ca4/20-1701/20-1701-2022-07-01.html
4. 340B Hospital Community Benefit Analysis. American Hospital Association. October 2023.
5. 340B Health and Advocacy. American Society of Healthcare Pharmacists. Last retrieved December 2023.
6. Don't believe drug companies: 340B is a program worth saving. The Hill. August 2023.
7. AHF Celebrates 30 years of 340B. Aids Healthcare Foundation. November 2022.
8. Claxton G, Rae M, Wager E, and Young G. Employer health benefits. 2022 summary of findings. Kaiser Family Foundation. 2022.
9. Tolbert J, Drake P, and Damico A. Key facts about the uninsured population. Kaiser Family Foundation. December 2023.
10. Employee Retirement Income Security Act (ERISA). U.S. Department of Labor. Retrieved October 2023.
11. What is self funding? Health Care Administrators Association. Retrieved October 2023. Retrieved October 2023.
12. Enthoven A. Employer self-funded health insurance is taking us in the wrong direction. Health Affairs Forefront. August 2021.
13. Surprising data on employer-PBM rebate pass-through arrangements in 2023. Drug Channels. August 2023.
14. "The Need to Make Insulin Affordable for All Americans". Testimony before the United States Senate Committee on Health, Education, Labor, and Pensions. A. Kautzner, President, Express Scripts. May 10, 2023.
15. "The Need to Make Insulin Affordable for All Americans". Testimony before the United States Senate Committee on Health, Education, Labor, and Pensions. D. Joyner, Executive VP, CVS Health and President, CVS Caremark. May 8, 2023.
16. Veterans Health Care Act of 1992, Public Law 102-585. § 602. Limitation on prices of drugs purchased by covered entities. 1992.
17. Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. Medical Expenditure Panel Survey Household Component.

18. Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. Medical Expenditure Panel Survey Insurance Component.

19. Social Security Administration. Use of average sales price payment methodology. Sec. 1847A. [42 U.S.C. 1395w–3a] (a). Last retrieved December 2023.

20. Notice regarding section 602 of the Veterans Health Care Act of 1992 patient and entity eligibility. Federal Register. Vol. 61, No. 20. October 24, 1996.

21. Martin R and Illich K. Are discounts in the 340B Drug Discount Program being shared with patients at contract pharmacies? IQVIA White Paper. September 2022.

22. Martin R, Sun C, and Illich K. Double trouble: how expanding eligibility could double the size of the 340B program. IQVIA white paper. 2023.

23. The prescription drug landscape, explored. The Pew Charitable Trusts. March 2019.

24. Martin R. The 340B drug discount program exceeds $100B in 2022. IQVIA white paper. 2023.

25. A profile of the working poor, 2021. Bureau of Labor Statistics. November 2023.

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