A Matter of Life, Death, & Healthcare Equity: The 340B Program in Tennessee

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Executive Summary

Sage Policy Group (Sage) reviewed and analyzed the federal government's 340B Drug Pricing Program to determine how proposed changes would impact Tennessee.

THE 340B PROGRAM

Congress enacted the 340B program in 1992 to assist safety-net providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Policymakers created the 340B program in part as a quid pro quo. Congress conditioned manufacturers' eligibility for Medicare Part B and Medicaid, two of the nation's largest health insurance programs, on participation in 340B.

The economic underpinnings of the 340B program are reasonably straightforward. While upfront development costs are massive, revenues inuring from successful drug introduction can be astronomical. From 2000 to 2018, 35 large pharmaceutical companies reported cumulative revenue of $11.5 trillion, gross profit of $8.6 trillion, and net income approaching $2 trillion.

Drug companies can generate these large profits because their marginal costs of production are low. As production is scaled, profit per unit produced surges. For instance, a 2018 study estimated the cost to produce a vial of analog insulin, the type used by most patients, at between $2 and $4. A report published last year indicates that today one vial can cost patients $250. Some people require six vials per month. Given those low marginal costs, there is an opportunity to supply people from disadvantaged circumstances with useful, often lifesaving and extending therapies at meaningfully discounted prices without unduly impacting pharmaceutical industry profits.

Due in part to concerns expressed by pharmaceutical manufacturers and restrictions imposed by them unilaterally on the 340B program, there is an ongoing debate regarding potential changes to program implementation. This report estimates the likely impacts of several of those potential modifications, which are largely designed to shrink the program's reach, on Tennessee.

ANALYZED PROPOSED CHANGES

Many proposed programmatic changes have been addressed in this report. Prospective impacts of two proposed programmatic modifications are modeled in this report. These are:

- Disallowance of patients with incomes greater than 200 percent of federal poverty levels.
- That the number of contract pharmacies serving a community health center (often serving vast areas with multiple sites) be limited to those located near the covered entity.

PRINCIPAL ANALYTICAL FINDINGS

- If income restrictions and restrictions on the number of contract pharmacies with which community health centers can work were both implemented, it is estimated that the number of patients served by Tennessee's community health centers would decline from almost 907,000 to roughly 477,000, a reduction of 47 percent.
- Tennessee's community health centers collectively served almost 907,000 patients in 2021.
- Roughly one-third of these patients are racial and ethnic minorities. Most of these patients are also low income, with 67 percent associated with incomes at or below the federal poverty level (FPL).
- Assuming there was no change in federal funding of these centers, if patients were limited to those with income below 200 percent of federal poverty levels, total revenue would decline by almost $33 million to $376 million, a loss exceeding 7percent of revenue.
- Were restrictions implemented on the ability of community health centers to secure arrangements with contract pharmacies, the state's community health centers could potentially lose the ability for 39 percent of all the state's delivery sites—mostly in rural areas—to participate in the 340B program.
- Total statewide community health center revenue would decline 20 percent under these circumstances.
- Were 340B program benefits limited to patients with incomes below 200 percent of federal poverty levels, the value of medicine/drug discounts to Tennessee's community health centers would decline by more than $10 million. The potential loss of insurance and other revenue would exceed $22 million.
- Lost patient volume at community health centers would translate into over 109,000 additional emergency department visits statewide. With an average cost of $570/visit, the value of these increased emergency department visits would exceed $62 million.
- Patients in rural areas would be especially vulnerable. They represent over 71 percent of patient volume at Tennessee's community health centers and would be more likely to have their most proximate delivery sites shuttered.

CONCLUSION

Proposed modifications to the 340B program would result in:

- Massive inconvenience to patients, especially in rural communities.
- Loss of access to life-enhancing and life-saving drugs for millions of patients nationally and thousands in Tennessee.
- Expanded numbers of emergency room visits and associated taxpayer expense.
- Likely closure of many healthcare delivery sites presently maintained by community health centers, with rural areas sustaining disproportionate loss.
- Increased costs to taxpayers for emergency department visits by former 340B program beneficiaries.

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NATURE OF THE ENDEAVOR

Sage Policy Group (Sage) reviewed and analyzed the federal government's 340B Drug Pricing Program to determine how proposed changes would impact Tennessee.

THE 340B PROGRAM

The 340B program has become a source of tension between certain pharmaceutical companies and healthcare providers who serve low-income patients and communities. Congress enacted the 340B program in 1992 to guarantee prescription drug discounts for medically vulnerable populations. The program is also intended to financially empower providers operating in underserved areas to maximize resources by purchasing drugs from participating manufacturers at discounted rates.

Policymakers created the 340B program in part as a *quid pro quo*. Congress conditioned manufacturers' eligibility for Medicare Part B and Medicaid, two of the nation's largest health insurance programs, on participation in 340B.[1] Pharmaceutical companies also benefit massively from contributions to basic research by federal laboratories, federal grants to university researchers, and FDA drug approval processes as well as patent and other judicial support.

The 340B program has been subject to numerous reviews and assessments by the federal government and other stakeholders over time. These studies have generated various recommendations regarding possible changes to the program.

METHODOLOGY

This report is an exercise in estimated impact measurement associated with several modifications that have been proposed for the 340B program and with regards to Tennessee. Input data and informational sources include federal agencies like the Department of Health and Human Services, the Congressional Research Service, and the Government Accountability Office as well as stakeholders such as the American Hospital Association and ASAP 340B, an organization supported by the pharmaceutical industry. Sage's policy impact analyses are largely based on data available from the Health Resources and Services Administration (HRSA), which administers the 340B program, and the National Association of Community Health Centers (NACHC), which represents a major category of covered entities.

Data from NACHC provide quantitative portraits of health center services and the communities they serve for each state and for Congressional districts. While data from NACHC and HRSA provide a basis for estimating impacts of some of the proposed modifications to the program on certain caregivers participating in the 340B program, these data do not provide a basis for estimating key potential impacts for all program participants, including disproportionate share hospitals (DSHs).

[1] In 1992, about 29 million people enrolled in Medicaid at a cost of $120 billion. In 2018, more than 76 million people enrolled at a cost of $616 billion. Medicaid and CHIP Payment and Access Commission, MACStats: Medicaid and CHIP Data Book, at 27-28 (Dec. 2019), *available at* https://www.macpac.gov/wp-content/uploads/2020/01/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf (last visited Nov. 4, 2021). Cited in Sanofi-Aventis v. U.S. Department of HHS, et al, November 5, 2021.

The Role of PBMs and Trends in Prescription Drug Spending

THE IMPACT OF PHARMACY BENEFIT MANAGERS

Pharmacy benefit managers' (PBM) actions may restrict access to medications regardless of 340B program status. The typical role of PBMs is to negotiate discounts and rebates with pharmaceutical manufacturers on behalf of their clients. These negotiations result in the creation of prescription medication formularies, which are lists of prescription medications covered by prescription drug plans.

PBMs may choose to exclude some medications from their formularies. Consequently, excluded medications are not available at prices covered by insurance. Such exclusions can effectively restrict access that patients have to these excluded medications. Without coverage by insurance, the only option patients may have to obtain these medications is to pay for them directly.

An Xcenda assessment of PBMs found that three companies—CVS Caremark, Express Scripts, and OptumRX—dominate the PBM market, accounting for 80 percent of all prescriptions in the U.S.[2] This assessment found that 1,156 unique prescription medications were excluded from formularies of one or more of these three PBMs in 2022. This was a dramatic increase from the 109 prescription medications excluded from the companies' formularies in 2014.

During the intervening years from 2014 to 2022, the number of excluded prescription medications increased each year by an average of 34 percent. These exclusions were defined as occurring for at least one plan year and applied to one or more of the companies' formularies. Over the 2014-2022 period, 1,357 unique prescription medications were excluded by one or more PBMs for at least one year. Nearly half of these exclusions were single-source brand medicines at the time of exclusion.

The most frequently targeted medications for exclusion were found to be those linked to chronic conditions requiring long-term and continuous treatment. These medications include insulin, antidepressants, antipsychotics, and antiarrhythmics. Conditions associated with these excluded medications include diabetes, cardiovascular disease, dermatological conditions, and autonomic and central nervous system disorders such as multiple sclerosis, mental health disorders, Parkinson's disease, and epilepsy.

In recent years, the number of exclusions of cancer medicines and supportive therapies have also increased significantly. Another set of medications facing increased exclusion has been drugs receiving FDA approval through expedited pathways created to develop new drugs. These drugs are developed to help patients with unmet medical needs who lack other treatment options. These drugs have been

[2] Amerisource Bergen Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," May 24, 2022. https://www.xcenda.com/insights/skyrocketing-growth-pbm-formulary-exclusions-concerns-patient-access

found to give patients larger health gains compared to drugs approved through conventional review processes.

In certain instances, several medications including lower-priced generic and biosimilar medications are available to treat conditions such as diabetes and hepatitis C virus. The Xcenda assessment found that PBMs often excluded these lower-priced medications in favor of keeping higher-priced products on the formularies. These higher-priced products may offer higher rebates, which benefit the PBMs.

Exclusions can substantially increase the cost to patients of treatment. These increased costs may preclude some patients from accessing needed medications altogether since they cannot afford to pay for medications directly. If the exclusion is a single-source medication, patients may have no access to needed medications. If patients cannot adhere to prescription medication regimes, their disease conditions may worsen, leading to poorer health outcomes and larger societal costs in the long term, which is precisely what the Xcenda assessment determined.

In particular, the assessment found that the patient-physician decision-making process that can determine the best therapy for an individual's medical condition can be undermined by the exclusion of certain medications from formularies. If medications determined to be best suited to patient needs are excluded from formularies, the unhappy alternative may be for patients to begin the difficult appeals process to gain access to needed medications. The initiation of treatment may then be delayed; medications may be unavailable or unaffordable; or treatment may be discontinued prematurely. These consequences have been found to be associated with worsening health outcomes and increased utilization of emergency departments and hospital care.

Impacts can be widespread. The three largest PBMs manage prescription drug coverage for tens of millions of individuals who have commercial health insurance. The annual exclusions of drugs from formularies may force hundreds of thousands of patients to switch medications annually to the drugs preferred by PBMs. Medicines that treat chronic diseases are among the most frequently targeted for exclusion. Consequently, **vulnerable patients with chronic conditions are disproportionately affected by PBM actions**. The increasing exclusion of drugs that treat cancer, HIV, autoimmune disorders, and other complex conditions also raises significant concerns regarding quality of care.

TRENDS IN THE COSTS OF PRESCRIPTION DRUGS

The expanding market power of PBMs correlates with rising patient and provider costs. Indeed, in recent years, spending on prescription drugs has increased significantly. An analysis of this spending by the U.S. Department of Health and Human Services found that total spending on prescription drugs increased 16 percent in inflation adjusted dollars from $520 billion in 2016 to $603 billion in 2021. The primary reason for this increase was the increased cost of individual prescriptions. A secondary driver was the 10.9 percent increase in the number of prescriptions from 2016 to 2021.

These prescriptions are defined as: 1) retail spending where prescriptions were filled in outpatient settings such as standalone pharmacies and mail-order prescriptions; and 2) non-retail spending for prescriptions administered in inpatient settings such as hospitals, clinics, physician offices, long-term care facilities, and home health. From 2016 to 2021, retail spending increased 12.5 percent while the number of prescriptions increased 5.7 percent. In the non-retail category, spending increased 25.1 percent and the number of prescriptions increased 19.2 percent.[3]

Increased spending on prescription medications is heavily influenced by a relatively small number of high-cost products. Specialty drugs are used to treat chronic, rare, or complex diseases and meet a range of criteria including being initiated and maintained by specialists, generally being injectable and/or not self-administered, needing greater care in their chain of custody, and having an annual cost of at least $6,000. Total spending on specialty drugs was $301 billion in 2021, roughly half of all prescription drug spending and a 42.5 percent increase from 2016.

Between 2016 and 2021, the top 10 percent of drugs by price accounted for less than 1 percent of all prescriptions. These high-priced drugs, however, accounted for 15 percent of retail spending and 20 percent to 25 percent of non-retail spending during that period.

The majority of prescriptions—80 percent—are for generic drugs. Brand names drugs, however, account for 80 percent of prescription drug spending in retail and non-retail settings, while only accounting for 20 percent of prescriptions.

[3] Assistant Secretary for Planning and Evaluation, "Trends in Prescription Drug Spending, 2016-2021," September 2022 https://aspe.hhs.gov/reports/trends-prescription-drug-spending

REACTIONS TO DRUG PRICE TRENDS AND CONCERNS WITH PHARMACY BENEFIT MANAGERS

There have been a number of governmental efforts to increase the transparency of costs associated with prescription drug programs. A focus of some of these activities has been spread pricing, which describes how a PBM works with a managed care organization (MCO) to manage prescription drug benefits. Spread pricing occurs when a PBM retains part of the payment made by the MCO for prescription drugs rather than passing the full payment to the pharmacy.

The Office of the Inspector General of the U.S. Department of Health and Human Services conducted an audit of contracts between the District of Columbia and its five MCOs and seven contracts between those MCOs and PBMs. The audit found that from October 2016 to September 2019, MCOs paid PBMs $364.5 million for prescription drugs. The PBMs paid the pharmacies $341.2 million and kept $23.3 million. This spread pricing was seen as potentially increasing the cost of Medicaid prescriptions to MCOs and the Medicaid program. The audit report included a recommendation that the District create policies and procedures to validate MCO, PBM, and pharmacy transactions ensuring transparency of costs associated with the prescription drug program.

The report also noted that several states (e.g., Ohio, Kentucky, Maryland, and Pennsylvania) had conducted similar audits of PBM spread pricing because of concerns regarding transparency of these practices in the Medicaid program. Other states (e.g., New York, Texas, and Virginia) have enacted or drafted legislation that increases transparency and changes contracting processes with PBMs.[4]

Concern with the transparency of PBM practices has also encouraged federal action. The Pharmacy Benefit Manager Transparency Act of 2022 was introduced in the U.S. Senate and approved with bipartisan support by the Commerce Committee. The legislation would render spread pricing illegal and would prohibit "claw backs" of any portion of reimbursement payments to pharmacists or pharmacies or increasing or lowering fees to pharmacies to offset reimbursement changes under any federally funded health plan.

[4] Office of Inspector General, "The District of Columbia Has Taken Significant Steps To Ensure Accountability Over Amounts Managed Care Organizations Paid to Pharmacy Benefit Managers," Department of Health and Human Services, March 2023. https://oig.hhs.gov

The legislation would also create incentives for the transparency of PBM transactions by encouraging complete disclosure of the cost, price, and reimbursement of prescription drugs to health plans, payers, and pharmacies and of all fees, markups, and discounts PBMs charge or impose on health plans, payers, and pharmacies. The Federal Trade Commission (FTC) released a July 2023 interim report on the ways that large PBMs affect prescription drug affordability and access. In that report, the FTC stated that PBMs "may be profiting by inflating drug costs and squeezing Main Street pharmacies."[5]

A similar bill, the Pharmacy Benefit Manager Transparency Act of 2023, was reintroduced in the U.S. Senate in January 2023. Other U.S. Senate legislation in 2023 included the Pharmacy Benefit Manager Reform Act and the Prescription Pricing for the People Act of 2023. The PBM Reform Act would ban spread pricing by PBMs, increase the transparency of PBM transactions, and commission studies to determine the effects of PBM regulation on the U.S. healthcare market. The Prescription Pricing for the People Act of 2023 would charge the FTC with reporting on PBM practices that affect drug prices and developing recommendations for improved transparency and reduced anticompetitive behavior in the pharmaceutical supply chain. The legislation also seeks to ensure that consumers benefit from any cost savings or industry efficiencies. A House-Senate bipartisan bill—Drug Price Transparency in Medicaid Act of 2023—was also reintroduced in 2023. This legislation would prohibit spread pricing by PBMs in the Medicaid program.[6]

[5] The Federal Trade Commission, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies." Interim Staff Report, July 2024. https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[6] Keller, Bridgette and Sophia Temis, "Pharmacy Benefit Managers are on the Federal Government's Radar: Senate, House, and Agency Proposals Seek to Increase PBM Oversight – Part 1," JDSupra, June 7, 2023 https://www.jdsupra.com/legalnews/pharmacy-benefit-managers-are-on-the-2575773/

POTENTIAL IMPACTS OF PHARMACY BENEFIT MANAGERS' ACTIONS

One perspective on the impacts of PBM actions is the potential for increased use of emergency departments as patients lose therapeutic care. As noted above, the Government Accountability Office found that a community health center had been able to reduce its patients' need for emergency department visits by 63 percent.[7] This could result in a reduction of the national rate of 40.5 emergency department visits annually per 100 individuals to 15.0 visits per 100 individuals.[8] Thus, if 1,000 patients lost therapeutic care because of the actions of PBMs, the number of emergency department visits these 1,000 individuals would generate annually could increase from 150 to 405.

Data on prescription drug use in the U.S. estimates that 64.8 percent of adults aged 18 years and older took prescription medication in a year's period.[9] Given Tennessee's population statistics, this suggests that over 5.5 million adults in Tennessee are taking prescription medications over a period of a year.[10] See Exhibit 1 for details.

Exhibit 1: Estimate of adults in Tennessee taking prescription medications

	Values
Total state population	7,126,489
Percentage of population 18 years and older	78.0%
Adult population 18 years and older	5,558,661
Percentage of adults taking prescription medications	64.8%
Number of of adults taking prescription medications	3,602,013

Sources: U.S. Census, National Center for Health Statistics;

As noted above, drugs with prices in the top 10 percent account for less than 1 percent of all prescriptions. These high priced drugs are often subject to restrictions by PBMs in Tennessee. If almost 1 percent of all prescriptions in the state were unavailable to patients, then over 36,000 patients might be affected. Loss of medications could lead to basic loss of therapeutic care.

[7] Op. cit., Government Accountability Office, "Hospital Emergency Departments: Health Center Strategies That May Help Reduce Their Use"
[8] Op. cit., National Center for Health Statistics
[9] *QuickStats*: Percentage of Adults Aged ≥18 Years Who Took Prescription Medication During the Past 12 Months, by Sex and Age Group — National Center for Health Statistics, National Health Interview Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:450. DOI: http://dx.doi.org/10.15585/mmwr.mm7216a7
[10] U.S. Census, Quick Facts Tennessee https://www.census.gov/quickfacts/fact/table/TN/PST045222

Loss of therapeutic care could lead to an increase of 255 emergency department visits per 1,000 patients. For over 36,000 patients who might lose therapeutic care, this increase would total over 9,000 emergency department visits. At a cost of $570 per visit, the total annual costs for these increased visits would exceed $5 million. This increased cost for emergency departments would have an impact on taxpayers. The majority of emergency visit costs—62 percent—are paid by government programs. These government programs include Medicaid, the Children's Health Insurance Program, and other state-based programs. Medicare alone covers almost 22 percent of these costs while a combination of Medicare and Medicaid covers nearly 4 percent of these costs. Non-government sources such as commercial health insurance cover approximately 38 percent of these costs.[11] The share of the total cost of these increased emergency department visits paid by these various government and non-government sources are detailed in Exhibit 2.

Exhibit 2: Potential Impact of PBM Actions on Annual Emergency Department Visits

Factors in increased emergency department visits	Values
Increased number of emergency department visits	9,185
Cost at $570 per visit	$5,235,525
Distribution of costs between government and non-government sources	
Medicaid, the Children's Health Insurance Program, or other state-based programs	$1,916,202
Medicare	$1,136,109
Combination of Medicare and Medicaid	$198,950
Sub-total, All government programs	**$3,251,261**
Non-government share	$1,984,264
Total	**$5,235,525**

Source: Government Accountability Office, National Center for Health Statistics, Medical News Today

While the potential increase in emergency department visits associated with loss of therapeutic care is quite high, it is not necessarily the only increase in healthcare costs when patients lose access to medications. In some cases, the loss of access to medications may lead to increased levels of hospital care beyond emergency departments. Thus, the cost of increased emergency department visits supplied in this report may be a conservative estimate of the total impact of losing access to prescription medications.

[11] Op. cit., Weber, Belinda

Background on the 340B Program

PROGRAM OVERVIEW

Congress created the 340B Drug Pricing Program in 1992 as part of the Veteran's Health Care Act. Congress established the program to enable healthcare providers serving low-income and uninsured patients to purchase drugs at lower costs. The Health Resources and Services Administration (HRSA), a part of the U.S. Department of Health and Human Services (HHS), administers the program.[12]

Authorizing legislation requires drug manufacturers that participate in the Medicaid Program to offer outpatient drugs at discounted prices to "covered entities" of the program. These covered entities include federally qualified health centers (FQHCs) and other healthcare providers receiving federal grants to serve uninsured and low-income patients. These federal grantee entities include Native Hawaiian Health Centers, Tribal and Urban Indian Organizations, family planning projects, AIDS drug purchasing assistance programs, black lung clinics, and hemophilia diagnostic treatment centers. Hospitals participating in the program include critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and disproportionate share hospitals (DSHs). DSHs are defined as hospitals that serve a disproportionate share of low-income patients who qualify for Medicare and Medicaid.

Beneficial impacts of the 340B program span well beyond drug savings among patients in need. Savings that covered entities realize from reduced costs of pharmaceutical products support and extend the services they provide to vulnerable communities. In particular, savings on lifesaving and life-enhancing drugs stretch limited federal resources available to support poorer communities so that more individuals can be served and more comprehensive services can be provided. Additional support may include free care for uninsured patients, free vaccines, and expanded care for dental, behavioral health, and specialty needs.

[12] The discussion of the 340B program is based on several documents including Congressional Research Service, "Overview of the 340B Drug Discount Program," October 14, 2022 https://crsreports.congress.gov/product/pdf/IF/IF12232; "Sec. 340B Public Health Service Act" www.hrsa.gov>phs-act-section-340b; American Hospital Association, "Fact Sheet: The 340B Drug Pricing Program," March 2023 https://www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program; National Association of Community Health Centers, "340B: A Critical Program for Health Centers," June 13, 2002 https://www.nachc.org/report-340b-a-critical-program-for-health-centers/

PROPOSED CHANGES

Because of the possibility of duplicate discounts, outright fraud, and a desire to measure programmatic impact on health outcomes, the 340B program has been the subject of scrutiny by various governmental and nongovernmental agencies. The Government Accountability Office (GAO), the National Association of Community Health Centers (NACHC), and ASAP 340B are among the entities that have assessed the program.

Indeed, the GAO has conducted several studies of the 340B program in support of congressional decision-makers. The two main recommendations the GAO has made are: 1) that HRSA increase oversight of covered entities to ensure that they meet program requirements. This recommendation particularly emphasized oversight of disproportionate share hospitals; and 2) that HRSA and CMS increase their oversight of the 340B and Medicaid rebate programs to ensure that covered entities are not receiving duplicate rebates or discounts on drugs covered by 340B.[13]

A recent assessment by the NACHC found the 340B program critically important to the ability of Community Health Centers to supply affordable or free outpatient medications and to invest in services meeting the unique needs of their communities.[14] The assessment determined that health centers are caught between pharmaceutical manufacturers, pharmacy benefit managers (PBMs) and health insurers, all of which want to secure a larger share of the 340B savings that health centers obtain through the program.

Several legislative fixes identified would protect health centers from practices that diminish benefits derived from the 340B program. Proposed federal legislation would protect health centers from having their 340B savings redirected to PBMs or insurers. Other potential federal legislation would ensure that manufacturers ship products to contract pharmacies unconditionally. This would protect the role of contract pharmacies in the delivery of medications to health centers.

Nearly two dozen states have passed legislation prohibiting PBMs from discriminating against contract pharmacies and argued for other states to enact similar legislation. These legislative efforts and administrative actions would protect the 340B program from efforts to diminish the delivery of medications to health centers and their patients. These actions would also frustrate efforts to deflect resources away from health centers, thereby limiting their capacity to preserve their segment of the healthcare safety net. These state legislative and administrative actions protecting contract pharmacy access would be overturned by legislation providing for federal pre-emption, the 340B Access Act.

[13] Rogers, Hannah-Alise, "Overview of the 340B Drug Discount Program," Congressional Research Service, October 14, 2022
[14] National Association of Community Health Centers, "340B: A Critical Program for Health Centers," June 13, 2022 https://www.nachc.org/report-340b-a-critical-program-for-health-centers/

ASAP 340B has also called for a range of federal legislative changes to the 340B program. These changes include redefining what ASAP 340B asserts is an overly broad definition of patients, which would place burdensome restrictions on what prescriptions qualify for the program. Prescriptions would need to "reflect a direct connection between the patient's medical condition and the services being provided or managed (through permitted referrals) by the covered entity." Prescriptions would also need to be written by providers directly employed by or linked to the covered entity.

These restrictions on the definition of eligible patients could potentially eliminate the ability of covered entities to provide follow-up care and medical management for patients with chronic conditions. That, in turn, could significantly limit access to critically needed medications for some patients, particularly those with lower incomes. Another proposed change would cap program patients to those with incomes no more than 200 percent of federal poverty levels.

It is also proposed that a range of restrictions be placed on contract pharmacies. Contract pharmacies could be limited, for instance, to covered entities in medically underserved areas or to prescriptions for specific populations such as those with HIV or chronic illness. It has also been proposed that the number of contract pharmacies serving a community health center (often serving vast areas with multiple sites) be limited to five.

ASAP 340B has advocated for severe limits on the number of contract pharmacies insisting they be near facilities. As noted above, one of the lawsuits brought by pharmaceutical manufacturers would limit contract pharmacies to one per covered entity under certain circumstances. ASAP 340 advocates for contract pharmacies to be located near where covered entities provide services, whereas 44 percent of community health centers have contract pharmacies that serve 20 or more ZIP codes.[15]

Another set of concerns focuses on so-called "child sites", which are outpatient facilities operated by disproportionate share hospitals at locations other than the hospital itself. The concern is rooted in the notion that many child sites are in areas associated with higher incomes and lower minority population shares than the actual location of affiliated hospitals. Ultimately, each of these proposals is intended to place additional limits on the 340B program's reach. Restrictions on contract pharmacies would also restrict the ability of all patients, and especially rural patients, to access the medications they need to receive the comprehensive services required for their medical conditions.

[15] Ibid.

Tennessee Community Health Centers and the 340B Program

Community health centers are major participants in the implementation of 340B. These centers are also important components of the healthcare safety net by providing services to vulnerable populations that may have difficulty accessing healthcare because of financial limitations, distance, or other factors. Community health centers are funded in part by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services.

Tennessee is representative of how these healthcare providers serve target populations. Typically, health centers operate numerous sites delivering services throughout a given state. In Tennessee, 27 health centers operate 237 delivery sites, accounting for approximately a sixth of all covered entities statewide. About 169 of these delivery sites are in rural locations.

As indicated in Exhibit 3, these delivery sites served almost 907,000 patients in 2021. These patients include a significant number of children and older adults. Roughly one in three are racial and ethnic minorities. Many of these patients are also low income, with 67 percent associated with incomes at or below the federal poverty level (FPL). Almost one-third of these patients are covered by Medicaid insurance while 30 percent are uninsured. Only 24 percent have private insurance and 13 percent are covered by Medicare.[16]

Exhibit 3: Characteristics of Patients at Tennessee Community Health Centers, 2021

	Number	Percentage
Total patients	906,816	100%
Children	196,609	22%
Older adults	114,163	13%
Patients experiencing homelessness	48,385	5%
Veterans	13,405	1%
Agricultural workers	14,019	2%
Racial/ethnic minority	322,325	36%
Income < 100% FPL	607,567	67%
Income 101-200% FPL	172,295	19%
Income > 200% FPL	126,954	14%
Patients Uninsured	272,045	30%
Patients with Medicaid	281,113	31%
Patients with Medicare	117,886	13%
Patients with private insurance	217,636	24%

Source: National Association of Community Health Centers

[16] National Association of Community Health Centers, "State Level Health Center Data & Maps" https://www.nachc.org/state-level-data-maps/

As indicated in Exhibit 4, community health centers generate a significant amount of economic activity in their communities. In 2021, community health centers in Tennessee directly supported the full-time equivalent of 3,247 jobs with associated income of $248 million. The value of services provided by centers was $409 million.

These direct effects are expanded through multiplier effects based on centers' expenditures on goods and services necessary for their operations (indirect effects). Economic effects are also multiplied by bolstered spending in local economies by those employed by the centers and by the employees of businesses that supply goods and services to the centers (induced effects). These secondary effects (i.e. indirect and induced effects) include 3,919 full-time equivalent jobs with associated income totaling more than $267 million and output (e.g., business sales) exceeding $812 million. In 2021 the total impact of community health centers in Tennessee included 7,166 full-time equivalent jobs with associated income of $515 million and economic output (e.g., business sales) of over $1.2 billion.

Exhibit 4: Economic Impact of Tennessee Community Health Centers, 2021

	Jobs (FTEs)	Labor Income (Millions $2021)	Economic Output (Millions $2021)
Direct effects	3,247	$247.7	$409.0
Secondary effects	3,919	$267.3	$812.7
Total*	7,166	$515.0	$1,221.7

Source: National Association of Community Health Centers

MAJOR PROPOSED CHANGES TO THE 340B PROGRAM

For Tennessee's community health centers, the proposed changes to the 340B program detailed earlier in this report could have major atrophying impacts. Given the almost 907,000 patients served by Tennessee community health centers in 2021, discounts on 340B purchases are estimated to have generated over $75 million in revenue for the centers or 18 percent of the total value of the services provided by these centers that year. Another significant source of revenue for the centers is the federal funds that HRSA provides. The remaining $160 million in revenue is derived from insurance payments, grants, and other sources, as listed in Exhibit 5.

Exhibit 5: Revenue Sources for Tennessee Community Health Centers ($ Millions), 2021

	Amount of Revenue	Share of Revenue
Value of medicine discounts	$75.3	18.4%
Federal funds for health centers	$173.7	42.5%
Other revenue	$160.0	39.1%
Total value of health center services	**$409.0**	**100.0%**

Source: Drug Channels, National Association of Community Health Centers

As noted, among proposed alterations to the 340B program is to contract the patient definition and limit eligibility to those who make no more than 200 percent of the federal poverty level. Federal poverty levels are defined in terms of the number of people in a household or family. Current poverty levels range from $14,580 for a single person household to $50,560 for households or families of eight people, and the 200 percent limit doubles those ranges.[17] Another proposed and major program alteration involves restricting the number of contract pharmacies permitted to work with health centers to deliver prescription medications.

[17] Poverty guidelines increase with household size. The table below lists guidelines for households of up to eight people. For one-person households, for example, the guideline is $14,580 which increases to $50,560 for a household of eight people. Source. U.S. Department of Health & Human Services, "U.S. Federal Poverty Guidelines Used to Determine Financial Eligibility for Certain Federal Programs" https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines

Poverty guidelines for 2023		
People in family/household	Poverty guideline	200% of poverty guideline
1	$14,580	$29,160
2	$19,720	$39,440
3	$24,860	$49,720
4	$30,000	$60,000
5	$35,140	$70,280
6	$40,280	$80,560
7	$45,420	$90,840
8	$50,560	$101,120
Source. U.S. Department of Health & Human Services		

As reflected in Exhibit 3, 14 percent of patients at Tennessee's Community Health Centers are associated with incomes above 200 percent of the federal poverty levels. At a minimum, the 200 percent limit would reduce the value of medicine discounts by 14 percent. Another potential impact is that these patients would not only lose the ability to get reduced price medications, but would also be less likely to receive valuable services from community health centers since they would no longer be able to afford medications central to acceptable healthcare outcomes. This potential impact could reduce insurance and other revenue for community health centers.

Exhibit 6 summarizes estimated reductions to revenues of Tennessee's community health centers by eliminating 340B program benefits to patients with incomes above 200 percent of federal poverty levels. The value of medicine/drug discounts would decrease by more than $10 million. The potential loss of insurance and other revenue would exceed $22 million. Assuming there was no change in federal funding of these centers, total revenue would decrease by $33 million to $376 million, a loss of over 7 percent of revenue.

Exhibit 6: Potential Impact: 200% Limit on Revenue Sources for Tennessee Community Health Centers ($ Millions)

Revenue source	Current revenue	Reduction in revenue	Reduced revenue
Value of medicine discounts	$75.3	$10.5	$64.8
Federal funds for health centers	$173.7	$0.0	$173.7
Other revenue	$160.0	$22.4	$137.6
Total value of health center services	**$409.0**	**$32.9**	**$376.1**

Source: Drug Channels, National Association of Community Health Centers

While the income limit provides a straightforward means of restricting 340B medicine discounts, the impact of restricting contract pharmacies is less clear. If community health centers face new barriers to maintaining contracts with pharmacies, then those centers may suffer greater difficulty in providing discounted medications or be unable to provide discounted medication for patients at some of their delivery sites. This restriction would almost certainly have greater impact in rural areas, where delivery sites are likely to be more geographically dispersed.

A listing of community health centers and their delivery sites by Congressional District in Tennessee provides perspective on whether these delivery sites are in more rural areas of the state.[18] These data are summarized in Exhibit 7. As noted, 29 percent of delivery sites are in clearly urban districts that include the cities of Nashville, Knoxville, and Memphis. An estimated 92 delivery sites are in rural areas and are associated with health centers that have more than five delivery sites. These sites are

[18] Op. Cit., National Association of Community Health Centers, "State Level Health Center Data & Maps"

more likely to face barriers to their patients' effective access to prescription medication based if there were a restriction that covered entities could maintain contracts with no more than five pharmacies.

These 92 excess delivery sites constitute roughly 39 percent of all delivery sites in the state and accordingly may account for roughly 39 percent of the patients served by the state's health centers.

Exhibit 7: Tennessee Community Health Centers' Patients by Urban/Rural Site

Nature of Delivery Sites	Number	Patients	Share of Total
Urban delivery sites	68	260,183	29%
Rural delivery sites	169	646,633	71%
Rural delivery sites in excess of five per health center	92	352,013	39%
Total delivery sites	**237**	**906,816**	**100%**

Source: Drug Channels, National Association of Community Health Centers

If restrictions were implemented on the ability of community health centers to secure arrangements with contract pharmacies, the state's community centers could potentially lose the ability for over one-third of all the state's delivery sites to participate in the 340B program. Other proposals would place heavy fines on errors pharmacies might make in determining patient eligibility when dispensing 340B. This could result in a share of pharmacies withdrawing from the program due to the risk of fines. These proposals would at a minimum eliminate the opportunity to capture discounts on medicine. Another possibility is that these rural centers would lose patient volume because their healthcare outcomes are largely dependent on the availability of discounted and affordable medicines.

Exhibit 8 summarizes potential impacts. The value of medicine discounts would be reduced by over $29 million. If the rural delivery sites in excess of five sites per health center also lost patients, it is estimated that insurance and other revenue would be reduced by more than $62 million. The total value of health center services could be reduced by as much as $91 million or 22 percent to $317.7 million.

Exhibit 8: Potential Impact of Restricting Contract Pharmacies on Revenue of Tennessee Community Health Centers ($ Millions)

Revenue source	Current revenue	Reduction at rural sites	Total revenue
Value of medicine discounts	$75.3	$29.2	$46.1
Federal funds for health centers	$173.7	$0.0	$173.7
Other revenue	$160.0	$62.1	$97.9
Total value of health center services	**$409.0**	**$91.3**	**$317.7**

Source: Drug Channels, National Association of Community Health Centers

The potential impact of both restricting 340B program benefits to those earning no more than 200 percent of the federal poverty levels and restricting the number of contract pharmacies for community health centers would be rather consequential. This impact would potentially eliminate all patients

served by many rural delivery sites for health centers and would also eliminate an estimated 14 percent of patients at all other delivery sites. As indicated in Exhibit 9, these two restrictions could potentially reduce the number of patients served by Tennessee community health centers from over 906,000 to roughly 477,000, a reduction of 47 percent.

Exhibit 9: Potential Impact of Both Restrictions on Patients Served by Tennessee Community Health Centers

Nature of Delivery sites	Current patients	Potential loss of patients	Remaining patients
Urban delivery sites	260,183	36,426	223,758
Rural delivery sites of centers with no excess sites	294,620	41,247	253,373
Rural delivery sites in excess of five per health center	352,013	352,013	0
Total	906,816	429,685	477,131

Source: Drug Channels, National Association of Community Health Centers

The 47 percent reduction in patients would have a substantial impact on community health center revenue. Assuming federal funding was unaffected, the impact of fewer patients would reduce revenue from medicine discounts by over $35 million and from insurance and other revenue by over $75 million. Under those circumstances, total revenue would be reduced by 27 percent to $297 million as shown in Exhibit 10.

Exhibit 10: Potential Impact of Both Restrictions on Revenue of Tennessee Community Health Centers

Revenue source ($ Millions)	Current revenue	Potential loss of revenue	Impact on total revenue
Value of medicine discounts	$75.3	$35.7	$39.6
Federal funds for health centers	$173.7	$0.0	$173.7
Other revenue	$160.0	$75.8	$84.2
Total value of health center services	**$409.0**	**$111.5**	**$297.5**

Source: Drug Channels, National Association of Community Health Centers

The potential loss of patients because of restrictions on the 340B program would lead to poorer health outcomes for patients unable to receive care from community health centers. One measure of these impacts on healthcare is the likelihood of increased visits to hospital emergency departments. A useful perspective regarding the nature of visits pertains to levels of acuity and urgency associated with those visits. For the 70 percent of visits in 2020 whereby patients were assessed for level of acuity, 18 percent were determined to have immediate or emergent conditions requiring care within 1 to 14 minutes. Half of patients needed urgent care within 15 to 60 minutes while 32 percent of patients needed semi-urgent or nonurgent care within 1 to 24 hours.[19]

Given the number of emergency department visits that can be addressed by community health centers, health centers have developed strategies to reduce emergency department use. These strategies

[19] National Center for Health Statistics, "National Hospital Ambulatory Medical Care Survey: 2020 Emergency Department Summary Tables" https://www.cdc.gov/nchs/fastats/emergency-department.htm

involve working with hospitals to divert patients from emergency departments, encouraging patients to initially seek care at health centers, and preventing disease-related emergencies by chronic condition management.

Strategies also include expanding hours of operation and offering same-day and walk-in services to increase access to care. While measured impacts of these strategies are largely anecdotal, the Government Accountability Office (GAO) found that one health center determined that emergency department visits declined 63 percent after the center implemented its strategy to reduce the need for such visits.[20]

The potential loss of patients due to 340B program restrictions could reverse the beneficial, cost-saving impacts of community health centers by expanding the number of emergency department visits in Tennessee. In 2020, there were 40.5 emergency department visits per 100 people.[21] The availability of healthcare at community health centers reduces this rate among patients. To estimate the potential impact, this assessment assumes that emergency room visits by community health center patients are reduced by 63 percent based on the experience documented by GAO. For patients who might lose access to community health centers, these reduced visits would be eliminated and annual emergency department visits could increase by roughly 26 per 100 patients. This would result in over 109,000 more emergency department visits. With an average cost of $570 per visit, the total cost of these increased emergency department visits would exceed $62 million as indicated in Exhibit 11.[22]

Exhibit 11: Potential Impact of Both Restrictions on Tennessee Emergency Department Visits ($ Millions)

Characteristic of delivery sites	Potential loss of patients	Potential increased ED visits	Cost of increased ED visits
Urban delivery sites	36,426	9,289	$5.3
Rural delivery sites of centers with no excess sites	41,247	10,518	$6.0
Rural delivery sites in excess of five per health center	352,013	89,763	$51.2
Total	429,685	109,570	$62.5

Source: Drug Channels, National Association of Community Health Centers, National Center for Health Statistics

[20] Government Accountability Office, "Hospital Emergency Departments: Health Center Strategies That May Help Reduce Their Use," April 11, 2011 https://www.gao.gov/products/gao-11-414r

[21] Op. cit., National Center for Health Statistics

[22] Weber, Belinda, "Should you go to the emergency room or visit urgent care?" Medical News Today, December 19, 2022 https://www.medicalnewstoday.com/articles/urgent-care-or-emergency-room

A major economic incentive driving emergency department utilization is that care is provided regardless of one's ability to pay. In 2020, the expected source of payment for 62 percent of emergency department visits involved government programs like Medicaid, the Children's Health Insurance Program, or other state-based programs (36.6 percent), Medicare (21.7 percent), or a combination of Medicare and Medicaid (3.8 percent). Accordingly, restrictions on the 340B program will place more pressure on taxpayers to pay for the healthcare of others.

Importantly, community health centers are only one of many types of covered entities in Tennessee that participate in the 340B program. As indicated in Exhibit 12, community health centers account for almost 17 percent of covered entities in the state. Altogether, there are 1,404 covered entities in the state, each vulnerable to the potential impacts of proposed changes to the 340B program.

Exhibit 12: Number of 340B Program Covered Entities in Tennessee 2021

	No. of covered entities	Share of total
Hospitals		
Disproportionate Share Hospitals	640	45.6%
Children's Hospitals	5	0.4%
Rural Referral Centers	40	2.8%
Critical Access Hospitals	33	2.4%
Sole Community Hospitals	8	0.6%
Subtotal	726	51.7%
Federal Grantees		
Consolidated Health Center Programs	237	16.9%
Ryan White HIV/AIDS Programs	15	1.1%
Sexually Transmitted Disease Clinics	165	11.8%
Comprehensive Hemophilia Treatment Centers	4	0.3%
Family Planning Programs	129	9.2%
Tuberculosis	128	9.1%
Subtotal	678	48.3%
Total	**1,404**	**100.0%**

Sources: HRSA Office of Pharmacy Affairs

Conclusion

This study assesses the impacts in Tennessee of proposed changes that would limit the 340B program's scope. Because of data limitations, Sage's impact estimates have primarily focused on impacts on consolidated health center programs.

PRINCIPAL ANALYTICAL FINDINGS

- Tennessee's community health centers collectively served almost 907,000 patients in 2021. Over one-third, 36 percent, are racial and ethnic minorities. Most of these patients are also low income, with 67 percent associated with incomes at or below the federal poverty level (FPL);

- Were 340B program benefits limited to patients with incomes below 200 percent of federal poverty levels, the value of medicine/drug discounts to Tennessee's community health centers would decline by more than $10 million. The potential loss of insurance and other revenue would exceed $22 million;

- Assuming there was no change in federal funding of these centers, if patients were limited to those with income below 200 percent of federal poverty levels, total revenue would decline by $33 million to $376 million, a loss exceeding 7 percent of revenue;

- Were restrictions implemented on the ability of community health centers to secure arrangements with contract pharmacies, the state's community centers could potentially lose the ability for roughly 92 of all the state's delivery sites to participate in the 340B program. Most of these are in rural areas;

- If income restrictions and restrictions on the number of contract pharmacies with which community health centers can work were both implemented, it is estimated that the number of patients served by Tennessee's community health centers would decline from almost 907,000 to about 477,000 a reduction of 47 percent;

- Total statewide community health center revenue would decline 27 percent under these circumstances;

- Lost patient volume at community health centers would translate into almost 110,000 additional emergency department visits statewide. With an average cost of $570/visit, these increased emergency department visits would cost taxpayers who pay for 62 percent of these visits $38.8 million;

- Patients in rural areas would be especially vulnerable. They represent 71 percent of patient volume at Tennessee's community health centers and would be more likely to have their most proximate delivery sites shuttered.

About Sage Policy Group

Sage Policy Group is an economic and policy consulting firm headquartered in Baltimore, MD. Dr. Anirban Basu, Sage's chairman and CEO, founded the firm in 2004. Over a period spanning two decades, Sage has managed to create a client base that encompasses more than forty states and seven countries and includes Fortune 500 companies, NFL teams, aquariums and zoos, state and local governments, insurance companies, banks, brokerage houses, major medical systems, trade organizations, and law firms, among others.

The company is especially well known for its analytical capabilities in economic impact estimation, school enrollment forecasting, economic development, economic forecasting, fiscal impact analyses, legislative analyses, litigation support, environmental economics, and industry outlooks, and has significant experience in the subject areas of construction, healthcare, energy, real estate, manufacturing, professional sports, lotteries, agriculture, tourism, entrepreneurship, government contracting, secondary and post-secondary education, and the economics of retirement. The firm is also known for its superior communications and messaging skills.

In addition to leading Sage, Dr. Basu has emerged as one of the nation's most recognizable economists. He serves as the chief economist to Associated Builders and Contractors and the International Food Distributors Association and as the chief economic adviser to the Construction Financial Management Association. He chaired the Maryland Economic Development Commission from 2014 to 2021 and currently chairs the Baltimore County Economic Advisory Committee. He has been interviewed by CNBC, CNN, Fox Business, Axios, the New York Times, and many others.

Dr. Basu's lectures in economics are delivered to audiences across the U.S. and abroad. In recent years, he has focused upon health economics, the economics of education, and economic development. He has lectured at Johns Hopkins University in micro-, macro-, urban, and international economics, and most recently, global strategy. He is now the Distinguished Economist in Residence at Goucher College, where he teaches History of Economic Thought.