On the Front Lines:

The Importance of the 340B Drug Discount Program to Kentucky Hospitals

Kentucky Hospital Association

Representing Kentucky Hospitals and Health Systems

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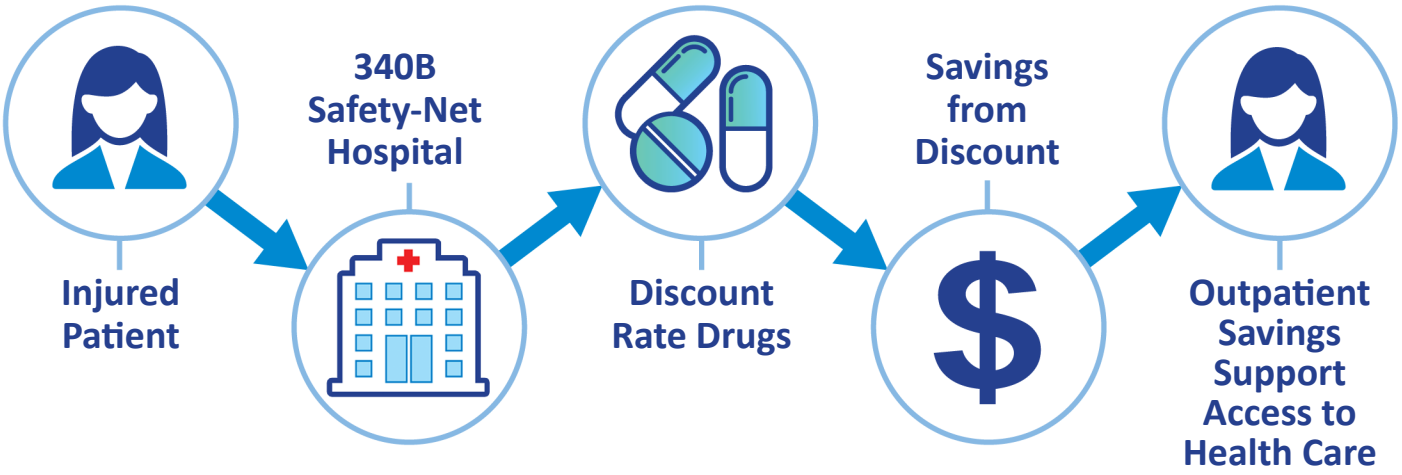
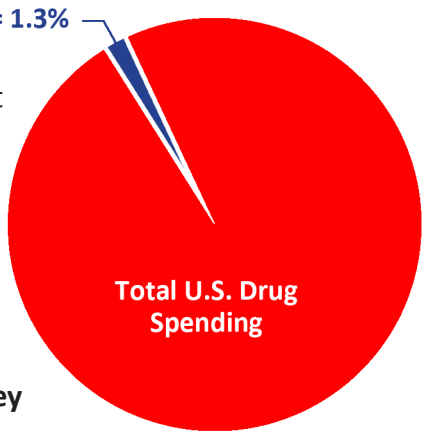
How the 340B Program Works



- A key federal program is delivering millions of dollars in cost savings on medications that safety-net hospitals use to help vulnerable Kentuckians, stretching limited resources.
- NO taxpayer money is used for the program.
- Drug manufacturers, while earning more profits than most other industries, want to scale back the program despite its proven record of decreasing government spending and expanding access to patient care.
- The Kentucky Hospital Association strongly opposes any efforts to eliminate, scale back or significantly reduce the benefits of the program.

Background

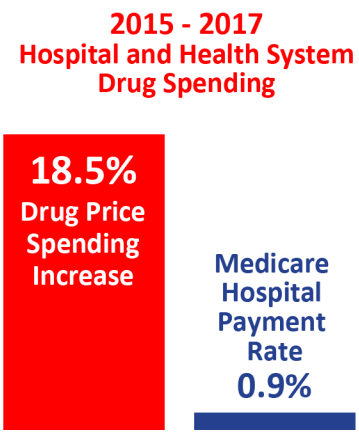


Enacted in 1992, Congress created the 340B Program for safety-net providers to stretch scarce resources to support their continued service to vulnerable patients. The law requires drug companies participating in the Medicaid program to sell outpatient drugs at a discounted price to eligible facilities. The law does not mandate that drug manufacturers sell drugs at a loss, just at their lowest price. In 2015, the Health Resources and Services Administration (HRSA) which oversees the 340B program estimated that **340B discounts accounted for only 1.3% of total U.S. drug spending. Manufacturers spent more than four times the amount of money on advertising than they provided in total 340B discounts.**

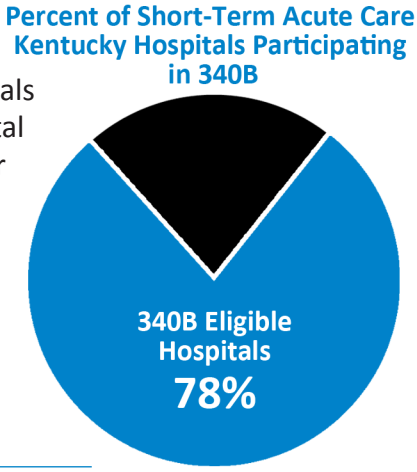
More important, because the 340B program is funded by drug company discounts, IT HAS NO COST TO TAXPAYERS.

Several recent reports highlight the profitability of pharmaceutical manufacturers and skyrocketing drug prices:

- A study published this year in *Journal of the American Medical Association* found the profits of large pharmaceutical companies were significantly higher than large corporations in other industries (median net income margin was 13.8% versus 7.7%)[1]
- The Government Accountability Office (GAO) examined data from 2006-2015 and also found higher profits for drug companies compared to other industries[2]:
  - Profits for the largest 25 drug companies fluctuated between 15%-20% compared to 4% - 9% for the 500 largest nonpharmaceutical companies.
  - The average profit margin for the largest 25 drug companies was 20.1% in 2015 and 17.1% for all drug companies
  - Hospitals bear a heavy financial burden when the cost of drugs increase. The University of Chicago studied rising drug prices for hospitals from 2015-2017 and found average hospital and health system drug spending increased 18.5%, far exceeding growth in general health care expenditures and Medicare hospital payment rates which averaged less than 1% (0.9%) over the same period.



To qualify for the 340B program, facilities must be non-profit or public hospitals and clinics that serve a high percentage of low income and governmental patients, or they must be a sole community hospital, rural referral center, or critical access hospital. Because Kentucky is the tenth most rural state, has the fourth highest population in poverty and the eleventh highest rate of Medicaid inpatients in the nation, a disproportionate number of Kentucky's hospitals qualify as safety-net providers under the 340B program. **In Kentucky, 73 hospitals out of 94 short-term acute care hospitals qualify to receive 340B discounted outpatient drugs.**



[1] Ledley,F., "Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies," JAMA. 2020; 323(9):934-843.
[2] Profits, Research and Development Spending, and Merger and Acquisition Deals. GAO. November 2017.

Profile of Kentucky's 340B Hospitals:

- **Provide 83% of all inpatient and outpatient hospital care to Medicaid patients and 81% of that care to Medicare patients – this is significant because both Medicare and Medicaid pay less than the actual cost of care. These hospitals have fewer commercial patients to make up the difference.**

- Kentucky's 340B hospitals operate on a thin margin due to treating a disproportionately high percentage of governmental patients where payment is below cost.
  - While the average drug company profit margin was 17.1% in 2015, the median total margin for Kentucky's 340B facilities was only 3.3%.
  - **The percentage of Kentucky 340B hospitals operating with negative margins or at near break-even (less than a 1% total margin) has risen from about 30% prior to 2015 to 40% from 2016-2018.**
- The majority (53%) have fewer than 100 beds, and nearly three-fourths (71%) are in a rural area
- Several recent studies have found a significant number of Kentucky hospitals are at risk of closure – one consultant identified 28 vulnerable rural hospitals prior to the COVID-19 pandemic. Hospital closure hurts communities through loss of jobs (340B hospitals employ more than 64,000 people), and declines in health status. Studies have found a six percent increase in mortality associated with rural hospital closure due to increased travel times and the loss of health professionals which reduces access to care.

The 340B program is highly regulated and audited by the federal government.

- The federal Health Resources and Services Administration (HRSA) audits covered entities to assure compliance plus each covered entity must recertify compliance each year.
- Hospitals and other qualifying entities may only provide discounted outpatient drugs to their own patients.
- Federal guidelines allow 340B covered entities to contract with outside pharmacies to act as a dispensing agent, but these arrangements are subject to audit and contract pharmacies must provide detailed records to assure that 340B drugs are only dispensed to patients of the covered entity.

Importance to Kentucky Patients

Kentucky's 340B safety-net providers use their estimated $400 million in annual savings from the program to help thousands of Kentuckians by providing expanded access, medication assistance, and covering the cost of uncompensated care for uninsured and underinsured patients. Many rural hospitals report they use their 340B savings to keep their doors open and maintain community access to emergency care and other services.

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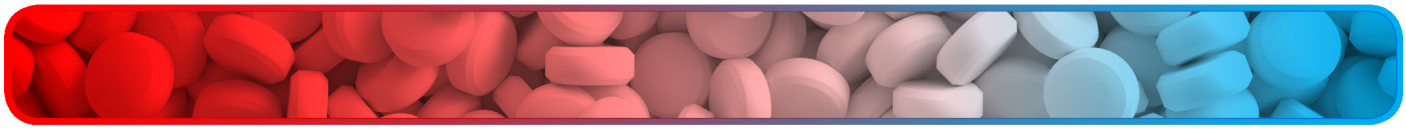
Examples of the ways Kentucky hospitals use 340B savings include:

- Keeping the doors open to maintain access to quality care in the community

- Providing free or reduced cost prescriptions for the uninsured and underinsured
- Providing expensive infusion, chemotherapy and specialty pharmacy medications to patients who cannot afford them
- Providing naloxone to first responders to combat the opioid epidemic
- Helping fund community health center services
- Helping cover copays for low-income patients
- Helping with charity care and Medicaid losses
- Providing community benefits such as free transportation, meals and clothing for indigent patients

The positive impact of the 340B Program is reflected in the story of Breckinridge Memorial Hospital in Hardinsburg. The hospital was on the brink of closing, largely because of ongoing federal reimbursement cuts to Medicare and Medicaid, but it was finally able to break even because it began participating in the 340B program.



The 340B Program is UNDER ATTACK

Despite the program's proven track record of decreasing government spending and expanding access to patient care, drug manufacturers want to scale back the program despite record profits. PhRMA has advocated new restrictions on the program, such as limiting use of the discounted drugs to "uninsured" patients instead of all patients of 340B-covered entities as intended under the law, and recently, some drug manufacturers have announced strategies to interfere with the 340B discount where drugs are distributed through contract pharmacies of 340B covered entities

- Placing new restrictions on patients that can receive discounted drugs would be particularly problematic in Kentucky. **The Medicaid expansion has resulted in 30% to 40% of hospital patients now being covered by Medicaid in addition to another 50% who are covered by Medicare. Restricting use of the 340B program to only "uninsured patients" would greatly harm the ability of Kentucky's safety-net hospitals to serve Medicare and Medicaid patients and would cost Kentucky hospitals millions of dollars annually.**
- Several major drug manufacturers have recently announced that they will limit or restrict 340B pricing based on where the safety-net provider elects to have its 340B drugs shipped. These actions are in violation of the statutory requirement that drug companies charge no more than the 340B ceiling

price when selling their products to 340B providers. Other manufacturers are threatening to deny 340B pricing unless 340B providers comply with demands for superfluous claims data that goes far beyond the scope of the 340B statute and raises issues related to patient privacy. These actions establish a dangerous precedent that will undermine the ability of safety-net 340B hospitals to serve vulnerable communities, particularly in rural areas. HHS recently admonished at least one company (Eli Lilly) for doing this, citing their actions to raise drug prices and their increase in income and stock prices at a time when most health care providers, including 340B providers, are financially struggling.

Legislation introduced in the 2020 Kentucky General Assembly that was ultimately amended would have removed pharmacy benefits from Kentucky's Medicaid Managed Care program and required drugs to be paid for through the old Medicaid fee for service system. The proposal would have cost Kentucky hospitals an estimated $200 million annually by eliminating all of their Medicaid 340B savings because the fee-for-service Medicaid reimbursement system requires that 340B drugs be paid without any drug markup that all other pharmacies receive. Although the "carve out" was touted by some as saving the state money, it would have harmed safety-net providers and their patients by eliminating millions of dollars that currently support services for thousands of Kentuckians.

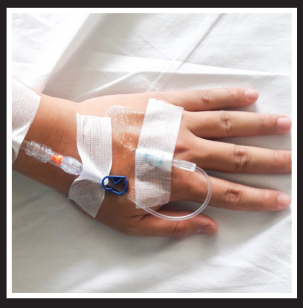
A Small Program with BIG BENEFITS

The 340B program generates savings for participating hospitals that enable them to provide a number of significant benefits to patients, such as expanded services, helping to cover copays for low-income patients, providing drugs to uninsured patients, and keeping their doors open to maintain community access to care. Data shows that Kentucky's 340B hospitals provide real value to their communities by treating a heavy load of Medicare and Medicaid patients where payment does not cover costs. Responding to the COVID-19 pandemic is estimated to cost Kentucky's hospitals $2.6 billion in 2020 - yet after federal relief funds are considered, $1.3 billion in losses still remains. Clearly, Kentucky hospitals cannot afford to lose the savings generated by the 340B program.

The issue comes down to protecting Kentucky's crucial hospitals, the vast majority of which are rural, non-profit, or sole community providers from the desires of the highly profitable pharmaceutical industry to shut down a program which helps hospitals keep the lights on at no cost to the taxpayers. Without the 340B program, a number of these hospitals will be forced to close their doors or turn to the taxpayers for help.

The Kentucky Hospital Association strongly opposes any efforts to eliminate, scale back or significantly reduce the benefits of the 340B Program.

The 340B program allows hospitals to provide expanded services, cover copays for low-income patients and provide drugs to uninsured patients.




340B Testimonial

Judith Overstreet
Campbellsville, Kentucky

When reviewing policy, it's often easy to be caught up in the legislation and forget about the profound impact it has upon lives. 340B can be a lifesaving program for many people, just as it was for Judith Overstreet.

Overstreet is a homemaker from Campbellsville, Kentucky. She cares for her husband, who has Alzheimers, and she is both a breast cancer and a colon cancer survivor! Even though she had Medicare with supplemental coverage, her breast cancer hormone blocker, Aromasin, was more than $100/month out of pocket at a local pharmacy.

However, because of the 340B program at her local hospital, Taylor Regional Hospital (TRH), her out-of-pocket cost was reduced to $25/month using TRH's outpatient pharmacy.

Without 340B, her treatment would have posed a significant financial hardship. She may have had to make the decision to change to a suboptimal class of drug, which could have caused health issues as she had side effects to similar drugs in this class that negatively affected her quality of life.

Today, both her breast cancer and colon cancer are in remission!

For more information about this report, contact:

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