Why Drug Pricing Programs Have Not Reduced Health Disparities

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Abstract

The COVID-19 pandemic and social unrest surrounding racial disparities and systemic racism have put renewed emphasis on closing health and wealth gaps.

Prescription drug pricing, always a hot topic in the battle for equity, has been at the forefront of this conversation. The disproportionate impact of COVID-19 intensified the scrutiny on access to medicines, co-morbidity, and other issues surrounding health equity.

While many of the issues surrounding prescription drug pricing have focused singularly on the manufacturers, this paper seeks to examine the current state of play in the prescription drug supply chain and marketplace.

In this paper, the authors reviewed the role of the 340B program, Pharmacy Benefit Managers (PBMs), Copay Accumulators, and the phenomenon of pharmacy deserts in the utilization of prescription drugs, their costs, and impact on racial health disparities.

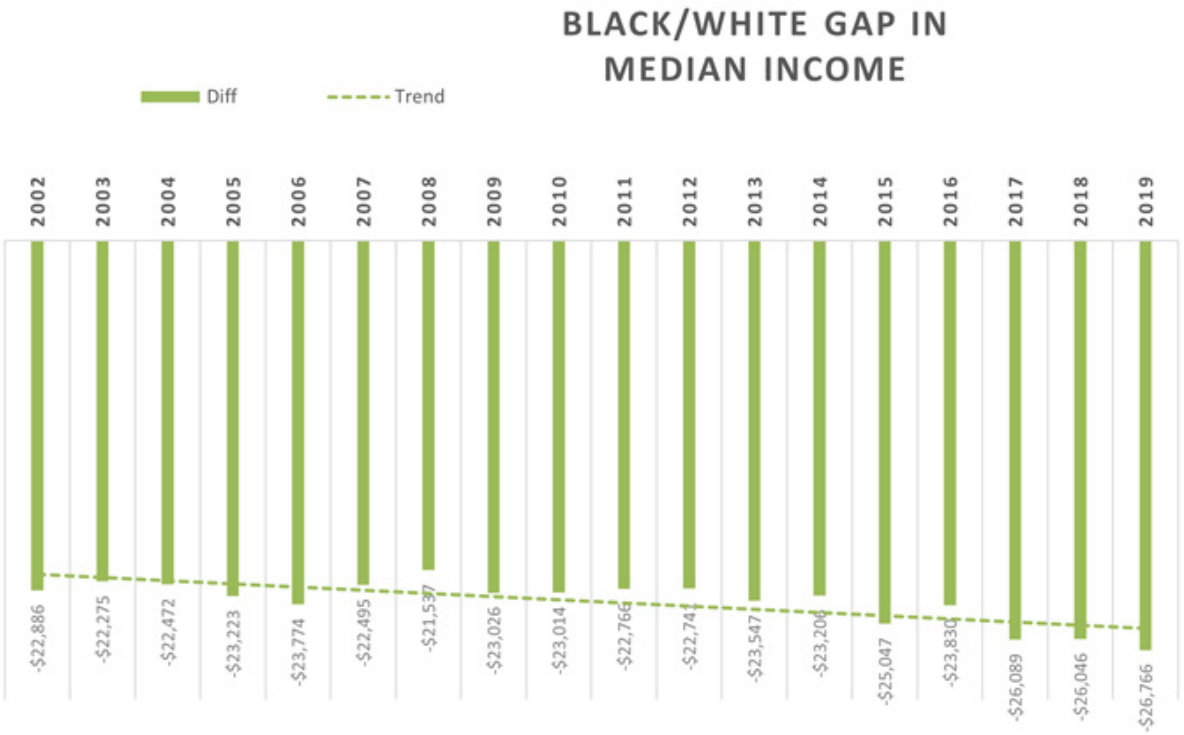
Introduction

Prescription drug pricing has been a significant source of concern for many years. Scientific advances in the pharmaceutical industry have been a boon for patients, extending and improving the quality of life for millions of people.

However, the cost of these new drugs has pushed them out of reach for many patients. This is particularly true for minority patients, who often must forgo lifesaving medications due to a lack of affordability and access.[1] Health disparities, particularly in minority communities, have come keenly into focus over the past year. The COVID-19 pandemic, the murders of Breonna Taylor and George Floyd, and other police abuses, plus the dismal socio-economic statistics on the state of Black America, now shine a bright light on systemic racism in America and its negative effect on the U.S. Economy.

While the debate on health care affordability and health disparities is not new, the past year's events have increased the urgency and desire to address many of our society's ills. The prescription drug debate is at the top of the list for many policymakers.

Many efforts have been made over the years to make medicines more affordable for patients. Both governments and the pharmaceutical industry have created programs designed to reduce costs for underserved and minority families.[2]



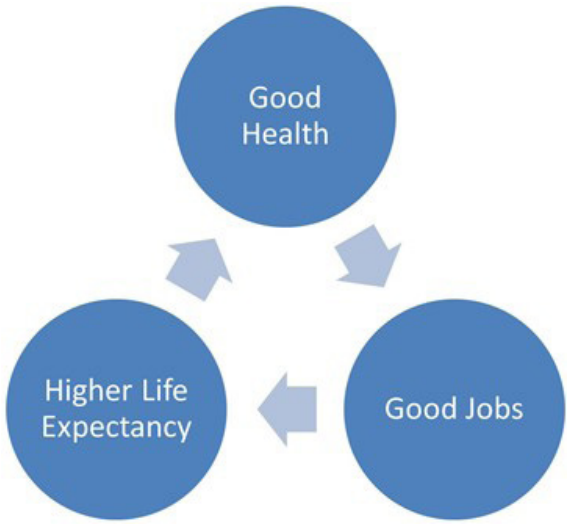
Source: Creative Investment Research from data provided by the U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplements (CPS ASEC).

Thesis Statement / Working Theory

The American healthcare system is much more expensive and less effective than others, especially for poor and minority communities. There are many programs aimed at helping disadvantaged communities access healthcare, but they have not yielded the desired results. Significant changes are needed for these programs to be impactful.

In terms of economic relevance, according to the Creative Investment Research Fully Adjusted Return Methodology, a proprietary social return measurement and analysis system, health care has the highest social impact coefficient of any factor.

We can see this by considering the following. Having good health allows people to obtain and keep good jobs, which, in turn, allows a person to receive the health care services needed to lengthen life expectancy.



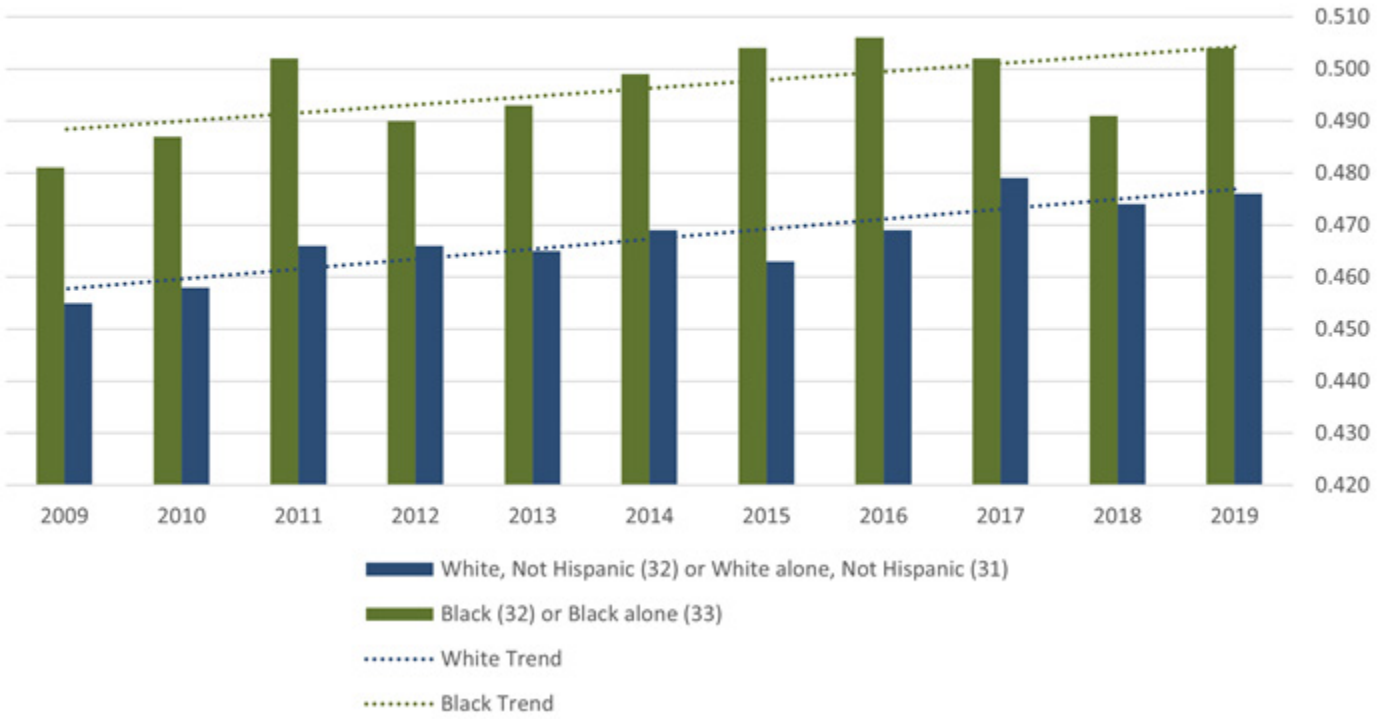
Source: Creative Investment Research

But the ability of specific segments of the U.S. population to secure good jobs has been falling, leading to greater inequality and lower life expectancy.

Statistics show inequality is still growing in the United States. The effect on income can be seen in the chart below as measured by the Gini Coefficient.[3]

The data demonstrates that health care delivery mechanisms in minority and underserved communities are broken. One program that has not received much attention as part of larger discussions of racial equity and how the health care system serves these communities is the 340B program. The 340B program, while well-intentioned, has been victimized by profit-maximizing behavior on the part of critical participants, including retail pharmacies, pharmacy benefit managers PBMs and hospitals. Unfortunately, these entities can use the 340B program to generate profits with no accountability for how they use the revenue from this program. This lack of accountability damages and lowers the delivery of critical health care services.

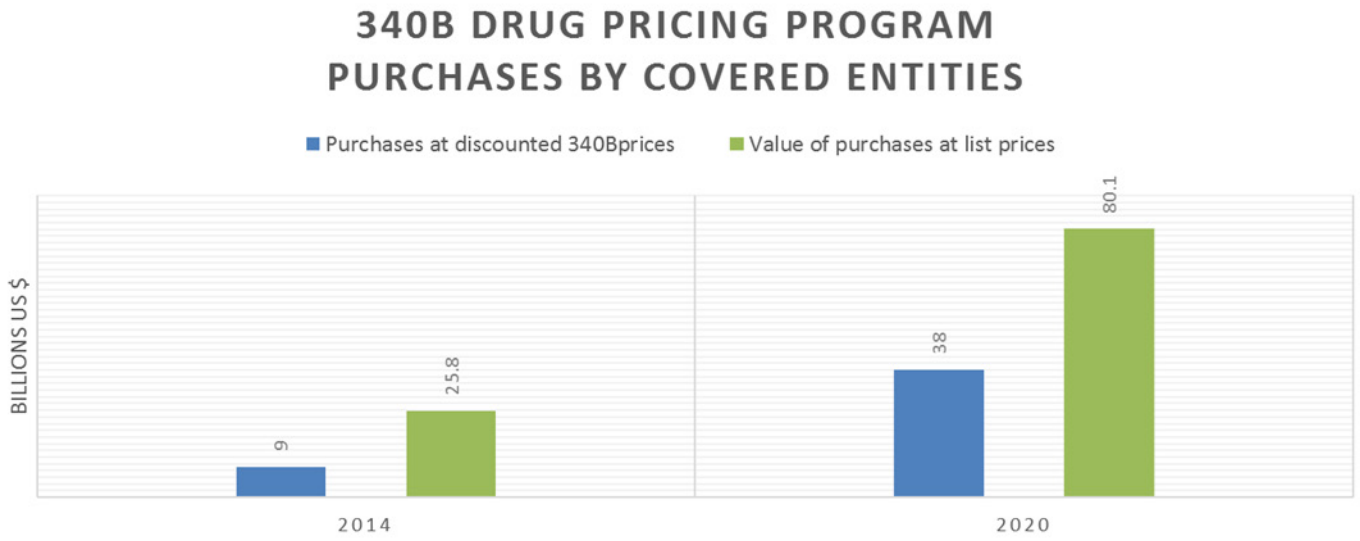
Gini Coefficient
Inequality, by Race of Household
2009 to 2019



Source: Creative Investment Research from the U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplements (CPS ASEC).

After Almost 30 Years The 340B Program Has Not Improved Pharmaceutical Drug Access or Life Expectancy for Minority Patients

According to the United States Government Accountability Office (GAO), the 340B Drug Pricing Program (340B Program) and the Medicaid Drug Rebate Program require manufacturers to provide discounts on outpatient drugs to have their drugs covered by Medicaid. These discounts take the form of reduced sales prices for (1) covered entities participating in the 340B program; (2) eligible hospitals and federal grantees; (3) rebates on drugs dispensed to Medicaid beneficiaries.



Source: Drug Channels Institute, June 16, 2021

Created in 1992, the 340B program was initially designed to replace manufacturers' voluntary discounts to safety-net clinics before the Medicaid statute was enacted. Under the 340B program, participating pharmaceutical manufacturers must provide discounted outpatient drugs to certain healthcare facilities ("covered entities") such a community health centers and certain types of hospitals. The eligible hospitals must meet various requirements, including serving a specified share of Medicaid and low-income Medicare inpatients as measured by the hospitals' Medicare Disproportionate Share Hospital (DSH) adjusted percentage.

In 2019 2,500 hospitals were participating in the program. Since 2010, 340B-covered entities have also accessed 340B pricing through contracts with for-profit pharmacies, known as "contract pharmacies."

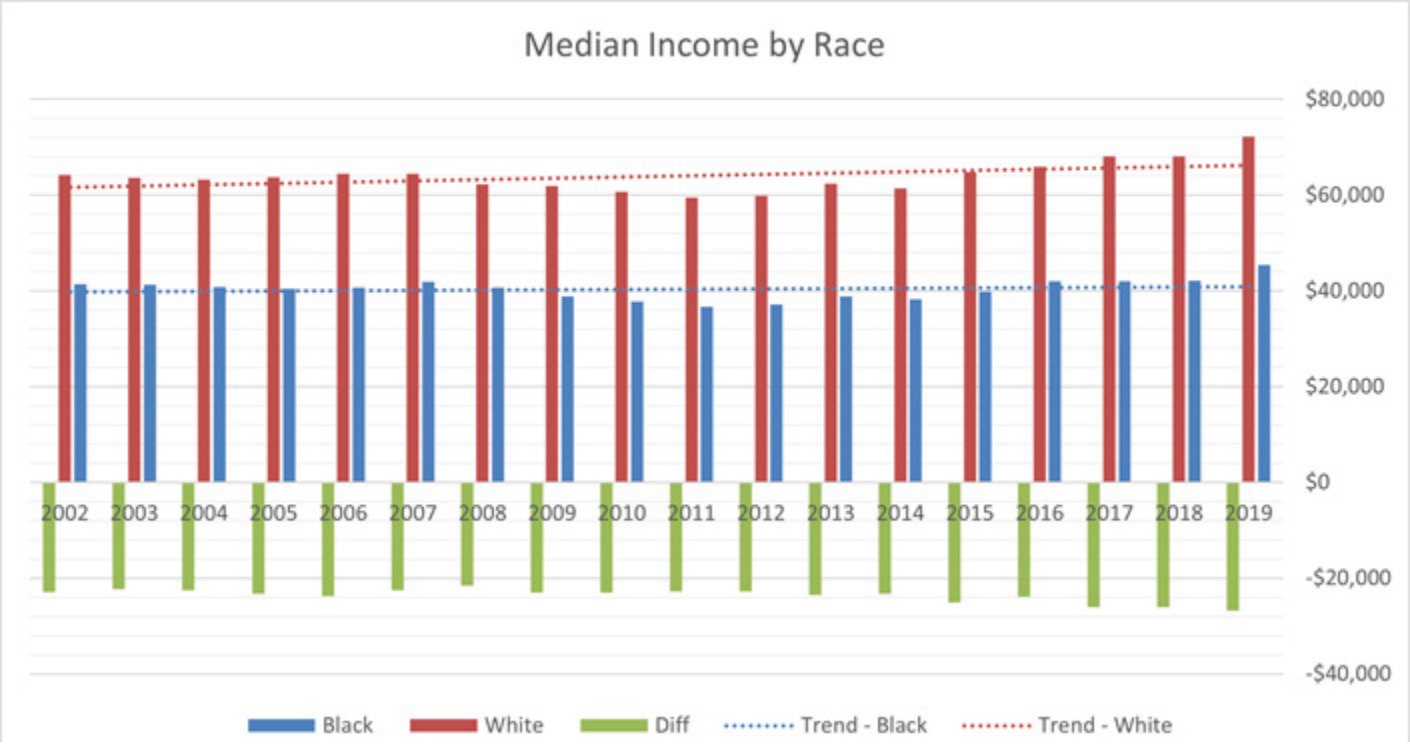
340B covered entities can obtain a significant stream of profits by capturing the difference between a drug's third-party reimbursement and the covered entity's 340B replacement cost. If 340B hospitals are receiving this additional benefit, it may translate into increased profits. These questions require further research concerning the differential in profits between 340B hospitals and non-340B hospitals.

The 340B ceiling price reflects a minimum of a 23.1 percent discount, but it can be much higher for specific medicines. In some cases, hospitals and other covered entities can acquire many brand-name specialty drugs for as little as $0.01, a practice known as penny pricing. Humira is one such drug [4]. As a consequence of the program's growth, it is estimated that 340B sales account for more than 8.3%

of net drug sales and represent 16% of discounts given on brand-name drugs. Drug sales under the 340B program are now larger than drug sales under any other federal program, except for Medicare Part D[5].

While the intent of the 340B program is admirable, given seemingly permanent health and pharmaceutical access disparities, we question its effectiveness for underserved communities, especially African American patients.

The chart below shows the general trend toward increasing inequality between black and white households over the past ten years, as measured by changes in median income by race.



Source: Creative Investment Research from the U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplements (CPS ASEC).

340B Program Life Expectancy Differentials During the Crisis

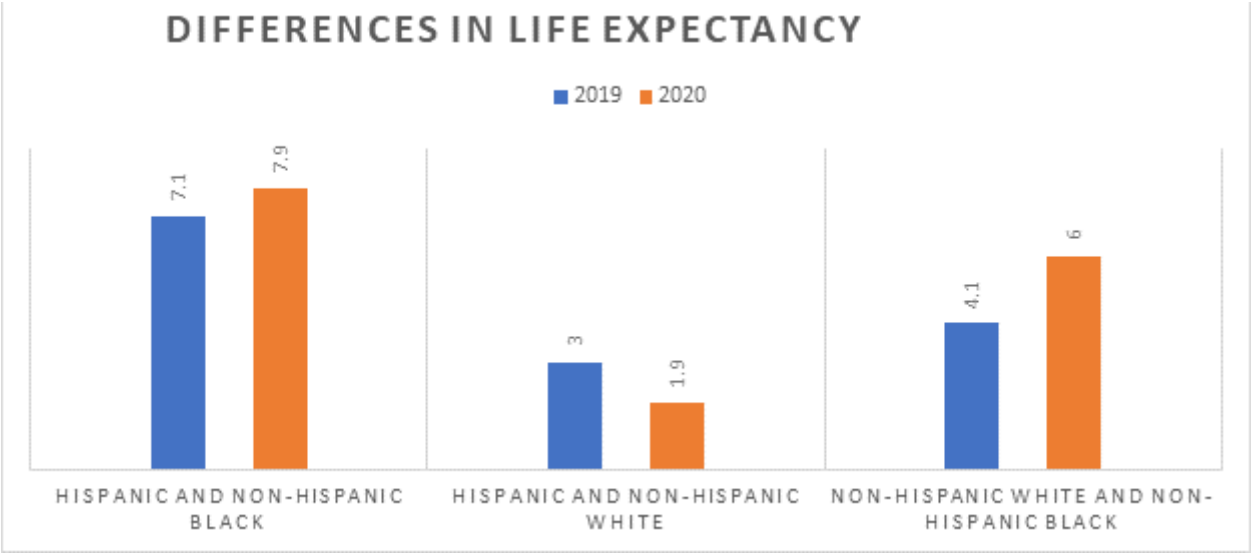
While we understand that the COVID-19 crisis has meaningfully impacted life expectancy, we suggest that the best way to measure the utility of the 340B program is in a time of crisis. The chart below shows increased: "life expectancy for the black population has consistently been lower than that of the white population, but the gap between the two races had generally been narrowing since 1993 when it was 7.1. The gap of 6.0 observed in the first half of 2020 is the largest since 1998."

This, combined with increases in the differential between Black and white life expectancy, shown below, suggests that the 340B program requires review and reform. While the program has grown dramatically in recent years (source)(endnote), that growth has not come with any requirements for hospitals to ensure patients directly benefit from the program or that revenue from 340B is used to reduce racial disparities.

Instead, there is evidence that many 340B hospitals use the profits from 340B to expand into wealthier areas instead of focusing on investing in care for vulnerable communities. (source)(endnote). This evidence begs the question: Does the inefficient use of 340B funds contribute to health disparities for minorities and other underserved populations?

Pharmaceutical access and resulting health disparities have only increased over the nearly 30 years of the 340B program. In fact, one study noted that "black beneficiaries have significantly fewer prescriptions filled and lower pharmacy costs in 8 of the 10 States examined (by the study authors), despite having higher physician costs."

Preliminary data from the National Center for Health Statistics show that life expectancy at birth for the total U.S. population declined from 78.8 years in 2019 to 77.8 years for January through June 2020. During that same time, life expectancy for non-Hispanic Black people decreased by 2.7 years (74.7 to 72); for Hispanic individuals, 1.9 years (81.8 to 79.9); and for non-Hispanic white people, 0.8 years (78.8 to 78).



Source: National Center for Health Statistics.

The current lack of transparency into the amount of earnings hospitals take from 340B and how those earnings are used is one challenge in considering how the 340B program could be better targeted to address health equity. The authors did not attempt to quantify the lost value of 340B benefit transfer because the data is not readily available. However, it was determined that the number of hospitals utilizing the program has grown significantly. According to a GAO report, in 2017, there were more than 12,000 covered entities and more than 38,000 total sites with roughly 20,000 contract pharmacies.

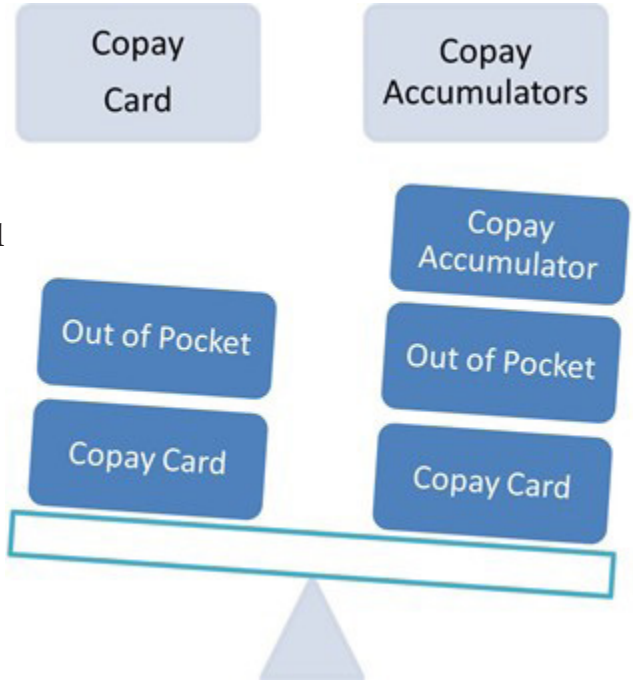
We note, however, that the number of communities without hospitals nearby has also grown. In particular, rural and underserved areas still lack hospital access. More than 100 rural hospitals have closed over the last ten years [source](endnote), and mortality rates for many groups in the U.S. are also rising [source](endnote).

Program Expenditures

According to HRSA, discounted 340B purchases were at least $38 billion in 2020[6] which is 23% higher than in 2018. Since 2014, purchases under the program have quadrupled.

Copay Accumulators Have Not Had a Demonstrable Impact On Pharmaceutical Usage in Minority Communities And May Have Had The Opposite Effect

In recent years, commercial health plans and their pharmacy benefit managers (PBMs) have launched copay accumulator adjustment programs (AAPs), insurance designs that exclude the value of manufacturer-sponsored copay assistance from a patient's accrual of out-of-pocket (OOP) expenses toward OOP limits throughout a plan benefit year.



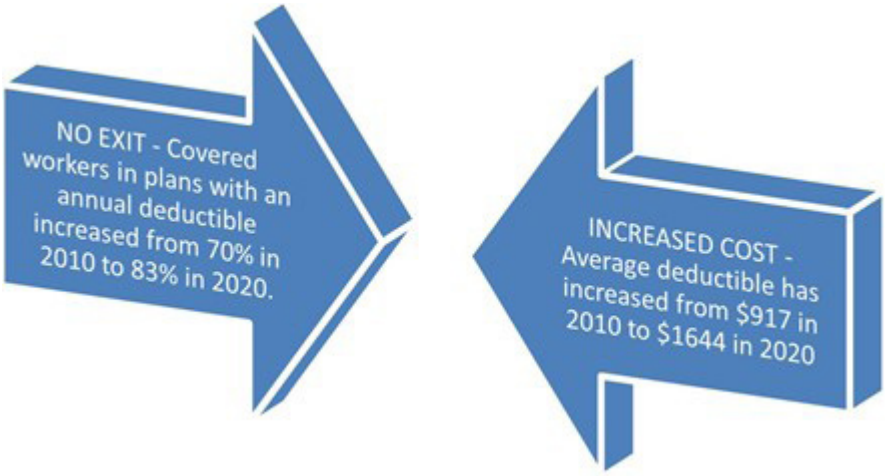
Graphic by Creative Investment Research

The restriction on copay assistance may have an adverse impact on patient's adherence to prescribed therapy regimens and therefore may affect patient health and overall healthcare costs.

Health insurers have designed benefits that result in patients absorbing a greater portion of their OOP healthcare costs for brand medicines, pushing some into precarious financial and/or health circumstances. Employer plans generally required patients to pay a percentage of the drug price (coinsurance) for specialty drugs, averaging a 26% coinsurance rate[7].

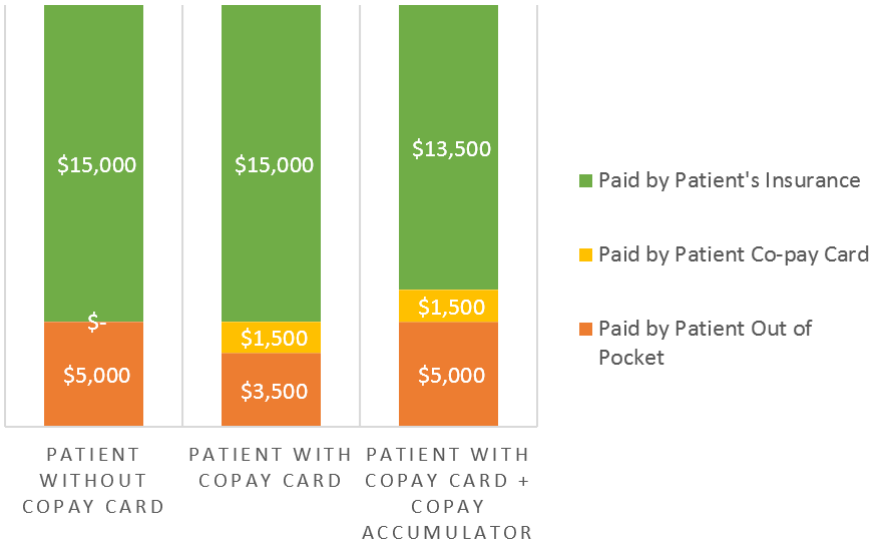
Deductibles are another contributor to higher OOP costs. The share of covered workers in plans with an annual deductible has increased significantly over time, from 70% in 2010 to 83% in 2020[8]. The average deductible over the same period has increased from $917 in 2010 to $1644 in 2020[9].

AAPs represent a considerable threat to patient access, given the adverse effect they may have on adherence to their treatment regimen. Patients may exhaust the manufacturer copay assistance for the year well in advance of hitting their plans deductible or Out of Pocket (OOP) maximum.



Graphic by Creative Investment Research

As a result, patients may face major financial challenges paying for their prescriptions once their copay assistance is exhausted. As most patients are unaware that their health plan may be suing an AAP, having to cover the deductible or other large OOP costs in the middle of the year, when they assumed the assistance was satisfying these OOP requirements can be a huge financial shock.



Source: Creative Investment Research

A IQVIA study found that from 2018 to 2020, 25%-36% of patients discontinued treatment when they faced an unexpectedly high OOP cost of $1500 or more in the middle of the plan year due to an Accumulator Adjustment Programs[10]. When patient cost-sharing starts to exceed $25, adherence can start dropping off by 10%[11].

A previous analysis found that most patients who abandon their prescriptions do not fill any other prescriptions within 3 months, suggesting that they are not using a lower-cost medicine but are instead failing to continue the treatment prescribed by their physician. Considering that 40% of Americans would have trouble paying an unexpected $400 emergency expense[12], the implications of AAPs on medication adherence are significant.

Medication nonadherence has dramatically negative effects on health and associated high costs, all of which are avoidable. A federal study reported that the lack of adherence is estimated to cause approximately 125,000 deaths in the US, at least 10% of hospitalizations and a substantial increase in morbidity and mortality[13].

Nonadherence has been estimated to cost the US healthcare system between $100 billion and $289 billion annually[14].

Pharmacy Benefit Managers Have Not Significantly Lowered Drug Prices for Minority Patients and Have Not Contributed to Higher Usage In These Population

Pharmacy Benefit Managers (PBMs) negotiate with medicine manufacturers on behalf of private and governmental insurers to determine medicine prices and the amount patients are responsible for paying out of pocket. In addition to these price negotiations, PBMs decide what drugs are covered. They decide whether patients will be required to get special approval (e.g., prior authorization) or fail on another treatment first (e.g., step therapy) before their insurer agrees to cover the prescribed medicine. Despite this vast influence over access and cost, consumers have very little insight into the workings of PBMs[15].

Even though PBMs report rebates and price concessions to the Centers for Medicare and Medicaid Services (CMS) for Medicare Part D plans, the law severely restricts access to this information. Private plans have no requirement to report this information publicly. The current system is so opaque that it raises many questions about PBMs' actions, motives, and practices. Do PBMs prefer high list price drugs with significant rebates over lower list price drugs? There may be evidence that incentives in the PBMs market may dissuade manufacturers from lowering their list price[16].

As a result of mergers and vertical consolidation, most major PBMs are owned by or affiliated with an insurance plan[17]. In many cases, the combined company also owns pharmacies and other players in the health industry. Stakeholders question whether this integration helps patients and consumers or whether it leads to anti-competitive activity that produces more profits for insurers and PBMs while driving up the costs for patients.

However, we note that a recent CMS study found that PBMs may negotiate larger rebates from manufacturers. If true, PBMs should be required to share these rebates with consumers as originally intended.[18] Additional research should focus on the specific mechanics and disaggregated data,

which links to the earlier suggestion that the profit differential between 340B hospitals and non-340B hospitals.

PBMs are often compensated based on a percentage of the medicine's list price. As a result, the system incentivizes PBMs to favor high list priced drugs with large rebates over drugs with lower list prices. Therefore, they benefit more from higher-priced medicines than from lower-cost medication. This has the potential to increase the out-of-pocket expenses of people with deductibles or coinsurance, which are tied to the list price of the medicines, not the amount the PBMs ultimately negotiate and the insurers ultimately pay.

A CMS study found that PBMs' ability to negotiate larger rebates from manufacturers has helped lower drug prices and slow drug spending growth over the last three years.[19] According to a recent analysis, in just four years, manufacturer rebates to PBMs more than doubled. Rebates dramatically increased from $39.7 billion in 2012 to $89.5 billion in 2016[20], partially offsetting list price increases. Researchers should examine the number of customers served during these two time periods.

There is also a separate controversy involves a practice known as "spread pricing," whereby PBMs receive higher reimbursements from health plans and employers for generic drugs[21]. Under this practice, PMBs charge plan sponsors more than they pay the pharmacy for a medication and keep the "spread" as profit. Plan sponsors typically do not know this practice is occurring. Spread pricing can increase drug costs by 15 to 30 percent.[22]

PBMs should use growing rebates and discounts they negotiate to lower the cost for patients taking those medicines, argue drug manufacturers. PBMs counter they have been passing a larger share of the rebates to insurers. However, insurers rarely use these rebates to lower the out-of-pocket cost for patients taking rebated medicines[23]. While a study indicated that PBMs passed 78% of their rebates to insurers and payers in 2012, increasing to 91% by 2016, racial disparities persist. This suggests the program is ineffective in providing benefits to minority group members. In addition, the marketplace structure suggests conflicts of interest, which further reduces the program's impact on minority populations. Many small insurers and employers say they do not receive this share of savings.[24]

Despite All the Money Being Dedicated to Prescription Drug Affordability, Pharmacy Deserts Are Increasing in Size, Primarily in Underserved and Minority Communities

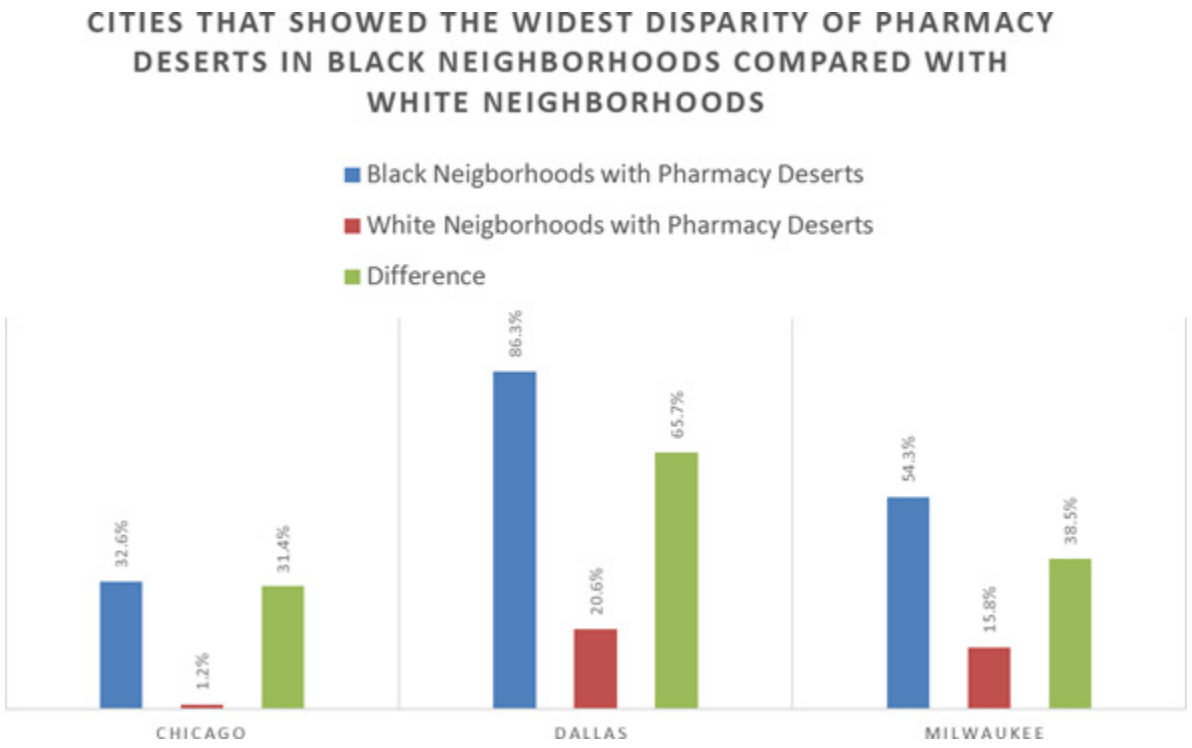
Research shows that one out of every three urban neighborhoods is in a pharmacy desert, meaning roughly 15 million Americans do not have access to a pharmacy[25]. Initially coined in 2014 by Dima M. Qato, PharmD, associate professor at the University of Southern California School of Pharmacy in Los Angeles, a "pharmacy desert" is an urban neighborhood more than a mile away from the nearest pharmacy. The distance is reduced to half a mile for areas with at least 100 households with no vehicle access or 20% of households below the federal poverty level[26].

In a recent study report, researchers focused on the 30 most populated cities using the U.S. Census Bureau's American Community Survey from 2007 to 2015[27]. Although there was an overall increase in the number of pharmacies over the eight years, Pharmacies located in Black and Latino neighborhoods declined. The study asserts this is due to a lack of new pharmacies opening in nonwhite neighborhoods and the rise of independent pharmacy closures.

Independent pharmacies comprise about 35 percent of pharmacies in the country but are disproportionately located in minority neighborhoods and at greater risk of closing than their corporate counterparts. This is due to tighter margins of operation and exclusion from insurance company's preferred pharmacy networks.

Cities that showed the widest disparity of pharmacy deserts in Black neighborhoods compared with white communities included Chicago (32.6% vs. 1.2%), Dallas (86.3% vs. 20.6%), and Milwaukee

(54.3% vs. 15.8%)[28]. The same holds for Latino neighborhoods.



Source: HEALTH AFFAIRS VOL. 40, NO. 5: Fewer Pharmacies In Black And Hispanic/Latino Neighborhoods Compared With White Or Diverse Neighborhoods, 2007–15. Jenny S. Guadamuz, Jocelyn R. Wilder, Morgane C. Mouslim, Shannon N. Zenk, G. Caleb Alexander, and Dima Mazen Qato. MAY 2021.

Additionally, many Americans live in medical deserts, regions with inadequate access to one or more kinds of medical services. An estimated 30 million Americans, many in the country's rural areas, live at least a 60-minute drive from a hospital with trauma care services. Limited access to emergency room services and medical specialists leads to increases in mortality rates and long-term care health problems, such as heart disease and diabetes.

Since 1975, over 1000 hospitals, many in rural regions, have closed their doors, unable to bear the cost of care of uninsured patients.

Health care deserts also exist in urban and suburban areas, particularly in Black communities in Chicago, Los Angeles, New York City, and Washington, DC. Specific to urban areas, the term medical desert applies to areas more than 5 miles from the nearest acute care facility. However, given the modern segregation of communities, the distance can be significantly less. For instance, in Washington DC, where Wards 7 & 8 have only one hospital between them, the hospitals in Wards 1 & 2 can be well over 30 minutes away depending on traffic.

Proposals to Address Disparities

As we examined the data and current situation, we concluded that African Americans and other underserved communities must be seen as full partners in the health care infrastructure. Currently, the ecosystem seems to view these communities as customers. Policymakers, insurance companies, hospitals, for-profit pharmacies, and other members of the health care ecosystem do not invest in these communities.

The following proposals are designed to better leverage the funds allocated to help underserved communities gain access to the health care system, and to develop health care facilities in those communities:

1. 340B REFORM - Congress should improve the oversight of the 340B program so that it works better for underserved patients and devise a plan to reallocate funding to health care deserts and medically underserved areas. As has been discussed, there is little oversight of the profits made from 340B discounts. The issue is that the 340B industry will say the profits go into one big pot, and they cannot carve them out. This response is not valid. Financial reporting in the modern age allows for a very detailed accounting of where the profits from the 340B program come from, and Congress should demand and analyze this data.

2. PMB and COPAY ACCUMULATOR REFORM - Money secured by hospitals and pharmacies for a prescription drug for underserved patients has not been passed along to those patients in the form of reduced drug prices, nor has it been used to build out health facilities in those communities. Consequently, these patients are being used to subsidize health facilities outside of their communities, leading to the continuation of Health care and pharmacy deserts.

3. MEDICARE PART D MODIFICATIONS - Congress should review measures to eliminate the caps on Medicare Part D – Studies have found that Black and Hispanics are more likely than whites to decrease their diabetes-related medications when they reach their Medicare part D limit. This reduction was twice as high for Hispanics and 33% more for African Americans. Money must be available for minority patients to support the existence of pharmacies and other medical facilities in these communities, so they do not reduce or stop medication use when their coverage ends.

4. MEDICAID EXPANSION - Congress should renew efforts to encourage Medicaid Expansion

There is strong evidence that Medicaid Expansion has helped narrow racial disparities in health coverage and access to care. The 36 states (plus the District of Columbia) that have implemented Medicaid expansion have made significant progress. Since the ACA took effect in 2014, data shows this increasing health coverage has narrowed the gaps in uninsured rates between Black and Hispanic and even white Americans far more than states that have not expanded. Further expansion and increased funding could provide even more support for facilities in health and pharmacy deserts.

5. FEDERAL RESERVE HEALTH EQUITY FACILITY - Federal Reserve should establish a Facility to help finance hospitals and pharmacies in Health Care Deserts modeled on the Municipal Liquidity Facility, the Main Street Lending Program, the Commercial Paper Funding Facility, the Primary Dealer Credit Facility, the Money Market Mutual Fund Liquidity Facility, the Primary Market Corporate Credit Facility, the Secondary Market Corporate Credit Facility, the Term Asset-Backed Securities Loan Facility, the Paycheck Protection Program Liquidity Facility, the Central Bank Liquidity Swaps, and the Temporary Foreign and International Monetary Authorities (FIMA) Repo Facility.[28]

6. OPPORTUNITY ZONE HEATLH EQUITY SET ASIDE - Congress should amend the Opportunity Zone Rules to require Opportunity Funds to dedicate at least 5% of their funds to financing Health Care projects in Health Care Deserts to qualify as a fund. As investors build developments in minority communities, they must live up to the promise of shared prosperity for the members of these communities. As condos and high-end apartment buildings are built, the strain on community resources falls most heavily on minority and underserved members of the communities. Requiring Opportunity Funds to commit a minimum of 5% of their investments in a community to building hospitals and pharmacies will help eliminate health care and pharmacy deserts.

Conclusion

Over the past 30+ years, policymakers, elected officials, industry leaders, and other stakeholders have worked to make healthcare, including prescription drugs, more accessible and affordable. While billions of dollars have been spent between the 340B drug rebate program and various insurance and drug company rebates, there remains an uneven and disparate availability of services for many communities.

While there is evidence these programs have provided some benefit to the intended, they have not improved the availability of care in underserved communities or reduced the disparity in life expectancy between Black and Brown Americans versus White Americans.

Addressing these deficiencies will require an honest review of the current situation and an innovative and dynamic rethinking of the existing programs and approaches. These will include a review and revamping of the guidelines and oversight of current programs, and the creation of new programs to address shortfalls.

The trillion-dollar American healthcare system is the most expensive globally, yet it yields less than the desired results for many of its citizens, especially its poor and minority communities. The research and evidence support the idea that solutions are available to end health disparities if the political will exists.

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