



AMERICA'S ESSENTIAL HOSPITALS

Defending 340B in a Challenging Environment

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340B AND THE AFFORDABLE CARE ACT

- House and Senate bills included language to extend 340B to inpatient treatment
- Pharmaceutical manufacturers lobbied successfully to have inpatient language removed in final ACA bill
- ACA 340B inpatient effort raised attention surrounding the program, leading to a larger anti-340B movement
- Before the ACA, 340B rhetoric on Capitol Hill was minimal

340B AND THE AFFORDABLE CARE ACT

- Other changes to 340B under the ACA included:
 - » Expanded eligibility for:
 - Children's hospitals
 - Freestanding cancer hospitals
 - Critical access hospitals
 - Rural referral centers
 - Sole community hospitals
 - » Narrow rulemaking authority for HRSA in these areas:
 - Ceiling price transparency
 - Dispute resolution
 - Civil monetary penalties

CONGRESSIONAL INVESTIGATION OF 340B

- During the 112th Congress (2011-2012), Republican congressional staff initiated an investigation of 340B
 - » Leaders:
 - Sen. Chuck Grassley (R-IA) -Senate Judiciary
 - Sen. Orrin Hatch (R-UT) -Senate Finance
 - Sen. Mike Enzi (R-WY) -Senate HELP
 - Rep. Joe Pitts (R-PA) - House Energy and Commerce
 - Rep. Bill Cassidy (R-LA) - House Energy and Commerce
 - » Investigation garnered significant attention and negative press for 340B
 - » However, final report was never released. Investigation unofficially ended when relevant staff left the Hill or changed jobs.

340B OPPONENTS

- AIR 340B – Alliance for Integrity and Reform
 - » “Coalition of patient advocacy groups, clinical care providers and biopharmaceutical innovators dedicated to reforming and strengthening the 340B program to ensure it directly supports access to outpatient prescription medicines for uninsured indigent patients.”
 - » Members include PhRMA, BIO, Baxter, and Eli Lilly and Company
 - » AIR 340B has been the most significant critic of the 340B program
 - » Their talking points are distributed to members of Congress in efforts to speak out against the program
 - » AIR 340B believes that 340B should be directed at uninsured patients
 - » AIR 340B lobbies for 340B program reform
 - » AIR 340B suggests that the program is facility-focused as opposed to patient-focused

HOT BUTTON 340B ISSUES

- Program intent
- Hospital eligibility
- Patient definition
- Contract pharmacies
- Program oversight
- Use of program savings
- Program growth
- Program transparency
- Medicare shared savings



HRSA AND THE “MEGA-REG”



- In 2014 HRSA planned to release an omnibus regulation making specific 340B program clarifications.
- In November 2014, the planned regulation was rescinded due to a U.S. District Court decision that HRSA did not have regulatory authority over the program.
- The court decision was the result of Pharmaceutical Research and Manufacturers of America (PhRMA) suing HRSA based on a previous rule, arguing that the agency did not have regulatory authority to issue final regulations surrounding 340B.
- HRSA now plans to release subregulatory guidance that will address the same issues as the originally planned “mega-reg” – expected summer or later this year.

2015 CONGRESSIONAL HEARING

- On March 24, the House Committee on Energy and Commerce, Subcommittee on Health held a hearing examining the program – first hearing on 340B in a decade
- Witnesses from HRSA, GAO, and OIG were present
 - » HRSA focused on auditing activity and impending guidance
 - » OIG focused on June 2011 report which addressed program oversight and transparency and February 2014 report on strengthening oversight of contract pharmacies
 - » GAO focused on September 2011 report addressing HRSA's oversight of 340B

WHAT'S NEXT?

- OIG expected to release 2015 report to measure potential Medicare Part B spending if Medicare shared 340B savings
- GAO expected to release a report late this spring or early summer to compare 340B hospitals with non-340B hospitals based on sources of revenues and margins.
- HRSA guidance
- MedPAC will include 340B chapter in its upcoming June report – focus on Medicare reimbursement for 340B drugs compared to the hospital 340B drug acquisition cost – will not include recommendations for the program
- America's Essential Hospitals work to protect 340B and combat potential legislative proposals that could harm the program or redirect 340B savings to Medicare or elsewhere

MAKING THE CASE FOR 340B



CAMPAIGN OF MISDIRECTION

What critics say:

- 340B savings enrich hospitals, rather than help vulnerable patients
- Levels of charity care not consistent with 340B savings
- Program growth beyond what Congress envisioned
- 340B costs the federal government and taxpayers
- The program operates largely without oversight



THE CHALLENGE

Counter a coordinated and targeted campaign of misinformation by the pharmaceutical industry to limit the scope of 340B



OUR STRATEGY

- Set the record straight and educate
- Demonstrate good stewardship
- Shift the argument from hospitals versus drug makers
- Remind policymakers they have skin in the game—and a gap to fill with federal dollars if 340B savings shrink

MESSAGES

- 340B is simple, and simply indispensable.
- 340B works for patients, providers—and taxpayers.
- Drug prices are unaffordable.
- Pull the thread of 340B and unravel the fabric of vital, communitywide health services.
- This isn't a fight between drug companies and providers—it's a fight between drug companies and patients and communities.
- Policymakers have a choice: An incremental increase in drug company profits or the health and economic vitality of communities.

NOW WHAT?



AMERICA'S ESSENTIAL HOSPITALS

Statement
U.S. House of Representatives
Subcommittee on
Hearing on Examining the
Tuesday, March 23, 2010
Bruce Siegel, MD, MPH
America's Essential Hospitals

America's Essential Hospitals appreciates the opportunity to testify before the Subcommittee on Health of the Committee on Energy and Commerce.

America's Essential Hospitals is the leading association of high-quality health care for all, especially the uninsured. America's Essential Hospitals has advocated, advanced, and helped these hospitals ensure access to care. Our more than 2,000 member hospitals provide primary care through trauma care, research, public health services, and population health programs.

Essential hospitals provide these services and more largely through local support, including savings from the 340B program. If support were to be cut, it would severely challenge essential hospitals' ability to safely and sustainably care for their patients. Cutting 340B support would not only severely challenge essential hospitals' ability to safely and sustainably care for their patients, but it would also compromise our hospitals' ability to provide high-quality health care.

America's Essential Hospitals and our members support integrity and health care programs. We welcome efforts to ensure the 340B program

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340B Benefits Vulnerable Patients. Essential Hospitals Support the Program

About the 340B Drug Pricing Program

In 1992, bipartisan congressional action created the 340B Drug Pricing Program to lower drug costs for hospitals that care for a disproportionate share of low-income patients. Under the program, pharmaceutical manufacturers agree to extend discounts to eligible providers on outpatient drugs as a condition of participating in the large Medicaid and Medicare Part B markets. These providers, known as covered entities, include essential hospitals, community health centers, AIDS clinics, and other safety-net hospitals. The law explicitly makes covered entities the recipients of discounts and allows them to pass discounted drugs to all patients, including the uninsured.

340B Supports Access to Care. Taxpayers Support the Program

Covered entities are committed to caring for vulnerable and use their 340B savings to purchase otherwise scarce resources. For patients with life-saving medications at reduced or no cost, 340B provides access to community-based specialty care, and help managing chronic disease.

Most important, 340B supports all patients while also reducing federal, state, and local taxpayer dollars.

Better Care through 340B Savings

The 340B program provides affordable medications, better health outcomes, and

costs

the 340B program really is that simple—and a largely indispensable part of the patient care that essential hospitals rely on to meet their commitment to their need. The program's ability to accomplish cost savings is a testament to the program's ability to make back what it's invested. Among the program's biggest detractors are pharmaceutical companies. With an eye toward reducing revenue they may provide to state and local governments, they've tried to make the program less visible and misdirected.

But to weigh the merits of these key features of the program, you need only understand how 340B works. First, 340B discounts are our most valuable tool. Only certain hospitals, community health centers, and other safety-net providers meet a statutorily defined threshold of care for low-income patients. The program's savings reach precisely those providers. Congress intended to help—and produce the intended result—to help hospitals attract scarce resources.

Keep 340B savings where they belong—with patients and communities

guest expert comment

Dr. Bruce Siegel

Few government programs produce as much good for so many people with as little cost to taxpayers as the 340B drug pricing program.

The concept is simple: Pharmaceutical manufacturers sell outpatient drugs at a discount to hospitals and other providers that serve large numbers of low-income patients. Hospitals agree to pass up the profit they would otherwise realize on the drugs to support not only affordable medications for indigent patients, but also to provide a broad variety of services to the vulnerable: community-based primary care, cancer clinics and other specialty care, mental health services, and emergency response. These safety-net hospitals prepare the next generation of health professionals, training them as other teaching hospitals. And they provide public and population health—sometimes serving as the



Dr. Bruce Siegel is president and CEO of America's Essential Hospitals, which represents more than 2,000 hospitals and health systems nationwide.

public health department for the local community.

Essential hospitals also use their 340B savings to support clinics that provide access to outpatient services for people who might otherwise lack the resources to see a physician. By doing so, the hospitals make good use of their savings to help the comprehensive, coordinated care through expensive outpatient and primary-care networks.

These are the services we put at risk if essential hospitals lose their 340B program savings. Our hospitals operate with the narrowest of margins or at a loss, so every dollar counts.

The 340B discounts take on particular importance when you consider the escalating cost of drugs. Recent examples include a pneumonia new hepatitis C drug for more than \$1,100 a pill and a top cancer drug regimen that costs more than \$100,000 a year. These are unaffordable costs, not only for low-income patients and the essential, local, state and federal governments, but for all taxpayers.

In the end, we face a choice: side with communities by keeping 340B discounts where they belong, with patients who safety-net hospitals—or chip away at support of care for the vulnerable and put everyone at risk. Retaining an discretionary profit to other purposes squares to meet hospital care—not higher costs, poorer health and lowered productivity in communities across the country. ■

Interested in submitting a guest expert comment? Send emails to essentialhospitals@essentialhospitals.org or call 202-336-1000. For more information, visit www.essentialhospitals.org.

March 2, 2010 | Modern Healthcare 25



Sentry Data Systems @sentrydata Mar 23
Safety-net hospitals treat 2X more poor patients and offer outsized uncompensated care bit.ly/1w0wkQk #340B #protect340B



Crystal Starlin @CrystalStarlin Mar 23
March madness? Solve the high drug cost problem don't target the #340B program #protect340B morningconsult.com/opinions/congr...



Essential Hospitals @OurHospitals Mar 23
Well said. @gigman! Tackle drug price problem and #protect340B thehill.com/blogs/congress...



Michael Hess and 5 others follow
The 340B Coalition @340BCoalition Mar 23
Total drug spending in the US equals \$328B. #340B discounts equal just 2% #protect340B ow.ly/zZA4H

RESOURCES AVAILABLE TO YOU

- Comprehensive talking points
- Advocacy materials
- Media relations support
- Guidance on placing commentaries
- Educational programming
- Real-time alerts and updates

HOW YOU CAN HELP US

- Stories
- Stories
- Stories
- Stories



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QUESTIONS?

