HB 1473 - Testimony by Dustin Gawrylow, ND Watchdog Network (#266)

HB 1473: North Dakota Must Reject Expansion of Broken 340B Drug Program and Demand Real Reform

The rising cost of prescription drugs is a significant concern for Americans. The 340B drug pricing program, created in 1992 with the aim of providing discounted medications to vulnerable patients through safety-net healthcare providers, has become problematic. Intended to help vulnerable populations access affordable medications and allow providers to stretch federal resources, the program suffers from critical flaws.

A central issue is the lack of adequate oversight, transparency, and a clear definition of a "340B patient." This deficiency has allowed large hospital systems, often for-profit, and major pharmacy chains to exploit the program for financial gain. They aggressively acquire smaller clinics to access 340B discounts, purchase drugs at reduced prices, but frequently charge full retail prices to insurers, Medicare, Medicaid, and even uninsured patients, pocketing the difference as profit. This practice diverts discounts intended for the needy to corporate bottom lines.

This flawed system has several negative consequences. It fuels healthcare consolidation, disadvantages independent pharmacies, and contributes to the growing problem of pharmacy deserts, especially in rural areas. Local, independent pharmacies struggle to compete with massive chains thriving on 340B profits, diminishing patient choice and personalized service.

The exponential growth of contract pharmacies, particularly for-profit chains (increasing by 8000% since 2010 HRSA guidance), has significantly altered the program's landscape and raised integrity concerns. These contract pharmacies generate substantial profit margins (estimated at 72% on 340B drugs), leading to situations where some 340B hospitals profit far more than they spend on charity care. Paradoxically, despite the overall growth of 340B pharmacies, their presence in socioeconomically disadvantaged neighborhoods has declined, and independent pharmacies vital in rural areas are closing.

There is significant doubt whether the program is effectively reaching vulnerable populations. Evidence suggests that the discounts are not consistently passed on to patients, especially the uninsured, and that the program may primarily be bolstering hospital profits. Some 340B entities even contradict the program's mission by not offering discounted prices to uninsured patients at contract pharmacies.

Expanding the 340B program in its current form, as proposed by North Dakota's House Bill 1473, is not a solution but an exacerbation of the existing problems. It would amplify the flaws and perverse incentives that have hijacked the program's original intent. Instead of expansion, fundamental reform is necessary.

Meaningful reform must include:

- **Clearly defining who qualifies as a 340B patient.**
- **Ensuring 340B patients are aware of their status and benefits.**
- **Demanding radical transparency** regarding where 340B money flows, including profits of hospital systems and pharmacy chains, and the amount reaching intended patients.
- **Implementing stronger oversight and accountability measures.**
- **Mandating a patient benefit focus, particularly for the uninsured.**
- **Re-evaluating contract pharmacy expansion and addressing socioeconomic disparities.**

Accountability for a public program is essential and does not necessitate revealing private patient information or legitimate trade secrets. North Dakota has an opportunity to lead the nation by rejecting HB 1473 and championing real reform. Prioritizing patients over profits and accountability over opacity is crucial to ensure the 340B program fulfills its original promise of providing affordable medications to vulnerable populations. It is time for policymakers, healthcare providers, and stakeholders to engage in thoughtful discussions and implement reforms to realign the program with its core mission and genuinely serve those it was designed to help.

To Summarize:

The premise of 340B was sound. Pharmaceutical companies would offer discounts, and those savings would be passed on to low-income and vulnerable patients. However, the program's fatal flaw lies in its lack of oversight, transparency, and a clear definition of who truly qualifies as a “340B patient.” This gaping hole has been exploited by large, often for-profit, hospital systems who have aggressively acquired smaller clinics, not out of altruism, but to gain access to those sweet 340B discounts.

These entities, alongside major pharmacy chains contracted with them, purchase drugs at drastically reduced 340B prices. Yet, when you or I, insured or uninsured, pick up our prescriptions at these locations, we rarely, if ever, see those savings directly. Instead, these hospitals and pharmacies often charge full retail prices to insurance companies, Medicare, Medicaid, and even the state health plan, pocketing the substantial difference as profit. It's a hidden windfall, a system where the discounts designed for the needy are diverted to pad corporate bottom lines.

This isn't just an abstract economic issue; it has real-world consequences. This flawed system fuels healthcare consolidation, disadvantages independent pharmacies, and contributes to the growing problem of pharmacy deserts in rural states like our own. Your local, trusted pharmacist on Main Street struggles, while massive chains thrive, often offering impersonal service in a transactional environment.

Instead of expansion, North Dakota must demand reform. Our legislators have a unique opportunity to lead the nation by injecting common-sense fixes into this broken system. We need to clearly define who a 340B patient is, ensure those patients are aware of their status and benefit, and, most importantly, demand radical transparency.

Transparency is not a dirty word. We must know where the 340B money is flowing. How much are hospital systems and pharmacy chains profiting from this program? How much is *actually* reaching the patients it was meant to serve? This is public money, ultimately derived from taxpayer dollars and insurance premiums. We, the public, have a right to see where it's going.

Some may raise the tired objections of “trade secrets” and “regulatory burdens.” But accountability for a public program is not about revealing private patient information or legitimate trade secrets. It’s about ensuring that a program intended to help the vulnerable is not being exploited for profit at the expense of patients and taxpayers alike.

North Dakota has a chance to be a beacon of reform, to demonstrate that we prioritize patients over profits and accountability over opacity. We urge our legislators to reject HB 1473 and instead champion real, meaningful reform of the 340B program. Let’s ensure this well-intentioned program finally delivers on its promise and truly benefits those it was originally designed to help – the vulnerable patients in our communities who need affordable medication most. It’s time for North Dakota to lead the way in fixing this broken promise.

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Outcomes of the 340B Drug Pricing Program

A Scoping Review

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Key Points

Question

How has the 340B Drug Pricing Program affected the US health care system?

Findings

This scoping review found evidence that the 340B program was associated with revenue to hospitals, clinics, and pharmacies; expanded services for patients; and costs to pharmaceutical manufacturers. The study found mixed evidence that 340B revenue funded health care specifically for low-income populations.

Meaning

The 340B program has benefited hospitals, clinics, pharmacies, and patients, but its expansion has led to calls for reform.

This scoping review assesses the literature on the foundations of and outcomes associated with the 340B Drug Pricing Program in the US health care system.

Abstract

Importance

The 340B Drug Pricing Program requires manufacturers to offer discounted drug prices to support safety net hospitals and clinics (covered entities) providing care to low-income populations. Amid expansion, the program has received criticism and calls for reform.

Objective

To assess the literature on the foundations of and outcomes associated with the 340B program.

Evidence Review

The databases searched in this scoping review included PubMed, Embase, EconLit, National Bureau of Economic Research (NBER), Westlaw, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) website, the Government Accountability Office (GAO) website, and Google in February 2023 for peer-reviewed literature, legal publications, opinion pieces, and government agency and committee reports related to the 340B program.

Findings

Among a collected 900 documents, 289 met inclusion criteria: 83 articles from PubMed, 12 articles from Embase, 2 articles from EconLit, 1 article from NBER, 28 articles from Westlaw, 23 legislative history documents, 103 documents from Google, 11 GAO reports, and 26 HHS-OIG reports. Included literature pertained to 4 stakeholders in the 340B program: covered entities, pharmacies, pharmaceutical manufacturers, and patients. This literature showed that hospitals, clinics, and pharmacies generated revenue and manufacturers have forgone revenue from 340B discounted drugs. Audits of covered entities found low rates of compliance with 340B program requirements, whereas mixed evidence was uncovered on how covered entities used their 340B revenue, with some studies suggesting use to expand health care services for low-income populations and others to acquire physician practices and open sites in higher-income neighborhoods. These studies were hampered by a lack of transparency and reporting on the use of 340B revenue. Studies revealed patient benefits from access to expanded health care services, but there was mixed evidence on patient cost savings. Although the review identified considerable research on 340B hospitals, pharmacies, and patients, less research was found evaluating the 340B program's effect on nonhospital covered entities, drug pricing, and racial and ethnic minority groups.

Conclusions and Relevance

In this scoping review of the 340B program, we found that the 340B program was associated with financial benefits for hospitals, clinics, and pharmacies; improved access to health care services for patients; and substantial costs to manufacturers. Increased transparency regarding the use of 340B program revenue and strengthened rulemaking and enforcement authority for the Health Resources and Services Administration would support compliance and help ensure the 340B program achieves its intended purposes.

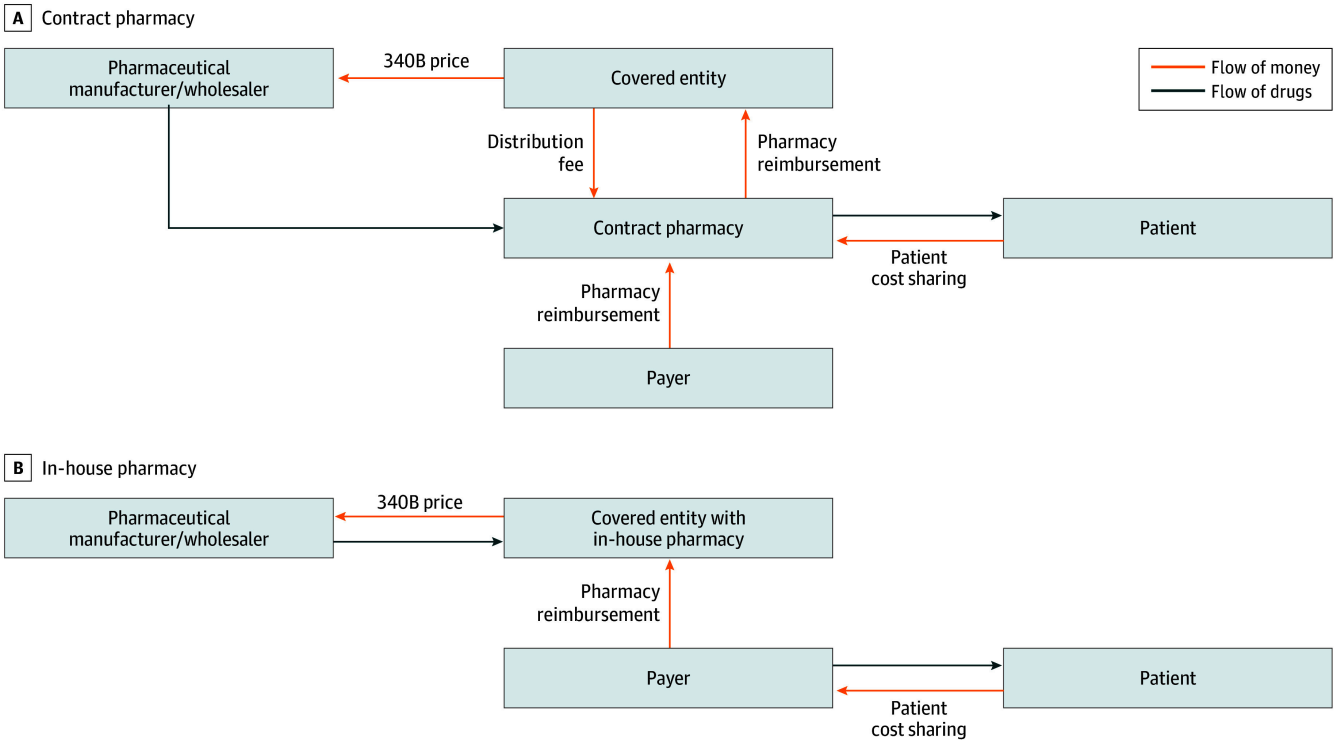
Introduction

The 340B Drug Pricing Program was created in 1992 to support safety net hospitals and clinics caring for low-income and underserved populations by discounting the cost of outpatient drugs.[1] The revenue from dispensing these discounted drugs allows these entities to reach more patients, provide more health care services and programs, and subsidize uncompensated care.

The origins of the 340B program stem from the establishment of the Medicaid Drug Rebate Program in 1990, which requires manufacturers to pay statutory rebates on drugs purchased by state Medicaid programs. These rebates include a best price discount to ensure that Medicaid pays no more than the lowest price paid by commercial insurers.[2] Many safety net hospitals and federally funded clinics had previously received substantial discounts on drugs purchased directly from manufacturers.[3,4] However, after the enactment of the Medicaid Drug Rebate Program, manufacturers ceased offering these discounts, reportedly because they would be included in best price calculations.[5] The resulting higher prices strained the budgets of hospitals and clinics, which then reduced their ability to provide health care services.[3,5]

The 340B program, enacted in response to these events, requires manufacturers participating in Medicaid to sell drugs at discounts to eligible clinics and hospitals, called "covered entities,"[6] and permits these entities to charge nondiscounted prices to all payers (Figure 1), generating revenue that could be used to subsidize health care services and operations.[5] Discounts are based on the average manufacturer price of the drug, or the average price wholesalers and retail pharmacies pay manufacturers for drugs distributed at retail pharmacies.[7] The 340B discounted price is equal to the average manufacturer price minus the average Medicaid rebate for a unit of that drug during the preceding quarter.[8] The discount is approximately 20% to 50%,[9] but can be higher because manufacturers of brand-name drugs subject to substantial price hikes over many years—such as adalimumab (Humira) and some insulins—are required to provide additional Medicaid rebates for price increases exceeding inflation.[10,11,12]

Figure 1. Flow of Money and Drugs in the 340B Drug Pricing Program.



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Authority over the 340B program was vested with the Department of Health and Human Services (HHS), which delegated authority to the Health Resources and Services Administration (HRSA) (Table). Initially, 13 categories of covered entities could participate, primarily federal grantee clinics and disproportionate share hospitals caring for many low-income patients and Medicaid patients. Congress added children's hospitals in 2005 and critical access hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals in 2010 (Box).

Table. Key Terms and Definitions.

Term	Definition
340B Statute	42 USC Section 256b
Child sites	Off-site outpatient clinics associated with covered entities
CMS	Centers for Medicare and Medicaid Services, the agency within the US Department of Health and Human Services responsible for overseeing Medicare and Medicaid programs
Contract pharmacies	Retail pharmacies that contract with covered entities to dispense drugs to patients
Covered entities	Hospitals and clinics eligible to participate in the 340B Drug Pricing Program
Diversion	Dispensing a drug purchased at a 340B discount to an individual who is not a patient of a covered entity; prohibited by the 340B statute
Duplicate discounting	When a manufacturer both (1) sells a drug to a covered entity at a 340B discount and (2) pays a Medicaid rebate to the state Medicaid program on that same drug; prohibited by the 340B statute
Federal grantees	Safety net clinics eligible to participate in the 340B Drug Pricing Program based on receiving certain federal grants
GAO	Government Accountability Office, an agency that provides auditing and research services to Congress
HHS	US Department of Health and Human Services
HRSA	US Health Resources and Services Administration, the agency within the US Department of Health and Human Services responsible for overseeing the 340B Drug Pricing Program
In-house pharmacies	Pharmacies owned by covered entities

Box. Categories of Covered Entities.

Hospital Covered Entities

- Disproportionate share hospitals
- Children's hospitals
- Critical access hospitals
- Freestanding cancer hospitals
- Sole community hospitals

Federal Grantee Covered Entities

- Federally qualified health centers and look-alikes
- Health centers for residents of public housing
- Family planning clinics
- Clinics receiving grants for outpatient early HIV/AIDS intervention services
- State AIDS drug purchasing assistance programs
- Black lung clinics
- Comprehensive hemophilia diagnostic treatment centers
- Native Hawaiian health centers
- Urban Indian organizations
- Ryan White program grantees
- Clinics receiving funds to treat sexually transmitted diseases
- Clinics receiving funds to treat tuberculosis
- Rural referral centers

The 340B program places 2 key requirements on covered entities' participation. First, it prohibits covered entities from duplicate discounting, or purchasing a drug at a 340B discount and submitting a claim to Medicaid for reimbursement that results in a rebate paid to the state Medicaid agency. Second, the 340B program bars covered entities from reselling 340B discounted drugs or providing them to patients not receiving care from the covered entity, a practice called "diversion." Covered entities are subject to audits to ensure compliance with these provisions.

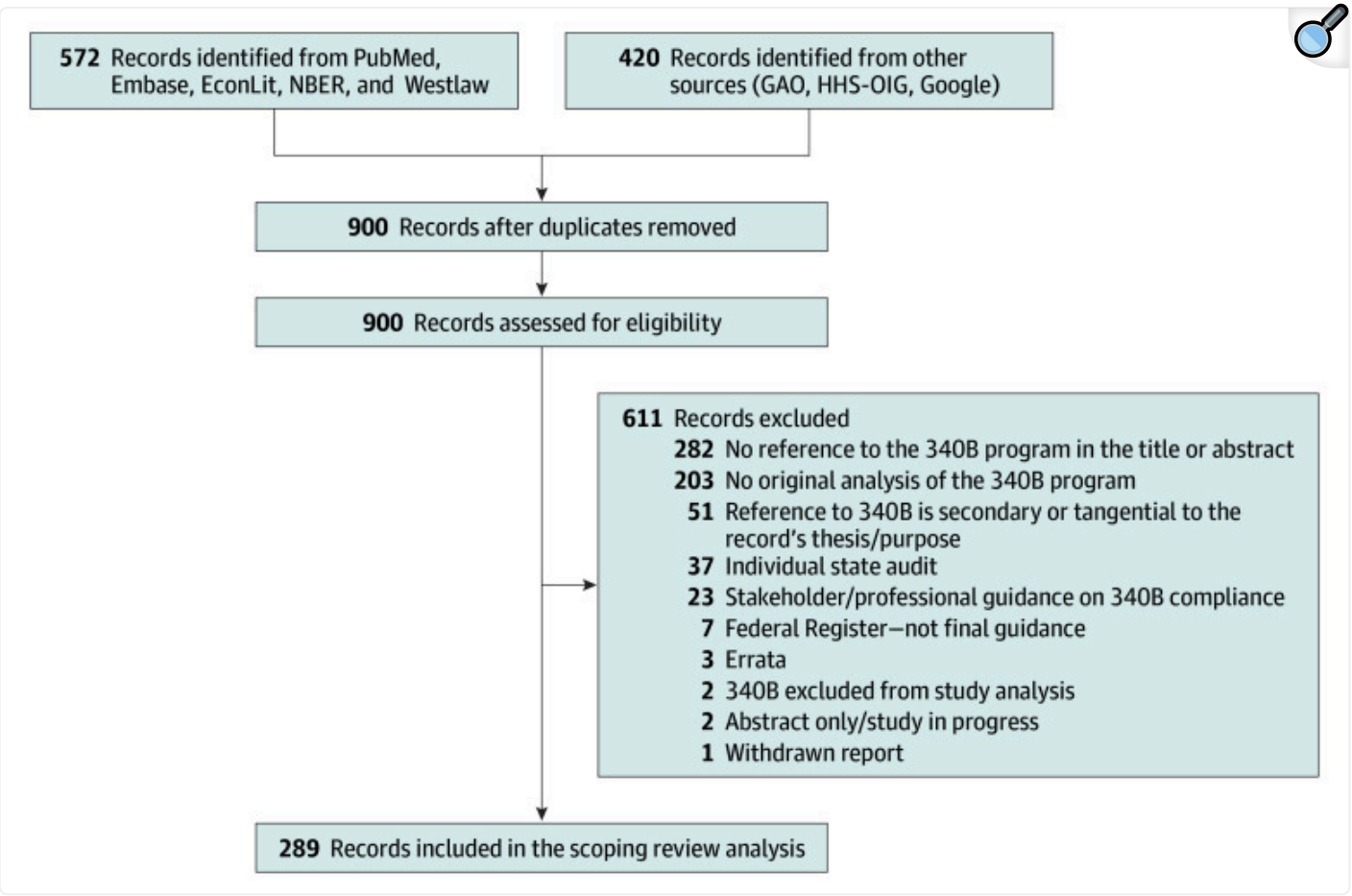
Critics of the 340B program, led by the pharmaceutical industry, have expressed concern about the program's growth in recent years.[13] We conducted a scoping review to assess the foundations of and outcomes associated with the 340B program.

Methods

Our study followed the scoping review methodology set forth by Arskey and O'Malley[14] and the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.[15]

We conducted article searches of PubMed, Embase, EconLit, NBER, and Westlaw as well as supplementary searches of Google, the Government Accountability Office (GAO) website, and the US Department of Health and Human Services Office of the Inspector General (HHS-OIG) website. Searches were updated iteratively from May 2022 to February 2023. Search terms included variations of *340B*, *340B Drug Pricing Program*, *340B Drug Discount Program*, and *340B program* (eAppendix 1 in Supplement 1). Duplicates of retrieved articles were removed. The titles and abstracts of articles were independently reviewed for inclusion by 2 authors (R.P.K. and J.W. for all sources except Westlaw and R.K. and A.S. for Westlaw), applying the exclusion criteria shown in Figure 2. Discordant categorizations for inclusion were resolved by discussion and involved a full-text review of the article. For all included articles, we recorded the (1) author, publication year, and publication type; (2) study objective or article thesis; (3) stakeholders discussed; (4) results or analyses; (5) conclusions; and (6) limitations. A wide range of document types were included in addition to articles from peer-reviewed literature, including law review articles, white papers published by various research groups, reports published by government agencies (eg, HHS-OIG, GAO, and the Congressional Research Service), Congressional committee reports and hearing transcripts, opinion pieces, blog posts, and webpages. The breadth of sources included ensured the identification of important evidence not reported in the peer-reviewed literature and was particularly valuable in identifying gaps in the evidence and translating the implications of the evidence to policy reforms.[16] Institutional board approval was not required for the study because it did not involve human participants.

Figure 2. Study Selection Flow Diagram.



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GAO indicates Government Accountability Office; HHS-OIG, US Department of Health and Human Services Office of the Inspector General.

Results

Our search yielded 900 documents, of which 289 met our inclusion criteria: 83 articles from PubMed, 12 articles from Embase, 2 articles from EconLit, 1 article from NBER, 28 articles from Westlaw, 23 legislative history documents, 103 articles from Google, 11 GAO reports, and 26 HHS-OIG Reports (Figure 2). This literature covered issues facing 4 stakeholders in the 340B program (1) covered entities, (2) pharmacies, (3) pharmaceutical manufacturers, and (4) patients (eAppendix 2 in Supplement 1).

Covered Entities

Included articles and reports revealed the dramatic increase in covered entities participating in the 340B program since its inception.[17,18] In 1992, there were approximately 1000 covered entities (including child sites, which are associated offsite facilities of covered entities); by 2021, there were over 50 000.[19] In 2021, approximately 60% of covered entities were hospitals (including child sites), while 40% were federal grantee clinics.[19] The 340B program now includes more than 40% of US hospitals.[20]

The 340B program can be lucrative for hospitals. One study found that hospitals' mean estimated 340B profits from Medicare Part B in 2016 were $2.5 million, whereas median profits were $0.8 million, equal to 0.3% of hospital operating budgets or 9.4% of uncompensated care costs.[21] Another study estimated that covered entities' collective profits doubled from $20.2 billion in 2015 to $40.5 billion in 2019.[22]

The locations of covered entities, particularly hospitals, have changed over time. One study found that disproportionate share hospitals joining the 340B program since 2004 served higher-income communities compared with disproportionate share hospitals joining before 2004.[23] Another study similarly found that disproportionate share hospitals joining before 2004 were located in counties with lower income levels and higher uninsurance rates.[24]

Covered entities are not required to report how they use 340B revenue as a condition of participation, creating challenges in studying this spending. In spite of this limitation, 340B revenue appeared to fund a range of health care services and programs. However, study findings conflicted as to whether the revenue is primarily directed toward charity care and low-income populations. Surveys and self-reported data from covered entities indicated that 340B program revenue funded free or low-cost medications for patients and subsidized uncompensated care and specialty clinics for diabetes, cancer, stroke, and brain injuries.[25,26,27,28,29] One study found that 340B participation of disproportionate share hospitals was associated with a 29% increase in charity care spending, a 4% increase in discounted care, and a 19% increase in the income eligibility limit for discounted care, but was not associated with the offering of low-profit medical services.[30] Another study found that 340B hospitals provided more medication access services and outpatient treatment services for drugs, alcohol, and HIV/AIDS compared with non-340B hospitals.[31]

By contrast, 1 study[32] found no evidence that hospitals increased uncompensated care after joining the 340B program. The GAO found in a study of almost 3000 hospitals that, although most 340B hospitals provided more uncompensated care and charity care than nonparticipating hospitals, 14% of the 340B disproportionate share hospitals studied were among the bottom quarter of all hospitals studied in providing uncompensated care.[20] Overall, 340B hospitals also increasingly purchased outpatient oncology clinics, moving oncology care from community-based practices to hospital outpatient sites.[30,33,34] This consolidation may increase cost of care because outpatient sites often provide more expensive services not offered in physician's offices.[20,33,34] However, similar consolidation was observed among oncology practices and non-340B hospitals,[35] making unclear the association with the 340B program.

Fewer included articles and reports focused on nonhospital 340B covered entities. In a survey of 31 hemophilia treatment centers, all reported that salaries of staff (including nurses, social workers, and physical

therapists) were supported by 340B revenue and almost half used 340B revenue to provide patients with financial assistance for transportation to access care.[36] One study[37] concluded that the 340B program saved sexually transmitted disease clinics almost 100% on the cost of penicillin treatment for syphilis, whereas another found that 55% of rural hospitals used 340B revenue to be able to stay open.[38] Similarly, a study[39] found hepatitis C virus infection treatment programs would lose $370 per patient and not be financially sustainable without revenue from the 340B program.

Covered entities' compliance with 340B program requirements has been closely scrutinized. The HRSA audits of covered entities between 2012 and 2016 found noncompliance rates (rates of 1 or more violations of 340B program requirements) between 63% and 82%.[40] A 2020 GAO study[41] of 1242 HRSA audits from 2012 through September 2020 found similarly high rates of noncompliance. Examples of noncompliance included recordkeeping flaws regarding 340B program eligibility, duplicate discounting, and diversion.

Pharmacies

Included literature revealed that covered entities have contracted with external pharmacies to dispense discounted drugs since the start of the 340B program.[42,43] Contract pharmacies were essential to the program because most covered entities lacked in-house pharmacies[42] and contract pharmacies made receiving prescription drugs more convenient for patients.[43] Contract pharmacies dispense drugs purchased by covered entities at 340B discounts to patients of the covered entities. In return, the pharmacies are paid a fee per prescription filled and in some cases a percentage of the revenue from 340B prescriptions.[26] One study[22] estimated that in 2019, contract pharmacy arrangements generated $5 billion in profit from 340B sales.

Investigations highlighted the dramatic increase in pharmacy participation since 2010. Although previous guidance only permitted a single contract pharmacy,[42] HRSA advised in 2010 that covered entities could use an unlimited number of contract pharmacies.[44] As a result, the number of contract pharmacies working with covered entities increased from approximately 1000 in 2010 to almost 28 000 in 2021.[19] In 2017, approximately 25% of US pharmacies participated in the 340B program,[45] with the 5 largest pharmacy chains accounting for 60% of contract pharmacies.[26] As of July that year, the number of contract pharmacies employed by individual covered entities ranged from 0 to 439.[26] The average among all covered entities using at least 1 contract pharmacy was 12, whereas the average among disproportionate share hospitals was 25.

The location of contract pharmacies varied widely. Although many contract pharmacies were within 30 miles of the covered entity in 2017, a GAO report[26] found that 45% of disproportionate-share hospitals engaged a contract pharmacy more than 1000 miles away. One study[45] of contract pharmacies found many stationed in higher-income, less diverse neighborhoods. Another study[46] found that contract pharmacies for safety net clinics were opening in poorer communities, whereas the locations of contract pharmacies for 340B hospitals were uncorrelated with rates of poverty or uninsurance. A third study[47] found that contract pharmacies were more prevalent in poorer communities but less prevalent in communities with high uninsurance rates.

The types of 340B discounted drugs dispensed by contract pharmacies differed from all prescriptions dispensed by pharmacies. For example, 1 study[48] found that 340B prescriptions dispensed by contract pharmacies had a higher share of antivirals and specialty medicines and a lower share of generic drugs.

Pharmaceutical Manufacturers

Pharmaceutical manufacturers face high costs through participation in the 340B program because they are required to provide steep discounts on their drugs to levels far below private market prices. In 2020, manufacturers sold more than $80 billion in drugs (or 16% of manufacturer US sales) at 340B discounted prices of approximately $38 billion.[49,50] Manufacturers have tried to limit the scope of the program, and in turn the amount of their 340B discounted sales, by challenging regulations implemented by HRSA and placing restrictions on their participation with contract pharmacies.[51,52]

The 340B program's effects on drug pricing remain unresolved. One study uncovered no data supporting an association between 340B discounts and related inflation penalties with manufacturer price increases in Medicare Part D.[53] A separate study[54] calculated that a 60% reduction in the list prices of hepatitis C drugs may have actually saved manufacturers $182 million from lower 340B discounts, whereas another suggested that the 340B program may have contributed to a 10% annual increase in list prices of cancer drugs between 1995 and 2013.[55] Still, to our knowledge, no study investigated the association between the 340B program and manufacturers' drug pricing practices broadly.

Patients

Patients benefited from the 340B program through the programs and health care services that covered entities provided to them. Surveys revealed that some covered entities used 340B funds to open specialty clinics, dispense free or low-cost medications, offer patients transportation, and provide patient education services.[29,36] However, 1 study[56] found no relationship between the 340B program and increased provision of such services to low-income patients. Little research was identified on the diversity of patients in the 340B program or the benefits of the program to racial and ethnic minority groups.

There was mixed evidence on the association between the 340B program and patient cost savings. Some studies showed that some patients received free or low-cost medications from covered entities or contract pharmacies.[26] A 2012 study[57] comparing uninsured patients' prescription drug costs and savings related to patient assistance programs and the 340B program at 2 community health centers found that patients receiving 340B medications had an average medication cost of $11.50 and average savings of $62.31 relative to list prices. However, in a GAO survey of 55 covered entities, 25 reported that they did not offer discounts at their contract pharmacies.[26] Another study[58] found that out-of-pocket costs increased for patients paying cash at 340B covered entities.

The association of the 340B program with patient outcomes was also mixed. One study[59] found an association between the 340B program and increased medication adherence: 340B clinics had 5% higher medication adherence for patients with diabetes and 3% higher for patients with hyperlipidemia and hypertension compared with the general patient population, and 340B hospitals had 7% higher medication adherence for patients with diabetes, 6% higher for patients with hyperlipidemia, and 5% higher for patients with hypertension. However, a different study[56] of 340B-eligible disproportionate share hospitals found no relationship between 340B program eligibility and mortality rates.

Discussion

Our scoping review revealed that the 340B program has grown substantially since it was launched and provided meaningful benefits to covered entities, pharmacies, and patients. Covered entities used revenue from the 340B program to expand health care services and programming, open specialty clinics, provide medications at reduced costs to patients, and subsidize uncompensated care and staff salaries. Patients of covered entities received greater access to health care services, but there was mixed evidence as to lower medication costs. However, covered entities—notably disproportionate share hospitals—also used 340B revenue for purposes seemingly unrelated to underserved patient care, including opening sites in higher-income neighborhoods and acquiring outpatient physician practices.

Pharmaceutical manufacturers, meanwhile, missed out on revenue as a result of the 340B program and pursued several legal challenges against it. Most recently, manufacturers challenged the HRSA mandate that manufacturers deliver 340B drugs to contract pharmacies.[52] District courts have reached different conclusions,[60,61,62,63] and there has been only 1 appeals court ruling thus far, supporting manufacturer restrictions on 340B drug sales.[64] Since then, at least 20 manufacturers have set conditions on their deliveries to contract pharmacies, although with other cases still pending, the propriety of these moves remains a source of legal uncertainty.[65]

The findings of this study demonstrate that the 340B program offers value to many stakeholders in the US health care system. Studies have shown that many covered entities used 340B revenue to provide additional health services to patients, subsidize uncompensated and charity care, and provide free or low-cost medications to patients. These findings should be considered against the increasing criticism of the 340B program. The benefits from the 340B program may vary based on the category of the covered entity. In particular, federally-funded clinics and disproportionate share hospitals likely benefit in different ways, with clinics seeming more reliant on 340B revenue to stay open and disproportionate share hospitals using 340B revenue to expand health care services. Still, our findings show that the 340B program has been successful in aiding safety net hospitals and clinics serving low-income and underserved populations and that the consequences of eliminating or substantially restricting the program would be great.

Even with the strengths of the program, our review identified facets of the 340B program for potential reform. Covered entities are financially benefitting from the 340B program, yet some hospitals may be operating inconsistently with its goals. There are no requirements on how covered entities spend their 340B revenue,

and it is difficult to study these activities and evaluate their effects. Covered entities' use of 340B funds has been a controversial area that received pushback from the federal government.[66,67,68] In 2017, the Centers for Medicare & Medicaid Services announced that it would decrease Medicare Part B reimbursement for 340B hospitals from average sales price plus 6% to average sales price minus 22.5% to account for discounts received under the 340B program. However, in 2022, the Supreme Court rescinded the rule,[69] and a federal court required repayment to the hospitals at the higher reimbursement rate.[70] Studies also conflict on the extent of patient financial benefits, particularly on whether 340B discounts are passed on to patients or are benefiting covered entities in unintended ways.[26,29,36,56,57,58,59] These critiques are more concerning in the context of audits showing duplicate discounting and diversion.[40,41] As the 340B program grows, involving more covered entities and contract pharmacies and reaching more patients, the need for additional data reporting and oversight is critical.

One avenue for reform would be new legislation requiring all covered entities to face greater transparency requirements. Federal grantees currently have some reporting conditions, including how they spend grant funds and data on the clients serviced and services provided.[71] Of specific concern are disproportionate share hospitals, which have increasingly served higher-income communities and have been criticized for their practices.[23,24] At a minimum, all covered entities should be required to report to HRSA data on 340B revenue and their spending to expand health care service offerings and programming. Additional requirements could be set for the proportion of 340B revenue that must be put toward community benefit spending. These rules will promote trust and accountability in the 340B program and support future evaluations of its successes and effectiveness. For example, data on use of 340B funds can inform rules on spending of 340B revenue or changes in the calculation of 340B discounts. Congress should also delegate HRSA additional rulemaking and enforcement authority to strengthen its administration and oversight of the 340B program. This authority would bolster the ability of HRSA to clarify program requirements and address compliance violations. It would additionally limit the need for Congressional intervention in the future.

Limitations

This study was limited by a lack of critical information on the 340B program, such as pricing, savings, and revenue, which were confidential, proprietary, or unavailable. Most literature focused on 340B disproportionate share hospitals, with less research on federal grantees and nonhospital covered entities. Greater attention is needed on the effects of the 340B program on these 340B-covered entities. Inherent limitations in scoping review methodology should also be noted.[16,72] The study did not formally evaluate the quality of the evidence, identify potential biases in the individual or collective studies, or address the relative weight of the evidence in presenting the findings. Further, scoping reviews focus on breadth rather than depth on a particular topic. However, this method was most appropriate given our objectives to provide an overview of several aspects of the 340B program with analyses from several perspectives.

Conclusions

In this scoping review of the 340B program, we found evidence that the 340B program benefited hospitals, clinics, pharmacies, and patients, with notable costs to pharmaceutical manufacturers. Increased transparency regarding the use of 340B program revenue and strengthened rulemaking and enforcement authority for HRSA would support compliance and help ensure the 340B program achieves its intended purposes.

Supplement 1.

eAppendix 1. Detailed Methodology

eReferences

eTable 1. Database Search Terms

eTable 2. All Documents Included in the Scoping Review

jamahealthforum-e233716-s001.pdf (1.6MB, pdf)

Supplement 2.

Data Sharing Statement

jamahealthforum-e233716-s002.pdf (10.6KB, pdf)

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Associated Data

This section collects any data citations, data availability statements, or supplementary materials included in this article.

Supplementary Materials

Supplement 1.

eAppendix 1. Detailed Methodology

eReferences

eTable 1. Database Search Terms

eTable 2. All Documents Included in the Scoping Review

jamahealthforum-e233716-s001.pdf (1.6MB, pdf)

Supplement 2.

Data Sharing Statement

jamahealthforum-e233716-s002.pdf (10.6KB, pdf)

New Study Exposes More Exploitation and Waste in the 340B Drug Discount Program

The WasteWatcher

June 9, 2023 — Christina Smith

Congress created the 340B drug discount program in 1992 to fix a problem it had created two years earlier when an overreaching government implemented price controls in the Medicaid drug benefit program. As a condition to participate in Medicaid, pharmaceutical companies are required to participate in the 340B program and give significant discounts of between 20-50 percent to certain federally-funded facilities and disproportionate share hospitals (DSH). These facilities and hospitals receive government subsidies to treat large numbers of low-income people on Medicare and Medicaid, as well as indigent, uninsured patients. Unfortunately, like many other well-intended programs 340B has ended up both wasting money and failing to provide the benefits that were supposed to go to the patients. The healthcare data analytics firm IQVIA released its latest annual study, "The 340B Drug Discount Program Exceeds $100B in 2022," which provides further evidence exposing the exploitation of the program. The report found that the misuse of the funds by hospitals and contract pharmacies is ongoing, and patients are still not getting the benefits Congress intended them to receive.

The program historically was intended to help low income and vulnerable patients get access to low-cost prescription drugs; however, the program has grown and continues to expand beyond its intended purpose to boost profits for hospitals and their contract pharmacies that are largely located in areas that don't serve low-income patients.

Citizens Against Government Waste (CAGW) first expressed its concerns over the 340B program in 2014, and has since published blog posts, op-eds, and other commentary about the shortcomings of the program. In 2018, the House Energy and Commerce Committee released recommendations for 340B reform, and the September 27, 2022 article in *The New York Times* about the abuses of the program at the Bon Secours-owned Richmond (Virginia) Community Hospital clearly demonstrated the need for changes to the program. But nothing has been done, and as the IQVIA study shows, the problems are only getting worse.

Beyond the impact of the 340B program on pharmaceutical sales, biopharmaceutical drug companies are facing further market challenges due to government price controls. The IQVIA study noted that the Inflation Reduction Act (IRA) price controls will impose additional pressure on future research and development. CAGW submitted comments in response to the Center for Medicare and Medicaid Services, "initial guidance for implementation of the Negotiation Program for initial price applicability year 2026." The price controls implemented from the IRA will further distort the medical marketplace. Additionally, the IRA expands the 340B drug discount program despite its flaws.

Congress has long distorted the medical marketplace by artificially imposing price controls and burdensome mandates. It is time Congress restores the 340B program back to its original intent. 340B reforms must include a clear definition of a patient as an uninsured, low-income individual that does not qualify for Medicare or Medicaid. Adopting that definition would go a long way to ensure that the program operates closer to the way it was originally intended.

Blog Tags: Healthcare | 340B Drug Discount Program | 340B Drug Discount Program; Charity Care; Price Controls

The WasteWatcher is the staff blog of Citizens Against Government Waste (CAGW) and the Council for Citizens Against Government Waste (CCAGW). For questions, contact blog@cagw.org.

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Legal Sidebar

Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program

Updated May 23, 2024

The 340B Drug Discount Program enables eligible hospitals and other safety net providers to purchase outpatient prescription drugs at discounted prices. The Health Resources and Services Administration (HRSA), an operating division of the U.S. Department of Health and Human Services (HHS), administers the program. In recent years, both legal and policy disagreements have arisen between HHS, drug manufacturers, eligible providers (known as "covered entities"), and other stakeholders about the size of the program, how it should function, and who should benefit from it. For example, disagreements about covered entities' use of retail pharmacies to distribute 340B drugs to patients have led to a number of lawsuits that challenge both the Secretary of HHS's and states' authority to regulate the program.

This Legal Sidebar discusses recent judicial opinions ruling on HHS's and states' ability to regulate the 340B program. The U.S. Court of Appeals for the Third Circuit (Third Circuit) (*Sanofi-Aventis U.S. LLC v. HHS*), the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) (*Novartis Pharmaceuticals Corp. v. Johnson*), and the U.S. Court of Appeals for the Eighth Circuit (Eighth Circuit) (*Pharmaceutical Research and Manufacturers of America (PhRMA) v. McClain*) each addressed interpretations of the 340B statute, focusing on the lack of statutory language around contract pharmacy use while addressing different legal questions associated with the same. According to the Third and D.C. Circuits, the statute restricts HHS from taking certain actions to address covered entities' use of contract pharmacies, which has enabled some drug manufacturers to effectively create 340B pricing restrictions for their drugs. The Eighth Circuit, assessing a different legal question, upheld an Arkansas law that prohibited such manufacturer restrictions, finding that the state prohibition was not preempted by the 340B statute.

Background

The 340B statute requires the Secretary of HHS to enter into purchase price agreements (PPAs) with drug manufacturers who participate in federal health care programs. The PPAs require manufacturers to "offer" to sell certain outpatient prescription drugs at a ceiling price, which is calculated based on a statutory formula. The statute provides a list of covered entities that may purchase drugs from manufacturers at the discounted ceiling price, including Federally Qualified Health Centers (FQHCs), Rural Referral Centers, and some hospitals, such as Disproportionate Share Hospitals and Children's Hospitals. Covered entities can generate revenue from 340B (known as "340B savings") by dispensing these lower-cost drugs to

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patients and receiving list price reimbursement from third-party payers (e.g., insurance companies). Rather than distributing 340B drugs through their own in-house pharmacies, the majority of covered entities contract with retail pharmacies, known as contract pharmacies, who then sell drugs to patients. In accordance with the statute, 340B drugs may be provided only to patients of covered entities, and the statute prohibits covered entities from receiving duplicate discounts from both Medicaid and 340B. For additional information, see CRS In Focus IF12232, *Overview of the 340B Drug Discount Program*, by Hannah-Alise Rogers.

In summer 2020, some drug manufacturers began announcing restrictions on 340B covered entities that distribute 340B drugs using contract pharmacies. These restrictions vary, but they generally aim to limit covered entities to distribution to one contract pharmacy. Manufacturers say that the restrictions are necessary to prevent duplicate discounting and unlawful distribution of 340B drugs to nonpatients (also known as *diversion*), arguing that such practices have grown more prevalent in recent years and that HRSA does not adequately police them. The restrictions have financial consequences for covered entities, who argue they are now paying more for certain 340B drugs and are unable to generate 340B savings from them. Currently, there are at least 20 manufacturers with such restrictions.

HRSA responded to the restrictions in 2021 by issuing violation letters to manufacturers, informing them that their policies violated the 340B statute and threatening civil money penalties if they continued. Several manufacturers then sued the agency, claiming it lacked the authority to issue the violation letters because the statute permitted manufacturers to enact such restrictions. Several district court decisions were appealed to the D.C. and Third Circuits as well as the U.S. Court of Appeals for the Seventh Circuit (Seventh Circuit). The Third and D.C. Circuits have issued rulings, discussed below, finding that HHS lacked authority to issue violation letters. The Seventh Circuit has not yet issued a decision. More information about the district court decisions may be found in CRS Legal Sidebar LSB10842, *Courts Evaluate the Role of Contract Pharmacies in the 340B Drug Discount Program*, by Hannah-Alise Rogers.

At the same time that manufacturers were challenging HHS's authority to regulate contract pharmacy use, several states began considering legislation to make it unlawful for drug manufacturers to restrict contract pharmacy use by covered entities within that state. For example, in May 2021, the Arkansas General Assembly enacted Act 1103, which says that manufacturers may not prohibit pharmacies "from contracting [with] or participating with any [covered] entity." PhRMA challenged the state law, arguing that it was preempted by the 340B statute and the Commerce Clause. In December 2022, the district court held that the 340B statute and the Food, Drug, and Cosmetic Act (FDCA) did not preempt the Arkansas law. The Eighth Circuit affirmed this ruling, and its decision is discussed below.

Litigation Concerning HHS's Regulation of Contract Pharmacies: The Third and D.C. Circuits' Decisions

After HHS issued violation letters to several drug manufacturers for restricting access to 340B pricing for covered entities that used contract pharmacies, some manufacturers, including Sanofi-Aventis, AstraZeneca, Novo Nordisk, Novartis, and United Therapeutics, sued the agency to challenge its authority to issue the letters. In the *Sanofi-Aventis* case, the District Court for the District of New Jersey upheld HHS's action, in part, finding that the drug manufacturer's 340B pricing restriction policy was unlawful; Sanofi appealed, and the government cross-appealed. The Third Circuit's decision on appeal focused on two issues: whether the 340B statute permits drug manufacturers to limit covered entity drug purchases that are distributed by contract pharmacies and whether the statute gives HHS the authority to stop such practices. Similarly, in the *Novartis* case, the D.C. Circuit reviewed the D.C. District Court's order setting aside HHS's violation letter. The issue on appeal was whether HHS's enforcement letter was

"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the Administrative Procedure Act.

In reaching its decision in favor of manufacturers, both the Third and D.C. Circuits began by considering the language of the 340B statute. The Third Circuit reasoned that the manufacturers' policies restricting contract pharmacy use were lawful because "[n]o . . . language in Section 340B requires delivery to an unlimited number of contract pharmacies." The D.C. Circuit's opinion further pointed out that the Secretary of HHS "lacks rulemaking authority over the 340B program." Both courts analyzed the statute's specific words, including that manufacturers are required to "offer" to sell 340B drugs, which are "purchased by" covered entities at or below a "ceiling price." The courts observed that the text of the statute did not speak directly to the delivery of drugs to contract pharmacies. The Third Circuit disagreed with HHS's argument that such terms required manufacturers to "offer" to sell and deliver drugs wherever the covered entity demands, holding this argument to be "one giant leap from the text," and observing that "when Congress's words run out, covered entities may not pick up the pen." The D.C. Circuit reached the same conclusion as the Third Circuit, finding that HRSA's position would "produce absurd consequences." The D.C. Circuit reasoned that under ordinary principles of contract law, offers may include price and nonprice terms. As for the statute's silence on contract pharmacies, the D.C. Circuit found that "[s]tatutory silence implies that manufacturers *may* impose distribution conditions by contract," consistent with the Supreme Court's ruling in *Christensen v. Harris County*, in which the Court held that a federal employment statute's silence on the imposition of contractual conditions did not implicitly prohibit the conduct.

The circuit courts also looked to the legislative history and overall purpose of the 340B statute, with the Third Circuit observing that "neither calls for a different outcome." With respect to the legislative history, the Third Circuit observed that previous attempts by Congress to amend the 340B statute to reference contract pharmacy use "can support opposite inferences," that either Congress did not want contract pharmacies to be part of the program, or that their use was so widespread that they were unnecessary to mention. The D.C. Circuit similarly disagreed with HRSA that the 340B statute's legislative history, specifically Congress rejecting an amendment that would have limited drug discounts to "on-site pharmacy services," supported a different result. The court stated that even if the "on-site pharmacy" amendment was significant, it "hardly suggests that Congress opted for the opposite extreme of categorically requiring manufacturers to deal with an unlimited number of contract pharmacies."

The courts were likewise unpersuaded by the government's argument that allowing drug manufacturers to limit contract pharmacy usage would "thwart Congress's purpose in enacting Section 340B." For example, the Third Circuit acknowledged that many covered entities would be unable to access 340B discounts without contract pharmacies, as most do not have their own pharmacies in-house. It found that "Congress might have expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy" but that this was a "far cry" from HHS's position that the statute allows covered entities to use an unlimited number of contract pharmacies. The D.C. Circuit also discussed HRSA's invocation of Justice Scalia's "predicate-act canon" of statutory interpretation, under which a court should disfavor a statutory construction that would frustrate congressional purpose or otherwise render a statute ineffective. The D.C. Circuit said, however, that "wider distribution" of 340B drugs via contract pharmacies "was not necessarily better," and that the agency's prior prohibition on the use of multiple contract pharmacies, which lasted nearly 20 years, "hardly rendered the scheme [of 340B] self-defeating or ineffectual."

The Third Circuit also pointed to other structural clues in the 340B statute to support its holding, citing the subsection of the statute that allows covered entities to contract with "prime vendors" to purchase and distribute drugs. The Third Circuit reasoned that Congress could have included similar language to permit covered entities to contract with outside pharmacies to distribute drugs or could have imposed delivery-related requirements on manufacturers, but it did not do so. The court also cited other language within the

Veteran's Health Care Act that enables Department of Veterans Affairs hospitals to access drug discounts that are purchased under "contracting systems." The court presumed that, because the 340B statute did not contain similar language, Congress did not intend for covered entities to contract with outside pharmacies to distribute 340B drugs.

Unlike the Third Circuit, the D.C. Circuit dedicated a portion of its opinion to analyzing the manufacturers' specific conditions on offers to sell drugs to 340B covered entities. For example, one manufacturer's condition is that it will deliver 340B drugs only to a covered entity's in-house pharmacy or a single contract pharmacy; the court observed that such a condition neither "precluded [the manufacturer] from making a bona fide 'offer'" to sell a 340B drug nor increased the requisite 340B ceiling price, in violation of the statute. The court did note, however, that a future, more "onerous" condition "might violate the statute," leaving open a window for future challenges.

Litigation Concerning State Attempts to Regulate Contract Pharmacies: The Eighth Circuit's Decision

PhRMA sued the State of Arkansas after it passed a law that prohibited drug manufacturers from restricting covered entities in the state from accessing 340B pricing when using contract pharmacies to distribute 340B drugs. The district court found that the state law was not preempted by the 340B statute, and PhRMA appealed this ruling to the Eighth Circuit. The issue on appeal concerns whether the 340B statute preempts Arkansas Act 1103, which was intended "to protect contract pharmacy arrangements in Arkansas." In addition to prohibiting manufacturers from disrupting contracts between pharmacies and covered entities, the law also prevents manufacturers from denying 340B pricing to community-based pharmacies in the state that receive 340B drugs for distribution.

The preemption doctrine stems from the Supremacy Clause, which states that federal laws made under the authority of the Constitution are the "supreme Law of the Land." Federal law preempts state law where (1) Congress expressly states its intention to prevent state regulation (express preemption), (2) state law stands as an obstacle to accomplishing the federal law's purpose (obstacle preemption), (3) Congress implicitly occupies the field (field preemption), or (4) where it is impossible to simultaneously comply with state and federal law (impossibility preemption). The Supreme Court has held that "[a] field is occupied when the federal regulatory scheme is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." PhRMA argued that Act 1103 is unconstitutional because the 340B Program occupies the field of federal law, it presents an obstacle to drug manufacturers who are attempting to comply with the 340B statute, and it is impossible to comply with both the state law and other federal laws under the FDCA.

The Eighth Circuit ultimately concluded that the 340B statute did not preempt Act 1103. In support of its decision, the Eighth Circuit first highlighted several facts about both the federal program and the state law. It considered the structure of the 340B statute, which it broke into three essential components: (1) capping manufacturer prices; (2) restricting covered entities from engaging in duplicate discounting or diversion; and (3) creating compliance mechanisms for both manufacturers and covered entities. Citing the Third Circuit's decision in *Sanofi Aventis*, the Eighth Circuit observed that "the 340B Program is silent about delivery and distribution of pharmaceuticals to patients." The court noted, however, that "pharmacies are essential, and legally required" for the functioning of the pharmaceutical supply chain, and that they "have always been important participants in delivering 340B drugs to patients." Although retail pharmacies are vital to the functioning of 340B, the court said they are merely "agent[s] of the covered entity," which both purchases and assumes legal responsibility for the drugs. The court then looked at the specific wording of the Arkansas law, observing that its primary focus is the agreements between covered entities and contract pharmacies.

After reviewing the relevant facts, the Eighth Circuit began its analysis with field preemption, quoting a Supreme Court decision holding that field preemption occurs when Congress leaves "no room for the states to supplement" federal law. Noting that the text of the statute does not mention the delivery of drugs, the court found that "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." The court further reasoned that Congress was aware that the regulation of pharmacies has traditionally been an issue of state law and thus "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." Although the Arkansas law empowers the state to penalize drug manufacturers who refuse to distribute drugs to covered entities' contract pharmacies, the court said this does not interfere with HHS's jurisdiction over the program, which concerns disputes between manufacturers and covered entities regarding pricing of drugs, rather than the distribution of those drugs.

The court further found that the Arkansas law is not unconstitutional due to obstacle preemption, because rather than creating an obstacle to 340B compliance, the Arkansas law "assists in fulfilling the purpose of 340B" by protecting the relationship between contract pharmacies and covered entities and ensuring that covered entities can distribute their drugs to patients. The court concluded that the state law "is simply deterring … manufacturers from interfering with a covered entity's contract pharmacy arrangements," and thus manufacturers could, and indeed have, complied with both the 340B statute and state law.

Finally, the court dismissed PhRMA's impossibility preemption argument that it was impossible to comply with both the state law and the FDCA's REMS provisions, which restrict distribution of certain drugs to ensure public safety. The court observed that covered entities are responsible for meeting REMS requirements, but that "just because a medication is subject to multiple legal requirements does not make it impossible to comply" with state law.

Now that the Eighth Circuit has ruled on the Supremacy Clause and federal preemption issues, litigation will continue on PhRMA's claims that the state law is invalid under the Commerce Clause, which the district court has not yet addressed. PhRMA argues that because the state law will "inevitably regulate commerce wholly outside" of its borders, it should be invalidated under the dormant Commerce Clause doctrine.

Considerations for Congress

Taken together, the Third, D.C., and Eighth Circuit rulings seem to suggest that states may use their authority to regulate pharmacies within their state to address the use of contract pharmacies in the 340B Program, even if HHS cannot do so. According to the Third and D.C. Circuits, the federal government lacks the authority to broadly prevent manufacturers from adopting policies that attempt to restrict covered entities' use of contract pharmacies, but the Eighth Circuit ruling suggests that states may address this problem by legislating on retail pharmacies. Without clarification from Congress on the appropriate role of contract pharmacies in the 340B program, uncertainty over their use may continue. Additionally, the matter could be further complicated if the Seventh Circuit splits from the Third and D.C. Circuits' rulings and finds that the 340B statute does enable HHS to enforce the 340B statute in such a way that would prevent manufacturers from restricting contract pharmacy use. If such a contrary ruling were to occur, HHS may be able to address manufacturers' policies in some states but not in others.

Even assuming that no contradictory rulings are issued, the decisions from the circuit courts did not resolve all facets of the contract pharmacy issue, and disagreements between HHS, drug manufacturers, and 340B covered entities are likely to continue. For example, in its ruling, the Third Circuit did not explicitly resolve the question of how many contract pharmacies a 340B covered entity should be permitted to use, finding HHS's "unlimited number" argument unpersuasive while simultaneously acknowledging that contract pharmacies seem vital to the program and that without them, many covered entities would be unable to generate 340B savings. The Third Circuit reasoned, "Congress might have

expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy. But this is a far cry from the government's current position that covered entities may use an unlimited number of contract pharmacies." Several manufacturers have subsequently interpreted the court's opinion to permit covered entities without a pharmacy in-house to use one contract pharmacy, and HHS has not publicly commented on whether it intends to take any action to try to expand this number. Similarly, the D.C. Circuit suggests that while the statute does not "categorically prohibit manufacturers from imposing conditions" on contract pharmacies and the specific conditions at issue did not violate 340B "on their face," this conclusion "do[es] not foreclose the possibility" that the conditions could violate the 340B statute "as applied in particular circumstances" or that "other, more onerous conditions might violate the statute."

Additionally, in light of the Eighth Circuit's ruling that the 340B statute does not preempt state laws regulating contract pharmacy use, other states may enact similar laws. A number of states considered enacting 340B legislation in 2023, and stakeholders expect a similar trend in 2024. For example, on March 27, 2024, West Virginia became the third state to enact protections for 340B covered entities' use of contract pharmacies. More changes to state law could lead to legal challenges and litigation in other federal district and circuit courts, and conflicting rulings are possible, depending on how those courts rule on the preemption question. Litigation will also continue in the Eighth Circuit, because the district court has not yet ruled on whether the Arkansas law is invalid under the dormant Commerce Clause.

Amidst this litigation, several Members of the 118th Congress have expressed interest in making changes to the 340B statute. For example, in June 2023, a group of six Senators released a letter to stakeholders and the public seeking information on how Congress could "further the original intent of the [340B] program" and strengthen its ability "to support entities serving eligible patients." In February 2024, the group released a discussion draft of a bill to reform the program, along with a supplemental request for information highlighting stakeholder concerns about contract pharmacy use, the prevention of duplicate discounts, transparency issues, and ensuring that drugs are dispensed only to eligible patients. In late 2023 and early 2024, one Senator also requested information from 340B stakeholders, including FQHCs and contract pharmacies, as a part of his investigation into how certain entities generate revenue from the 340B program. Additionally, the House is considering legislation to address contract pharmacy use, such as the PROTECT 340B Act. Further congressional action to address these or other issues could impact the outcome of the litigation and the program as a whole.

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FEATURED

Experts say federal drug pricing program has been abused, misused

Thelma Grimes thelma.grimes@coloradopolitics.com
Nov 13, 2024

Dr. William Smith and Courtney Christian speak during The Hidden Costs in Colorado Healthcare panel on Tuesday, Nov. 12, 2024 in Denver, Colo.

Tom Hellauer

A program developed in the 1990s allowing healthcare organizations to purchase discounted outpatient drugs to help low-income patients has grown into a system of abuse and misuse without government oversight, according to industry insiders.

During a breakfast hosted by Colorado Politics in Downtown Denver on Tuesday, a panel discussed the state and national effects that the drug pricing program known as 340B is having on the healthcare industry. More specifically, the three-member panel talked about how much it costs the healthcare industry.

The federal 340B Drug Pricing Program allows eligible healthcare organizations to purchase outpatient drugs at a discount from manufacturers. The program was established in 1992 as part of the Public Health Service Act.

William Smith, senior fellow in life sciences at the Pioneer Institute, said that after the Affordable Healthcare Act was approved during the Obama Administration, more people became insured, and the 340B program evolved into something it was never intended to be, starting around 2010 and 2011.

Smith said pharmacy benefit managers (PBMs) and large hospitals have learned how to profit from the program. For example, a cancer drug costing around $200,000 is only $25,000 for hospitals with 340B status. However, the hospital is still billing insurance companies for $200,000 and “pocketing $175,000 in profits,” he said.

“That's really what's driving this program — is the ability of hospitals to arbitrage the discounts,” Smith said. “And what's happened is hospitals have gone out into wealthy neighborhoods and have purchased physician practices, particularly physician practices that prescribe high-cost drugs, like rheumatologists or oncologists, and they bought them up so that they could charge more to the discounts for profit.”

Smith said PBMs "rushed to this program because there's so much cash in it,” adding that reimbursements are higher than they would be through a regular commercial health plan.

When the program, which the Health Resources and Services Administration oversees, started in the 1990s, Smith estimated that only 500 entities were eligible. Today, that number has grown to 10,000 entities.

“And let me say something about hospitals because the implication might be that I’m critical of hospitals, and that’s not the case,” Smith said. “I have a very balanced view of hospitals.”

Smith said he knows of hospitals doing the work 340B is supposed to do by treating uninsured and low-income patients. However, he also knows of wealthy hospitals leveraging the program, while decreasing “charity-care” services.

The panelists said not all hospitals are exploiting the program and that it comes down to a “few bad actors.”

The result, the panelists stressed, is that insurance premiums go up and the costs are pushed onto employers.

In addition to employers, there is real concern about how the 340B program now affects patients, said Jonathan Campbell, chief science officer for the National Pharmaceutical Council.

Campbell, joining the healthcare breakfast virtually from Washington, D.C., said patients might not be positively affected by 340B when there is a “buy low, sell high” approach to patient care.

“Buy low, sell high means that payers are paying the highest amount,” Campbell said. “Often an unrelated amount for medicines. And those concerns are that employers are not receiving the discounts.”

Patients and employers are footing the bill for overbilling to the tune of $5 billion, Campbell said.

Courtney Christian, deputy vice chair of policy and research for PhRMA who also attended the panel in person, said the solution could not be to eliminate the 340B program because it has value to hospitals when applied correctly, noting that its primary purpose is to help patients in need and support charitable programs.

Christian described a bleak picture of the program's continued growth.

PhRMA estimated that 57% of all hospitals in the U.S. participate in 340B, with discount program purchases reaching an estimated $54 billion in 2022, a 23% increase from 2021.

PhRMA data shows that the number of contract pharmacies participating has grown by 8,000% since 2010.

In Colorado, 64 hospitals participate in the 340B program. PhRMA estimated that there were 1,118 contracts between Colorado 340B hospitals and pharmacies nationwide.

Christian said only 25% of the contract pharmacies are in medically underserved areas.

According to PhRMA data, hospitals in Colorado make 2.8 times as much from 340B as they spend on charity care.

Meanwhile, Christian said there are still 40 million uninsured citizens who need programs like 340B.

A federal fix

When asked if states can adopt a policy to fix the problem, Reid Porter, senior director of public affairs for PhRMA, said 340B is a federal program that “is in desperate need of a federal fix.”

Christian said state lawmakers could help by putting pressure on Congress to update policies and require more hospital accountability.

Smith said the biggest problem is transparency. As the policy currently stands, hospitals are not required to report the charity projects the funds are going toward.

Christian and Smith agreed that simply requiring hospitals to report how much in 340B funds they are receiving and where they are spending them could solve many of the issues.

Smith warned that the hospital lobby is strong and could deter Congress from acting.

Christian said some members of Congress are reviewing the data and considering updating the 340B policies that have not changed since being approved over 30 years ago. She said there is hope for some progress in the 2025 session.

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Thelma Grimes
Deputy Reporter

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BLOG

Next Congress must address 340B abuse

Oct 18, 2024

In 1992, Congress established a program to help low-income patients access medications they couldn't afford. The law required drug companies to offer substantial discounts to hospitals and clinics serving financially vulnerable patients, known as 340B hospitals, with the intent to use discounted drugs for charity care.

However, the law lacks accountability for how hospitals use these savings. Currently, 340B hospitals use only 42% of the billions in discounts to aid low-income patients. These hospitals often buy drugs at a discounted price but sell them to patients at full price.

A new report shows that 340B abuse not only fails to help low-income patients but also increases the federal deficit and raises costs for employer-based health plans. Last year, 340B discounts totaled around $70 billion, shifting this amount from for-profit pharmaceutical companies to tax-exempt nonprofit entities. This shift led to an estimated $14 billion in lost federal tax revenue.

Additionally, 340B impacts employer-provided health plans by reducing rebates from pharmaceutical manufacturers to health plans or pharmacy benefit managers. This results in employers and employees losing some or all of the rebates they would have otherwise received if claims were not 340B eligible.

Sen. Kennedy (R-La.) has introduced the 340B Reporting and Accountability Act, which aims to increase transparency and ensure that 340B entities provide drugs at a price that does not exceed what they paid. However, no action has been taken on the bill, and it is unlikely to advance during the lame-duck session.

The lack of congressional action is frustrating, as the funds are available to reduce costs for low-income patients but are currently directed toward hospital profits. The Colorectal Cancer Alliance is working with coalitions like Air 340B to push for reforms, making 340B accountability a priority for 2025.

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