



The Hospital + Healthsystem
Association of Pennsylvania

Leading for Better Health

July 16, 2018

Secretary Alex M. Azar II
U.S. Department of Health and Human Services
200 Independence Ave., SW, Room 600E
Washington, DC 20201

RE: RIN 0991–ZA49; Department of Health and Human Services Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs—Section on the 340B Drug Pricing Program)

Dear Secretary Azar:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 240 member institutions, we appreciate the opportunity to comment about the 340B section of the Department of Health and Human Services' (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

While we appreciate the Administration's focus on the issue of unsustainable drug prices, which threaten patient access to care, the focus on the 340B program as part of a plan to lower drug prices is misplaced. A number of the questions raised by HHS suggests that the 340B program might contribute to higher drug prices. However, it is drug manufacturers, not 340B entities, which are solely responsible for setting list prices as well as determining subsequent price increases. The 340B program, which represents a very small portion of drug spending nationally, is not responsible for drug manufacturers' decisions. Any effort to scale back this vital program would not lower drug prices. Rather, a smaller 340B program would increase revenue for drug manufacturers at the expense of vulnerable patients and the community served by hospitals across the Commonwealth of Pennsylvania.

The 340B Program in Pennsylvania

- 57 Pennsylvania hospitals participate in the 340B program
- About half of 340B participating hospitals are in urban counties
- 80 percent of Pennsylvania's Critical Access Hospitals are part of the program
- 30 percent of Pennsylvania's 340B hospitals operate with a negative total margin
- The median average three-year total margin is 2.32 percent for 340B participating hospitals, far below the 4–6 percent needed to remain open
- 340B hospital's located in 32 of Pennsylvania's 67 counties, affecting a large part of the entire state

Hospitals in Pennsylvania have cited that the program allows them to reach more patients and provide more comprehensive services. Many hospitals that participate in the program use the savings to help patients by offering their prescription medications at significantly reduced costs, or no cost at all. Additionally, the program supports initiatives such as providing transportation



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services to get patients to their doctor appointments, or expanding access to wellness and medication management programs.

Specific examples of the impact of the program include:

- **Mercy Health System** cited in an [op-ed](#) in the *Delaware County Daily Times* that it uses the savings generated through the 340B program to hold free mammogram screening programs, free community athletic screening programs for students and free, monthly community health education sessions. In addition, this program allows Mercy to provide bedside prescription deliveries prior to a patient's discharge. Ultimately, the program helps keep readmission rates down.
- **Einstein Healthcare Network** states that participation in the 340B Program enable them to provide a variety of programs that help improve access and quality of care for low-income and uninsured individuals that might not otherwise be available. Specifically, Einstein utilizes 340B savings to assist low-income patients, many of whom lack adequate prescription drug coverage for expensive treatments such as cancer, or the means to pay for or pick up prescriptions upon discharge from an inpatient stay. These patients also benefit from navigation services that support care transitions, and the community-at-large benefits from community wellness programs. Einstein offers an array of critical medication management programs with dedicated resources and genuinely caring health care professionals to service the needs of its vulnerable population. Since 2010, Einstein has utilized the 340B program to provide an initial 30-day prescription at the time of discharge regardless of ability to pay. This discharge pharmacy is utilized by 15,000 patients per year. Patients have benefitted from Einstein's Medication REACH program which includes Reconciliation of their medication lists, Education that is custom to the patient's needs with a transitions of care pharmacist, a resolution of Access to care issues, and Counseling post-discharge resulting in healthier patients at Home. Einstein has seen a 50 percent less likely chance of readmission when the REACH model is deployed. Einstein's Medication REACH program has been recognized as a national best practice by the American Society of Health-System Pharmacists (ASHP) and the American Pharmaceutical Association (APhA) in medication management at care transitions.
- **Allegheny Health Network (AHN)** asserted that 340B savings allow AHN to reach more patients and provide comprehensive health care to many more uninsured and underinsured patients in its service areas. Specific AHN programs and services supported by 340B program savings include:
 - Access to oncology care and treatment in multiple communities throughout the Western Pennsylvania region so patients can receive care close to home
 - Designing a comprehensive system that provides patients with access to quality care and a better patient experience through necessary support services such as social work, navigation, financial counseling, and charity care for cancer patients



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- Providing technologically advanced and expensive oncological care as a supplement or alternative to traditional chemotherapy
 - Prescription medications for free and/or reduced prices
 - Providing new and cutting-edge drugs that would otherwise be a burden on any organization and most standalone physician practices
 - Expansion of “care coordination clinics,” such as West Penn Hospital’s Care Partner Clinic, which identify high-risk patients throughout Western Pennsylvania that do not have resources to obtain health care or medications
 - Free annual influenza and pneumonia vaccines for high-risk populations which prevents hospitalizations and deaths
 - Prevention of the spread of HIV transmission through programs to increase medication compliance
 - The Perinatal Hope Program—a one-stop care program aimed at ensuring successful outcomes for expectant mothers addicted to drugs or alcohol and their newborn babies
 - The Positive Health Clinic—a Ryan White Care Act/Health Resources and Services Administration funded medical clinic for persons with HIV, providing comprehensive state-of-the art primary and specialized care to HIV-positive persons, regardless of their medical insurance coverage or ability to pay
- **[Penn State Health Milton S. Hershey Medical Center \(Penn State Hershey\)](#)** articulated that 340B savings allow Penn State Hershey to fund many programs and reach more patients with comprehensive pharmacotherapy services. Some examples include:
 - A medication bedside delivery program upon discharge
 - Supporting Hemophilia Treatment Center—provider salaries, patient supplies, and educational materials
 - HIV Program—physician, pharmacist, nursing salaries; planning mail order dispensing service for patients
 - Adherence monitoring, education for patients
 - Personnel to operate Patient Drug Assistance Program which has saved approximately \$2 million-plus annually for uninsured and underinsured patients
 - Emergency Department Pharmacy clinical services funded with the savings from the 340B program
 - Unit-based pharmacists to provide discharge counseling and medication reconciliation for patients
 - Ambulatory clinical pharmacy services initiated in oncology, HIV clinic, rheumatology, to improve patient outcomes through ongoing care management and adherence monitoring
 - Prior authorization services for patients prescribed specialty pharmaceuticals
 - Community outreach—17 free flu vaccine clinics during 2017 in underserved areas, including food pantries, schools, senior centers, etc.



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Growth in the 340B Program

HHS has asked how growth in the 340B program has affected list prices. Drug manufacturers inaccurately claim that programs such as 340B have driven them to raise prices to unsustainable levels, allegedly because of growth in the program. While the 340B program clearly expanded because of Congressional extension of the program to support more vulnerable communities, much of the program growth also can be attributed to drug manufacturers' dramatic price increases for outpatient drugs as well as to medical advances that have enabled more care to be provided in the outpatient setting.

Similar to the national trend, Pennsylvania hospitals are adjusting to dynamic changes in the market as more services are delivered in outpatient settings. In fiscal year 2016, outpatient revenue as a percent of total revenue was 45.3 percent. In fiscal year 2017, it moved to 46.8 percent.

Program Eligibility

HHS has asked whether several changes to the program, including the definition of a "patient" are needed to "refocus the program toward its intended purposes." The 340B program is working as Congress intended by helping hospitals expand access to life-saving prescription drugs and comprehensive health care services to vulnerable communities across the country, including to low-income and uninsured individuals. Changes to the 340B patient definition or added regulatory burden that provide no benefit to taxpayers only put access to care for vulnerable communities at risk.

The current 340B patient definition is based on the relationship the eligible patient has with his or her hospital. It includes patients who receive health care services from a health care professional who either is employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. Changing the definition of patient, in the requirements governing covered entities, would undermine the benefits of the program.

Past proposals to narrow the patient definition would effectively limit discharge prescriptions or infusion-only services, which could have jeopardized the ability of Pennsylvania hospitals to serve the most disadvantaged patients in their communities, including low-income patients, uninsured patients and patients receiving cancer treatments. HAP is extremely concerned about the harmful effect these types of proposals would have on Pennsylvania's patients' access to care.

Conclusion

Pennsylvania hospitals and health systems rely on drug therapies to save lives every day, and are deeply committed to ensuring that their patients have access to the drugs and care they need. However, as major purchasers, hospitals cannot continue to sustain the high and rising



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drug prices that have strained budgets. Far from contributing to higher drug prices, the 340B program has been a crucial tool for hospitals to continue to care for their communities. If the

340B program is curtailed, it will be Pennsylvania patients and the communities served by 340B hospitals who will pay the price through more limited access to needed services.

HAP has advocated for Congress and federal policymakers to review 340B policy in the context of the following goals:

- Safeguard the long-term sustainability of the 340B Drug Pricing Program
- Solidify the important benefits of the program which play a key role in helping hospitals balance the increasing burden of ever-increasing drug costs
- Promote program reforms that enhance transparency and accountability without placing onerous hardships upon hospitals providing care to vulnerable patient populations

We appreciate this opportunity to our share concerns with you. We look forward to working with you and your staff to work to safeguard this valuable program.

Sincerely,

A handwritten signature in black ink that reads 'Jolene H. Calla'. The signature is written in a cursive, flowing style.

Jolene H. Calla, Esquire

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