2025 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1473

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB 1473
2/10/2025

A BILL for an Act to create and enact a new subsection to section 43-15.3-08 of the North Dakota Century Code, relating to prohibited acts of drug manufacturers; and to provide a penalty.

2:29 p.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Member Absent: Representative Christy

Discussion Topics:

- 340B Program
- Under insured
- Contract pharmacy restrictions
- Critical access medication
- Drug manufacturers limiting pharmacy access
- Duplicated discounts
- Penalties over licensure
- Dollars in drug programs

2:30 p.m. Representative Jon O. Nelson, District 14, Rugby, ND, introduced and testified.

2:33 p.m. Eric Christensen, CEO, Heart of America Medical Center, testified in favor and submitted testimony #36564.

2:44 p.m. Mike Schwab, Executive Vice President, ND Pharmacists Association #36788.

3:00 p.m. Erin Navarro, Grand Forks, ND, testified in favor and submitted testimony #36587.

3:17 p.m. Alyssa Wolden, Director of Pharmacy, Coal Country Community Health Center & Sakakawea Medical Center, testified in favor and submitted testimony #36689.

3:23 p.m. Dr. Aaron M. Garman, Medical Director, Coal Country Community Health Center, testified in favor and submitted testimony #36374.

3:27 p.m. Jesse Breidenbach, VP Pharmacy, Sanford Health, testified in favor.

3:32 p.m. Jessica Lynch, Director of State Policy, PhRMA, testified in opposition and submitted testimony #36757

3:40 p.m. Chairman Warrey called a 5-minute recess.

3:49 p.m. Kent P. Kaiser, Secretary/Treasurer, Domestic Policy Caucus, testified (online) in opposition and submitted testimony #36446.

3:57 p.m. Mark J. Hardy, Executive Director, ND Board of Pharmacy, testified as neutral and submitted testimony #36651.

Robert Popovian, Visiting Health Policy Fello, Pioneer Institute, testified (online) as neutral and submitted testimony #36278.

Additional written testimony:
Dustin Gawrylow, North Dakota Watchdog Network, submitted testimony in opposition #36361.
Leah M. Vukmir, Brookfield, WI, submitted testimony in opposition #36540.
Willliam S. Reid, Vice President, State Government Affairs, Lilly, submitted testimony in opposition #36549.
Tim Blasl, President, ND Hospital Association, submitted testimony in favor #36570.
Shelly Ten Napel, CEO, Community HealthCare Association of the Dakotas, submitted testimony in favor #36696
Rayette Brown, WomenHeart Jamestown, submitted testimony in favor #36744.
Gentry Collins, CEO, American Free Enterprise Chamber of Commerce, submitted testimony in opposition #36752.
Kalvin Pugh, State 340 Policy director, Community Access National Network, submitted testimony in opposition #36762.
Justin Forde, Americans for Prosperity North Dakota, submitted testimony in opposition #36765.
Jack Baum, Americans for Tax Reform, submitted testimony in opposition #36866.
4:30 p.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk

House Industry, Business and Labor Public Hearing
HB 1473
Relating to prohibited acts of drug manufacturers

Dear Committee Chair and Members:
Thank you for allowing me to provide you with the following written testimony concerning HB 1473. I am providing this testimony as a neutral observer. All of the data provided in this testimony is available online through a tool developed by the Pioneer Institute utilizing data from the Health Resources and Services Administration (HRSA) and Rand Corporation. The website for the tool is https://pioneerinstitute.org/340babuse/. The information I am providing summarizes the findings regarding the 340B program in North Dakota.

Key Points:
• North Dakota's low-income taxpayers are required to utilize for-profit 340B contract pharmacies in Hawaii and California, amongst many other states.
• **70%** of the contract pharmacies intended to serve poor patients in North Dakota are located in affluent neighborhoods.
• North Dakota 340B hospitals (**0.90%**) provide less charity care than the national average (**2.15%**).

Total number of contract pharmacies intended to serve needy patients in North Dakota – **261**
Number of contract pharmacies intended to serve North Dakota's needy patients that are located outside of North Dakota – **134**
Summary: **51%** of 340B pharmacies serving poor patients in North Dakota are located outside the state.

Top 5 340B Hospitals in North Dakota and Percentage of Contract Pharmacies Outside the State Lines
SANFORD MEDICAL CENTER FARGO (69%)
SANFORD BISMARCK (54%)
INNOVIS HEALTH (76%)
ALTRU HOSPITAL (71%)
NELSON COUNTY HEALTH SYSTEM-HOSPITAL (70%)

Summary: **67%** of 340B contract pharmacies for North Dakota's Top 5 340B hospitals are based outside the state.

Distribution of contract pharmacies in the State of North Dakota in affluent and poor neighborhoods
Summary: **70%** of the 340B pharmacies supposedly serving the poor are in affluent neighborhoods in North Dakota.

Most out-of-state contract pharmacies providing care for North Dakota patients are owned by for-profit chain drug stores or pharmacy benefit management (PBM) companies.

Provision of charity care: North Dakota hospitals eligible for the 340B discount provide less charity care (**0.90%**) than the national average for similar hospitals (**2.15%**).

North Dakota hospitals eligible for the 340B discount provide only (**0.53%**) charity care for uninsured patients.

The top North Dakota hospital with the highest operating expenses eligible for 340B discounts provides more charity care (**1.06%**) than the state (**0.90%**) but less than the national average (**2.15%**).

The questions the committee should consider are:
1. Why so many contract pharmacies?
2. Why are there so many contract pharmacies outside North Dakota, as far as Hawaii and California?
3. Why are so many contract pharmacies in affluent neighborhoods instead of poorer neighborhoods where patients live?
5. Why do the institutions eligible for 340B discounts in North Dakota provide less charity care than the national average?

340B is a great program that ought to be preserved. Unfortunately, large hospitals and contract pharmacies have taken over the program without much accountability.

The 340B program requires more transparency, not less. In fact, through transparency, pharmacies, and institutions that do right by patients will be rewarded. The prohibition of biopharmaceutical companies from determining whether a drug was dispensed for an eligible 340B patient through contract pharmacies creates an environment for further opacity and potential for abuse.

Federal law explicitly prohibits "duplicate discounts," where manufacturers must give both a steep 340B discount to hospitals and substantial rebates to State Medicaid programs for the same dispensed drug for the same patient. That's why biopharmaceutical companies need the information to ensure compliance with federal law. The General Accountability Office (GAO) has already voiced their opinion that the potential for noncompliance is a reality.

The passage of legislation denying the need for transparency and provision of data by contract pharmacies to ensure that the right patients benefit from this program is a step in the wrong direction.

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

Ryan P Knox [1,2], Junyi Wang [2], William B Feldman [2,3], Aaron S Kesselheim [2], Ameet Sarpatwari [2,✉]

Author information Article notes Copyright and License information

PMCID: PMC10665972 PMID: 37991784

This article has been corrected. See JAMA Health Forum. 2024 Sep 27;5(9):e243404.

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.

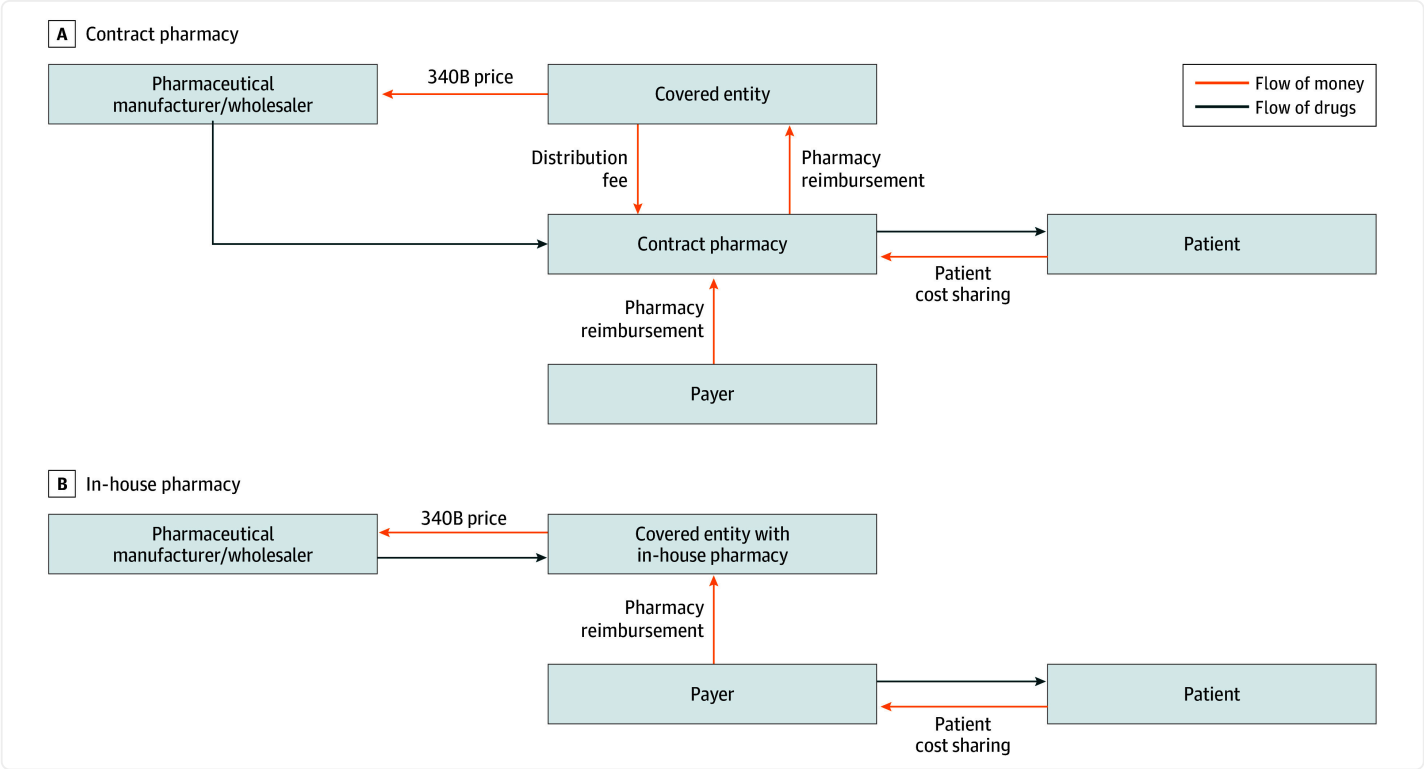
Introduction

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.

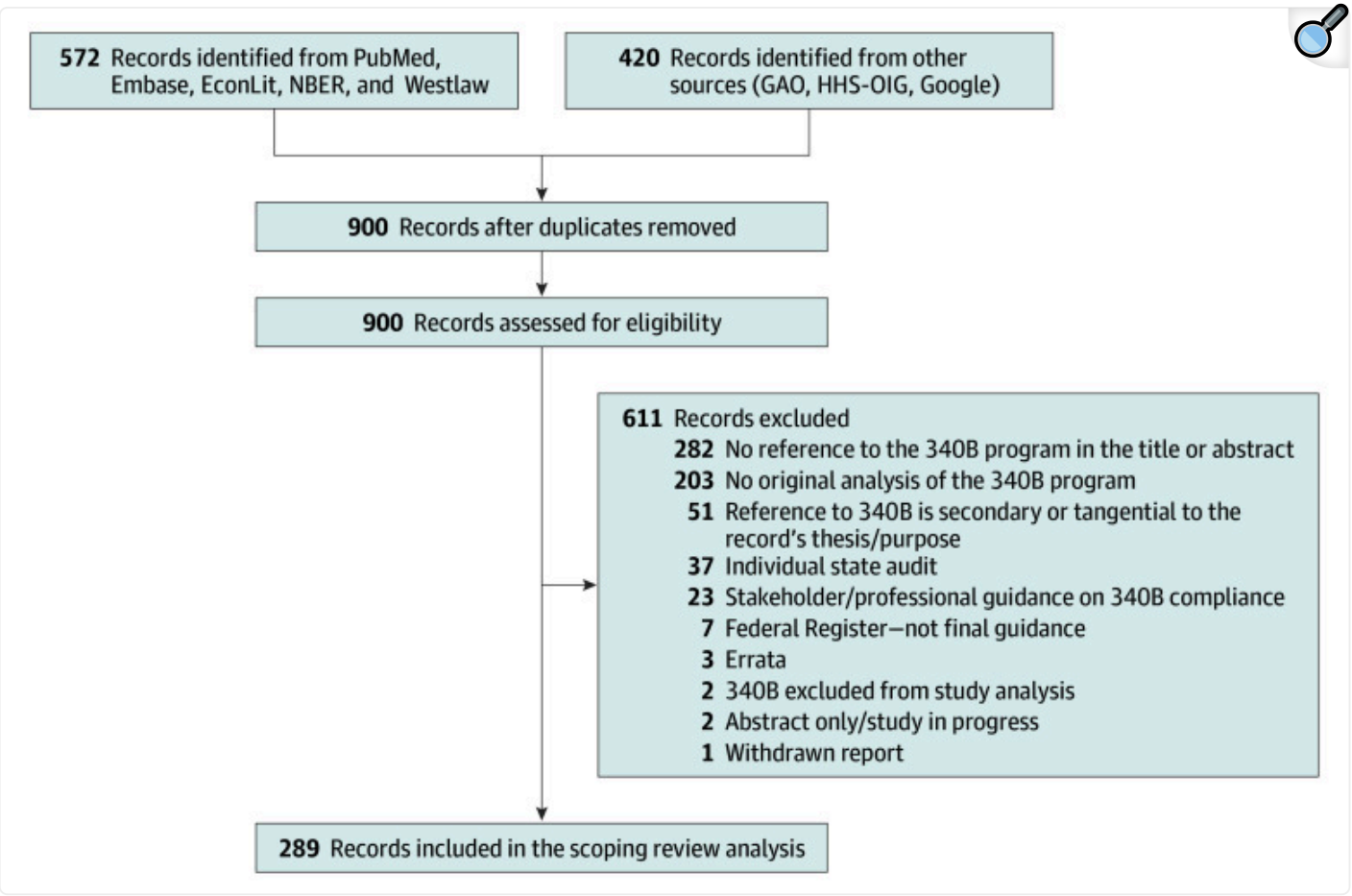
Critics of the 340B program, led by the pharmaceutical industry, have expressed concern about the program's growth in recent years.[13] We conducted a scoping review to assess the foundations of and outcomes associated with the 340B program.

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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https://www.coloradopolitics.com/news/340b-program-abuse-costs/article_617e9d9c-a20c-11ef-b2ab-63bc2a1d1e4f.html

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.

YES NO

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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1025 Vermont Ave NW, Suite 1066. Washington, DC 20005

Testimony in support of:

House Bill 1473, with the 2025-2027 Industry, Business and Labor

Recommendation to prohibit acts of drug manufacturers; and to provide a penalty.

February 10, 2025

Chairman Warrey, Vice Chair Johnson and Members of the Committee,

My name is Dr. Aaron Garman, and I am a Family Physician practicing in rural North Dakota for the past 25 years. For the last 22 years, I have also had the privilege of serving as the Medical Director of a Community Health Center in Beulah, ND, with additional sites in Center, Killdeer, and Hazen. Over the years, I've been deeply involved in the 340B program, both administratively and in direct patient care.

When I first began practicing, the challenge of affording necessary medications was an all-too-common and heartbreaking reality for many of my patients. I often had discussions with patients about treatment options, only to have them tell me, "Doc, I just can't afford that pill." It was devastating to know that these patients—many of them farmers and ranchers—had to choose between life-saving medications for conditions like diabetes, heart disease, and stroke prevention, and basic necessities like feeding their families.

In those early years, we did everything we could to help, including Dr. Jackson, my colleague, who would occasionally pay out of his own pocket to cover the cost of medications for patients who needed them the most. This approach was not sustainable, and it highlighted a painful gap in our healthcare system: the ability to access the treatments they desperately needed.

Everything changed when we became a Federally Qualified Health Center in 2003, granting us access to the 340B program. With 340B, we could provide medications to these same patients at a nominal cost, ensuring they receive the care they needed without having to make impossible choices. Thanks to this program, I no longer have those difficult conversations with patients. I no longer must watch them struggle to choose between essential care and putting food on the table.

The impact of 340B has been nothing short of transformative. In addition to providing medications, this program has enabled us to reinvest savings into other crucial services for our community. These funds have been vital in supporting our *Impact Program*, which offers mental health counseling in schools for elementary, middle, and high school students. The 340B program also supports our Behavioral Health and Medication Assisted Therapy programs—critical services for individuals facing mental health challenges and addiction issues in our rural community.

However, the future of the 340B program is under threat. Pharmaceutical companies are making it increasingly difficult for health centers like mine to access the program, setting up barriers that are frustrating and time-consuming. While these changes may not be immediately fatal, they create a thousand small cuts that slowly erode the very foundation of this program.

I urge you to understand that the 340B program is not just a benefit to health centers; it is a lifeline for patients who would otherwise go without essential medications, and it ultimately helps to lower overall healthcare costs by preventing expensive emergency room visits and hospitalizations. Furthermore, it supports programs that are essential for the mental and behavioral health of our most vulnerable residents.

The 340B program is not a tax on North Dakota citizens, nor is it a burden on pharmacies. Rather, it is a crucial tool that helps communities like mine thrive by ensuring access to affordable healthcare. It may be a challenge to pharmaceutical companies, but I believe it is a challenge they should embrace, knowing the good it does for patients and communities.

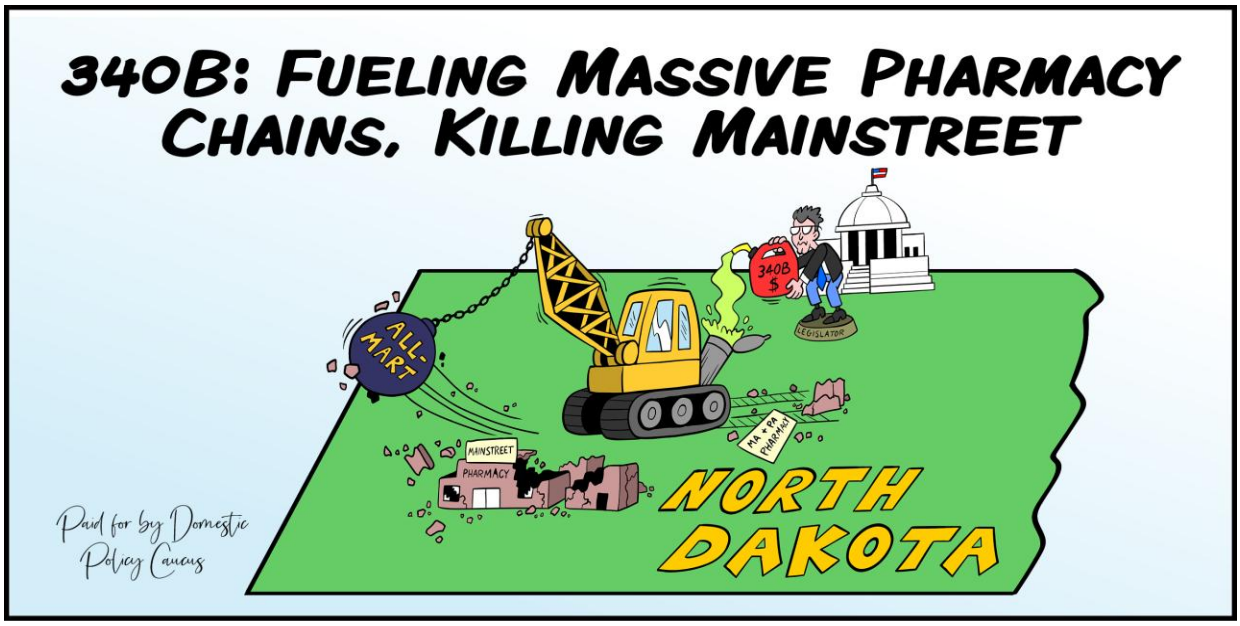
For those of us in rural North Dakota, the 340B program has been a lifesaving, life-altering resource that our patients, families, and friends depend on. I hope that you will continue to support this program and protect the ability of centers like mine to serve those who need us most.

Thank you for your time and consideration.

Respectfully submitted,

Aaron Garman, MD

Domestic Policy Caucus
Testimony Opposing HB1473 – House Industry, Business, and Labor Committee
February 10, 2025



On behalf of the Domestic Policy Caucus, I am writing to express our opposition to the expansion of 340B, the federal law on prescription drugs, in North Dakota, as contained in HB1473.

If they were made aware of it, most North Dakotans probably would find it baffling that their state legislators are considering the expansion of a massive federal healthcare mandate. It's troubling that this appears to be occurring with little discussion about the financial impacts of the policy or the impact on rural North Dakota.

The law was meant to help low-income people afford their medicines. Unfortunately, The financial benefits of the 340B discounts are accruing almost entirely to hospitals, clinics, and physicians; and patients' out-of-pocket costs are increasing, and that's according to the JAMA. Indeed, the profit has become a major revenue source for some providers, with little to no benefit for the patient.

What's more is that an expansion of 340B would hand over even more economic power to massive, national chain pharmacies—so called contract pharmacies—that have driven so many local, mom-and-pop pharmacies out of business over the past several years. Haven't the likes of Walmart and Walgreens done enough to harm main streets across North Dakota?

An expansion of 340B would create an economic environment in which incentives would be put in place to encourage even more consolidation of healthcare systems, to put healthcare farther

out of reach of rural North Dakotans, and to imperil the ability of underserved residents to receive the care and discounts they need, all while lining the pockets of big healthcare systems and giant chain pharmacies. Meanwhile, it would do nothing to reduce patient costs, which is what everyone really wants.

As you know, pharmacies are essential to the communities they serve. But in North Dakota and throughout America, independent drugstores are struggling.

In a 2022 policy brief, the Rural Policy Research Institute reported this troubling fact: The number of independently owned retail pharmacies declined by 16 percent in the United States between 2003 and 2021. According to NPR, that has contributed to the appearance of what are called "pharmacy deserts"—areas where residents must drive more than 15 minutes to a drugstore. In fact, according to a 2021 report issued by GoodRx called "Mapping Credit Deserts," of all the states, North Dakota has among the most counties having insufficient access to a drugstore. Expanding 340B would exacerbate the problem.

Disparities in access to care and health outcomes for rural, underserved, and minority populations have long been significant issues. Any policy that could further restrict the accessibility of medicines to these populations—like forcing them to travel farther to obtain them—needs to take the issue of health equity into consideration.

Making a bad program bigger is not the answer. The 340B program should be fixed before there's any discussion about expanding it. You should provide oversight to hold covered entities responsible for delivering on 340B's stated purpose. Simply defining who is a 340B patient and ensuring the money flows to those eligible patients—instead of big box pharmacies and hospital systems—is a commonsense first step.

The bottom line: There should be much more discussion, analysis, and debate before determining whether to head down this uncertain and troubling healthcare policy path.

Don't be like the legislator in our cartoon: Please vote "no" on HB1473 and expanding 340B in North Dakota.

Thank you,

Kent Kaiser, Ph.D.
Secretary/Treasurer
Domestic Policy Caucus
651-338-1777
www.domesticpolicycaucus.com

Monday, February 10, 2025

The Honorable Jonathan Warrey
North Dakota House Industry, Business and Labor Committee
600 E. Boulevard Avenue
Bismarck, ND 58501

Dear Chairman Warrey and members of the North Dakota House Industry, Business and Labor Committee,

On behalf of National Taxpayers Union (NTU), America's oldest taxpayer advocacy organization, I respectfully urge you to oppose HB 1473, a bill which would ban prescription drug manufacturers from imposing reasonable limits on contract pharmacies and Pharmacy Benefit Managers (PBMs) for procuring heavily discounted drugs offered through the federal 340B program.

I have three lenses from which to observe and analyze the merits and flaws of the 340B program. First, as a former pediatric nurse practitioner who worked with the very patients for whom this program was designed. I have personally witnessed the value this program has provided in its original intent and design.

Second, I look at this issue through the lens of a former state senator who served on the finance committee in my home state of Wisconsin where, as you are well aware, decisions regarding the allocation of precious taxpayer dollars can be quite contentious and challenging. I understand the pressure you are under to make sure these dollars are spent wisely and efficiently and that those in most need of government assistance are prioritized.

And lastly, I look at this program in my current role as senior VP of state affairs for National Taxpayers Union where I am in a position to advocate on behalf of taxpayers across the entire country.

With that as a backdrop, let me implore you to fully and thoughtfully evaluate this issue before being swept into supporting legislation that will harm those who desperately rely on the helping hand of government. As you know, the 340B federal drug program was conceived as a targeted

method of providing affordable medicines to low-income and uninsured families. Since its creation in 1992, the 340B program has become controversial amid allegations that providers are "gaming" its structure to earn revenues and distribute medications well outside the communities the program was supposed to serve.

What do I mean by "gaming" the structure? As the 340B program has expanded, it has been criticized for an overall lack of transparency and accountability resulting in the ability for entities who receive discounted drugs from pharmaceutical companies to profit from the discount instead of assisting poorer patients.

Additionally, instead of serving the most vulnerable as the program was intended — those living in low-income areas — there has been a proliferation of 340B pharmacies in more affluent neighborhoods. These expansion pharmacies are owned by for-profit Pharmacy Benefit Managers (PBMs) and chain drug stores. A 2024 Pioneer Institute Report, found 70% of 340B North Dakota pharmacies supposedly serving the poor are in affluent neighborhoods. The report also found that North Dakota's 340B hospitals provided a mere 0.87% charity care component, compared to the national average of 2.28%. A goal of the 340B program, from its inception, was to pass the discounted savings afforded by the pharmaceutical companies on to the needy through charity care. This does not appear to be occurring in North Dakota.

Rather than expand the 340B program to more entities, the North Dakota Legislature ought to support measures to increase transparency and accountability for participating pharmacies and hospitals and to share this information with members of your federal delegation. The 340B program is a federal program and care should be taken to not codify state law to include aspects of a poorly designed federal program. Indeed, NTU is among many organizations that has advocated reforms to 340B through Congress.

Additionally, as you examine HB 1473, please consider the effects this bill may have on overall healthcare spending in your state, specifically the cost of providing healthcare to the nearly 10,000 North Dakota state employees. Many 340B entities are billing insured patients in state health plans at higher costs than their discounted acquisition costs. In the case of state employees, this means their copays are based on a list price not the discounted price. A recent report released by North Carolina State Treasurer Dale Folwell shows the extent to which hospitals in the 340B Program in North Carolina are overcharging cancer patients through the state's health plan. Patients are being charged at an average rate greater than five times the cost of cancer drugs. These higher rates are being borne on the backs of patients and all taxpayers in North Carolina. This report only considers cancer medications, so the full extent to which patients and taxpayers are being burdened is not known. Currently, the North Carolina State Health Plan faces a $32 billion unfunded healthcare liability.

One final - and not minor - reason to reject HB 1473 is the very real constitutional concern this bill raises. The 340B program is wholly governed by federal law, therefore states are not in a position to create additional requirements to the program. Based on our research, some half dozen states are currently embroiled in lawsuits over this issue. Also, just this past December, the U.S. District Court for the Southern District of West Virginia enjoined that state's 340B law once it appeared likely that the plaintiffs would succeed on their claim that the federal law superseded state law.

Given all of the concerns raised here, I urge you to oppose HB 1473 and instead work to develop measures for evaluating a federal program that is clearly fraught with controversy. I understand what it is like to be in your shoes as stewards of the taxpayers. You face significant pressure to properly utilize and allocate precious taxpayer dollars to your citizens and to programs designed to provide a helping hand to those in need. Support for this bill puts these individuals at greater risk - a consequence I know you would not intend.

Please do not hesitate to contact me if you have further questions or concerns.

Respectfully submitted,

Leah Vukmir
Senior Vice President of State Affairs
National Taxpayers Union
lvukmir@ntu.org

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February 10, 2025

The Honorable Representative Jonathan Warrey, Chairman
House Industry, Business and Labor
North Dakota House of Representatives
1321 Morningside Drive
Casselton, ND 58012-3716

Dear Chairman Warrey,

I am writing to express Eli Lilly and Company's opposition to House Bill 1473 (HB 1473), which proposes to alter the federal 340B program by requiring that pharmaceutical manufacturers extend federal 340B discounts to for-profit contract pharmacies. Not only would HB 1473 expand the 340B program – a program that recent studies have shown results in higher costs for patients and payers – but it would also go further than any other existing state law in intruding into an exclusively federal program, making it patently unconstitutional. In fact, West Virginia was recently enjoined from implementing a less aggressive proposal. For these reasons, we encourage the legislature to focus on reforms that help ensure patients benefit from the discounts and rebates that are paid into the healthcare system.

1. **Although the 340B program has exponentially expanded,[1] patients do not benefit from the 340B program. In fact, patients' costs may go up.**

Recent studies demonstrate that participation in the 340B program does not result in additional patient benefit – at the pharmacy counter or otherwise. For example, the North Carolina State Treasurer's Office recently found that North Carolina 340B hospitals charged cancer patients – on average – 5.4 times more than what the hospitals paid to acquire the oncology medicines.[2] In addition, the New York Times recently reported that a New Mexico 340B hospital charged an *insured* patient in New Mexico more than $2,500 for her cancer drug, more than half her take-home salary for a month. Even though the medicine's *list price* was about $2,700, and the hospital purchased the medicine for less than $2200, the hospital billed Mrs. King's insurance company $22,700.[3] This is consistent with our experience. 340B hospitals are able to purchase many of our insulins for a penny per milliliter (mL), but contract pharmacies frequently charge patients significantly more. For example, one pharmacy we interviewed marked up the price of a vial of insulin over 330,000%, charging an uninsured patient over $500 for a product they purchased for 15 cents.

Although proponents of state 340B contract pharmacy bills argue that 340B profits are used to help patients in other ways, data show this is false – 340B hospitals do not spend more on charity care than non-340B hospitals. For example, the North Carolina Treasurer's Office concluded that

[1] In 2023, the number of hospitals participating in the 340B program has grown from 45 to more than 2,600. The number of contract pharmacy arrangements has grown over 9,500% from 2,300 to 220,000, and discounted purchases have reached a record $66.3 billion. See: https://www.gao.gov/products/gao-23-106095; https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html; https://www.drugchannels.net/2024/10/hospitals-are-relying-more-on-pbms-to.html

[2] ttps://www.shpnc.org/what-the-health/north-carolina-340b-hospitals-overcharged-state-employees-cancer-drugs.

[3] https://www.nytimes.com/2025/01/15/us/340b-apexus-drugs-middleman.html. A 340B hospital's purchase price generally will be at least 23% less that the medicine's list price.

the vast majority of 340B hospitals did not provide enough charity care to equal the estimated value of their tax exemptions and were among those that reported the **lowest investments in charity care** from 2011 to 2021.[4] Another study found that "at least 56% of 340B profits do not go to patients in any form."[5] And another found that 340B hospitals make up all 10 of the non-profit hospitals found to provide the least amount of community benefit relative to the value of their tax breaks.[6]

2. **Large hospitals and for-profit pharmacies are benefiting from the expansion of the 340B program through contract pharmacy arrangements – smaller hospitals and payers (like Medicaid) are not.**

A first of its kind report from Minnesota highlights how large hospital systems and their contract pharmacies are using the 340B program to increase their profits. The Minnesota Department of Health determined that large 340B hospitals benefited the most from the program, accounting for only 13% of all entities **but comprising 80% (approximately $500 million)** of state 340B revenue.[7] Additionally, the report found that one out of every six dollars in 340B profit went to for-profit contract pharmacies or other vendors, underscoring the significant share of financial benefits captured by these entities. In fact, certain small grantees **reported losing money** on 340B purchases as a result of payments to contract pharmacies and other vendors.

One state concluded that "[t]oo many hospitals have converted the 340B drug discount program into a **profit center** at the expense of state employees, cancer patients, and taxpayers."[8] For example, North Carolina found that 340B hospitals charged higher rates – billing 84.8% higher prices on average than non-340B hospitals. And recent studies revealed that the growth in 340B provider participation drove an increase in Medicaid spending of $1100 per patient,[9] and over $32 billion per year.[10]

3. **State proposals to modify the federal 340B program are unconstitutional.**

HB 1473 would expand the ability of for-profit pharmacies and large hospital systems to use the 340B program to generate profit at the expense of patients. Doing so raises significant legal concerns, both under the United States Constitution and in light of several recent court rulings. In particular, on December 17, 2024, a federal district court judge ruled that West Virginia's contract pharmacy law (SB 325) is unconstitutional and officials cannot enforce the law while three drug

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[4] https://www.shpnc.org/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment

[5] N. Masia and F. Kuwonza, Health Capital Group, Measuring the 340B Drug Purchasing Program's Impact on Charitable Care and Operating Profits for Covered Entities, 2022.

[6] Lown Institute 2022 Hospitals Index, https://lownhospitalsindex.org/2022-fair-share-spending/. *See also* New England Journal of Medicine, "Consequences of the 340B Drug Pricing Program." (2018). Consequences of the 340B Drug Pricing Program | NEJM (finding that although 340B hospitals purchase drugs at steep discounts the "[f]inancial gains for [340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.").

[7] The report excluded physician administered drugs, which the state believed resulted in under reporting of 2-3X 340B revenues. https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

[8] https://www.shpnc.org/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment (emphasis added).

[9] Jung, J., Xu, W.Y. and Kalidindi, Y. (2018), Impact of the 340B Drug Pricing Program on Cancer Care Site and Spending in Medicare. Health Serv Res, 53: 3528-3548. https://doi.org/10.1111/1475-6773.12823.

[10] https://www.healthcapitalgroup.com/340b-and-total-medicaid

industry legal challenges play out.[11] SB 325, like the North Dakota bill, would have required that manufacturers extend discounts to contract pharmacies and would have prohibited manufacturers from requiring claims data submissions. For example, the court found that the claims data provision conflicted with the 340B statute's goal of preventing fraud by putting covered entities in control of whether manufacturers can audit. As the court aptly put it, the "340B Program certainly did not establish a system where the fox guards the hen house." North Dakota's proposed HB 1473 goes further than the West Virginia bill, attempting to prohibit "offers" in the "form of a rebate," a concept explicitly allowable under federal law. Such prohibition is not only clearly preempted, but it also risks prohibiting the form of in-kind rebates that are used pervasively today.

4. Lawmakers should focus on reforms that benefit patients, not big business.

Lilly supports other state policies that make medicines more affordable for patients such as first dollar coverage for insulin, cost-sharing based on net price, ensuring patients benefit from cost-sharing assistance at the pharmacy counter, and increasing awareness of affordability programs. We commend North Dakota for passing policies such as copay caps for insulin and we encourage the legislature to evaluate other policies that have a more direct impact on patients' out-of-pocket experiences. We would welcome the opportunity to speak with you about these policies.

* * * * * * *

We appreciate the opportunity to express our views on HB 1473. Given the bill does not advance patient drug affordability goals, and raises serious federal preemption concerns, we respectfully request that you oppose.

Sincerely,

William S. Reid

William Reid
Vice President
State Government Affairs
Eli Lilly and Company

[11] *Pharm. Rsch. & Mfrs. Of Am. v. Morrisey*, 2024 U.S. Dist. LEXIS 227964 (S.D.W.V. Dec. 17, 2024); *See also Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023) (holding that the government cannot require manufacturers to "[deliver] discounted drugs to an unlimited number of contract pharmacies," and that "drug makers' policies [with respect to contract pharmacies] are lawful); *Novartis v. Johnson*, No. 21-5299, (D.C. Cir. May 21, 2024) (rejecting "HRSA's position that section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities").

HEART OF AMERICA
MEDICAL CENTER

Heart of America Medical Center
2975 Hwy 2 east
Rugby, ND 58368
(701) 776-5261

February 9, 2025

Industry, Business, and Labor Committee
600 East Boulevard Avenue
Bismarck, ND 58505

Subject: Support for HB 1473: Prohibited Acts of Drug Manufacturers

Dear Committee Members,

I am writing to express my support for HB 1473 and for the strengthening of rural health care quality and access. This legislation would help ensure the 340B program is carried out in the spirit that is was originally intended, namely for the benefit of underserved patients.

The original intent of the 340B Drug Pricing Program, established in 1992, was to provide financial relief to healthcare organizations that serve uninsured and low-income patients, allowing them to stretch scarce resources and provide more comprehensive care. The program was created under the Veterans Health Care Act of 1992 and requires pharmaceutical manufacturers that participate in Medicaid to offer discounted outpatient drugs to eligible healthcare facilities. Drug manufactures are not required to publicly report their profits by participating in the Medicaid Drug Rebate Program, but this does require them to participate in the 340B program. The dollars that are part of the 340B program are not funded by the taxpayers, but rather the 340B funds are a portion of the savings that drug manufacturers earn by participating in the rebate program.

As a health care provider, administrator, and a patient of a critical access hospital I know firsthand the importance of local rural health care. This care absolutely saves lives. However, this care is not fully paid for by many of our various revenue streams. For example, at the Heart of America Medical Center we lose about $400,000 dollars every year by operating our EMS service, $70,000 yearly for day care, $20,000 for diabetes education, and we must spend about $2,000,000 annually on contract labor primary for elder care needs. We also provide about $250,000 annually in the form of charity care. The 340B program helps to offset these expenses and allows us to continue these services.

As a health care facility, we are more than happy to make this data clearly available to the public. In fact, HAMC has developed a report to clearly track savings from the 340B program. These savings have been used to ensure a functional EMS program, a diabetes educator, and a fully staffed swing-bed and acute care departments. It should also be noted that over the past few years many requirements from drug manufactures have attempted to erode 340B savings for rural health care, while our expenses continue to rise. If this trend continues services will be cut for our rural communities.

HEART OF AMERICA
MEDICAL CENTER

Heart of America Medical Center
2975 Hwy 2 east
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Our rural hospitals have nothing to hide regarding the 340B program. However, we do need this program to remain robust and functioning as the original intent has been generally understood. If this program is significantly inhibited, services will be lost for our low-income and uninsured rural residents.

I urge you to support HB 1473 and support policies that strengthen quality and access to rural health care. Thank you for your time and consideration.

Sincerely,

Erik Christenson
CEO

2025 HB 1473

House Industry, Business and Labor Committee

Representative Jonathan Warrey, Chairman

February 10, 2025

Chairman Warrey and members of the House Industry, Business and Labor Committee, I am Tim Blasl, President of the North Dakota Hospital Association. I am here to testify in support of House Bill 1473. I ask that you give this bill a **Do Pass** recommendation.

This bill aims to create a new subsection to section 43-15.3-08 of the North Dakota Century Code, related to prohibited acts of drug manufacturers; and to provide a penalty.

Hospitals support this bill because it would help strengthen the 340B program. The 340B program was created by congress over 30 years ago. The program requires drug manufacturers to provide outpatient drugs at reduced prices to eligible health care organizations that serve more low-income and underserved patients. Pharmaceutical companies are incentivized to offer these discounts to eligible health care providers in exchange for coverage of these drugs by Medicaid and Medicare.

The 340B program allows eligible hospitals to stretch limited federal resources to provide more affordable health care services to the patients they serve. The program savings have allowed North Dakota hospitals to maintain or enhance health care services in their communities.

Today, the Health Resources and Services Administration (HRSA) administers the 340B program. HRSA does allow covered entities to contract with pharmacies to dispense drugs on their behalf to their eligible patients. Contract pharmacies serve as an extension of the 340B covered entity.

HRSA does conduct audits of covered entities to ensure they are complying with 340B rules and regulations. These audits ensure that 340B drugs are being given only to eligible patients. Also, covered entities conduct self-audits to make sure they are following program rules.

We ask that you give the bill a **Do Pass** recommendation because this legislation aims to ensure that patients have access to discounted drugs. Thank you.

Respectfully Submitted,

Tim Blasl, President
North Dakota Hospital Association

2025 1473
House Industry, Business and Labor
Representative Warrey, Chairman
February 10, 2025

Chairman Warrey and members of the House Industry, Business and Labor Committee. My name is Erin Navarro, and I serve as the Director of Pharmacy at Altru Health System (Altru). I am honored to represent Altru and share my passion for ensuring patients remain at the heart of everything we do in healthcare and proud to be part of improving healthcare for the communities we serve. I write in favor of House Bill 1473 and ask that you give this bill a **Do Pass** recommendation.

Sole Community Hospital

Altru is a Sole Community Hospital (SCH) and 340B Drug Pricing Program covered entity, serving over 200,000 residents in northeast North Dakota and northwest Minnesota. As a covered entity and health system, Altru ensures that care is provided to our patients regardless of their ability to pay. To be designated as a SCH, a hospital must meet specific criteria set by the Centers for Medicare & Medicaid Services (CMS). Here are the key requirements:

1. **Location**: The hospital must be located more than 35 miles from other like hospitals. Alternatively, if the hospital is in a rural area, it can be located between 25 and 35 miles from other like hospitals, provided it meets additional criteria such as having no more than 25% of residents or Medicare beneficiaries in the hospital's service area admitted to other like hospitals within a 35-mile radius.
2. **Special Circumstances**: The hospital can also qualify if it is located between 15 and 25 miles from other like hospitals but is inaccessible for at least 30 days in each of 2 out of 3 years due to local topography or severe weather conditions.
3. **Service Area**: The hospital must draw at least 75% of its inpatients from its service area during the most recent 12-month cost reporting period.

Regarding the impact on 340B eligibility, Sole Community Hospitals must meet additional requirements to participate in the 340B Drug Pricing Program:

1. **Disproportionate Share Adjustment**: The hospital must have a disproportionate share adjustment percentage greater than or equal to 8% for the most-recently filed cost report.
2. **Non-Profit Status**: The hospital must be a private non-profit hospital under contract with state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid, or it must be owned or operated by a unit of state or local government.
3. **Certification**: The hospital must certify that it meets the statutory definition of a Sole Community Hospital and that such status is recognized by CMS.

These requirements ensure that SCH can access discounted drug prices under the 340B program, which can offer significant savings on pharmaceuticals.

Altru's 340B Program

Altru has been a covered entity in the 340B program for nearly a decade. Altru runs a conservative and compliant program, with accurate 340B policies and procedures and an internal team dedicated to those compliance standards. Annually, Altru recertifies our 340B Program to maintain compliance. The annual recertification is a vital component of maintaining the program's integrity. It ensures that only eligible entities continue to benefit from the 340B discounts, thereby preventing misuse and preserving the program's resources for those who truly need them. The recertification includes complete transparency to the federal government. This transparency includes creating a trial balance that ties every applicable line of the Medicare Cost Report to registered 340B child sites to include outpatient expense and revenue at each location 340B drugs are purchased. Altru also includes our Medicare Cost Report in full and include our government contract. Meaning our books are open and fully transparent to the federal government, namely Health Resources and Services Administration (HRSA).

In addition to this annual recertification, Altru has also responded to all HRSA requests for information and was successful in a recent HRSA audit of the Altru 340B Program which verified that Altru adheres to the program's rules and regulations, ensuring that the benefits of the 340B Program are being used appropriately to support patient care for underserved populations. The audit examines various aspects of the covered entity's participation in the 340B Program, including:

- **Eligibility**: Confirming that the entity meets the eligibility criteria for participation in the program.

- **Duplicate Discounts**: Ensuring that the entity is not receiving both a 340B discount and a Medicaid rebate for the same drug.
- **Diversion**: Checking that 340B drugs are only dispensed to eligible patients and not diverted to ineligible patients or entities.

Process: The audit process typically involves several steps:

- **Notification**: Altru was notified of the upcoming audit and provided with details 30 days in advance.
- **Documentation Review**: HRSA reviewed the Altru's uploaded records and documentation to verify compliance with 340B Program requirements.
- **Site Visit**: HRSA came to Altru to further assess compliance and gather additional information.

Outcomes: Depending on the audit findings, outcomes can range from no adverse findings to the requirement for corrective actions. In cases of significant non-compliance, entities may be required to repay manufacturers for any discounts received inappropriately or face removal from the 340B Program. Altru was thrilled to report that our organization did not have any deficiencies and successfully passed the HRSA audit in April 2022.

Community Benefit

The Altru 340B Program is crucial to the communities Altru services in that we rely on 340B savings to keep services open in our region, to include but are not limited to:

- Devils Lake Dialysis;
- Altru in and outpatient behavioral health;
- Altru's Level 2 Trauma status;
- Altru's investment in the Devils Lake Critical Access Hospital;
- Over 60 Altru specialists services;
- Altru Home Health services;
- Emergency care services to include ground and air ambulance; and
- Onsite intensivists in Altru's ICU.

Our 340B Program also support our community's low-income populations in tandem with Grand Forks BlueZones and Public Health with transportation to chemotherapy appointments and food insecurity. Altru is able to provide nurse at Grand Forks Lagrave on Frist as well as Altru's Food Pantry and other charitable care.

Unfortunately, over the past two years, Altru and Altru patients have felt the financial impact of manufacturers continuously pulling medications from the 340B Program. As of this date, Altru has received communication from 33 manufacturers pulling medications.

Impact

In the last 3 years our ability to purchase 340b drugs has been impacted by manufacturers imposing their own mandates on who they give discounts to. Most of this impact has been in the community, contract pharmacy setting. Manufacturers have limited our ability to partner with community pharmacies by prohibiting such arrangements and refusing to honor 340B discounts on certain drugs. Unfortunately, we are on the verge of needing to terminate our contracts with many independent pharmacies across the state due to big pharma's refusal to comply with the intent of the program. Let the law be followed as the legislature that drafted it intended. Don't let big pharma rewrite the laws to our state's hospitals and constituents' detriment.

I appreciate the opportunity to be part of improving healthcare across the state of North Dakota. We ask that you give the bill a Do Pass recommendation. Thank you for your consideration. I am to answer questions.

Thank you,

Erin Navarro

STATE OF NORTH DAKOTA
GOVERNOR DOUG BURGUM

NORTH DAKOTA STATE BOARD OF PHARMACY
OFFICE OF THE EXECUTIVE DIRECTOR

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Bill No 1473 – Prohibited Acts of Drug Manufacturers

House Industry, Business and Labor Committee- 327C
2:30 P.M. - Monday – February 10th, 2025

Chairman Warrey, Members of the Industry Business and Labor Committee, for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here today and provide a testimony on behalf of the Board on House Bill 1473.

This bill adds to the prohibitive acts section of the Wholesale Drug license requirements to provide safeguards for 340B covered entities and contract pharmacies on actions of the manufacturer to limit or restrict access to the 340B drug discount program. The 340B program (created in 1992) is a discount program which is intended to help health care entities care for low income and uninsured patients. The 340B Program was expanded over the years to include other eligible health care entities. Critically, the overall federal authority of 340B is the Federal Health Resources and Services Administration (HRSA).

The 340B program financially supports both covered entities and contract pharmacies. Like it or not, to be clear, this program supports our state's health care infrastructure in a big way.

If enacted, the Board of Pharmacy would be tasked with enforcing the provisions on the licensed manufacturers and virtual manufactures conducting business in the state. We are willing to take on this responsibility.

I would be happy to answer any questions which you may have for me, and I appreciate your time and consideration of this legislation.

Testimony in support of House Bill 1473:

February 10, 2025

Mr. Chairman and Members of the Committee,

My name is Dr. Alyssa Wolden, and I am a Pharmacist with Coal Country Community Health Center, which provides essential medical services to the rural communities of Beulah, Hazen, Center, and Killdeer. I am aware of the profound importance of the 340B program to our Health Center's patients, as it offers crucial access to medications and vital health programs.

The manufacturer requirements and restrictions have significantly impacted our 340B program. Initially, we intended to continue our operations as usual and exclude manufacturers whose requirements we could not meet, expecting only a few. However, by early 2024, we realized that for our program to survive, we needed to adapt and start attempting to meet these requirements.

It is virtually impossible for our program to gain the access to medications we once had with the current manufacturer requirements and restrictions. Despite our best efforts to overcome the multitude of barriers and steps outlined in the manufacturers' 340B policies, and even with the addition of dedicated staff and advanced technology, the challenges persist. The lack of a standardized framework for manufacturer requirements and restrictions within these policies has made it exceptionally difficult for us to navigate each policy and remain up-to-date with their frequent changes. These constant updates often necessitate adjustments or actions within our program, further complicating our efforts to provide essential care.

Our 340B program adheres to standardized requirements, including comprehensive monitoring, detailed reporting, and thorough internal auditing, as mandated by HRSA and the Office of Pharmacy Affairs Information System. While these processes require substantial time and resources, they ensure patient eligibility and program compliance. Despite being smaller than most, we take immense pride in the transparency of our policies and procedures, as well as our unwavering commitment to a patient-centered approach.

House Bill 1473 protects our 340B programs, our patients' access to medications and services, and allows us to focus on "What more can we do for our patients?" rather than "How do we keep our program operational?"

Thank you for your time and consideration. I urge you to consider the vital role the 340B program plays for rural North Dakota and to support measures that will ensure its sustainability.

Community HealthCare Association of the Dakotas

Testimony in Support of House Bill 1473

House Industry, Business and Labor Committee
Representative Jonathan Warrey, Chair
February 10, 2025

Chairman Warrey, Vice Chair Johnson, and Members of the Committee:

I am Shelly Ten Napel, the CEO of the Community HealthCare Association of the Dakotas (CHAD) testifying on behalf of our member community health centers. Thank you for the opportunity to submit testimony in strong support of House Bill 1473. This bill would protect the 340B drug discount program that so many of our patients rely on for access to needed medications by stopping Big Pharma from imposing arbitrary and unnecessary contract pharmacy restrictions.

CHAD is the non-profit primary care association representing community health centers across North Dakota and South Dakota. These non-profit, community-driven clinics provide high-quality primary and preventative care to all individuals, regardless of their ability to pay. Here in North Dakota, five community health centers provide care at 22 delivery sites in 20 communities, located in both rural and urban areas of our state. This includes primary medical, dental, behavioral health, and substance use disorder care.

The 340B Drug Pricing Program was established in 1992 and enables certain health care providers to purchase outpatient drugs at discounted prices from pharmaceutical manufacturers. Its goal is to stretch scarce resources to serve low-income and uninsured populations. Health centers use these savings to lower medication costs for patients and to fund vital health services. The program operates without taxpayer funding and ensures health care access for rural and underserved populations. Further, the program has reporting expectations with which our members comply.

As you may know, all pharmacies in North Dakota must be majority-owned by a local pharmacist. Health centers and other facilities therefore rely on contract pharmacies for patients to get needed medications near home. Through the 340B program, our members are able to partner with their local pharmacies to ensure their patients receive affordable prescriptions. These discounts enable many patients to adhere to recommended treatment plans which improve their health outcomes and quality of life.

The impact of 340B extends well beyond the patients who receive discounted medications. Health centers and other covered entities reinvest 340B savings into services that further benefit their patients and communities. At health centers, 340B savings fund a variety of patient services, including transportation, telehealth, behavioral health, chronic disease management, and more. 340B savings also play a critical role in sustaining the overall operations and staffing of many health centers, keeping access to care available in rural and underserved communities.

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Community HealthCare Association of the Dakotas

Unfortunately, pharmaceutical companies are increasingly imposing restrictions on the use of contract pharmacies. As a rural state that relies on contract pharmacies, these restrictions undermine the very purpose of the 340B program in North Dakota. Contract pharmacy restrictions imposed by Big Pharma have negatively impacted health centers and their patients, and 340B savings trends are in decline. One of our member health centers explained, "Contract pharmacy restrictions have reduced our revenue from the program, therefore decreasing our overall impact opportunities. We anticipate the reduction in our upcoming fiscal year to be about one-third of our annual 340B revenue."

North Dakota is on solid legal ground to pass this bill. Eight other states have already passed similar laws, and 10 more states have introduced legislation this session just like North Dakota. Big Pharma lost their legal challenge to a similar law in Arkansas in the 8th Circuit of Appeals (the 8th Circuit also covers North Dakota), and the Supreme Court declined to hear Big Pharma's appeal of that case.

Please support your local community health centers, non-profit hospitals, contract pharmacies, and local communities, and vote yes on HB 1473. Thank you for your consideration, and we welcome you to reach out with any questions.

Sincerely,

Shelly Ten Napel, CEO
Community HealthCare Association of the Dakotas

196 E. 6th Street, Suite 200, Sioux Falls, SD 57104 | 216 N 2nd Street, Suite 104, Bismarck, ND 58501
Phone: (605) 275-2423 | Phone: (701) 221-9824
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Dear North Dakota Legislator:

We are writing to express our concern for HB 1473 that would expand the 340B Drug Pricing Program in the midst of its far-reaching impacts on patients, taxpayers, and employers in North Dakota. Originally created to help low-income and uninsured patients access affordable medications, 340B has become a hospital markup program riddled with loopholes that allow large hospitals, pharmacy benefit managers (PBMs), and chain pharmacies to profit at the expense of patients. Instead of lowering costs for those in need, many 340B hospitals mark up the price of discounted drugs—charging insurers and patients full price while pocketing the difference.

Before expanding a program with known loopholes and misaligned incentives, we must address the fundamental issues plaguing 340B today:

- **Hospital Markups & Rising Costs:** Many 340B hospitals in North Dakota markup medicine prices rather than passing discounts to patients, leading to significantly higher prescription costs compared to non-340B providers. This drives up insurance premiums and out-of-pocket expenses for families and employers statewide.
- **Loopholes That Undermine Rural Access:** Today, 41 healthcare entities participate in 340B, with 430 contracts between North Dakota hospitals and out-of-state pharmacies. However, only 38% of these contract pharmacies are in medically underserved communities, meaning most program savings flow to wealthier areas – funneling resources away from rural communities while benefiting wealthier urban areas.
- **Lack of Transparency & Minimal Charity Care:** Despite generating millions in 340B revenue, 80% of North Dakota's 340B hospitals provide charity care below the national average. With an average charity care rate of just 1.1%, far below the national average of 2.5%, many uninsured patients still pay full price for medicines acquired at steep discounts. North Dakota's 340B entities generate 6.6 times more in program profits than they spend on charity care, while large hospitals and PBMs pocket the difference with no requirement to reinvest savings into patient care.

Without meaningful reform, 340B will continue to function as a loophole for hospital markups and corporate profits rather than a program benefiting the patients it was intended to serve. Expanding a broken system will only exacerbate these issues, leaving North Dakota's most vulnerable patients without the care they need.

We urge you to prioritize transparency and accountability reforms that ensure 340B savings directly benefit patients and support rural healthcare expansion rather than fueling profit-driven hospital tactics. We welcome the opportunity to work with you on solutions that put North Dakota patients first.

Sincerely,

Biomarker Collaborative
Community Liver Alliance
Exon 20 Group
H.E.A.L.S. of the South
Hispanic Business Alliance
Infusion Access Foundation
International Cancer Advocacy Network
Lupus and Allied Diseases Association, Inc.
MET Crusaders
National Infusion Center Association
North Dakota Watchdog Network
PD-L1 Amplifieds
WomenHeart Jamestown

AMERICAN FREE ENTERPRISE CHAMBER OF COMMERCE

February 10, 2025

The Honorable Scott Louser
1718 Birch Place SW
Minot, North Dakota 58701-7097

Dear Chairman Louser and members of the Industry, Business, and Labor Committee:

As a membership organization representing small businesses and employers nationwide, we fight for jobs, growth, and freedom while opposing burdensome regulations. Like you, we are concerned about government and corporate cronyism that threatens our economic future.

We urge you to oppose House Bill 1473, which expands the 340B drug program—benefiting corporate health systems, major chain pharmacies, and pharmacy benefit managers (PBMs) at the expense of North Dakota's employers and workers. The latest reports show **340B costs North Dakota small businesses $54 million, and taxpayers are on the hook for another $10 million.**

340B is no longer the program Congress created in 1992 to assist low-income patients and safety-net providers. Today, large health systems exploit it, buying medications at steep discounts and reselling them at higher prices—pocketing profits instead of passing savings to patients. The program lacks oversight, and there are no requirements to ensure proceeds help low-income or uninsured patients. This is the exact reason the U.S. Senate Committee on Health, Education, Labor & Pensions is investigating its abuses.

Expanding 340B worsens rising health care costs. The average profit margin on 340B medicines commonly dispensed through contract pharmacies – like those named in House Bill 1473 – is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies, generating $13 billion in gross profits in 2018.

Just next door, Minnesota Governor Tim Walz signed nearly identical legislation last year—guaranteeing massive pharmacy chains' access to 340B discounts. Months later, a state report revealed that 340B cost taxpayers $87 million while chain pharmacies and PBM middlemen pocketed $120 million in profits. North Dakota should not be following in Governor Walz's footsteps.

With $66 billion in discounted drugs flowing through 340B annually, much of the intended aid never reaches low-income families. Taxpayer watchdogs, like the Government Accountability Office and the Office of the Inspector General, have flagged 340B for needed reforms. Instead of fixing these problems, House Bill 1473 would codify abusive practices, shifting more power to large health care systems at employers' and taxpayers' expense.

We urge you to oppose this misguided bill. Thank you for the opportunity to comment on this legislation. Please contact me if you need further information.

Sincerely,

Gentry Collins
CEO
American Free Enterprise Chamber of Commerce

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to North Dakota House Bill 1473
340B Prescription Drug Program
February 2025

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes North Dakota House Bill (HB) 1473. HB 1473 would prohibit biopharmaceutical manufacturers from interfering with the acquisition of a 340B drug by a contract pharmacy on behalf of a covered entity. This type of provision not only raises constitutional concerns but also exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

Congress created the 340B program in 1992 to help vulnerable and uninsured patients access prescription medicines at safety-net facilities.

Through the program, biopharmaceutical manufacturers provide tens of billions of dollars in discounts each year to qualifying safety-net hospitals and certain clinics ("covered entities"), but patients are often not benefitting. Today, large hospital systems, chain pharmacies, and pharmacy benefit managers (PBMs) are generating massive profits from the 340B program even though its intended beneficiaries were true safety-net hospitals and clinics and the low-income and vulnerable patients they treat. The 340B program has strayed far from its safety-net purpose, and Congress needs to fix the program to ensure that it is reaching its intended populations.

There is little evidence to suggest that patients have benefited from contract pharmacy growth.

Since 2010, the number of contracts with pharmacies has grown by more than 12,000%, with roughly 33,000 pharmacies participating in the program in 2024.[i] Because the program has no transparency or guardrails on how hospitals and clinics use 340B profits, the money often is not going to help low-income and uninsured patients access medicines. An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B.[ii] Additional studies have found that 65% of the roughly 3,000 hospitals that participate in the 340B program are not located in medically underserved areas,[iii] and in North Dakota, only 38% of contract pharmacies are located in medically underserved areas. Research has also found that more than 77% of 340B hospitals provide less charity care than the national average for all hospitals, and they often spend less on charity care and community investment than the estimated value of their tax breaks as nonprofits.[iv] In fact, 88% of 340B hospitals in North Dakota are below the national average for charity care levels.[v]

The 340B markup program has become a hidden tax on employers, patients, and state employees.

Marking up the costs of 340B medicines for employer-sponsored commercial plans and patients with private insurance generates significant revenue for 340B hospitals. 340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patients[vi] and average spending per patient in the commercial market on outpatient medicines was more than 2.5 times higher at 340B hospitals than non-340B hospitals.[vii]

In addition, the current design of the program directly increases costs for employers by an estimated 4.2%, or $5.2 billion, due to reduced rebates from manufacturers, and indirectly increases employer costs by incentivizing provider consolidation and use of higher cost medicines.[viii,ix] With no obligation to invest profits from 340B markups at satellite facilities into underserved communities, 340B hospitals frequently purchase independent physician offices so they can then buy more medicines and increase their 340B profits.[x] Further, incentives in the 340B program increase the use of higher-cost medicines as hospitals participating in 340B generally obtain substantially larger profits from more expensive medicines.[xi,xii]

In an unprecedented report examining 340B hospital practices in its state, the North Carolina State Treasurer found North Carolina 340B hospitals charged state employees massive markups for oncology medicines.[xiii] According to the report, North Carolina 340B hospitals charged state employees, on average, a price markup of 5.4 times the hospitals' discounted 340B acquisition cost for outpatient infused cancer medicines.[xiv] This resulted in billing the North Carolina State Health Plan for Teachers and State Employees a price markup on cancer medicines that was 84.8% higher than North Carolina hospitals outside of the 340B program.[xv]

HB 1473 will further exacerbate 340B created market distortions that increase health care spending for people with commercial insurance, which raises costs for state governments and taxpayers.

The 340B program has often been touted as cost-free to taxpayers. However, research from IQVIA found that the 340B program increases drug costs for self-insured employers and their workers by 4.2% due to lost manufacturer rebates (which reduce the price of medicines) when a 340B drug is dispensed.[xvi] IQVIA reports that employers in North Dakota pay an estimated $53.4 million more in health care costs due to foregone rebates as a result of the 340B program.[xvii]

Based on analysis by IQVIA, a state 340B contract pharmacy mandate in North Dakota is estimated to increase health care costs for employers and state and local governments by $16.4M due to additional foregone rebates.[xviii]

These higher costs also impact state budgets through both higher spending for state employees' health care and forgone tax revenue due to higher premiums for state residents. Based on analysis of recent reports by IQVIA and Magnolia Market Access indicates the 340B program increased state and local governments' health care costs by $1.9 billion (4.2%) in 2022 alone.[xix]

Additional analysis from Magnolia Market Access found that the 340B program caused a combined $7.8 billion increase in health care costs for self-insured and fully insured employers and workers in 2021,

leading to $1.8 billion in lost federal and state tax revenue. In North Dakota, the impact of lost state tax revenue was $0.5 million.[xx]

HB 1473 will line the pockets of PBMs, pharmacy chains, and large hospital systems.

Many contract pharmacies charge a patient based on a drug's full retail price because they are not required to share any of the discount with those in need.[xxi] Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. North Dakota 340B hospitals have nearly 250 contracts with pharmacies outside the state. These out-of-state arrangements are not subject to North Dakota's pharmacy ownership law.

Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements. Recent analysis by Avalere found that 69% of 340B contract pharmacies were associated with a PBM through vertical integration (53%) or contractual arrangement (16%). Only 16% of non-340B pharmacies were vertically integrated or affiliated with a PBM.[xxii] Notably, 44% of contract pharmacy arrangements are with pharmacies affiliated with the three largest PBMs – OptumRx, CVS Caremark and Express Scripts.[xxiii] The five largest contract pharmacy parent companies earned an estimated $2.9 billion from 340B in 2023.[xxiv] These earnings are part of the hidden tax the 340B markup program has created. The program reached $66.3 billion in 2023, a 23% growth increase from the previous year.[xxv]

In North Dakota, PBMs and large pharmacies make up 60% of contract pharmacy arrangements. PBM-owned pharmacies specifically account for 26% of all arrangements with 340B contract pharmacies in North Dakota.[xxvi]

In 2023, the Minnesota Legislature passed legislation[xxvii] that requires the Minnesota Department of Health (MDH) to collect and aggregate data from Minnesota providers that participate in the federal 340B program and prepare a report with findings for the legislature and public. The first Minnesota 340B report was released in November 2024 and provides further evidence that for-profit middlemen are profiting from the 340B program. Specifically, the report found that payments to contract pharmacies and third-party administrators (TPAs) were over $120 million, representing approximately $16 of every $100 of gross 340B revenue generated paid to external parties.[xxviii] In fact, 10% of safety-net federal grantees reported a negative net 340B revenue due to payments made to middlemen.[xxix] The top 10% of critical access hospitals and disease-specific grantees with the highest external operational costs lost at least half their gross 340B revenue to TPAs and contract pharmacies.[xxx]

The Minnesota 340B report also sheds light on the massive profits 340B hospitals retain from the 340B program. Minnesota providers participating in the 340B program earned a collective net 340B revenue of at least $630 million for the 2023 calendar year.[xxxi] Based on national data, MDH believes this figure may represent as little as half to one-third of the actual total 340B revenue for Minnesota providers due to lack of reporting from the covered entities for office administered drugs.[xxxii, xxxiii] Most entities did not report data for office administered drugs, which are estimated to account for 80% of all 340B drug spending.[xxxiv] The state's largest 340B hospitals benefitted most from the 340B program, accounting for 13% of reporting entities but representing 80%—more than $500 million—of net 340B revenue.[xxxv]

Additional analysis of the Minnesota 340B report reveals the largest single beneficiary of 340B markups was M Health Fairview University of Minnesota Health Center ("M Health Fairview"), which reported an astounding $130 million in net 340B revenue. By comparison, M Health Fairview reported higher revenue than all the state's 72 critical access hospitals, 17 community health centers, 9 Ryan White AIDS clinics, and 63 STD clinics combined.[xxxvi]

HB 1473 would require manufacturers to provide 340B-priced drugs to all pharmacies that contract with 340B covered entities.

The 340B program is a comprehensive federal program that is governed exclusively by federal law. States do not have the authority to create new requirements that are not in the federal statute or that conflict with the statute. Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in several federal courts across the country.

PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing HB 1473.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

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COMMUNITY ACCESS NATIONAL NETWORK

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February 10, 2025

North Dakota State Assembly
Industry, Business and Labor Committee
600 East Boulevard Avenue
Bismarck, ND 58505
Via electronic mail

RE: HB 1473

Dear Honorable Chairman Warrey, Vice Chairman Johnson, Vice Chairman Ostlie Members of the North Dakota Industry, Business and Labor Committee, and your respected staff,

The Community Access National Network (CANN) writes in **OPPOSITION** to **HB 1473**, which would expand the federal 340B Drug Pricing Program in North Dakota without sufficient oversight to ensure the program appropriately serves patients, particularly those living with HIV and other chronic health conditions.

The **Community Access National Network (CANN)** is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. The 340B Drug Pricing Program is of profound importance to our community.

On May 28th, 2024, the "340B Affording Care for Communities and Ensuring a Strong Safety-net Act" or "340B ACCESS Act" was unveiled in the United States House of Representatives. The bill represents a careful negotiation between a variety of stakeholders affected by the 340B program, including but not limited to the National Association of Community Health Centers, a trade organization representing pharmaceutical manufacturers, and several patient advocacy organizations. CANN is proud to count ourselves among the members working to find consensus on reforming the 340B drug discount program.

HB 1473 undermines the well-recognized need for reform to align 340B with its original intent because the bill seeks an avenue to expand 340B contract pharmacy arrangements without limitation – particularly, limitations necessary to ensure proper transparency and accountability.

The primary harm of contract pharmacies in the 340B program is that they can divert profits intended for low-income patients by allowing large, for-profit retail pharmacies to capitalize on discounted drug prices, potentially leading to less money being reinvested in patient care and a lack of transparency regarding how the savings are being used; this can be considered an abuse of a program designed to help vulnerable populations access affordable medications.

Similarly, diversion of program benefit from needy communities and into wealthier communities is only further enabled when the program is expanded without sufficient guardrails. Unchecked, 340B has encouraged consolidation, community pharmacy closures, harms rural access, and in an extraordinary example of abuse, been the driving financing force in mismanaged housing programs that have left patients dead.

HB 1473 poses the potential to exacerbate problems in the 340B program without sufficiently ensuring the expansion actually benefits patients.

If this body seeks to positively impact patient access to care, priority on PBM reform is a must. PBM reform, not unchecked 340B expansion, speaks most directly to patient concerns regarding pharmacy access, benefit design, and medication affordability.

To be clear, CANN supports a strong 340B program. When 340B operates the way it is intended, safety-net providers thrive and vulnerable communities, families, and individuals gain access to healthcare they might otherwise not have. CANN welcomes discussion on instituting appropriate guardrails into legislation that would serve to strengthen the program, shield good stewards, and hold accountable bad actors within the appropriate limitations of state powers associated with this federal program.

Respectfully submitted,

Sincerely,
Kalvin Pugh
Director of State Policy, 340B
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

In Opposition to North Dakota HB 1473
340B Mandate

HB 1473 would prohibit biopharmaceutical manufacturers from interfering with the acquisition of a 340B drug by a contract pharmacy on behalf of a covered entity. This type of provision not only raises constitutional concerns but exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

Created in 1992 to help low-income and uninsured patients obtain prescription drugs at discount prices, this little-known, and poorly designed, program has expanded unchecked and strayed far from its purpose.

Today, despite its purpose, hospitals are using the program as a cash cow, racking up profits without passing the savings on to patients, as Congress intended.

And while on paper it has no taxpayer cost, 340B has quietly grown into the second-largest federal prescription drug program, surpassing Medicare Part B and Medicaid in volume.

To understand the program, it helps to understand its history — a history both fascinating and disheartening.

In 1990, Congress enacted the Medicaid Best Price Rule, the goal of which was to save taxpayer money on prescription drugs that are purchased for low-income Americans through state-run Medicaid programs. The rule requires drug manufacturers who want to sell their products to Medicaid to do so at their "best price," meaning the lowest price they sell to anyone.

But the law had a flaw. It included in the definition of "best price" gifts of free and charitably discounted drugs. Traditionally, drug companies make their products available at low or no cost to patients who simply cannot afford them. By treating these acts of charity as sales, the rule caused drug manufacturers to lose money on Medicaid. The companies faced a dilemma: either stop selling to Medicaid altogether or stop providing free and discounted drugs to low income and uninsured patients. They chose the latter.

How did Congress respond? Instead of amending "best price," Congress established the Section 340B Discount Drug Pricing Program, which entitles certain safety-net hospitals and health clinics ("covered entities") to buy drugs from manufacturers at a discount and then resell them

at a profit. (The average discount is around 55%.) This, the authors assumed, would enable safety-net providers to "stretch scarce federal resources" and provide medicines to the needy more affordably. But remarkably, the law did not require entities to pass the discounts on to patients. Instead, the entities can pocket the money.

Well, almost. They *are* supposed to use the money to benefit "qualified patients." But the statute does not define that term. Federal efforts to enforce the law, and curb abuses, have been hampered by this and other ambiguous provisions.

Thirty years on, evidence suggests most covered entities are *not* passing the discounts on to the intended beneficiaries. According to one comprehensive study, discounts reach as few as 1.4% of patients. The study concludes: "It's clear the majority of low income, uninsured, 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts."

Meanwhile, some providers illicitly divert their 340B drugs, selling them to patients who do not qualify for the program.

The number of covered entities has boomed, rising from 2,140 in 2014 to 12,700 in 2020 — a 600% increase in six years. Non-safety net providers lobby to get themselves included in the program. Some sneak in through a side door, buying up local safety-net providers and capturing their 340B profits for themselves. This is fueling local hospital market consolidation, which means less competition, higher prices, and higher insurance premiums and out-of-pocket costs for everyone.

Today, 40% of hospitals in the U.S. are classified as a 340B "covered entity."

A 2022 Milliman analysis found the average cost of an outpatient medicine administered at a 340B hospital is more than 150% higher than the average cost of an outpatient drug administered at a non-340B hospital.

- 340B hospitals provide less charity care than the average of all hospitals.
- 340B hospitals tend to be larger entities, located in more affluent areas.

Driving Up Prices

The estimated dollar value of total 340B drug sales has grown from $7 billion in 2012 to $54 billion in 2022. (It jumped 23% in 2021 alone.) Tellingly, from 2018 to 2023, while non-340B sales grew by 41.4%, 340B sales grew by 129.4%, more than three times as fast.

340B sales now represent more than 7% of all drug sales in the United States. And there's evidence the program's explosive growth is driving up Medicare Part B premiums, which, if you think about it, means seniors are subsidizing hospital corporations.

How to Fix It

Clearly, the wayward 340B program cries out for oversight.

Three important principles:

1. Fund patients, not systems.
2. Protect taxpayers.
3. Reduce prices through competition and choice, not mandates and price controls.

The simplest remedy would be to exempt drugmakers' gifts of free and discounted products from the definition of "best price" — in other words, reverse the error that started it all.

1. **Focus on the Vulnerable**. Define "340B patient" in statute to prevent abuse and ensure discounted drugs actually go to low-income and uninsured patients.
2. **Tighten Eligibility**. Narrow the definition of "covered entity" to true safety-net hospitals only.
3. **Maximize Transparency**. Require hospitals to report exactly how they use their 340B profits.

Ultimately, we need to reform *health care* to be more affordable and accessible. Let's remove barriers and empower consumers to unleash the world-class innovation — and generous safety nets for the vulnerable — that only free markets can deliver.

In conclusion,

This legislation does not address patient access or help patients better afford their medicines. The 340B program is a comprehensive federal program that is governed exclusively by federal law. State governments do not have authority to place these requirements on how manufacturers engage in the 340B program, let alone create new requirements that are not in the federal statute to begin with or that conflict with requirements in the statute.

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

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House Industry, Business and Labor Committee
HB 1473 – 2/10/25
Rep. Jonathan Warrey - Chairman

Chairman Warrey and member of the committee, for the record, my name is Mike Schwab, Executive Vice President of the ND Pharmacists Association. We are here today in support of HB 1473.

HB 1743 centers around what is known in the healthcare industry as the 340B Program. Established in 1992, the 340B program enables certain healthcare providers such as Federally Qualified Health Centers (FQHC's), Community Health Centers, Critical Access Hospitals and other non-profit hospitals to purchase outpatient drugs at discount prices from drug manufacturers. The entities mentioned above are considered "covered entities" by definition under the federal 340B program. The goal of the 340B program is to stretch scarce federal resources and dollars as far as possible to serve low-income, underinsured and uninsured populations. The 340B program allows covered entities to provide increased access to care, discounted medications and allows additional services to be offered.

Covered entities can contract with pharmacies to help dispense medications to patients who are receiving care from the covered entities. In this instance, pharmacies that elect to participate in an agreement with a covered entity are considered "contract pharmacies" by definition under the federal 340B program. Contract pharmacies participate in 340B program through an agreement with the covered entity to help serve and provide access to the covered entities patients. The contract pharmacy is responsible for keeping a separate inventory for the program, lots of back-and-forth reporting to the covered entity, processes claims, inventory ordering, etc. all of which are subject to audits and compliance checks. The 340B program is administered by the Health Resources & Services Administration (HRSA) which is a division of the U.S. Department of Health and Human Services.

So why are we here today supporting this specific bill? HB 1473 is trying to address issues that critical access hospitals, federally qualified health centers, non-profit hospitals, community health

NDPhA
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centers and contract pharmacies are experiencing due to restrictions or mandates that drug manufacturers have implemented on their own. In 2010, HRSA authorized and stated covered entities could use more than one contract pharmacy. In recent years, drug manufacturers have taken it upon themselves to try and change how the 340B program operates. Currently, in a number of instances, drug manufacturers are restricting or holding covered entities to the use of no more than one contract pharmacy contrary to HRSA's 2010 published rule. Drug manufacturers have also attempted to gain access to patient claims data, utilization data and other encounter data. Federally, HRSA has sent numerous letters and follow-up warning letters to drug manufacturers regarding their attempts to change how the federal program is supposed to operate.

To-date, I believe there are at least eight states that have passed laws to stop drug manufacturers from implementing contract pharmacy restrictions and more than 10 states have introduced legislation this year, similar to North Dakota. In 2021, Arkansas was the first state to pass legislation that required drug manufacturers to adhere to HRSA's 2010 rule allowing covered entities to use more than one contract pharmacy. The pharmaceutical industry decided to sue Arkansas following the passage of the law. The State of Arkansas won in their lower federal court. The pharmaceutical industry decided to appeal that decision to the 8th Circuit of Appeals. The 8th Circuit of Appeals upheld the lower court's decision in favor of the State of Arkansas. The pharmaceutical industry then appealed the 8th Circuit decision to the U.S. Supreme Court. In late 2024, just before this legislative assembly came into session, the U.S. Supreme Court denied their appeal and sided with the 8th Circuit and lower court in favor of the State of Arkansas. As a reminder, North Dakota is also in the 8th Circuit of Appeals which is important to note as this committee continues to discuss HB 1473.

Drug manufacturers state the 340B program has seen outsized growth over recent years and they disagree with how federally HRSA is running the program. North Dakota does not appear to be the problem regarding the outsized growth of contract pharmacies. Some of the information and materials taken directly from the PhRMA's own website state the following:

- PhRMA states 60% of 340B contract pharmacies represent 5 large corporate chains (CVS, Walgreens, Wal-Mart, Rite-Aid and Kroger).

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- PhRMA further states there has been a growing number of Pharmacy Benefit Manager (PBM) owned specialty pharmacies now participating as contract pharmacies in the program.
- Additional information on PhRMA's website states "PBM's now own the vast majority of pharmacies. The big three PBM-owned specialty pharmacies account for 26% of contract pharmacy arrangements."

As you can see, the vertical integration of the insurance carriers/PBMs and large chain pharmacy corporations account for over 85% of 340B contract pharmacies according to PhRMA's own information. Blanket restrictions applied across the program by drug manufacturers have a negative effect on a small rural state like North Dakota.

We have been told there are roughly 250 out-of-state contract pharmacies participating in the ND 340B program effort. Yes, there are a number of contract pharmacies in our border communities like Moorhead, Aberdeen, etc. However, there are a large number of contract pharmacies representing PBM specialty pharmacies and other PBM owned pharmacies. In addition, sometimes covered entities are required to sign agreements with a suite of chain pharmacies. Often times, the suite of out-of-state pharmacies aren't used very much, if at all, and would be considered dormant contract pharmacies.

I also think it is important to talk about "duplicate discount" prevention requirements briefly. Federally, HRSA prohibits duplicate discounts, that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate. This would cause the drug manufacturer to pay two discounts on the same drug. North Dakota Medicaid already has an established process in place to avoid duplicative discounts between the two programs. Most of the concern around duplicative discounts seems to come from when a PBM administers Medicaid programs for states under a managed care agreement (basically a PBM administers the prescription drug benefit for State Medicaid Departments). A few years back, North Dakota used a PBM to administer the Medicaid Expansion prescription drug benefit. However, after a number of questions and concerns, North Dakota Department of Health and Human Services (Medicaid) and the ND Legislative Assembly made the

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decision to move Medicaid Expansion back in-house with traditional Medicaid. The state saved $17+ million dollars the next biennium by removing the PBM from administering the ND Medicaid Expansion program. Again, we feel a lot of the concerns drug manufacturers raise regarding duplicative discounts are already addressed because of how North Dakota operates and complies with existing 340B laws. We also do not see Medicaid managed care for the prescription drug benefit in ND like you do in a large number of states.

HB 1473 adds a new section to 43-15. 3-08 under the Board of Pharmacy's prohibited acts section. The prohibited acts section is automatically tied to the penalties section under 43-15 3-09 which is how other prohibited acts are referenced already. The Board of Pharmacy already licenses drug manufacturers and other states have taken this same approach for enforcement purposes. The Board of Pharmacy would be in charge of enforcing these sections.

In conclusion, HB 1473 helps to stop drug manufacturers from implementing their own rules outside of an already established federal program. If and when federal reforms to the program take place, we are ready and more than willing to comply with any of those changes. By supporting HB 1473, you are supporting your local critical access hospitals, federally qualified health centers, non-profit hospitals, contract pharmacies and community health centers. If HB 1473 is not passed, drug manufacturers will continue to provide fewer discounted drugs to North Dakota contrary to how the federal 340B program is supposed to be operating according to HRSA and HHS.

Thank you for your time and attention. I will try my best to answer any questions. There are a number of others who will be testifying today, who can hopefully answer your questions if I am not able to do so.

Respectfully submitted,

Mike Schwab

Mike Schwab

North Dakota Legislators Should Reject 340B Expansion - Americans for Tax Reform

Jack Baum

02/04/2025

Next week, North Dakota HB 1473 will be heard in the Industry Business and Labor Committee of the North Dakota House of Representatives. Americans for Tax Reform (ATR) and our supporters across North Dakota strongly oppose HB 1473 which would expand the second largest federal drug program: 340B. Expanding 340B would result in taxpayers footing the bill against costly lawsuits as well as a number of unintended negative consequences for patients across North Dakota.

Today, the biopharmaceutical industry is one of the most heavily regulated industries in the United States. It costs more than $2.5 billion and can take over a decade for just one new drug to make it through the Food and Drug Administration (FDA) approval process. Introducing even more layers of government intervention and bureaucratic red tape at the state level would only exacerbate the current problems and make pharmaceutical development that much more costly and complicated. Additionally, the 340B program is a comprehensive federal program that is governed exclusively by federal law – not state law. State governments do not have the authority to create new requirements that are not in the federal statute or that conflict with requirements in said statute.

Specifically, HB 1473 would require biopharmaceutical manufacturers to ship 340B drugs to all contract pharmacies that contract with 340B "covered entities" and by extension offer 340B pricing at these locations. The legislation makes no effort to address concerns about patient access and would only exacerbate existing problems with the 340B program.

While the 340B program was originally designed to help hospitals serve vulnerable populations, its unintended consequences have been dramatic. The norm has become that instead of directing savings towards patient care, hospitals use 340B to buy drugs at discounted prices and then bill significantly higher amounts to patients with commercial and employer-based insurance. This practice has inflated healthcare costs for both these patients and their employers. According to a 2024 report from the North Carolina State Auditor, North Carolina hospitals in the 340B program billed the North Carolina State Health Plan, the plan which covers teachers and state employees, at an 84.8% higher price markup than hospitals outside of the program. A recent analysis by IQVIA similarly showed that the 340B program has not saved costs as intended. According to the analysis, the 340B program increased state and local governments' health care costs by $1.9 billion in 2022 alone.

Additionally, the program has evolved into a giveaway for pharmacy benefit managers, who often negotiate deals with hospitals to further profit from discounted prices.

Continued escalation of 340B – far greater than originally intended – would leave manufacturers with even fewer resources available to invest in research and development for the next generation of lifesaving, life-improving medications. This would jeopardize pharmaceutical innovation as well as access to current medicines, resulting in the people of North Dakota being left with even fewer, lower-quality choices. Despite the remarks of those in favor of HB 1473 and other similarly passed legislation across the country, expanding 340B would actually lead to higher healthcare costs over the long term.

HB 1473 would also require manufacturers to ship 340B drugs to all contract pharmacies that contract with 340B covered entities and by extension offer 340B pricing at these locations. Currently, there is ongoing litigation in two other states which passed similar legislation over the question of whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers. Expanding the 340B program before there is a judgment in these other lawsuits will guarantee costly legal battles for the state of North Dakota, bills foot by the North Dakota taxpayer.

Americans for Tax Reform strongly opposes expanding the 340B program and urges all North Dakota legislators to vote against HB 1473.

https://atr.org/north-dakota-legislators-should-reject-340b-expansion/

5 REASONS HB1473 IS WRONG FOR NORTH DAKOTANS

1. $5.2 BILLION in HEALTHCARE COSTS TO EMPLOYERS

How the 340B Program Impacts Federal & State Tax Liability
Magnolia Market Access, January, 2025

The 340B program has often been touted as cost-free to taxpayers, as the discounted pricing comes from drug manufacturers directly. However, a recent IQVIA study found that contrary to this narrative, discounted pricing on drugs sold under the 340B program displaces manufacturer rebates to commercial health insurance plans (including employer health plans) as duplicative discounts in the commercial market are often prohibited by contracts. This displacement of manufacturer commercial rebates in favor of 340B discounted pricing corresponded to a **$5.2B increase in healthcare costs for self-insured employers and workers in 2021**. The increase in healthcare costs associated with drugs sold under the 340B program corresponds to a decrease in taxable income for affected employers and workers, resulting in lost tax revenue for the federal and state governments.

The combined increase of $7.8B in healthcare costs for both self-insured and fully insured employers and workers from forgone manufacturer rebates due to the 340B program resulted in $1.8 billion in lost federal and state tax revenue in 2021.

Forgone commercial rebates are just one way 340B drives up costs for employers, the government and taxpayers. Research suggests 340B also contributes to increased spending by incentivizing the use of more and higher-cost medicines, shifting care to more expensive settings, and driving provider consolidation.

2. STATE HEALTH PLANS OVERCHARGED

Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program
North Carolina State Treasurer, May 2024

Despite the charitable mission of the program, 340B hospitals billed the State Health Plan at an **84.8% higher price markup** than hospitals outside of the program, according to an analysis of medical claims from the North Carolina State Health Plan for Teachers and State Employees from 2020 to 2022.

3. WINDFALL FOR CHAIN PHARMACIES AND PBM'S

340B: An Out-of-Control Federal program with no oversight
Fix340B, Domestic Policy Caucus, 2025

State-by-state 340B expansion over the years has given more and more economic power to the already-monstrous, national chain pharmacies that have driven many local, mom-and-pop pharmacies out of business over the past several years.

Pharmacies are essential to the communities they serve. Yet throughout America, rural independent drugstores are struggling.

4. 340B ABUSE SHOULD TOP DEPT. OF GOVERNMENT EFFECIENCY LIST

340B Program Should Be a Priority for DOGE
Brooklyn Roberts, ALEC, January, 2025

Rule changes by the Health Resources and Services Administration (HRSA) allowed participating hospitals to contract with an unlimited number of outside pharmacies to fill 340B prescriptions—allowing the hospitals, pharmacies, and pharmacy benefit managers (PBMs) to share the profits. Patients, insurers, employers and taxpayers are bearing the brunt of the cost.

Hospitals have identified ways to maximize profits from the program, including through the state legislative process. Despite 340B being a federal program, bills have been introduced in states across the country to require drug manufacturers to sell to all pharmacies that participate in the program (called "contract pharmacies") at 340B prices.

5. PATIENTS AREN'T BENEFITTING

Medicaid's "340B" drug program is exploding – and driving up insurance costs
Dean Clancy, Americans for Prosperity, June, 2024

Evidence suggests most covered entities are *not* passing the discounts on to the intended beneficiaries. According to one comprehensive study, discounts reach as few as 1.4% of patients. The study concludes: "It's clear the majority of low income, uninsured, 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts."

The number of covered entities has boomed, rising from 2,140 in 2014 to 12,700 in 2020 — a 600% increase in six years. Non-safety net providers lobby to get themselves included in the program. Some sneak in through a side door, buying up local safety-net providers and capturing their 340B profits for themselves. This is fueling local **hospital market consolidation, which means less competition, higher prices, and higher insurance premiums and out-of-pocket costs for everyone.**

A 2022 Milliman analysis found the average cost of an outpatient medicine administered at a 340B hospital is more than 150% higher than the average cost of an outpatient drug administered at a non-340B hospital.

There's evidence the program's explosive growth is driving up Medicare Part B premiums, which, if you think about it, means seniors are subsidizing hospital corporations.

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB 1473
2/18/2025

A BILL for an Act to create and enact a new subsection to section 43-15.3-08 of the North Dakota Century Code, relating to prohibited acts of drug manufacturers; and to provide a penalty.

9:19 p.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Member Absent: Representative Christy

Discussion Topics:

- Reporting from drug companies
- Limit covered entities
- 340B drug program
- Pharmacy discounts
- ERISA Audits

9:20 a.m. Don Larson, Pharmaceutical Manufacturers of America submitted testimony

#37994.

9:38 a.m. Mike Schwab ND Pharmacists Association, submitted testimony #37982.

10:30 a.m. Chairman Warrey closed the hearing.

Diane Lillis, Committee Clerk

HB 1473 – Proposed Amendment

P. 1, line 2, after manufacturers, add ", to provide a report"

P. 1, after line 15 add: (4) "340B program" means the federal drug pricing program under section 340B of the federal Public Health Service Act [42 U.S.C. 201 et seq.].

P. 2, after line 10, add:

SECTION 2. Report on participation in 340B program.

Beginning January 1, 2026, each covered entity participating in the 340B program shall make available a report of the covered entity's:

a. Total annual estimated 340B program drug savings;
b. Total annual cost of providing charity care;
c. Total annual costs in excess of Medicaid payments;
d. Total annual costs in excess of Medicare payments;
e. Total annual costs of care provided without compensation;
f. Total annual amount of discounts offered to uninsured patients
g. Total annual cost of community services
h. Total annual costs of education, workforce development, and research

Before August first of each even-numbered year, the North Dakota Hospital Association shall make publicly available a biennial report compiling and summarizing data publicly reported by covered entities.

[Number] [Date]

PROPOSED AMENDMENT TO HOUSE BILL NO. 1473

Pages 1 through 2, overstrike everything.

Page 1, line 1, insert:

"A BILL for an Act to create and enact section 23-01-45 of the North Dakota Century Code, relating to 340B covered entity transparency reporting and charity care to increase accountability to safeguard benefit.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section 23-01-45 of the North Dakota Century Code is created and enacted as follows:

1. For purposes of this section:

   a. "340B drug" means a covered outpatient drug, as defined in 42 U.S.C. 1396r–8(k)(2), that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b(a)(1), and is purchased by a covered entity.

   b. "340B profits" means the difference between (i) aggregated payments received from insurers, third-party payers, or self-paying patients for all 340B drugs, and (ii) aggregated acquisition cost paid for all 340B drugs.

   c. "340B program" means the federal drug pricing program described in 42 U.S.C. 256b.

   d. "Charity care" has the same meaning as ascribed to that term in line 23 of worksheet S–10 to the Medicare cost report or in any successor form.

   e. "Contract pharmacy" means a pharmacy with which a covered entity has contracted to dispense 340B drugs on behalf of the covered entity to patients of the covered entity, whether distributed in person, via mail, or other means.

   f. "Covered entity" has the same meaning as under 42 U.S.C. 256b(a)(4).

   g. "Low-income patient" means a patient of the covered entity with a family income below 200 percent of the Federal Poverty Guidelines,

2. Beginning on July 1, 2026, and by July 1 each year thereafter, each covered entity shall report to the department of health and human services with respect to the covered entity and separately for each offsite facility associated with the

covered entity, the following information about the prior year, in a form and manner determined by the department of health and human services:

a. Delineated by form of insurance or third-party payer type, including but not limited to Medicaid, Medicare, commercial insurance, and uninsured:

(1) Aggregated acquisition costs paid for all 340B drugs, i.e., the metric that was used to calculate 340B profits;

(2) Aggregated payments received from insurers or third-party payers for all 340B drugs, i.e., the metric that was used to calculate 340B profits;

(3) Total number of prescriptions and the percentage of the covered entity's prescriptions that were filled with 340B drugs; and

(4) Percentage of patients served by a sliding fee scale for 340B drugs at the point of sale for low-income patients;

b. Total operating costs of the covered entity, and itemized costs for:

(1) Implementing direct pass through of 340B profits to patients in the form of lower cost sharing for 340B drugs at the point of dispensing or administration;

(2) Implementing a sliding fee scale for 340B drugs at the point of sale for low-income patients; and

(3) Charity care;

c. Total payments made to:

(1) Contract pharmacies for 340B program-related services and other functions;

(2) Third-party administrators for managing any components of the covered entity's 340B program; and

(3) Any other third parties in connection with 340B program-related compliance, legal, educational, and/or administrative costs;

d. Total number of contract pharmacies, and

(1) Number of contract pharmacies located out-of-state and the states in which out-of-state contract pharmacies are located;

(2) Total number of prescriptions and the percentage of the covered entity's prescriptions that were filled at contract pharmacies, delineated by in-state and out-of-state contract pharmacies;

(3) Total remuneration paid to or retained by contract pharmacies or their affiliates for any 340B program-related services performed on behalf of the covered entity; and

(4) The percentage change in subsection (2)(d)(3) of this section compared to the prior year;

3. An officer of the covered entity shall certify the completeness and accuracy of the report submitted pursuant to subsection (2) of this section.

4. The department of health and human services shall use the information described in subsection (2) of this section to prepare a report detailing aggregate information received from the covered entity, including 340B program revenue across all covered entities in the state. The department of health and human services shall submit this report to the Legislature by October 1, 2026. The department of health and human services shall post the report submitted to the legislative assembly and all reports submitted by covered entities pursuant to this section on a publicly accessible website.".

PROPOSED AMENDMENT TO HOUSE BILL NO. 1473

Page 2, after line 8, insert:

"c. This subsection shall only apply with respect to physical contract pharmacy locations in North Dakota."

Reletter accordingly

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB 1473
2/18/2025

A BILL for an Act to create and enact a new subsection to section 43-15.3-08 of the North Dakota Century Code, relating to prohibited acts of drug manufacturers; and to provide a penalty.

3:35 p.m. Chairman Warrey opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Member Absent: Representative Christy

Discussion Topics:

- Critical access to hospitals
- Rural healthcare
- Contract pharmacies
- Comprehensive care
- 340B pricing program

3:35 p.m. Tim Blasl, ND Hospital Association, submitted testimony #38012.

3:56 p.m. Chairman Warrey closed the meeting.

Diane Lillis, Committee Clerk

HOUSE BILL No. 1473

Prescription drug transparency report

1. Hospital defined. For purposes of this section, "hospital" means an acute care institution licensed and operating in this State as a hospital under (NDCC section).

2. Report on participation in federal 340B drug program. Beginning January 1, 2026, each hospital participating in the federal drug pricing program under Section 340B of the federal Public Health Service Act, 42 United States Code, Section 256b, referred to in this section as "the 340B program," shall provide an annual report to N.D. Department of Health and Human Services. NDDHHS shall post the report on its publicly accessible website. Each hospital shall report in a standardized format as agreed upon by NDDHHS and the hospitals, and include, at a minimum, the following information in the report consistent with the annual reporting of hospitals voluntarily participating in the good stewardship program of the American Hospital Association:

A. A description of how the hospital uses savings from participation in the 340B program to benefit its community through programs and services funded in whole or in part by savings from the 340B program, including services that support community access to care that the hospital could not continue without savings from the 340B program. The reporting must include annual charity care, prescription assistance programs, investments in healthcare workforce development, total annual costs in excess of Medicaid payments and Medicare payments, examples of subsidized services and the hospital's low-income and uninsured volume (also known as hospital disproportionate share, or DSH);

B. The annual estimated savings from the 340B program to the hospital, comparing the acquisition price of drugs under the 340B program to group purchasing organization pricing. If group purchasing organization pricing is not available for a drug under the 340B program, the acquisition price for that drug must be compared to a price from another acceptable pricing source;

C. A comparison of the hospital's estimated savings under the 340B program to the hospital's total drug expenditures;

D. A description of the hospital's internal review and oversight of the 340B program, which must meet the federal Department of Health and Human Services, Health Resources and Services Administration's program rules and guidance for compliance; and

E. Total aggregated payments made by hospitals to contract pharmacies for 340B program services.

3. Reporting. NDDHHS shall produce and post on its publicly accessible website a report that includes a summary of the aggregate information received from hospitals required to report under subsection 2. NDDHS shall annually provide a report to the interim Health Care Committee.

2025 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Room JW327C, State Capitol

HB 1473
2/19/2025

A BILL for an Act to create and enact a new subsection to section 43-15.3-08 of the North Dakota Century Code, relating to prohibited acts of drug manufacturers; and to provide a penalty.

10:04 a.m. Vice Chairman Ostlie opened the meeting.

Members Present: Chairman Warrey, Vice Chairman Ostlie, Vice Chairman Johnson, Representatives Bahl, Brown, Finley-DeVille, Grindberg, Kasper, Koppelman, D. Ruby, Schatz, Schauer, Vollmer

Member Absent: Representative Christy

Discussion Topics:

- 340B federal program
- Critical care hospitals
- PBM's contracting
- Price split PBM's and hospitals
- Qualifying hospital systems

10:05 a.m. Representative Koppelman proposed amendment LC:25.1047.01000, testimony #38056.

10:07 a.m. Representative Vollmer moved Adopt Amendment #38056.

10:07 a.m. Representative Kasper seconded the motion.

10:24 a.m. Representative Vollmer withdrew his motion.

10:39 a.m. Representative Schauer moved to amend by adding Section 1, by adding "d. This subsection shall only apply with respect to physical contract pharmacy locations in North Dakota, #38056

10:39 a.m. Representative Koppelman seconded the motion.

Representatives	Vote
Representative Jonathan Warrey	AB
Representative Mitch Ostlie	N
Representative Landon Bahl	Y
Representative Collette Brown	N
Representative Josh Christy	AB
Representative Lisa Finley-DeVille	N
Representative Karen Grindberg	Y

Representative Jorin Johnson	N
Representative Jim Kasper	N
Representative Ben Koppelman	Y
Representative Dan Ruby	Y
Representative Mike Schatz	N
Representative Austin Schauer	Y
Representative Daniel R. Vollmer	N

Motion failed 5-7-2.

10:41 a.m. Representative Kasper moved Do Pass.

10:41 a.m. Representative Johnson seconded the motion.

Representatives	Vote
Representative Jonathan Warrey	AB
Representative Mitch Ostlie	Y
Representative Landon Bahl	Y
Representative Collette Brown	Y
Representative Josh Christy	AB
Representative Lisa Finley-DeVille	Y
Representative Karen Grindberg	Y
Representative Jorin Johnson	Y
Representative Jim Kasper	Y
Representative Ben Koppelman	N
Representative Dan Ruby	N
Representative Mike Schatz	Y
Representative Austin Schauer	Y
Representative Daniel R. Vollmer	Y

Motion passed 10-2-2.

10:49 a.m. Representative Vollmer will carry the bill.

10:49 a.m. Vice Chairman Ostlie closed the meeting.

Diane Lillis, Committee Clerk

REPORT OF STANDING COMMITTEE
HB 1473 (25.1047.01000)

Industry, Business and Labor Committee (Rep. Warrey, Chairman) recommends **DO PASS** (10 YEAS, 2 NAYS, 2 ABSENT OR EXCUSED AND NOT VOTING). HB 1473 was placed on the Eleventh order on the calendar.

25.1047.01000-
Koppelman
Amendments

HOUSE BILL NO. 1473

Sixty-ninth
Legislative Assembly
of North Dakota

Introduced by

Representatives Nelson, Mitskog, Murphy, Bahl, O'Brien

Senators Axtman, Dever, Lee

A BILL for an Act to create and enact a new subsection to section 43-15.3-08 of the North Dakota Century Code, relating to prohibited acts of drug manufacturers; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new subsection to section 43-15.3-08 of the North Dakota Century Code is created and enacted as follows:

a For purposes of this subsection:

(1) "340B savings" means the difference between (i) aggregated payments received from insurers, third-party payers, or self-paying patients for all 340B drugs, and (ii) aggregated acquisition cost paid for all 340B drugs.

(2) "340B program" means the federal drug pricing program described in 42 U.S.C. 256b.

(3) "Contract pharmacy" means a pharmacy with which a covered entity has contracted to dispense 340B drugs on behalf of the covered entity to patients of the covered entity, whether distributed in person, via mail, or other means.

(4) "Low-income patient" means a patient of the covered entity with a family income below 200 percent of the Federal Poverty Guidelines,

~~(1) "Contract pharmacy" means a pharmacy that has a contract with a covered entity to receive and dispense drugs to the covered entity's patients on its behalf.~~

~~(2)~~ (6) "Covered entity" means an entity participating or authorized to participate in a federal drug discount program under 42 U.S.C. 256b.

- ~~(3)~~ (7) "340B Drug" means a drug purchased under reduced pricing under section 340B of the federal Public Health Service Act [42 U.S.C. 201 et seq.] by a covered entity.

b. Except as otherwise provided under section 43-15.3-09, it is a class B misdemeanor for a manufacturer, an agent or affiliate of that manufacturer, virtual manufacturer, or third-party logistics provider of a manufacturer's drugs, to:

(1) Directly or indirectly deny, restrict, prohibit, or otherwise interfere with the acquisition of a drug by a contract pharmacy on behalf of a covered entity unless receipt of the drug is prohibited by federal law.

(2) Prohibit a contract pharmacy from dispensing a drug by denying access to the drug.

(3) Require a covered entity or contract pharmacy to submit any claims, encounter, or utilization data as a condition for acquiring or receiving a drug, unless the claims, encounter, or utilization data sharing is required by federal law.

(4) Interfere with the ability of a covered entity or contract pharmacy to dispense a drug to an eligible patient of the covered entity.

(5) Offer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law.

c. This subsection does not apply to the limited distribution of a drug as required under 21 U.S.C. 355-1.

d. This subsection shall only apply with respect to physical contract pharmacy locations in North Dakota.

SECTION 2.

a. Beginning on July 1, 2026, and by July 1 each year thereafter, each covered entity shall report to the department of health and human services with respect to the covered entity the following information about the prior year, in a form and manner determined by the department of health and human services:

1) Delineated by form of insurance or third-party payer type, including but not limited to Medicaid, Medicare, commercial insurance, and uninsured:

(a) Aggregated acquisition costs paid for all 340B drugs, i.e., the metric that was used to calculate 340B savings;

(b) Aggregated payments received from insurers or third-party payers as well as for self-paying patients for all 340B drugs, i.e., the metric that was used to calculate 340B savings;

(c) Total number of prescriptions and the percentage of the covered entity's prescriptions that were filled with 340B drugs; and

(d) Percentage of patients served by a sliding fee scale for 340B drugs at the point of sale for low-income patients;

2) Total payments made to:

(a) Contract pharmacies for 340B program-related services and other functions;

(b) Third-party administrators for managing any components of the covered entity's 340B program; and

(c) Any other third parties in connection with 340B program-related compliance, legal, educational, and/or administrative costs;

3) Total number of contract pharmacies, and

(a) Number of contract pharmacies located out-of-state and the states in which out-of-state contract pharmacies are located;

(b) Total number of prescriptions and the percentage of the covered entity's prescriptions that were filled at contract pharmacies, delineated by in-state and out-of-state contract pharmacies;

(c) Total remuneration paid to or retained by contract pharmacies or their affiliates for any 340B program-related services performed on behalf of the covered entity; and

(d) The percentage change in subsection (2)(d)(3) of this section compared to the prior year;

b. An officer of the covered entity shall certify the completeness and accuracy of the report submitted pursuant to subsection (2) of this section.

c. The department of health and human services shall use the information described in subsection (2) of this section to prepare a report detailing aggregate information received from the covered entity, including 340B program revenue across all covered entities in the state. The department of health and human services shall submit this report to the Legislature by October 1, 2026. The department of health and human services shall post the report submitted to the legislative assembly and all reports submitted by covered entities pursuant to this section on a publicly accessible website.".

2025 SENATE HUMAN SERVICES

HB 1473

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

HB 1473
3/12/2025

Relating to prohibited acts of drug manufacturers; and to provide a penalty.

9:00 a.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- 340B Program
- Healthcare Expenses
- Rural Assistance
- Comparable Legislation in United States

9:00 a.m. Representative Nelson, District 14, testified in favor.

9:11 a.m. Mike Schwab, ND pharmacists Association, testified in favor and submitted testimony #40862.

9:24 a.m. Tim Blasl, President of North Dakota Hospital Association, submitted written testimony in favor #40731.

9:24 a.m. Erik Christenson, CEO of Heart of America Medical Center, testified in favor and submitted testimony #40602.

9:30 a.m. Jesse Breidenbach, Vice President Pharmacy Services of Sanford Health, testified in favor and submitted testimony #40889.

9:47 a.m. Brittney Blake, Altru, testified in favor.

9:51 a.m. Shelly Ten Napel, CEO of Community HealthCare Association of the Dakotas testified in favor and submitted testimony #40743.

9:58 a.m. Margaret Asheim, Chief Executive Officer of Family Healthcare Center, testified in favor and submitted testimony #40837.

10:01 a.m. Randy Schnider, Executive Director of ND Biosciences Association, testified in opposition.

10:03 a.m. Jessica Lynch, Director of State Policy of PhRMA, testified in opposition and submitted testimony #40541.

10:14 a.m. Mark Howell, Director of Public Policy with GSK, testified in opposition and submitted testimony #40781.

10:19 a.m. Dustin N. Gawrylow, Policy Matters, LLC, testified in opposition and submitted testimony #40811.

10:22 a.m. Kent P. Kaiser, Domestic Policy Caucus, testified in opposition and submitted testimony #40491.

10:28 a.m. Mark Hardy, Executive Director of ND Board of Pharmacy, testified in neutral and submitted testimony #40677.

10:29 a.m. Chrystal Bartuska, Health Division Director with the North Dakota Insurance Department, testified in neutral and submitted testimony #40986.

10:30 a.m. Megan Ruby, Blue Cross Blue Shield of ND, testified in neutral and submitted testimony #40989.

Additional written testimony:

Kathleen K. Traylor MD, Director of Government affairs with Amgen, submitted written testimony in opposition #40856.

Terry M. Wilcox, Co-Founder and CEO of Patients Rising, submitted written testimony in opposition #40848.

Aaron M Garman, Medical Director Coal Country Community Health Center, submitted written testimony in favor #39922.

Terry Dick submitted written testimony in favor #41038.

Erin Navarro, Altru, submitted written testimony in favor #40449.

Genevieve C. Plumadore, State Director of Government Affairs with Bristol Myers Squibb, submitted written testimony in opposition #40676.

Lilly Melander, Biotechnology Innovation Organization, submitted written testimony in opposition #39814.

Leah Vukmir, Senior VP of State Affairs National Taxpayers Union, submitted written testimony in opposition #40182.

Madelaine Feldman, Coalition of State Rheumatology Organizations, submitted written testimony in opposition #40486.

Rayette Brown, Women Heart Jamestown, submitted written testimony in opposition #40653.

Lilly Melander, Biotechnology Innovation Organization, submitted written testimony in opposition #39814.

10:35 a.m. Chairman Lee closed the hearing.

Adrew Ficek, Committee Clerk

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

March 12, 2025

Senate Human Services Committee
State Capitol
600 East Boulevard Avenue
Bismarck, ND 58505

Dear Chair Lee and Members of the Senate Human Services Committee,

The Biotechnology Innovation Organization (BIO) respectfully asks for your opposition to H.B. 1473. BIO respectfully opposes H.B. 1473, as it distorts the 340B program beyond the scope of federal statute and makes it more difficult for the state, payers, and manufacturers to identify illegal duplicate discounts and diversion (and waste in the system).

The bill prohibits manufacturers from withholding 340B-discounted drug products from a pharmacy that has contracted with a 340B covered entity. **This restriction creates perverse incentives in an already opaque program, ultimately making it harder to hold covered entities accountable and ensure that the benefits they are trusted to deliver to patients aren't being diverted to intermediaries' profit margins.** Many contract pharmacies are for-profit corporations whose shareholders benefit from exponential growth in the 340B program. In 2023, the program reached approximately $66.3 billion, equating to approximately 20% of gross US sales of brand-name drugs.[1] According to an October 2020 study, the number of contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 in 2020,[2] and as of July 2023 this number increased to 194,016.[3] According to one analysis, "the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72% compared with just 22% for non-340B medicines dispensed through independent pharmacies."[4] This explosive growth has occurred because it is extremely profitable for pharmacies to share in the 340B discount provided to covered entities. The restrictions in H.B. 1473 would further benefit contract pharmacies' profit margins rather than the vulnerable patients the 340B program seeks to protect and serve.

Contract pharmacies are also known to be greater risk of diversion and duplicate discounts. Fraud, waste, and abuse within the 340B program often comes in the form of "duplicate discounts" and "diversion," which are prohibited by the 340B federal statute. A duplicate discount is when an entity illegally collects discounts under multiple programs for the same drug, such as receiving discounts from both the 340B Program and the Medicaid Drug Rebate Program. Diversion is when a non-eligible patient receives a 340B discounted drug. The US Government Accountability Office (GAO) notes that contract pharmacies are a significant source of diversion and duplicate discounts, in part due to the fact that they often do not identify patients as 340B-eligible until after the prescription has been dispensed.[5] The GAO also notes, "66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies. . ."[6] The GAO and the US Health and Human Services Office of Inspector General (OIG) have both

[1] Op Cit.
[2] Vandervelde, Aaron, et al., "For-Profit Pharmacy Participation in the 340B Program," BRG Group, October 2020. https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/ (Accessed: April 25, 2023)
[3] Fein, Adam, "Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market," July 11, 2023. Accessed July 13, 2023. https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html
[4] Vandervelde, October 2020.
[5] GAO Report, June 2018.
[6] Ibid.

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acknowledged in reports and before Congress that the complexity of contract pharmacy arrangements makes oversight difficult, in part, because the definition of "patient" is ambiguous,[7,8] leading to prohibited duplicate discounts and diversion. Both agencies have also noted that HRSA does not scrutinize contract pharmacy arrangements.

H.B. 1473 would increase the risk of fraud, waste, and abuse by preventing the identification of 340B claims. H.B. 1473 prohibits manufacturers from requiring data to identify 340B claims. However, claims data is essential to prevent fraud, waste and abuse in the program. Manufacturers and states rely on 340B claims data to prevent inappropriate duplicate discounts and diversion. Without this information, it is much more difficult for manufacturers to conduct audits to ensure that fraud, waste, and abuse are not taking place.

In FY 2024, HRSA found that 46% of the covered entities that were audited had adverse findings, including dispensing drugs at a contract pharmacy for prescriptions written at ineligible sites.[9] The Centers for Medicare and Medicaid Services (CMS) issued a bulletin in January 2020 that made "best practice" recommendations to states on minimizing duplicate discounts.[10] States are required to report data excluding 340B claims to CMS for the purposes of billing manufacturers for Medicaid drug rebates. In their recommendations, CMS notes that states should have a means to identify 340B drug claims. The Agency also confirmed that "HRSA encourages 340B covered entities to work with the [applicable] state to develop strategies to prevent duplicate discounts on drugs covered by Medicaid managed care plans."[11]

Further, as required by the Medicaid Managed Care Final Rule, 42 CFR §438.3(s)(3), "claims for 340B drugs that are the responsibility of the Medicaid managed care plan must be identified and excluded from the general managed care utilization data reported to the state for purposes of billing manufacturers for Medicaid rebates."[12]

The prohibition on claims data as outlined in H.B. 1473 runs counter to CMS' and HRSA's recommendations, increasing the likelihood for diversion and duplicate discounts, as prohibited by federal statute.

For these reasons, BIO opposes H.B. 1473 and urges the Legislature not to move forward with the bill. Please do not hesitate to contact us for any further information.

Sincerely,

/S/

Lilly Melander
Senior Director, State Government Affairs
Biotechnology Innovation Organization

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[7] Ibid.
[8] "Contract Pharmacy Arrangements in the 340B Program," *Memorandum to HRSA Administrator Mary Wakefield*, Office of Inspector General, February 4, 2014.
[9] HRSA Program Integrity: FY 24 Audit Results. Retrieved: https://www.hrsa.gov/opa/program-integrity/fy-24-audit-results?order=field_opa_audit_entity&sort=asc
[10] Lynch, Calder, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid," *CMS Information Bulletin*, Centers for Medicare and Medicaid Services, January 8, 2020.
[11] Ibid.
[12] Best Practices, January 8, 2020.

Testimony in support of:

House Bill 1473, with the 2025-2027 Senate Human Services Committee

Recommendation to prohibit acts of drug manufacturers; and to provide a penalty.

March 12, 2025

Chairman Lee and Members of the Committee,

My name is Dr. Aaron Garman, and I am a Family Physician practicing in rural North Dakota for the past 25 years. For the last 22 years, I have also had the privilege of serving as the Medical Director of a Community Health Center in Beulah, ND, with additional sites in Center, Killdeer, and Hazen. Over the years, I've been deeply involved in the 340B program, both administratively and in direct patient care.

When I first began practicing, the challenge of affording necessary medications was an all-too-common and heartbreaking reality for many of my patients. I often had discussions with patients about treatment options, only to have them tell me, "Doc, I just can't afford that pill." It was devastating to know that these patients—many of them farmers and ranchers—had to choose between life-saving medications for conditions like diabetes, heart disease, and stroke prevention, and basic necessities like feeding their families.

In those early years, we did everything we could to help, including Dr. Jackson, my colleague, who would occasionally pay out of his own pocket to cover the cost of medications for patients who needed them the most. This approach was not sustainable, and it highlighted a painful gap in our healthcare system: the ability to access the treatments they desperately needed.

Everything changed when we became a Federally Qualified Health Center in 2003, granting us access to the 340B program. With 340B, we could provide medications to these same patients at a nominal cost, ensuring they receive the care they needed without having to make impossible choices. Thanks to this program, I no longer have those difficult conversations with patients. I no longer must watch them struggle to choose between essential care and putting food on the table.

The impact of 340B has been nothing short of transformative. In addition to providing medications, this program has enabled us to reinvest savings into other crucial services for our community. These funds have been vital in supporting our *Impact Program*, which offers mental health counseling in schools for elementary, middle, and high school students. The 340B program also supports our Behavioral Health and Medication Assisted Therapy programs—critical services for individuals facing mental health challenges and addiction issues in our rural community.

However, the future of the 340B program is under threat. Pharmaceutical companies are making it increasingly difficult for health centers like mine to access the program, setting up barriers that are frustrating and time-consuming. While these changes may not be immediately fatal, they create a thousand small cuts that slowly erode the very foundation of this program.

I urge you to understand that the 340B program is not just a benefit to health centers; it is a lifeline for patients who would otherwise go without essential medications, and it ultimately helps to lower overall healthcare costs by preventing expensive emergency room visits and hospitalizations. Furthermore, it supports programs that are essential for the mental and behavioral health of our most vulnerable residents.

The 340B program is not a tax on North Dakota citizens, nor is it a burden on pharmacies. Rather, it is a crucial tool that helps communities like mine thrive by ensuring access to affordable healthcare. It may be a challenge to pharmaceutical companies, but I believe it is a challenge they should embrace, knowing the good it does for patients and communities.

For those of us in rural North Dakota, the 340B program has been a lifesaving, life-altering resource that our patients, families, and friends depend on. I hope that you will continue to support this program and protect the ability of centers like mine to serve those who need us most.

Thank you for your time and consideration.

Respectfully submitted,

Aaron Garman, MD

Monday, March 10, 2025

The Honorable Judy Lee
Human Services Committee, North Dakota Senate
600 East Boulevard Avenue
Bismarck, ND, 58501

Dear Chairman Lee and Honorable Members of the Senate Human Services Committee,

On behalf of National Taxpayers Union (NTU), America's oldest taxpayer advocacy organization, I respectfully urge you to oppose HB 1473, a contract pharmacy mandate that fundamentally changes how the federal 340B Drug Pricing Program functions in North Dakota.

The federal 340B Drug Pricing Program was conceived as a targeted method of providing affordable medicines to low-income and uninsured families. Since its creation in 1992, the 340B program has become controversial amid allegations that providers are "gaming" its structure to earn revenues and distribute medications well outside the communities the program was supposed to serve.

What do I mean by "gaming" the structure? As the program has expanded, it has been criticized for an overall lack of transparency and accountability resulting in the ability for entities who receive discounted drugs from pharmaceutical companies to profit from the discount instead of assisting poorer patients.

Instead of serving the most vulnerable as the program was intended — those living in low-income areas — there has been a proliferation of 340B pharmacies in more affluent neighborhoods. These expansion pharmacies are owned by for-profit Pharmacy Benefit Managers (PBMs) and chain drug stores. A 2024 Pioneer Institute Report, found 70% of 340B North Dakota pharmacies supposedly serving the poor are in affluent neighborhoods.

The report also found that North Dakota's 340B hospitals provided a mere 0.87% charity care component, compared to the national average of 2.28%. A goal of the 340B program, from its inception, was to pass the discounted savings afforded by the pharmaceutical companies on to the needy through charity care. This does not appear to be occurring in North Dakota.

There are lessons to be learned from other states. A recently released PEHP fiscal analysis of similar 340B contract pharmacy mandate legislation in Utah found that this policy could increase pharmacy costs for the state's public employee health program. The report conservatively expects a 10% increase in drugs purchased through the 340B program resulting in a loss of $1,987,674 in rebates - a cost the state will need to cover. The Utah 340B mandate bill failed to pass out of a senate committee last month.

In North Carolina, 340B entities are billing insured patients in state health plans at higher costs than their discounted acquisition costs and copays are based on a list price not the discounted price. A recent report released by North Carolina State Treasurer Dale Folwell shows the extent to which hospitals in the 340B Program in North Carolina are overcharging cancer patients through the state's health plan. Patients are being charged at an average rate greater than five times the cost of cancer drugs. These higher rates are being borne on the backs of patients and all taxpayers in North Carolina. This report only considers cancer medications, so the full extent to which patients and taxpayers are being burdened is not known. Currently, the North Carolina State Health Plan faces a $32 billion unfunded healthcare liability.

In November, the Minnesota Department of Health (MDH) analyzed data from Minnesota providers participating in the 340B Drug Pricing Program. Their report details the extent to which 340B hospitals are profiting from the program. Providers earned a net revenue of at least $630 million in 2023, which may only represent half of the total. The state's largest 340B hospitals benefited the most from the program.

One final - and not minor - reason to reject HB 1473 is the very real constitutional concern this bill raises. The 340B program is wholly governed by federal law, therefore states are not in a position to create additional requirements to the program. Based on our research, some half dozen states are currently embroiled in lawsuits over this issue. Also, just this past December, the U.S. District Court for the Southern District of West Virginia enjoined that state's 340B law once it appeared likely that the plaintiffs would succeed on their claim that the federal law superseded state law.

Rather than expand the 340B program to more entities, the North Dakota Legislature ought to support measures to increase transparency and accountability for participating pharmacies and hospitals and to share this information with members of your federal delegation. The 340B program is a federal program and care should be taken to not codify state law to include aspects of a poorly designed federal program. Indeed, NTU is among many organizations that has advocated reforms to 340B through Congress.

Given all of the concerns raised here, I urge you to oppose HB 1473 and instead work to develop measures for evaluating a federal program that is clearly fraught with controversy. I humbly offer this advice as both a former pediatric nurse practitioner who worked with the very patients for whom the 340B Drug Pricing Program was intended and as a former Wisconsin state senator who understands how contentious and challenging it is to allocate taxpayer dollars wisely.

Please do not hesitate to contact me if you have further questions or concerns.

Respectfully submitted,

Leah Vukmir
Senior Vice President of State Affairs
National Taxpayers Union
lvukmir@ntu.org

2025 1473
Senate Human Services
Senator Lee, Chairman
March 12, 2025

Chairman Lee and members of the Senate Human Services Committee. My name is Erin Navarro, and I serve as the Director of Pharmacy at Altru Health System (Altru). I am honored to represent Altru and share my passion for ensuring patients remain at the heart of everything we do in healthcare and proud to be part of improving healthcare for the communities we serve. I write in favor of House Bill 1473 and ask that you give this bill a **Do Pass** recommendation. The 340B Drug Pricing Program has no impact on our tax dollars but paramount to Altru's ability to serve our community.

Sole Community Hospital

Altru is a Sole Community Hospital (SCH) and 340B Drug Pricing Program covered entity, serving over 200,000 residents in northeast North Dakota. As a covered entity and health system, Altru ensures that care is provided to our patients regardless of their ability to pay. To be designated as a SCH, a hospital must meet specific criteria set by the Centers for Medicare & Medicaid Services (CMS). Here are the key requirements:

1. **Location**: The hospital must be located more than 35 miles from other like hospitals. Alternatively, if the hospital is in a rural area, it can be located between 25 and 35 miles from other like hospitals, provided it meets additional criteria such as having no more than 25% of residents or Medicare beneficiaries in the hospital's service area admitted to other like hospitals within a 35-mile radius.
2. **Special Circumstances**: The hospital can also qualify if it is located between 15 and 25 miles from other like hospitals but is inaccessible for at least 30 days in each of 2 out of 3 years due to local topography or severe weather conditions.
3. **Service Area**: The hospital must draw at least 75% of its inpatients from its service area during the most recent 12-month cost reporting period.

Regarding the impact on 340B eligibility, Sole Community Hospitals must meet additional requirements to participate in the 340B Drug Pricing Program:

1. **Disproportionate Share Adjustment**: The hospital must have a disproportionate share adjustment percentage greater than or equal to 8% for the most-recently filed cost report.
2. **Non-Profit Status**: The hospital must be a private non-profit hospital under contract with state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid, or it must be owned or operated by a unit of state or local government.
3. **Certification**: The hospital must certify that it meets the statutory definition of a Sole Community Hospital and that such status is recognized by CMS.

These requirements ensure that SCH can access discounted drug prices under the 340B program, which can offer significant savings on pharmaceuticals.

Altru's 340B Program

Altru has been a covered entity in the 340B program for nearly a decade. Altru runs a conservative and compliant program, with accurate 340B policies and procedures and an internal team dedicated to those compliance standards. Annually, Altru recertifies our 340B Program to maintain compliance. The annual recertification is a vital component of maintaining the program's integrity. It ensures that only eligible entities continue to benefit from the 340B discounts, thereby preventing misuse and preserving the program's resources for those who truly need them. The recertification includes complete transparency to the federal government. This transparency includes creating a trial balance that ties every applicable line of the Medicare Cost Report to registered 340B child sites to include outpatient expense and revenue at each location 340B drugs are purchased. Altru also includes our Medicare Cost Report in full and include our government contract. Meaning our books are open and fully transparent to the federal government, namely Health Resources and Services Administration (HRSA).

In addition to this annual recertification, Altru has also responded to all HRSA requests for information and was successful in a recent HRSA audit of the Altru 340B Program which verified that Altru adheres to the program's rules and regulations, ensuring that the benefits of the 340B Program are being used appropriately to support patient care for underserved populations. The audit examines various aspects of the covered entity's participation in the 340B Program, including:

- **Eligibility**: Confirming that the entity meets the eligibility criteria for participation in the program.

- **Duplicate Discounts**: Ensuring that the entity is not receiving both a 340B discount and a Medicaid rebate for the same drug.
- **Diversion**: Checking that 340B drugs are only dispensed to eligible patients and not diverted to ineligible patients or entities.

Process: The audit process typically involves several steps:

- **Notification**: Altru was notified of the upcoming audit and provided with details 30 days in advance.
- **Documentation Review**: HRSA reviewed the Altru's uploaded records and documentation to verify compliance with 340B Program requirements.
- **Site Visit**: HRSA came to Altru to further assess compliance and gather additional information.

Outcomes: Depending on the audit findings, outcomes can range from no adverse findings to the requirement for corrective actions. In cases of significant non-compliance, entities may be required to repay manufacturers for any discounts received inappropriately or face removal from the 340B Program. Altru was thrilled to report that our organization did not have any deficiencies and successfully passed the HRSA audit in April 2022.

Community Benefit

The Altru 340B Program is crucial to the communities Altru services in that we rely on 340B savings to keep services open in our region, to include but are not limited to:

- Devils Lake Dialysis;
- Altru in and outpatient behavioral health;
- Altru's Level 2 Trauma status;
- Altru's investment in the Devils Lake Critical Access Hospital;
- Over 60 Altru specialists services;
- Altru Home Health services;
- Emergency care services to include ground and air ambulance; and
- Onsite intensivists in Altru's ICU.

Our 340B Program also support our community's low-income populations in tandem with Grand Forks BlueZones and Public Health with transportation to chemotherapy appointments and food insecurity. Altru is able to provide nurse at Grand Forks Lagrave on Frist as well as Altru's Food Pantry and other charitable care.

Unfortunately, over the past two years, Altru and Altru patients have felt the financial impact of manufacturers continuously pulling medications from the 340B Program. As of this date, Altru has received communication from 33 manufacturers pulling medications.

Impact

In the last 3 years our ability to purchase 340b drugs has been impacted by manufacturers imposing their own mandates on who they give discounts to. Most of this impact has been in the community, contract pharmacy setting. Manufacturers have limited our ability to partner with community pharmacies by prohibiting such arrangements and refusing to honor 340B discounts on certain drugs. Unfortunately, we are on the verge of needing to terminate our contracts with many independent pharmacies across the state due to big pharma's refusal to comply with the intent of the program. Let the law be followed as the legislature that drafted it intended. Do not let big pharma rewrite the laws to our state's hospitals and constituents' detriment.

I appreciate the opportunity to be part of improving healthcare across the state of North Dakota. We ask that you give the bill a Do Pass recommendation. Thank you for your consideration. I am to answer questions.

Thank you,

Erin Navarro, Director of Pharmacy at Altru Health System

CSRO
Coalition of State Rheumatology Organizations

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March 11, 2025

Senate Human Services Committee
600 East Boulevard Avenue, Fort Lincoln Room
Bismarck, ND 58505

Concerns re: HB 1473 – Federal 340B Drug Pricing Program

Chair Lee, Vice Chair Weston and members of the Senate Human Services Committee:

The Coalition of State Rheumatology Organizations (CSRO) would like to express concerns regarding HB 1473, which would address aspects of the federal 340B drug pricing program. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic diseases, such as rheumatoid arthritis, psoriatic arthritis and lupus, are systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

HB 1473 would allow for significant growth in the 340B drug pricing program and fails to incorporate guardrails that ensure patient access to discounted medications. Section 340B of the federal Public Health Service Act, known as the 340B drug pricing program, was created to provide discounted outpatient medications for disproportionate share hospitals (DSH) and federally qualified clinics that treat low-income and uninsured patients. However, over the past three decades, the program has grown greatly, demonstrating weaknesses in its implementation and execution.

Contract Pharmacy Expansion
HB 1473 would enable greater expansion of contract pharmacies within the 340B program, without any oversight to ensure that underserved patients actually receive discounted medications from the contract pharmacies associated with DSHs. According to a 2018 U.S. Government Accountability Office (GAO) report, the number of pharmacies that contract with 340B entities has increased "more than fifteen-fold" since the 2010 guidance that allows for an unlimited number of contracts. Initially these contract pharmacies were primarily located in the same communities as the covered entity. However, GAO reported that contract pharmacies are located between 0-5,000 miles away from their associated covered entity.[i]

More than half of all U.S. pharmacy locations act as a contract pharmacy for a covered entity participating in the 340B program.[ii] CVS Health, Walgreens, Cigna (via Express Scripts), UnitedHealth (via OptumRx), and Walmart – all publicly traded, vertically integrated subsidiaries of pharmacy benefit managers (PBMs) – account for 75% of all

contract pharmacy relationships with 340B covered entities.[iii] These pharmacies are all top Fortune 30[iv] companies, profiting off of underserved patients through their 340B business arrangements. Clearly, access to contract pharmacies is *not* what is limiting patient access to 340B medications, and provisions within HB 1473 would only allow large PBMs to continue to profit from these broken aspects of the system.

Healthcare Consolidation

The Health Resources and Services Administration (HRSA) allows 340B covered entities to register their off-campus outpatient facilities, or child sites, under their 340B designation. Covered entities, such as hospitals and their off-campus facilities, have a competitive advantage as they can purchase drugs at a 20-50% discount through their 340B status. Covered entities acquire drugs at the 340B price, while imposing markups on the reimbursement they submit to private insurance.

According to a study in the New England Journal of Medicine, after accounting for drug, patient, and geographic factors, price markups at 340B eligible hospitals were 6.59 times as high as those in independent physician practices. In this study, 340B eligible hospitals earned $650.24 more per drug unit than independent physician practices. This may also have the unintended consequence of exacerbating government healthcare spending.

The additional revenue these covered entities can pocket provides them with a cash flow advantage that physician practices and outpatient clinics will never be able to actualize. These child site clinics compete with independent community practice rheumatologists and oncologists, who prescribe many of the expensive medications available to 340B DSH, and eventually run them out of business. This uneven playing field may make rheumatology practices more susceptible to hospital acquisitions. In fact, between 2016-2022, large 340B hospitals were responsible for approximately 80% of hospital acquisitions.[v]

This consolidation was also recognized in a 2022 Congressional Budget Office report, which states the 340B program could encourage large healthcare systems that prescribe expensive 340B eligible medications to acquire physician practices, such as rheumatology and oncology. These acquisitions threaten the viability of rheumatology practices across the United States. We are concerned that HB 1473 could lead to greater healthcare consolidation throughout the state, jeopardizing the viability of North Dakota-based rheumatology practices and leading to increased costs for patients and the healthcare system in general.

Weaknesses in 340B Implementation

In recent years, rheumatologists have seen the effects of the weaknesses within the 340B program as Medicaid patients have been turned away from 340B DSH clinics for their regular treatments. Medicaid patients with chronic conditions are certainly "underserved" and do not always benefit from the discounted medications made available through the 340B program. This clearly falls outside of the original mission of the 340B program. This is just one of the weaknesses in the 340B system, particularly with large DSH systems, that reveal a failure to consistently serve patients in need, in spite of large profits that come from contract pharmacies and child site clinics.

CSRO believes that the 340B drug pricing program was created with a noble mission – to ensure that underserved, low-income and uninsured patients receive the medications they need at little to no cost. However, expanding access through unrestricted contract pharmacy access is not the solution and offers no assurances of benefit to the intended patients. Instead, to ensure the program's success, the mission should be realigned to prioritize the patient and establish greater transparency and accountability. For more information on CSRO's position, please visit https://csro.info/UserFiles/file/CSRO-340B-Statement-2024.pdf.

We appreciate your consideration and request that you do not advance HB 1473. We thank you for your consideration and are happy to further detail our comments to the Committee upon request.

Respectfully,

Aaron Broadwell, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

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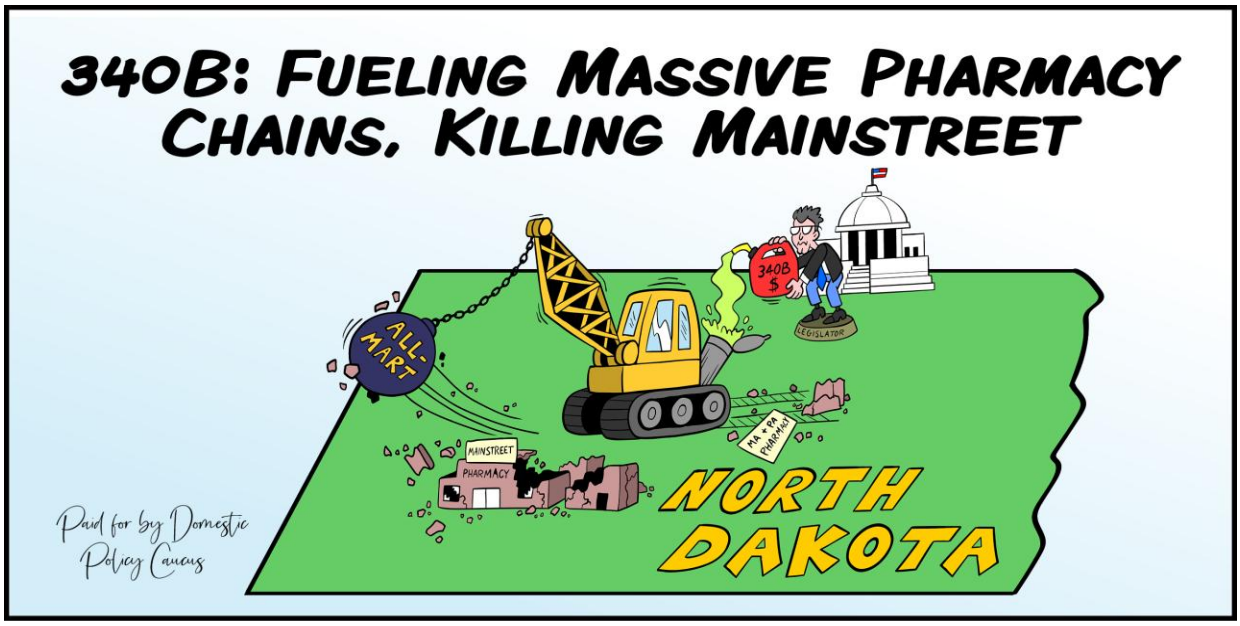
[i] U.S. Government Accountability Office. "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." June 2018.
[ii] Drug Channels. "EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market." July 2023.
[iii] ibid
[iv] Fortune. "Fortune 500." 2024.
[v] Avalere. "Characteristics of Hospitals Undergoing Mergers and Acquisitions." February 2023.

Domestic Policy Caucus
Testimony Opposing HB1473 – Senate Human Services Committee
March 12, 2025



On behalf of the Domestic Policy Caucus, I am writing to express our opposition to the expansion of 340B, the federal law on prescription drugs, in North Dakota, as contained in HB1473.

If they were made aware of it, most North Dakotans probably would find it baffling that their state legislators are considering the expansion of a massive federal healthcare mandate. It's troubling that this appears to be occurring with little discussion about the financial impacts of the policy or the impact on rural North Dakota.

The law was meant to help low-income people afford their medicines. Unfortunately, The financial benefits of the 340B discounts are accruing almost entirely to hospitals, clinics, and physicians; and patients' out-of-pocket costs are increasing, and that's according to the JAMA. Indeed, the profit has become a major revenue source for some providers, with little to no benefit for the patient.

What's more is that an expansion of 340B would hand over even more economic power to contract pharmacies—that have driven so many local, mom-and-pop pharmacies out of business over the past several years.

An expansion of 340B would create an economic environment in which incentives would be put in place to encourage even more consolidation of healthcare systems, to put healthcare farther out of reach of rural North Dakotans, and to imperil the ability of underserved residents to

receive the care and discounts they need, all while lining the pockets of big healthcare systems and giant chain pharmacies. Meanwhile, it would do nothing to reduce patient costs, which is what everyone really wants.

As you know, pharmacies are essential to the communities they serve. But in North Dakota and throughout America, independent drugstores are struggling.

In a 2022 policy brief, the Rural Policy Research Institute reported this troubling fact: The number of independently owned retail pharmacies declined by 16 percent in the United States between 2003 and 2021. According to NPR, that has contributed to the appearance of what are called "pharmacy deserts"—areas where residents must drive more than 15 minutes to a drugstore. In fact, according to a 2021 report issued by GoodRx called "Mapping Healthcare Deserts," of all the states, North Dakota has among the most counties having insufficient access to a drugstore. Expanding 340B would exacerbate the problem.

Disparities in access to care and health outcomes for rural, underserved, and minority populations have long been significant issues. Any policy that could further restrict the accessibility of medicines to these populations—like forcing them to travel farther to obtain them—needs to take the issue of health equity into consideration.

Making a bad program bigger is not the answer. The 340B program should be fixed before there's any discussion about expanding it. You should provide oversight to hold covered entities responsible for delivering on 340B's stated purpose. Simply defining who is a 340B patient and ensuring the money flows to those eligible patients—instead of pharmacy owners and hospital systems—is a commonsense first step.

The bottom line: There should be much more discussion, analysis, and debate before determining whether to head down this uncertain and troubling healthcare policy path.

Don't be like the legislator in our cartoon: Please vote "no" on HB1473 and expanding 340B in North Dakota.

Thank you,

Kent Kaiser, Ph.D.
Secretary/Treasurer
Domestic Policy Caucus
651-338-1777
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STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to North Dakota House Bill 1473
340B Prescription Drug Program
March 2025

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes North Dakota House Bill 1473 ("HB 1473"). HB 1473 would prohibit biopharmaceutical manufacturers from interfering with the acquisition of a 340B drug by a contract pharmacy on behalf of a covered entity. This type of provision not only raises constitutional concerns but also exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

Congress created the 340B program in 1992 to help vulnerable and uninsured patients access prescription medicines at safety-net facilities.

Through the program, biopharmaceutical manufacturers provide tens of billions of dollars in discounts each year to qualifying safety-net hospitals and certain clinics ("covered entities"), but patients are often not benefitting. Today, large hospital systems, chain pharmacies, and pharmacy benefit managers (PBMs) are generating massive profits from the 340B program even though its intended beneficiaries were true safety-net hospitals and clinics and the low-income and vulnerable patients they treat. The 340B program has strayed far from its safety-net purpose, and Congress needs to fix the program to ensure that it is reaching its intended populations.

There is little evidence to suggest that patients have benefited from contract pharmacy growth.

Since 2010, the number of contracts with pharmacies has grown by more than 12,000%, with roughly 33,000 pharmacies participating in the program in 2024.[i] Because the program has no transparency or guardrails on how hospitals and clinics use 340B profits, the money often is not going to help low-income and uninsured patients access medicines. An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B.[ii] Additional studies have found that 65% of the roughly 3,000 hospitals that participate in the 340B program are not located in medically underserved areas,[iii] and in North Dakota, only 38% of contract pharmacies are located in medically underserved areas. Research has also found that more than 77% of 340B hospitals provide less charity care than the national average for all hospitals, and they often spend less on charity care and community investment than the estimated value of their tax breaks as nonprofits.[iv] In fact, 88% of 340B hospitals in North Dakota are below the national average for charity care levels.[v]

The 340B markup program has become a hidden tax on employers, patients, and state employees.

Marking up the costs of 340B medicines for employer-sponsored commercial plans and patients with private insurance generates significant revenue for 340B hospitals. 340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patients[vi] and average spending per patient in the commercial market on outpatient medicines was more than 2.5 times higher at 340B hospitals than non-340B hospitals.[vii]

In addition, the current design of the program directly increases costs for employers by an estimated 4.2%, or $5.2 billion, due to reduced rebates from manufacturers, and indirectly increases employer costs by incentivizing provider consolidation and use of higher cost medicines.[viii,ix] With no obligation to invest profits from 340B markups at satellite facilities into underserved communities, 340B hospitals frequently purchase independent physician offices so they can then buy more medicines and increase their 340B profits.[x] Further, incentives in the 340B program increase the use of higher-cost medicines as hospitals participating in 340B generally obtain substantially larger profits from more expensive medicines.[xi,xii]

In an unprecedented report examining 340B hospital practices in its state, the North Carolina State Treasurer found North Carolina 340B hospitals charged state employees massive markups for oncology medicines.[xiii] According to the report, North Carolina 340B hospitals charged state employees, on average, a price markup of 5.4 times the hospitals' discounted 340B acquisition cost for outpatient infused cancer medicines.[xiv] This resulted in billing the North Carolina State Health Plan for Teachers and State Employees a price markup on cancer medicines that was 84.8% higher than North Carolina hospitals outside of the 340B program.[xv]

HB 1473 will further exacerbate 340B created market distortions that increase health care spending for people with commercial insurance, which raises costs for state governments and taxpayers.

The 340B program has often been touted as cost-free to taxpayers. However, research from IQVIA found that the 340B program increases drug costs for self-insured employers and their workers by 4.2% due to lost manufacturer rebates (which reduce the price of medicines) when a 340B drug is dispensed.[xvi] IQVIA reports that employers in North Dakota pay an estimated $53.4 million more in health care costs due to foregone rebates as a result of the 340B program.[xvii]

Based on analysis by IQVIA, a state 340B contract pharmacy mandate in North Dakota is estimated to increase health care costs for employers and state and local governments by $16.4M due to additional foregone rebates.[xviii]

These higher costs also impact state budgets through both higher spending for state employees' health care and forgone tax revenue due to higher premiums for state residents. Based on analysis of recent reports by IQVIA and Magnolia Market Access indicates the 340B program increased state and local governments' health care costs by $1.9 billion (4.2%) in 2022 alone.[xix]

Additional analysis from Magnolia Market Access found that the 340B program caused a combined $7.8 billion increase in health care costs for self-insured and fully insured employers and workers in 2021,

leading to $1.8 billion in lost federal and state tax revenue. In North Dakota, the impact of lost state tax revenue was $0.5 million.[xx]

HB 1473 will line the pockets of PBMs, pharmacy chains, and large hospital systems.

Many contract pharmacies charge a patient based on a drug's full retail price because they are not required to share any of the discount with those in need.[xxi] Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. North Dakota 340B hospitals have nearly 250 contracts with pharmacies outside the state. These out-of-state arrangements are not subject to North Dakota's pharmacy ownership law.

Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements. Recent analysis by Avalere found that 69% of 340B contract pharmacies were associated with a PBM through vertical integration (53%) or contractual arrangement (16%). Only 16% of non-340B pharmacies were vertically integrated or affiliated with a PBM.[xxii] Notably, 44% of contract pharmacy arrangements are with pharmacies affiliated with the three largest PBMs – OptumRx, CVS Caremark and Express Scripts.[xxiii] The five largest contract pharmacy parent companies earned an estimated $2.9 billion from 340B in 2023.[xxiv] These earnings are part of the hidden tax the 340B markup program has created. The program reached $66.3 billion in 2023, a 23% growth increase from the previous year.[xxv]

In North Dakota, PBMs and large pharmacies make up 60% of contract pharmacy arrangements. PBM-owned pharmacies specifically account for 26% of all arrangements with 340B contract pharmacies in North Dakota.[xxvi]

In 2023, the Minnesota Legislature passed legislation[xxvii] that requires the Minnesota Department of Health (MDH) to collect and aggregate data from Minnesota providers that participate in the federal 340B program and prepare a report with findings for the legislature and public. The first Minnesota 340B report was released in November 2024 and provides further evidence that for-profit middlemen are profiting from the 340B program. Specifically, the report found that payments to contract pharmacies and third-party administrators (TPAs) were over $120 million, representing approximately $16 of every $100 of gross 340B revenue generated paid to external parties.[xxviii] In fact, 10% of safety-net federal grantees reported a negative net 340B revenue due to payments made to middlemen.[xxix] The top 10% of critical access hospitals and disease-specific grantees with the highest external operational costs lost at least half their gross 340B revenue to TPAs and contract pharmacies.[xxx]

The Minnesota 340B report also sheds light on the massive profits 340B hospitals retain from the 340B program. Minnesota providers participating in the 340B program earned a collective net 340B revenue of at least $630 million for the 2023 calendar year.[xxxi] Based on national data, MDH believes this figure may represent as little as half to one-third of the actual total 340B revenue for Minnesota providers due to lack of reporting from the covered entities for office administered drugs.[xxxii, xxxiii] Most entities did not report data for office administered drugs, which are estimated to account for 80% of all 340B drug spending.[xxxiv] The state's largest 340B hospitals benefitted most from the 340B program, accounting for 13% of reporting entities but representing 80%—more than $500 million—of net 340B revenue.[xxxv]

Additional analysis of the Minnesota 340B report reveals the largest single beneficiary of 340B markups was M Health Fairview University of Minnesota Health Center ("M Health Fairview"), which reported an astounding $130 million in net 340B revenue. By comparison, M Health Fairview reported higher revenue than all the state's 72 critical access hospitals, 17 community health centers, 9 Ryan White AIDS clinics, and 63 STD clinics combined.[xxxvi]

HB 1473 would require manufacturers to provide 340B-priced drugs to all pharmacies that contract with 340B covered entities.

The 340B program is a comprehensive federal program that is governed exclusively by federal law. States do not have the authority to create new requirements that are not in the federal statute or that conflict with the statute. Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in several federal courts across the country.

PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing HB 1473.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

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[vi] Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance, New England Journal of Medicine, 390, 4, (338-335), (2024). DOI: 10.1056/NEJMsa2306609

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[xv] *Ibid.*

[xvi] IQVIA. The Cost of the 340B Program Part 1: Self-Insured Employers. March 12, 2024. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/iqvia-cost-of-340b-part-1-white-paper-2024.pdf

[xvii] IQVIA, "The Cost of 340B to States," Feb. 2025.

[xviii] *Ibid.*

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[xxvii] 2023 Minnesota Statutes, Section 62J.312

[xxviii] Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. https://www.health.state.mn.us/data/340b/docs/2024report.pdf

[xxix] *Ibid.*

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[xxxi] *Ibid.*

[xxxii] *Ibid.*

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[xxxv] Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. https://www.health.state.mn.us/data/340b/docs/2024report.pdf

[xxxvi] *Ibid.*

HEART OF AMERICA
MEDICAL CENTER

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Rugby, ND 58368
(701) 776-5261

March 11, 2025

Senate Human Services Committee
600 East Boulevard Avenue
Bismarck, ND 58505

Subject: Support for HB 1473: Prohibited Acts of Drug Manufacturers

Dear Committee Members,

I am writing to express my support for HB 1473 and for the strengthening of rural health care quality and access, thus ensuring the stability of rural North Dakota culture. This legislation would help ensure the 340B program is carried out in the spirit that it was originally intended, namely for the benefit of underserved patients.

The original intent of the 340B Drug Pricing Program, established in 1992, was to provide financial relief to healthcare organizations that serve uninsured and low-income patients, allowing them to stretch scarce resources and provide more comprehensive care. The program was created under the Veterans Health Care Act of 1992 and requires pharmaceutical manufacturers that participate in Medicaid to offer discounted outpatient drugs to eligible healthcare facilities. Drug manufactures are not required to publicly report their profits by participating in the Medicaid Drug Rebate Program, but this does require them to participate in the 340B program. The dollars that are part of the 340B program are not funded by the taxpayers, meaning there are no federal or state dollars directly involved, but rather the 340B funds are a portion of the savings that drug manufacturers earn by participating in the rebate program. This fact translates to the reality that any drug manufacture-initiated inhibition of the 340B program will not save taxpayers any money.

As a health care provider, administrator, and a patient of a critical access hospital I know firsthand the importance of local rural health care. This care absolutely saves lives. However, this care is not fully paid for by many of our various revenue streams. For example, at the Heart of America Medical Center we lose about $400,000 dollars every year by operating our EMS service, $365,000 for bad debt, $20,000 for diabetes education, and we must spend about $2,000,000 annually on contract labor primary for elder care needs. We also provide about $250,000 annually in the form of charity care. The 340B program helps to offset these expenses and allows us to continue these services.

As a health care facility, we are more than happy to make this data clearly available to the public. In fact, HAMC has developed a report to clearly track savings from the 340B program. These savings have been used to ensure a functional EMS program including lifesaving timely ambulance transfers, a diabetes educator, and fully staffed swing-bed and acute care departments. It should also be noted that over the past few years many requirements from drug

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manufacturers have attempted to erode 340B savings for rural health care, while our expenses continue to rise. If this trend continues services will be cut for our rural communities.

Our rural hospitals have nothing to hide regarding the 340B program. However, we do need this program to remain robust and functioning as the original intent has been generally understood. We also believe that as locally owned rural health care providers we know best how to utilize the 340B savings to ensure affordable and available care for our communities. If this program is significantly inhibited, services will be lost for our low-income and uninsured rural residents.

I urge you to support HB 1473 and support policies that strengthen quality and access to rural health care. Thank you for your time and consideration.

Sincerely,

Erik Christenson
CEO

Dear North Dakota Legislator:

We are writing to express our concern for HB 1473 that would expand the 340B Drug Pricing Program in the midst of its far-reaching impacts on patients, taxpayers, and employers in North Dakota. Originally created to help low-income and uninsured patients access affordable medications, 340B has become a hospital markup program riddled with loopholes that allow large hospitals, pharmacy benefit managers (PBMs), and chain pharmacies to profit at the expense of patients. Instead of lowering costs for those in need, many 340B hospitals mark up the price of discounted drugs—charging insurers and patients full price while pocketing the difference.

Before expanding a program with known loopholes and misaligned incentives, we must address the fundamental issues plaguing 340B today:

- **Hospital Markups & Rising Costs:** Many 340B hospitals in North Dakota markup medicine prices rather than passing discounts to patients, leading to significantly higher prescription costs compared to non-340B providers. This drives up insurance premiums and out-of-pocket expenses for families and employers statewide.
- **Loopholes That Undermine Rural Access:** Today, 41 healthcare entities participate in 340B, with 430 contracts between North Dakota hospitals and out-of-state pharmacies. However, only 38% of these contract pharmacies are in medically underserved communities, meaning most program savings flow to wealthier areas – funneling resources away from rural communities while benefiting wealthier urban areas.
- **Lack of Transparency & Minimal Charity Care:** Despite generating millions in 340B revenue, 80% of North Dakota's 340B hospitals provide charity care below the national average. With an average charity care rate of just 1.1%, far below the national average of 2.5%, many uninsured patients still pay full price for medicines acquired at steep discounts. North Dakota's 340B entities generate 6.6 times more in program profits than they spend on charity care, while large hospitals and PBMs pocket the difference with no requirement to reinvest savings into patient care.

Without meaningful reform, 340B will continue to function as a loophole for hospital markups and corporate profits rather than a program benefiting the patients it was intended to serve. Expanding a broken system will only exacerbate these issues, leaving North Dakota's most vulnerable patients without the care they need.

We urge you to prioritize transparency and accountability reforms that ensure 340B savings directly benefit patients and support rural healthcare expansion rather than fueling profit-driven hospital tactics. We welcome the opportunity to work with you on solutions that put North Dakota patients first.

Sincerely,

Biomarker Collaborative
Community Access National Network
Community Liver Alliance
Exon 20 Group
H.E.A.L.S. of the South
Hispanic Business Alliance
Infusion Access Foundation
International Cancer Advocacy Network
Lupus and Allied Diseases Association, Inc.
MET Crusaders
National Infusion Center Association
Neuropathy Action Foundation
North Dakota Watchdog Network
PD-L1 Amplifieds
WomenHeart Jamestown

Bristol Myers Squibb™

March 11, 2025

VIA ELECTRONIC SUBMISSION

Senator Judy Lee, Chairman
Human Services Committee

North Dakota State Capitol
600 E. Boulevard Ave
Bismarck, ND 58505

Re: House Bill 1473

Dear Chair Lee and Members of the Human Services Committee:

Bristol Myers Squibb ("BMS") strongly opposes HB 1473 that includes provisions on the federal 340B program. These provisions would enable unchecked growth in abuses of the federal 340B Program in North Dakota and would not help vulnerable patients but rather enhance profits of big-chain pharmacies and others who exploit the 340B program for financial gain.

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through lifesaving, innovative medicines in areas such as hematology, oncology, immunology, cardiovascular, and neuroscience. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. In North Dakota, we partner with patients and scientific experts on the ground to conduct clinical studies across multiple therapeutic areas to help patients with chronic conditions.

* * * * *

In 1992, the United States Congress created the federal 340B program with the worthy goal of supporting uninsured, low-income, and other vulnerable patients by ensuring that certain providers (known as "covered entities") receive discounts on outpatient drugs for the benefit of those patients. Unfortunately, the 340B program has since become subject to vast profiteering and abuse, all at the expense of the vulnerable patients Congress meant to help. Not just covered entities, but other enterprising intermediaries, including for-profit entities known as "contract pharmacies," have exploited the program for their private gain. Indeed, national big-chain pharmacies have publicly disclosed that 340B is "material" to their bottom line, signaling that recent program integrity measures to keep widespread abuse in check is a risk to their pursuit of profits over patient benefit. Legislation like the provisions in HB 1473 will only further exacerbate these problems.

For the reasons set forth below, we respectfully request that you consider the serious negative implications that could result from the implementation of the 340B provisions in HB 1473 and continued abuses of the 340B program in North Dakota and oppose this legislation.

The 340B provisions in HB 1473 seek to regulate a pharmaceutical manufacturer's participation in the federally regulated 340B program in a way that both conflicts with the federal 340B statute and, even more importantly, enhances the profiteering and abuse that has undermined Congressional purpose. Rather than helping push back against the exploitation of the 340B program (e.g., requiring actual direct support of vulnerable patients in affording outpatient medicines), the provisions would instead protect and expand such exploitation through the unlimited and unregulated use of contract pharmacies, all without consideration of any common-sense measures to combat well-documented abuses.

Indeed, **contract pharmacies have become a vehicle to dramatically expand the scope and scale of their sale of drugs purchased with 340B program discounts**, allowing them to retain the resulting profits or deploy them for purposes unrelated to the 340B program's goal of supporting uninsured and other vulnerable populations in affording outpatient drugs. The contract pharmacies themselves, which benefit from lucrative contracts to provide access to discounted drugs, are often large, for-profit national pharmacy corporations, with two of America's largest pharmacies providing more than 60 percent of contract pharmacy services.[1] In fact, since 2019, in-state contract pharmacy arrangements increased 83% while out-of-state arrangements for in-state 340B covered entities grew 104%.[2]

Reports from the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General (OIG) highlight the many troubling issues with the program. For example, the GAO found that a lack of adequate oversight and transparency and the "identified noncompliance at contract pharmacies raises questions about now the effectiveness of covered entities' current oversight practices."[3] The GAO further found that "operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."[4] The OIG has raised similar concerns and has testified before Congress stating that there are "a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements."[5]

After over a decade of growing unlawful and documented abuses fostered by runaway non-adherence, manufacturers established permissible practices setting forth reasonable conditions on contract pharmacy arrangements for the purchase of their 340B outpatient

[1] Adam Fein, Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, *Drug Channels* (July 14, 2020), available at: https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html.
[2] Analysis of HRSA OPAIS data.
[3] GAO, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." (2018). https://www.gao.gov/assets/gao-18-480.pdf
[4] U.S. Government Accountability Office (GAO), "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement." (2011). GAO-11-836 Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement.
[5] HHS OIG, "Examining Oversight Reports on the 340B Drug Pricing Program. Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections before the United States Senate Committee on Health, Education, Labor and Pensions." (2018). Examining Oversight Reports on the 340B Drug Pricing Program (05/18) (hhs.gov).

drugs. Federal court decisions have since confirmed the legality of these practices.[6] In fact, the United States Court of Appeals for the DC Circuit recently joined the 3rd Circuit Court of Appeals by upholding the reasonable conditions set by manufacturers stating that "[S]ection 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." **Now, the 340B interests—which themselves may be funded by discounts meant to go to vulnerable patients—are seeking to use state legislation as an alternative path to profit from contract pharmacy arrangements—without actual regard for the vulnerable patients meant to benefit from 340B-discounted purchasing.** But as a federal appellate court explained when upholding manufacturer practices supporting program integrity: "Though covered entities cannot squeeze as much revenue out of [the 340B Program] as they once could, drug makers need not help them maximize their 340B profits." By contrast, the 340B provisions in HB 1473 would seek to disallow the reasonable conditions allowed under federal law and seek instead to encourage the maximizing of 340B "profits."

We at BMS are committed to meaningful and common-sense reforms that will protect the 340B program and ensure that its benefits reach those patients it was intended to serve. By contrast, the 340B provisions in HB 1473 would do nothing to address these issues. To the contrary, the legislation, if enacted, would allow current abuses of the program to continue to grow unchecked while increasing costs to North Dakota employers and workers by more than $67 million annually.[7]

We respectfully urge you to oppose HB 1473.

Sincerely,

/s/ Genevieve Plumadore

Director, State & Local Government Affairs
Upper Midwest Region
Bristol Myers Squibb

[6] See, Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs., Nos. 21-3167 & 21-3379 (3d Cir. Jan. 30, 2023).
[7] IQVIA, "The Cost of the 340B Program to States. (February 2025), available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cost-of-340b-to-states-whitepaper-2025.pdf.

STATE OF NORTH DAKOTA
GOVERNOR DOUG BURGUM

NORTH DAKOTA STATE BOARD OF PHARMACY
OFFICE OF THE EXECUTIVE DIRECTOR

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Bill No 1473 – Prohibited Acts of Drug Manufacturers

Senate Human Services Committee- Fort Lincoln Room
9:00 A.M. - Wednesday – March 12th, 2025

Madam Chair Lee, Members of the Senate Human Services Committee, for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here today and provide a testimony on behalf of the Board on House Bill 1473.

This bill adds to the prohibitive acts section of the Wholesale Drug license requirements to provide safeguards for 340B covered entities and contract pharmacies on actions of the manufacturer to limit or restrict access to the 340B drug discount program. The 340B program (created in 1992) is a discount program which is intended to help health care entities care for low income and uninsured patients. The 340B Program was expanded over the years to include other eligible health care entities. Critically, the overall federal authority of 340B is the Federal Health Resources and Services Administration (HRSA).

The 340B program financially supports both covered entities and contract pharmacies. Like it or not, to be clear, this program supports our state's health care infrastructure in a big way.

If enacted, the Board of Pharmacy would be tasked with enforcing the provisions on the licensed manufacturers and virtual manufactures conducting business in the state. We are willing to take on this responsibility.

I would be happy to answer any questions which you may have for me, and I appreciate your time and consideration of this legislation.

2025 HB 1473

Senate Human Servies Committee

Senator Judy Lee, Chairman

March 12, 2025

Chairman Lee and members of the Senate Human Services Committee, I am Tim Blasl, President of the North Dakota Hospital Association. I am here to testify in support of House Bill 1473. I ask that you give this bill a **Do Pass** recommendation.

This bill aims to create a new subsection to section 43-15.3-08 of the North Dakota Century Code, related to prohibited acts of drug manufacturers; and to provide a penalty.

Hospitals support this bill because it would help strengthen the 340B program. The 340B program was created by congress over 30 years ago. The program requires drug manufacturers to provide outpatient drugs at reduced prices to eligible health care organizations that serve more low-income and underserved patients. Pharmaceutical companies are incentivized to offer these discounts to eligible health care providers in exchange for coverage of these drugs by Medicaid and Medicare.

The 340B program allows eligible hospitals to stretch limited federal resources to provide more affordable health care services to the patients they serve. The program savings have allowed North Dakota hospitals to maintain or enhance health care services in their communities.

Today, the Health Resources and Services Administration (HRSA) administers the 340B program. HRSA does allow covered entities to contract with pharmacies to dispense drugs on their behalf to their eligible patients. Contract pharmacies serve as an extension of the 340B covered entity.

HRSA does conduct audits of covered entities to ensure they are complying with 340B rules and regulations. These audits ensure that 340B drugs are being given only to eligible patients. Also, covered entities conduct self-audits to make sure they are following program rules.

We ask that you give the bill a **Do Pass** recommendation because this legislation aims to ensure that patients have access to discounted drugs. Thank you.

Respectfully Submitted,

Tim Blasl, President
North Dakota Hospital Association

Community HealthCare Association of the Dakotas

Testimony in Support of House Bill 1473

Senate Human Services Committee
Senator Judy Lee, Chair
March 12, 2025

Chair Lee, Vice Chair Weston, and Members of the Committee, I am Shelly Ten Napel, CEO of the Community HealthCare Association of the Dakotas (CHAD). On behalf of CHAD and our member community health centers, thank you for the opportunity to testify in strong support of House Bill 1473, which would protect the 340B drug discount program that so many of our patients rely on for access to needed medications. I am joined today by Margaret Asheim, CEO of Family HealthCare, who will also share testimony.

CHAD is the non-profit primary care association representing community health centers across North Dakota and South Dakota. These non-profit, community-driven clinics provide high-quality primary and preventative care to all individuals, regardless of their ability to pay. Here in North Dakota, five community health centers provide care at 22 delivery sites in 20 communities, located in both rural and urban areas of our state. This includes primary medical, dental, behavioral health, and substance use disorder care.

The 340B Drug Pricing Program was established in 1992 and enables certain health care providers to purchase outpatient drugs at discounted prices from pharmaceutical manufacturers who choose to participate. Its goal is to stretch scarce resources to serve low-income and uninsured populations. Health centers use these savings to provide patients with discounted medications and to fund vital health services. For example, a patient may only need to pay a nominal fee – such as $10 – for a prescription that would have cost them hundreds of dollars. The program operates without taxpayer funding and ensures health care access for rural and underserved populations. Health centers and other covered entities comply with the Federal government's established reporting requirements for this program.

Dr. Aaron Garman, a Family Physician of 25 years and Medical Director with Coal Country Community Health Centers, is not able to be here in person today, as he is seeing patients. He did, however, submit written testimony, and I'd like to share a few of his comments with you this morning. He states:

> *"When I first began practicing, the challenge of affording necessary medications was an all-too-common and heartbreaking reality for many of my patients. I often had discussions with patients about treatment options, only to have them tell me, "Doc, I just can't afford that pill." It was devastating to know that these patients—many of them farmers and ranchers—had to choose between life-saving medications for conditions like diabetes, heart disease, and stroke prevention, and basic necessities like feeding their families.*

In those early years, we did everything we could to help, including Dr. Jackson, my colleague, who would occasionally pay out of his own pocket to cover the cost of medications for patients who needed them the most. This approach was not sustainable, and it highlighted a painful gap in our healthcare system: the ability to access the treatments they desperately needed.

Everything changed when we became a Federally Qualified Health Center in 2003, granting us access to the 340B program. With 340B, we could provide medications to these same patients at a nominal cost, ensuring they receive the care they needed without having to make impossible choices. Thanks to this program, I no longer have those difficult conversations with patients. I no longer must watch them struggle to choose between essential care and putting food on the table."

As you can see from Dr. Garman's comments, the 340B program has enabled health centers to pass discounts directly to patients who need them. In addition to providing patients with discounted medications, health centers reinvest 340B savings into services that further benefit their patients and communities. This includes behavioral health, chronic disease management, telehealth, transportation for medical appointments, and more.

Today, this program is under threat. Pharmaceutical companies are increasingly imposing restrictions on the number of pharmacies that a health center or covered entity can contract with. As a rural state that relies on contract pharmacies, these restrictions undermine the very purpose of the 340B program in North Dakota.

For example, Coal Country Community Health Center has locations in Beulah, Hazen, Killdeer, and Center. If they were to choose Beulah as their only 340B contract pharmacy, this would leave their Killdeer patients having to travel an hour to Beulah for discounted medications. Imagine you already can't afford needed medication, and now you are told you must come up with the gas money to drive a full hour to access discounted medication, despite the fact that that same medication is sitting on the shelves at your hometown pharmacy. We are simply asking today that patients not be put in that position and that local health centers and other covered entities be trusted to contract with the local pharmacies their patients rely on to access 340B medications. According to Dr. Garman, "The changes that PhRMA is making to this program make it impossible to meet requirements and thus will force our clinic to abandon the program. This will negatively affect the patients that we serve and our communities."

North Dakota is on solid legal ground to pass this bill. Eight other states have already passed similar laws, and 10 more states have introduced legislation this session just like North Dakota. Big Pharma lost their legal challenge to a similar law in Arkansas in the 8th Circuit of Appeals (the 8th Circuit also covers North Dakota), and the Supreme Court declined to hear Big PhRMA's appeal of that case.

Please support your local community health centers, non-profit hospitals, contract pharmacies, and local communities, and vote yes on HB 1473. Thank you for your consideration, and we

welcome you to reach out with any questions.

#40781

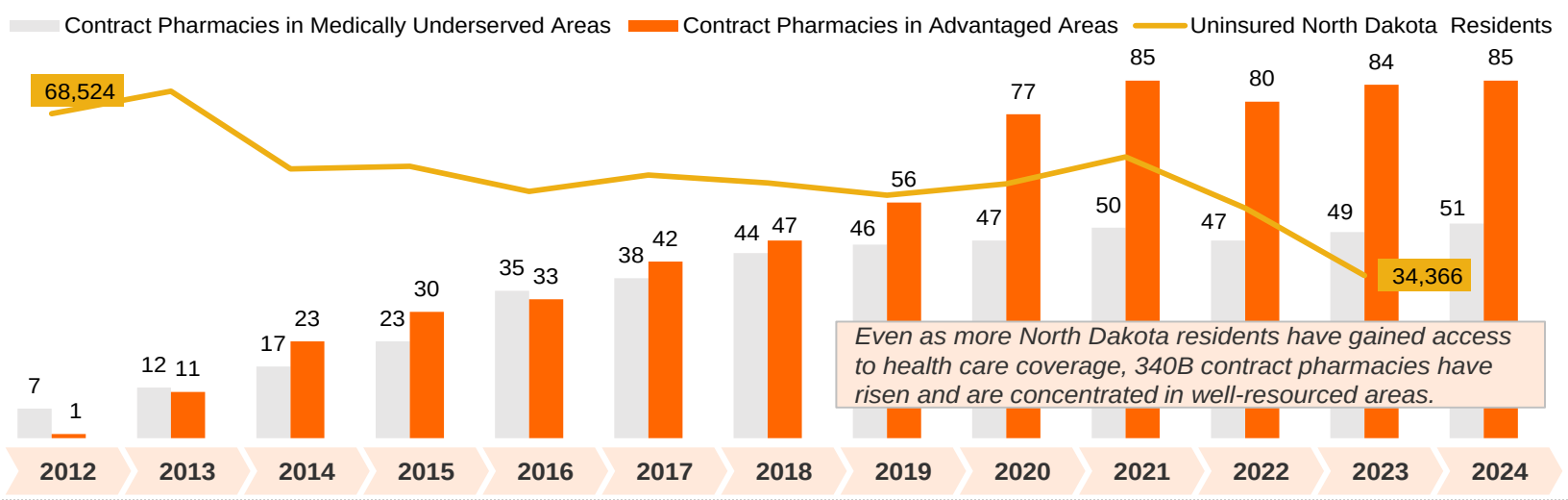
340B: A Federal Program That Has Veered Off Course

GSK

The 340B program was initiated to help select safety net providers extend their scarce resources to more vulnerable patients. ***Since its creation in 1992, abuse has been rising with more issuances of duplicate discounts and diversion. The program is not working as intended.***

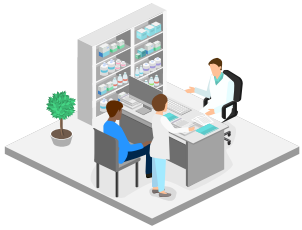
GSK supports care for vulnerable patients but opposes 340B program abuses that do the opposite.

Contract Pharmacies in North Dakota



Even as more North Dakota residents have gained access to health care coverage, 340B contract pharmacies have risen and are concentrated in well-resourced areas.

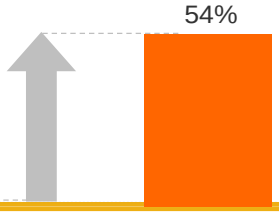
66% of North Dakota 340B hospital satellite clinics are located in advantaged areas.

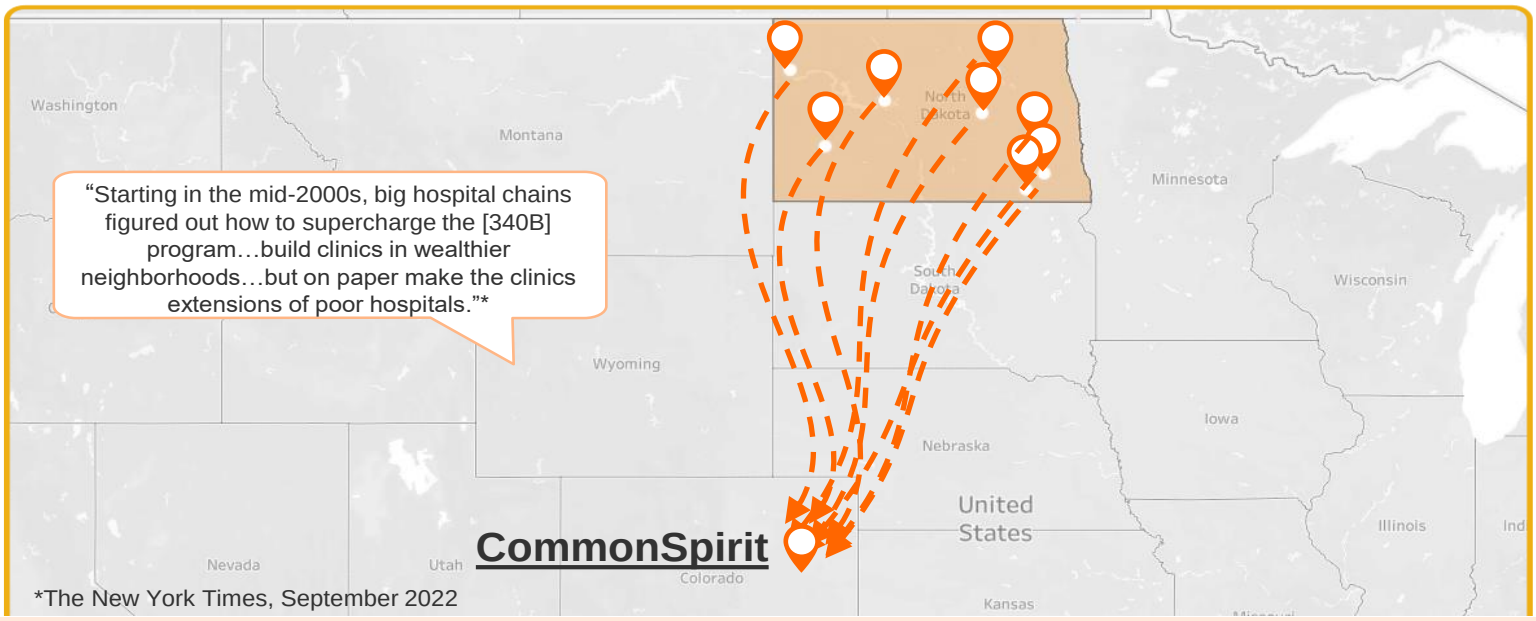


Based on BRG analysis of HRSA and Census data as of February 2025.

In 2012 **0%** of North Dakota contract pharmacy partnerships were with out-of-state pharmacies.

This share grew to **54%** by 2024.





*The New York Times, September 2022

The use of the 340B program to increase profits transcends state borders. As a federal program that has lost its focus on covered entities extending scarce resources to more vulnerable patients, 340B requires a federal fix.

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.

JAMA Health Forum. 2023 Nov 22;4(11):e233716. doi: 10.1001/jamahealthforum.2023.3716

Outcomes of the 340B Drug Pricing Program

A Scoping Review

Ryan P Knox [1,2], Junyi Wang [2], William B Feldman [2,3], Aaron S Kesselheim [2], Ameet Sarpatwari [2,✉]

Author information Article notes Copyright and License information

PMCID: PMC10665972 PMID: 37991784

This article has been corrected. See JAMA Health Forum. 2024 Sep 27;5(9):e243404.

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.

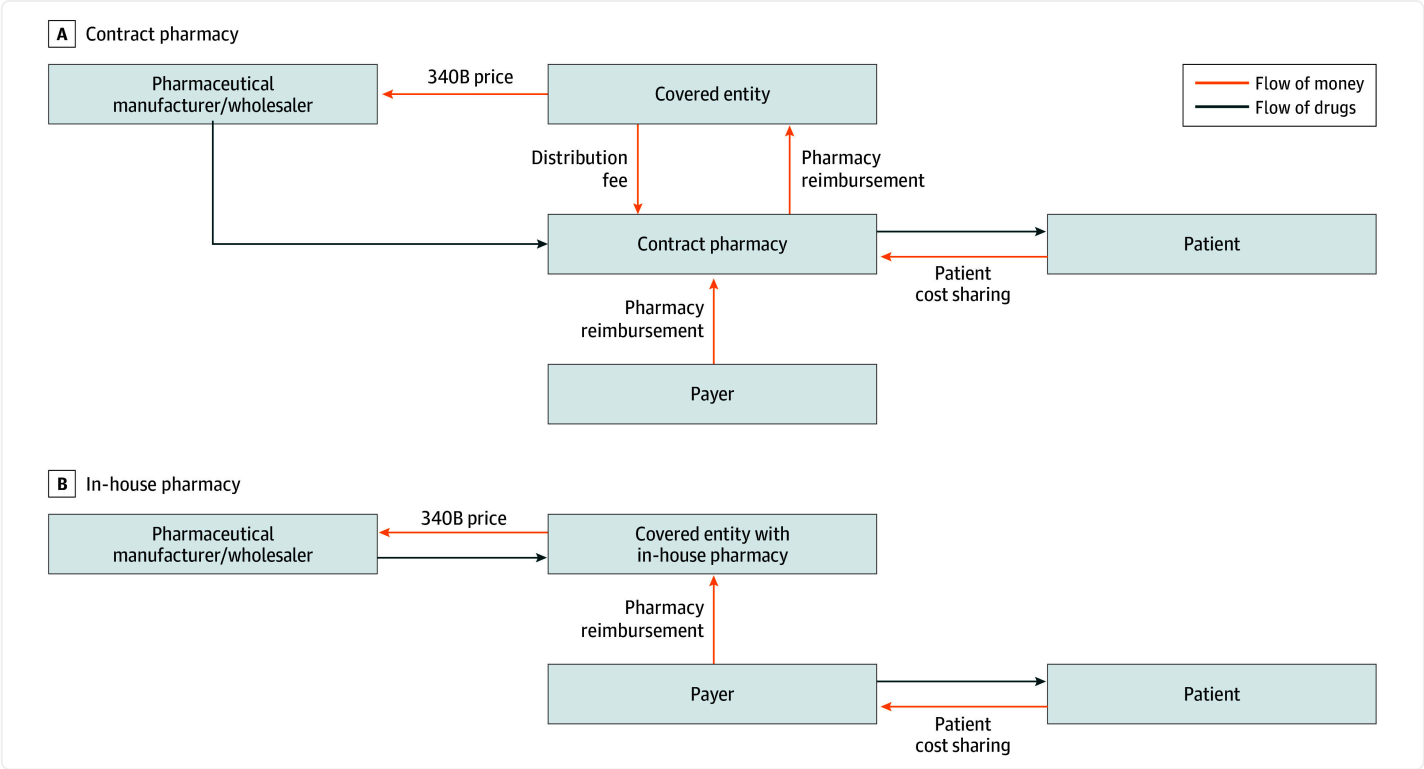
Introduction

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.

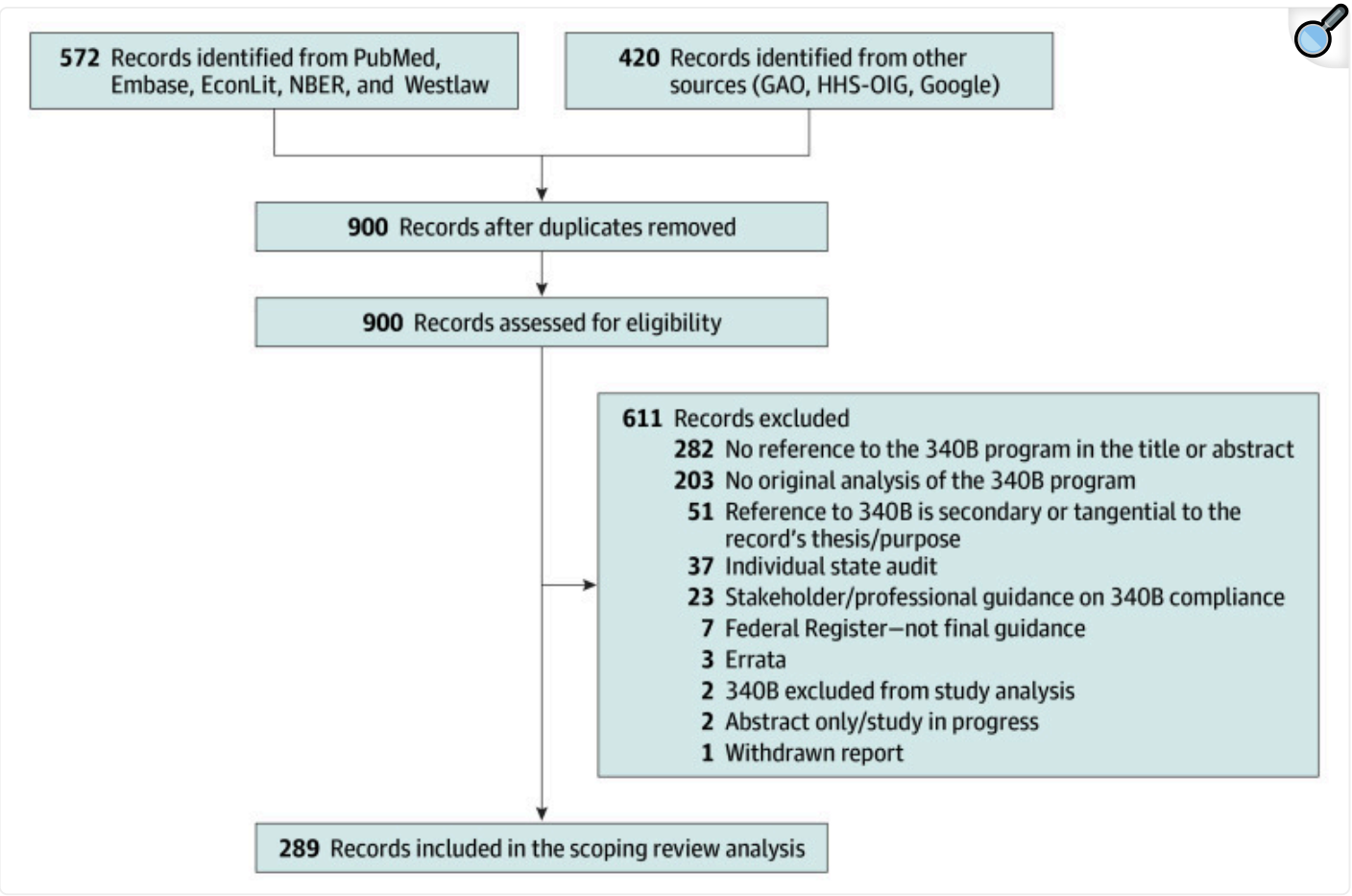
Critics of the 340B program, led by the pharmaceutical industry, have expressed concern about the program's growth in recent years.[13] We conducted a scoping review to assess the foundations of and outcomes associated with the 340B program.

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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https://www.coloradopolitics.com/news/340b-program-abuse-costs/article_617e9d9c-a20c-11ef-b2ab-63bc2a1d1e4f.html

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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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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Testimony in Support of House Bill 1473
Senate Human Services Committee
Senator Judy Lee, Chair
March 12, 2025

Chair Lee, Vice Chair Weston, and Members of the Committee:

I am Margaret Asheim, CEO of Family HealthCare, based out of Fargo, ND. I am pleased to present testimony in support of HB 1473 as passed in the House. This bill would stop pharmaceutical companies from imposing contract pharmacy restrictions and protect the 340B drug discount program that is so critical to our organization's mission of providing high quality health care to every person.

Family HealthCare is a private, non-profit, federally qualified health center (FQHC) and has been operating in our community for over 30 years. As an FQHC, Family HealthCare provides comprehensive primary care, including medical, dental, behavioral health, pharmacy, optometry, lifestyle medicine, and other services to all people, regardless of their insurance status or ability to pay. Nearly 25% of our patients are uninsured and approximately 50% of our patients are covered by Medicaid. Most of our patients have incomes at or below the 200% poverty level.

In 2024, we provided care to nearly 15,000 patients in our clinics and dispensed over 80,000 prescriptions through our two contract pharmacies, which operate solely for our patients' benefit. Both our patients and our organization have been directly affected by the negative impacts of the 340B contract pharmacy restrictions imposed by pharmaceutical companies. Increasingly, more pharmaceutical companies are enforcing limitations, often allowing us to designate only one contract pharmacy for 340B pricing. Consequently, we are unable to secure 340B pricing for many medications at our second contract pharmacy, or we can only obtain the discounted pricing by navigating a complex and burdensome array of reporting requirements, which can be challenging for smaller operations like ours to manage.

Uniquely, as a Federally Qualified Health Center, the 340B savings are passed on directly to our low-income patients on our sliding fee discount program. In most cases, those patients pay only $1.00 above what it costs the pharmacy to acquire the drug from the wholesaler. Without the 340B pricing, these medications are NOT affordable to our patients, even with the sliding fee discount. For example, a 90-day fill of a diabetes drug that costs a few dollars under the 340B program would cost the patient over $1,100 without the program. In 2024 alone, the 340B program allowed our health center pharmacies to provide savings of $3.7 million directly to 340B eligible patients in the form of reduced copays. This access to needed medications vastly improves health outcomes for our patients.

In addition to the direct impact of lowering the cost of prescriptions to uninsured patients, the savings we realize on the cost of drugs prescribed to our insured patients are critical to helping us sustain our operations as an FQHC, providing comprehensive primary care to the underserved and uninsured low-income population in our service areas. These are savings that would ultimately provide funds for us to expand access to care and continue to work to prevent unnecessary emergency room visits and avoidable hospitalizations in our communities, creating shared savings across the healthcare continuum.

Thank you for the opportunity to provide this testimony today and I would be happy to answer your questions.

Sincerely,

Margaret Asheim
Chief Executive Officer
Family HealthCare

Oral Testimony in Opposition to HB 1473
Terry Wilcox, Patients Rising
North Dakota Legislative Committee
March 12, 2025

Good morning, Chairman Lee and Members of the Senate Human Services Committee.

My name is Terry Wilcox. I'm here today on behalf of Patients Rising, a national nonprofit, nonpartisan patient advocacy organization. We represent millions of patients across the country, including patients right here in North Dakota.

We speak for patients that desperately want transparency, affordability, and access to healthcare.

Through our patient advocate network, we hear every day from North Dakotans struggling with rising healthcare costs and medical debt, many of whom depend on hospitals in the 340B program.

I'm here to urge you to vote NO on HB 1473. This bill might look like it protects the 340B Drug Pricing Program, but it doesn't. Instead, it locks in a broken system that puts hospital profits and out-of-state pharmacy chains ahead of North Dakota patients —especially in North Dakota's rural communities.

Let me start with what 340B was supposed to do: help rural and underserved hospitals get discounted drugs to support vulnerable patients. That's not what's happening.

Today, 67% of contract pharmacies tied to North Dakota's largest 340B hospitals are out of state—some as far away as Hawaii and New York. Meanwhile, 70% of these so-called "low-income" 340B pharmacies are in affluent neighborhoods, not the rural areas that need them most. And North Dakota's 340B hospitals are providing less charity care than the national average – just 0.87%

North Dakota prides itself on not having chain pharmacies, yet the 340B program is funneling benefits to national pharmacy chains through an out-of-state network. That's not helping rural North Dakotans—it's padding the bottom line of corporate players thousands of miles away. At the same time, families in North Dakora are drowning in medical debt—$1,551 per person on average, with $490 of that in collections, according to the Consumer Financial Protection Bureau. We can't say exactly how much of that comes from 340B hospitals, but our research in other states suggests it's a big chunk.

So how does HB 1473 make this worse? First, it doesn't force hospitals to reinvest 340B savings into rural access—like clinics or transportation for patients. Instead, it lets them keep partnering with out-of-state pharmacies. Second, it drives up costs. A 2025 IQVIA analysis shows the unchecked 340B program already costs insured North Dakotans $231 per person per year.

HB 1473 would tack on another $59 per beneficiary.

Third, it's a $4.3 million hit to taxpayers in lost drug rebates—money that's already tight for families, farmers, and small businesses.

We're not against 340B—we're for fixing it. Patients Rising supports reforms that put patients first.

We want transparency. North Dakota scores a measly 2 out of 10 for hospital accountability, according to the Cicero Institute. Patients deserve to know how much hospitals profit from 340B and how much goes back to care, especially in rural areas.

We also want hospitals to invest in rural communities. If you don't oppose, why not amend the bill to make sure every 340B dollar supports rural health care?

Finally, protect patients' right to know: amend the bill to ensure that patients have a right to know if they're getting a 340B drug and what it really costs the hospital.

We support rural access to care. This bill doesn't expand access for rural communities in North Dakota.

340B should work for patients, not big hospital corporations and out-of-state chains.

We respectfully ask that you vote NO on HB 1473. Thank you.

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HB 1473 – Testimony by Amgen Inc.

H.B. 1473 would mandate that drug manufacturers facilitate delivery of their deeply discounted 340B-priced products to commercial pharmacies in an improper expansion of the federal 340B program. This bill contradicts federal court rulings, exacerbates program integrity concerns, and increases costs for patients and employers.

The 340B program was established in 1992 to help safety-net providers and their patients, but its expansion, particularly via significant growth in contract pharmacy arrangements, has greatly transformed the program. Instead of serving low-income and uninsured patients, large hospital systems and their for-profit pharmacy partners are exploiting the program's lack of oversight. For instance, a report by the North Carolina State Treasurer, found that NC 340B hospitals charged state employees an average markup of 5.4 times the acquisition cost for cancer drugs.[1]

Recent research published by IQVIA found that, in 2023, the 340B program increased costs to employers by $6.6B and state and local governments by $1B because 340B discounts displaced manufacturer rebates on the same drug.[2] According to the study, contract pharmacy legislation is increasing costs due to further expansion of 340B utilization, representing an additional $1.9B in cost to employer-sponsored plans and $273M to state and local government plans. In 2023, North Dakota had the second highest rate of 340B drug sales per capita in the country resulting in the forfeiture of over $53 million in rebates that would otherwise have reduced costs for employers and the state.[3]

In recent years, investigative journalism by the Wall Street Journal[4,5] and New York Times[6] has exposed that a significant portion of 340B revenue is not reinvested into patient care but is instead retained as additional revenue for hospitals and contract pharmacies. This exploitation calls into question whether 340B is fulfilling its purpose or simply enriching intermediaries at the expense of manufacturers, patients, and employers.

H.B. 1473 is contrary to two recent federal Courts of Appeals rulings. In 2023, the U.S. Court of Appeals for the Third Circuit held that "[s]ection 340B [of the federal

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[1] North Carolina State Health Plan for Teachers and State Employees. Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program (2024). https://www.shpnc.org/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment.
[2] IQVIA. The Cost of the 340B Program to States. February 2025. https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-to-states
[3] Ibid.
[4] Wall Street Journal. "Hospitals Often Don't Help Needy Patients, Even Those Who Qualify." November 2022.
[5] Wall Street Journal. "Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients." December 2022.
[6] The New York Times. "Profits over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits." September 2022.

statute] does not require delivery to an unlimited number of contract pharmacies" and "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies."[7] In 2024, the U.S. Court of Appeals for the D.C. Circuit unequivocally reinforced this ruling.[8] Thus, the 340B statute, which governs all aspects of participation in the program, does not require manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies.

Further, H.B. 1473 is preempted by federal law. H.B. 1473 offends the Supremacy Clause because it would thrust North Dakota into the middle of a complex federal healthcare regime and meddle with the substantive rules and enforcement mechanisms that Congress created to govern it. H.B. 1473 attempts to regulate the price at which drug products are sold to pharmacies, not any aspect of delivery or safety that might normally be a state concern. Because federal law exclusively mandates which entities are entitled to the federal 340B discount, the bill's attempts to expand that universe are improper and preempted.

This bill conflicts with these precedents and risks legal challenges.

Amgen urges the rejection of H.B. 1473. Rather than reinforcing a flawed contract pharmacy model, reforms should focus on ensuring that 340B discounts directly benefit patients. The expansion of contract pharmacy mandates is preempted by federal law, contradicts federal rulings, increases costs, and undermines program integrity. North Dakota should not pursue legislation that ultimately increases the financial burden on patients while benefiting intermediaries that operate beyond the original intent of the 340B program.

[7] *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs*., 58 F.4th 696 (3d Cir. 2023).
[8] *Novartis Pharms. Corp. v. Johnson*, Nos. 21-5299, 21-5304 (D.C. Cir. May 21, 2024).

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Senate Human Service Committee
HB 1473 – 3/12/25
Madam Chair, Senator Judy Lee

Madam Chair Lee and member of the committee, for the record, my name is Mike Schwab, Executive Vice President of the ND Pharmacists Association. We are here today in support of HB 1473.

HB 1743 centers around what is known in the healthcare industry as the 340B Program. Established in 1992, the 340B program enables certain healthcare providers such as Federally Qualified Health Centers (FQHC's), Community Health Centers, Critical Access Hospitals and other non-profit hospitals to purchase outpatient drugs at discount prices from drug manufacturers. The entities mentioned above are considered "covered entities" by definition under the federal 340B program. The goal of the 340B program is to stretch scarce federal resources and dollars as far as possible to serve low-income, underinsured and uninsured populations. The 340B program allows covered entities to provide increased access to care, discounted medications and allows additional services to be offered.

Covered entities can contract with pharmacies to help dispense medications to patients who are receiving care from the covered entities. In this instance, pharmacies that elect to participate in an agreement with a covered entity are considered "contract pharmacies" by definition under the federal 340B program. Contract pharmacies participate in 340B program through an agreement with the covered entity to help serve and provide access to the covered entities patients. The contract pharmacy is responsible for keeping a separate inventory for the program, lots of back-and-forth reporting to the covered entity, processes claims, inventory ordering, etc. all of which are subject to audits and compliance checks. The 340B program is administered by the Health Resources & Services Administration (HRSA) which is a division of the U.S. Department of Health and Human Services.

So why are we here today supporting this specific bill? HB 1473 is trying to address issues that critical access hospitals, federally qualified health centers, non-profit hospitals, community health

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centers and contract pharmacies are experiencing due to restrictions or mandates that drug manufacturers have implemented on their own. In 2010, HRSA authorized and stated covered entities could use more than one contract pharmacy. In recent years, drug manufacturers have taken it upon themselves to try and change how the 340B program operates. Currently, in a number of instances, drug manufacturers are restricting or holding covered entities to the use of no more than one contract pharmacy contrary to HRSA's 2010 published rule. Drug manufacturers have also attempted to gain access to patient claims data, utilization data and other encounter data. Federally, HRSA has sent numerous letters and follow-up warning letters to drug manufacturers regarding their attempts to change how the federal program is supposed to operate.

To-date, I believe there are at least nine states that have passed laws to stop drug manufacturers from implementing contract pharmacy restrictions and more than ten states have introduced legislation this year, similar to North Dakota. In 2021, Arkansas was the first state to pass legislation that required drug manufacturers to adhere to HRSA's 2010 rule allowing covered entities to use more than one contract pharmacy. The pharmaceutical industry decided to sue Arkansas following the passage of the law. The State of Arkansas won in their lower federal court. The pharmaceutical industry decided to appeal that decision to the 8th Circuit of Appeals. The 8th Circuit of Appeals upheld the lower court's decision in favor of the State of Arkansas. The pharmaceutical industry then appealed the 8th Circuit decision to the U.S. Supreme Court. In late 2024, just before this legislative assembly came into session, the U.S. Supreme Court denied their appeal and sided with the 8th Circuit and lower court in favor of the State of Arkansas. As a reminder, North Dakota is also in the 8th Circuit of Appeals which is important to note as this committee continues to discuss HB 1473.

Drug manufacturers state the 340B program has seen outsized growth over recent years and they disagree with how federally HRSA is running the program. North Dakota does not appear to be the problem regarding the outsized growth of contract pharmacies. Some of the information and materials taken directly from the PhRMA's own website state the following:

- PhRMA states 60% of 340B contract pharmacies represent 5 large corporate chains (CVS, Walgreens, Wal-Mart, Rite-Aid and Kroger).

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- PhRMA further states, there has been a growing number of Pharmacy Benefit Manager (PBM) owned specialty pharmacies now participating as contract pharmacies in the program.
- Additional information on PhRMA's website states "PBM's now own the vast majority of pharmacies. The big three PBM-owned specialty pharmacies account for 26% of contract pharmacy arrangements."

As you can see, the vertical integration of the insurance carriers/PBMs and large chain pharmacy corporations account for over 85% of 340B contract pharmacies according to PhRMA's own information. Blanket restrictions applied across the program by drug manufacturers have a negative effect on a small rural state like North Dakota.

We have been told there are roughly 250 out-of-state contract pharmacies participating in the ND 340B program effort. Yes, there are a number of contract pharmacies in our border communities like Moorhead, Aberdeen, etc. However, there are a large number of contract pharmacies representing PBM specialty pharmacies and other PBM owned pharmacies. In addition, sometimes covered entities are required to sign agreements with a suite of chain pharmacies. Often times, the suite of out-of-state pharmacies aren't used very much, if at all, and would be considered dormant contract pharmacies.

I also think it is important to talk about "duplicate discount" prevention requirements briefly. Federally, HRSA prohibits duplicate discounts, that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate. This would cause the drug manufacturer to pay two discounts on the same drug. North Dakota Medicaid already has an established process in place to avoid duplicative discounts between the two programs. Most of the concern around duplicative discounts seems to come from when a PBM administers Medicaid programs for states under a managed care agreement (basically a PBM administers the prescription drug benefit for State Medicaid Departments). A few years back, North Dakota used a PBM to administer the Medicaid Expansion prescription drug benefit. However, after a number of questions and concerns, North Dakota Department of Health and Human Services (Medicaid) and the ND Legislative Assembly made the

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decision to move Medicaid Expansion back in-house with traditional Medicaid. The state saved $17+ million dollars the next biennium by removing the PBM from administering the ND Medicaid Expansion program. Again, we feel a lot of the concerns drug manufacturers raise regarding duplicative discounts are already addressed because of how North Dakota operates and complies with existing 340B laws. We also do not see Medicaid managed care for the prescription drug benefit in ND, like you do in a large number of states.

HB 1473 adds a new section to 43-15. 3-08 under the Board of Pharmacy's prohibited acts section. The prohibited acts section is automatically tied to the penalties section under 43-15 3-09 which is how other prohibited acts are referenced already. The Board of Pharmacy already licenses drug manufacturers and other states have taken this same approach for enforcement purposes. The Board of Pharmacy would be in charge of enforcing these sections.

In conclusion, HB 1473 helps to stop drug manufacturers from implementing their own rules outside of an already established federal program. By supporting HB 1473, you are supporting your local critical access hospitals, federally qualified health centers, non-profit hospitals, contract pharmacies and community health centers. If HB 1473 is not passed, drug manufacturers will continue to provide fewer discounted drugs to North Dakota contrary to how the federal 340B program is supposed to be operating according to HRSA and HHS.

Thank you for your time and attention. I will try my best to answer any questions. There are a number of others who will be testifying today, who can hopefully answer your questions if I am not able to do so.

Respectfully submitted,

Mike Schwab
NDPhA - EVP

SANFORD HEALTH

Senate Human Services
Senator Judy Lee, Chair
March 12, 2025
HB 1473

Chair Lee and members of the Senate Human Services Committee: For the record my name is Jesse Breidenbach and I serve as vice president of pharmacy services for Sanford Health. I grew up in Reynolds, ND, I am a lifelong ND resident, and I am an NDSU college of pharmacy graduate. I have worked for Sanford in Fargo for the past 18 years, and I have worked with the 340B program at Sanford for the past 12 years dating back to when Sanford entered the 340B program.

Thank you for the opportunity to testify in support of HB 1473.

Opponents of this bill have claimed that North Dakota covered entities—hospitals and federally qualified health centers—are not meeting the intent of the 340B program and related transparency requirements. Allow me to clarify the current 340B program requirements and provide forward-looking information on this matter.

To qualify for and maintain participation in the 340B program, covered entities must comply with all reporting and audit requirements set by the Health Resources and Services Administration (HRSA), the U.S. Department of Health and Human Services agency that oversees the program. Non-compliance can result in penalties, including repayment of improperly used discounts or removal from the program. Contrary to what opponents may suggest or attempt to distract with, covered entities are committed to complying with the intent of the program and its requirements. Arguments to the contrary are an attempt to detract from the devoted rural health care and rural pharmacy services that our North Dakota providers do day in and day out.

Program Qualifications
Program qualifications are slightly different for each category of covered entities. Sanford Health hospitals in ND qualify as non-profit Disproportionate Share Hospitals (aka DSH hospitals) (Fargo and Bismarck) and critical access hospitals (Mayville and Hillsboro). Disproportionate Share Hospital is a term that refers to the percentage of patients we care for that are uninsured, covered by the Medicaid program or low income Medicare patients. The minimum DSH percentage to qualify as a 340B DSH hospital is 11.75 percent; Sanford Bismarck and Sanford Fargo's most recently filed CMS cost reports demonstrate DSH percentages of 13.65 and 14.44, respectively. In other words, Sanford Health is well established as a covered entity in the program due to our Medicaid, low income Medicare and uninsured population that we have privilege to serve.

Program Recertification
Program recertification is required on an annual basis to ensure covered entities remain compliant with the program's eligibility and operational requirements. Recertification includes the following:

- **Confirm eligibility**: Covered entities must confirm that they continue to meet the eligibility requirements including meeting the minimum DSH threshold (and various other criteria for different entity types). To prove we meet this requirement we are required to upload our CMS cost reports annually to verify our status of meeting the DSH percentage or critical access status.

- **Comply with current 340B policies and procedures**: It is the covered entity's responsibility to ensure internal policies and procedures comply and are in alignment with any new guidance or changes in the program. In HRSA audits we are required to share our 340B policy with the HRSA auditors so that HRSA has full visibility of how we conduct our program, and visibility of our policies complying with the 340B program statute and HRSA regulations and guidelines.
- **Program integrity and reporting**: Ensure accurate reporting of all required data, including history of self-audits and a summary of external consultant audits, eligible patients and any changes in operations.
    - **Attest to compliance**: Covered entities must attest that they are compliant with all 340B program requirements, including assurance that that drugs purchased under the 340B program are not resold or diverted to ineligible patients, and that we do not purchase 340B drugs for Medicaid patients if Medicaid would be seeking a rebate for the same transaction.

Covered entities must maintain supporting documentation that shows their continued compliance with the program. HRSA may audit covered entities to verify this compliance at any time, and entities need to have evidence in place to demonstrate they meet program requirements.

Covered-Entity Audit
As part of HRSA's program integrity oversight, HRSA conducts random audits of covered entities to ensure compliance with all program requirements.

The audit scope includes:
- Eligibility: Verification that the covered entity and its contract pharmacies continue to meet eligibility requirements for the 340B Program.
- Diversion: Ensuring 340B drugs are only dispensed to eligible patients (i.e., outpatients of the covered entity) and not diverted to ineligible patients.
- Duplicate discounts: Confirming that 340B drugs are not subject to both a 340B discount and a Medicaid rebate, which is prohibited under the program.
- Contract pharmacy oversight: Ensure agreements are compliant and that the covered entity monitors these pharmacies to prevent diversion or duplicate discounts.

If the audit has findings of noncompliance, covered entities typically have 60 days to provide a corrective action plan to address the issue and is subject to HRSA approval. Noncompliance may require repayment to manufacturers or removal from the 340B program. Findings are posted on a public-facing website. Most HRSA audit finding are database/registration related, not compliance related. Database findings can be as simple as an incorrect address on a registered location in HRSA's Office of Pharmacy Affairs Information System (OPAIS) database.

Manufacturer Good Faith Inquiries of 340B Program Covered Entities
HRSA expects all covered entities to respond and accommodate reasonable good faith inquires any given manufacturer might have regarding the covered entity's 340B program and purchasing of 340B drugs. Such inquiries might arise when a manufacturer has concerns about a covered entity's purchasing patterns that could suggest 340B diversion or duplicate discounts; which are both prohibited by the 340B statute. There is no formal HRSA process outlining manufacturer good faith inquiries of covered entities, but HRSA does recommend that manufacturers and covered entities work together to resolve such concerns. If a manufacturer is not satisfied

with the covered entity's engagement in the good faith inquiry, or the covered entity is not able to clarify the inquiry to the manufacturer's satisfaction a good faith inquiry could escalate to the point of a HRSA-approved manufacturer audit of the covered entity. At Sanford we have participated in several good faith inquiries over the life of our program and none of these inquires has escalated to a HRSA approved manufacturer audit of any of our covered entities.

HRSA-Approved Manufacturer Audits of 340B Program Covered Entities

To ensure accountability while balancing the interests of both manufacturers and covered entities, drug manufacturers are permitted to audit covered entities to verify compliance. This aspect cannot be overlooked – pharmaceutical manufacturers are equipped today to request an audit of covered entities. A manufacturer audit is designed to ensure that the covered entity is adhering to the rules and requirements of the 340B Program, specifically regarding the prohibition of drug diversion[1] and duplicate discounts[2].

The audit focuses on the covered entity's records directly related to the manufacturer's drugs purchased under the 340B Program. HRSA requires all entities to maintain auditable records demonstrating compliance with eligibility, patient definition and proper use of discounted drugs.

If non-compliance is found (e.g., diversion or duplicate discounts), the covered entity may be required to repay the manufacturer for discounts received improperly. Serious or repeated violations could lead to further action, such as removal from the 340B Program.

To put it plainly, covered entities are strictly scrutinized for their participation in the 340B program through oversight by HRSA, manufacturer initiated good faith inquiries or manufacturer audits, and additional enforcement levers. Conversely, pharmaceutical manufacturers are under no obligation to stay in the 340B program. This program is voluntary and if manufacturers feel the program is no longer in their best interest, they have the option to leave the program. While the same argument can be made against covered entities, we remain – and always will be – committed to ensuring access to health care in North Dakota, and this program is currently helping us meet this commitment.

Strengthening the 340B Program

When drug manufacturers say the program would benefit from targeted changes to improve transparency and strengthen the program, we agree. To that end there is good work being done at the federal level to improve upon the processes I just outlined.

A bipartisan group of six influential U.S. Senators – known as the 340B Gang of Six[3] – support and have initiated work on bipartisan legislation designed to bring more predictability, stability, transparency and accountability to the program.

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[1] Drug Diversion: Ensuring 340B drugs are not diverted to individuals who are not eligible patients of the covered entity.

[2] Duplicate Discounts: Preventing a situation where a 340B discount is applied to a drug, and the manufacturer also provides a rebate for the same drug under the Medicaid Drug Rebate Program.

[3] Sens. John Thune (R-S.D.), Debbie Stabenow (D-Mich.), Shelley Moore Capito (R-W.Va.), Tammy Baldwin (D-Wis.), Jerry Moran (R-Kan.), and Ben Cardin (D-Md.)

Recognizing such policymaking needs to be informed by the recommendations of all 340B stakeholders, the Gang of Six established a multi-sector coalition of hospitals and health systems, community health centers, and biopharmaceutical manufacturers to work together to find common ground on federal policies and make consensus-based recommendations to Congress on ways to improve the 340B program. The Gang of Six put out two separate requests for information in 2024 and received informative feedback from all stakeholders.

I have personally met with the Gang of Six on three different occasions in 2024 as part of a multidisciplinary stakeholder group. This group, known as the Working Table, included manufacturers, FQHCs, health systems and critical access hospitals. This group is truly trying to find the middle ground within the 340B program; which is what we seek to provide stability, transparency and accountability within the program at the federal level.

This work culminated in creation of draft legislation called the Sustain 340B Act. This bill was released in the form of a discussion draft in February 2024, and a legislative draft of the Act was nearly introduced in late 2024 but fell short in large part due to leadership changes that resulted from the November 2024 election. Their work, however, continues, and we expect to see a new gang of six announced in the coming weeks to pick up where the original group left off.

The bottom line is that the 340B drug discount program is a federal program and North Dakota hospitals, FQHCs and the contract pharmacies we work with are complying with all federal requirements.

Thank you for your consideration of HB 1473. I would stand for any questions you may have.

Jesse Breidenbach, Pharmacy Vice President
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LEGISLATURE OF THE STATE OF IDAHO
Sixty-eighth Legislature First Regular Session - 2025

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 136

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO 340B DRUG PRICING PROGRAM REPORTING; AMENDING CHAPTER 3, TITLE 41, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 41-351, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING 340B DRUG PRICING PROGRAM REPORTING; AND DECLARING AN EMERGENCY AND PROVIDING AN EFFECTIVE DATE.

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Chapter 3, Title 41, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 41-351, Idaho Code, and to read as follows:

41-351. 340B DRUG PRICING PROGRAM REPORTING. (1) As used in this section, "340B covered entity" means an entity authorized to participate in the federal 340B drug pricing program under section 340B(a)(4) of the federal public health service act and includes any pharmacy under contract with the entity to dispense drugs on behalf of the entity.

(2) Before April 1 of each year, a 340B covered entity shall report the following information to the state department of health and welfare, the state controller's office, and the attorney general concerning the 340B covered entity's participation in the federal 340B drug pricing program for the previous calendar year:

(a) The name of the covered 340B entity;

(b) The aggregate acquisition cost for prescription drugs obtained under the 340B program;

(c) The aggregate payment amount received for drugs obtained under the 340B program and dispensed to patients;

(d) The aggregate payment made to pharmacies under contract to dispense drugs obtained under the 340B program;

(e) The number of claims for prescription drugs described in paragraph (c) of this subsection; and

(f) How the 340B covered entity uses any savings from participating in the 340B program, including the amount of savings used for the provision of charity care, community benefits, or a similar program of providing unreimbursed health care to the indigent.

(3) The information required to be reported pursuant to subsection (2) of this section shall be reported by payer type, including the following:

(a) Commercial;

(b) Medicaid; and

(c) Medicare.

(4) The data submitted in the reports required pursuant to subsection (2) of this section is confidential and shall not be made available for public inspection.

(5) Before November 15 of each year, the state controller's office shall prepare a report that aggregates the data submitted pursuant to subsection (2) of this section and:

(a) Submit the report to the legislative council in an electronic format; and

(b) Make such report available on the transparent Idaho website.

(6) The attorney general may use the information in the reports required pursuant to subsection (2) of this section for the purposes of investigating medicaid fraud and ensuring compliance with health resources and service administration requirements.

SECTION 2. An emergency existing therefor, which emergency is hereby declared to exist, this act shall be in full force and effect on and after July 1, 2025.

62J.461 340B COVERED ENTITY REPORT.

Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "340B covered entity" or "covered entity" means a covered entity as defined in United States Code, title 42, section 256b(a)(4), with a service address in Minnesota as of January 1 of the reporting year. 340B covered entity includes all entity types and grantees. All facilities that are identified as child sites or grantee associated sites under the federal 340B Drug Pricing Program are considered part of the 340B covered entity.

(c) "340B Drug Pricing Program" or "340B program" means the drug discount program established under United States Code, title 42, section 256b.

(d) "340B entity type" is the designation of the 340B covered entity according to the entity types specified in United States Code, title 42, section 256b(a)(4).

(e) "340B ID" is the unique identification number provided by the Health Resources and Services Administration to identify a 340B-eligible entity in the 340B Office of Pharmacy Affairs Information System.

(f) "Contract pharmacy" means a pharmacy with which a 340B covered entity has an arrangement to dispense drugs purchased under the 340B Drug Pricing Program.

(g) "Pricing unit" means the smallest dispensable amount of a prescription drug product that can be dispensed or administered.

Subd. 2. **Current registration.** Beginning April 1, 2024, each 340B covered entity must maintain a current registration with the commissioner in a form and manner prescribed by the commissioner. The registration must include the following information:

(1) the name of the 340B covered entity;

(2) the 340B ID of the 340B covered entity;

(3) the servicing address of the 340B covered entity; and

(4) the 340B entity type of the 340B covered entity.

Subd. 3. **Reporting by covered entities to the commissioner.** (a) Each 340B covered entity shall report to the commissioner by April 1 of each year the following information for transactions conducted by the 340B covered entity or on its behalf, and related to its participation in the federal 340B program for the previous calendar year:

(1) the aggregated acquisition cost for prescription drugs obtained under the 340B program;

(2) the aggregated payment amount received for drugs obtained under the 340B program and dispensed or administered to patients;

(3) the number of pricing units dispensed or administered for prescription drugs described in clause (2); and

(4) the aggregated payments made:

(i) to contract pharmacies to dispense drugs obtained under the 340B program;

(ii) to any other entity that is not the covered entity and is not a contract pharmacy for managing any aspect of the covered entity's 340B program; and

(iii) for all other expenses related to administering the 340B program.

The information under clauses (2) and (3) must be reported by payer type, including but not limited to commercial insurance, medical assistance, MinnesotaCare, and Medicare, in the form and manner prescribed by the commissioner.

(b) For covered entities that are hospitals, the information required under paragraph (a), clauses (1) to (3), must also be reported at the national drug code level for the 50 most frequently dispensed or administered drugs by the facility under the 340B program.

(c) Data submitted to the commissioner under paragraphs (a) and (b) are classified as nonpublic data, as defined in section 13.02, subdivision 9.

Subd. 4. **Enforcement and exceptions.** (a) Any health care entity subject to reporting under this section that fails to provide data in the form and manner prescribed by the commissioner is subject to a fine paid to the commissioner of up to $500 for each day the data are past due. Any fine levied against the entity under this subdivision is subject to the contested case and judicial review provisions of sections 14.57 and 14.69.

(b) The commissioner may grant an entity an extension of or exemption from the reporting obligations under this subdivision, upon a showing of good cause by the entity.

Subd. 5. **Reports to the legislature.** By November 15, 2024, and by November 15 of each year thereafter, the commissioner shall submit to the chairs and ranking minority members of the legislative committees with jurisdiction over health care finance and policy, a report that aggregates the data submitted under subdivision 3, paragraphs (a) and (b). The following information must be included in the report for all 340B entities whose net 340B revenue constitutes a significant share, as determined by the commissioner, of all net 340B revenue across all 340B covered entities in Minnesota:

(1) the information submitted under subdivision 2; and

(2) for each 340B entity identified in subdivision 2, that entity's 340B net revenue as calculated using the data submitted under subdivision 3, paragraph (a), with net revenue being subdivision 3, paragraph (a), clause (2), less the sum of subdivision 3, paragraph (a), clauses (1) and (4).

For all other entities, the data in the report must be aggregated to the entity type or groupings of entity types in a manner that prevents the identification of an individual entity and any entity's specific data value reported for an individual data element.

History: *2024 c 127 art 59 s 2*

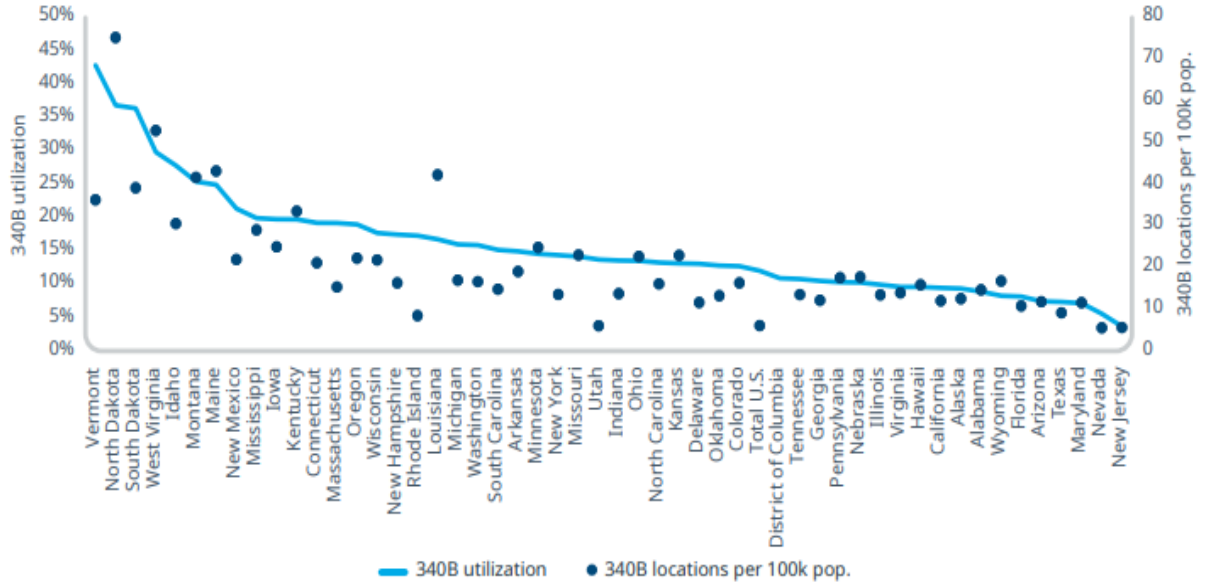
Good morning, Madam Chair and members of the Senate Human Services Committee. My name is Megan Hruby and I am here on behalf of Blue Cross Blue Shield and our over 450,000 members statewide.

I want to take a few minutes to share a couple of points that may not have been mentioned today. I appreciate the committee's patience and thoughtfulness as we navigate a really important issue.

A few areas for your consideration:

1. According to a recent study, North Dakota ranks second in the nation in 340B utilization, highlighting the significance of the program in our state.

Appendix figure 1: 340B utilization and number of 340B locations per 100k population by state



2. That same study estimates that if this bill passes allowing for more pharmacies to participate as a contract pharmacy, North Dakota's 340B revenue will grow to nearly $100 million. The study also estimates that eligible claims will grow from approximately 37% to 65%; which is over 20% higher than any other state's utilization.

3. According to Minnesota's 340B report, commercial payers paid 54% of 340B revenue. 340B revenue is the difference between payments received and the discounted price. Minnesota's 340B Legislative Report 2024. If we apply Minnesota's 54%, this bill will potentially cost North Dakota commercial carriers, and by proxy, policy holders, including BCBSND over $50 million. In reality, because of the lack of information, we simply don't know if these numbers are good estimates of impact or inaccurate representations.

4. If we review the broader impact of this bill and the entire pharmacy legislative landscape, North Dakota has other pharmacy protection and 340B laws in place that other states, including Minnesota, do not, including:

    a. The Any Willing Pharmacy law passed in the early nineties which prohibits a carrier from forming networks that would use a non-340B pharmacy to save money for our members.

    b. HB 1492 passed in 2021 which requires retail price reimbursement for 340B drugs no matter the purchase price for the covered entity or contracted pharmacy. An example of this is if the covered entity acquires Humira, a specialty drug for rheumatoid arthritis, for a penny under 340B pricing, carriers are required to reimburse the full $87000 per treatment retail price pursuant to Section 19-02.1-16.5 of the North Dakota Century Code. If we were to meet in the middle, at $3500 for example, the hospital or covered entity would still receive funding to improve access and BCBSND members would also see a cost savings.

    c. There are gag clauses that prevent insurance companies from asking pharmacies and hospitals about 340B claims to understand the scope and impact of the 340B program.

However, I'm not here today to debate or ask you to change any of that. I'm here asking for transparency and reporting on the 340B program in North Dakota. As it stands today, there is no accurate picture of the impact of 340B on North Dakotans. We have no idea how many covered entities or contracted pharmacies there are, how much funding they are getting from carriers or any other entity, and very few covered entities or contracted pharmacies report on how they are improving access for underserved populations (which is the intent of the program from its inception.) According to state law, we aren't allowed to ask, despite paying for over half of the program. We cannot honestly start thoughtful policy conversations about whether or not the 340B program is "out of control" if we don't have any information on the scope of the program in our state. Therefore, we respectfully

request that the legislation be amended to include reporting requirements and would be happy to provide recommendations upon request.

With that Madam Chair, I will stand for any questions.

VOTE YES - HB 1473

- STOP BIG PHARMA from side-stepping federal rules that require certain discounted drugs be provided to eligible health care entities and patients in North Dakota.
- Support your local community health centers, federally qualified health centers, non-profit hospitals, contract pharmacies and local communities.
- Drug manufacturers admit the vast majority of their issues (close to 90%) are with PBM owned pharmacies and large chain pharmacies…but yet they place blanket restrictions on a small rural state like North Dakota. We are not like Chicago, New York or Seattle.
- From 2012-2020, The U.S. Department of Health & Human Services undertook several regulatory actions to strengthen program compliance and integrity within the federal 340B program.
- Audits by HRSA take place with one recent on being conducted on Altru Hospital and they testified to no compliance issues and passed the audit.
- Drug manufacturers can request an audit of the entities as well under the program.
- 8 other states have already passed similar laws and 10 more states have introduced legislation this session similar to ND.
- Big Pharma lost their legal challenge in the 8th Circuit and the SCOTUS declined big pharma's appeal regarding a similar law in Arkansas. As a reminder, the 8th Circuit of Appeals covers ND as well.
- **HB 1473 DOES NOT EXPAND the 340B program!** It actually requires the drug manufacturers to comply with how the federal program is supposed to operate.

- South Dakota overwhelmingly just passed a very similar bill this month (March 2025) and it is headed to the Governor's office for signature. Very few members of the SD Legislature opposed the bill they just passed.

- Big Pharma has been trying to impose multiple layers of amendments to HB 1473. The ND House rejected those amendments. As providers under 340B, we have a ton of federal regulations and are subject to audits not only by HRSA but drug manufacturers can also audit providers in the program. We all know who federal requirements work…providers already dedicate a lot of time to compliance and integrity processes under the 340B program.

VOTE YES ON HB 1473!

2025 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Lincoln Room, State Capitol

HB 1473
3/24/2025

Relating to prohibited acts of drug manufacturers; and to provide a penalty.

9:10 a.m. Chairman Lee opened the hearing.

Members Present: Chairman Lee, Vice-Chairman Weston, Senator Van Oosting, Senator Clemens, Senator Hogan, Senator Roers.

Discussion Topics:

- Improper Use of Funds

9:10 a.m. Chairman Lee opened discussion on 340B of Public Health Service Act.

9:13 a.m. Senator Hogan moved Do Pass.

9:13 a.m. Senator Weston seconded the motion.

Senators	Vote
Senator Judy Lee	Y
Senator Kent Weston	Y
Senator David A. Clemens	N
Senator Kathy Hogan	Y
Senator Kristin Roers	Y
Senator Desiree Van Oosting	Y

Motion passed 5-1-0.

Senator Lee will carry the bill.

9:20 a.m. Chairman Lee closed the hearing.

Andrew Ficek, Committee Clerk

REPORT OF STANDING COMMITTEE
HB 1473 (25.1047.01000)

Human Services Committee (Sen. Lee, Chairman) recommends **DO PASS** (5 YEAS, 1 NAY, 0 ABSENT OR EXCUSED AND NOT VOTING). HB 1473 was placed on the Fourteenth order on the calendar. This bill does not affect workforce development.