

Statement for the Record Submitted to U.S. Senate Committee on Health, Education, Labor, and Pensions Perspectives on the 340B Drug Discount Program Thursday, March 15, 2018 By Bruce Siegel, MD, MPH, President and CEO America's Essential Hospitals

Chairman Alexander, Ranking Member Murray, and honorable members of the committee, thank you for the opportunity to speak today about how the 340B Drug Pricing Program helps low-income patients and their hospitals—and how we can work together to strengthen this vital program.

My name is Dr. Bruce Siegel, president and CEO of America's Essential Hospitals. We are an association of 325 hospitals and health systems that form the backbone of the nation's health care safety net. Essential hospitals care for millions of people in every corner of our country—from the largest cities to broad regions of urban, suburban, and rural communities. In fact, one in 10 U.S. residents are born at an essential hospital.¹ Essential hospitals are diverse: large academic medical centers with statewide or regional scope and unique specialty services, multihospital systems with extensive outpatient networks, and city and county public hospitals that anchor communities.

But underlying this diversity is a shared and defining mission: to provide care to all people, regardless of social, financial, or health status.

It was precisely for hospitals with this mission that Congress created the 340B program more than 25 years ago. The historical record is clear: The legislative authors of this program were explicit in their language and unequivocal about their intention to protect hospitals of the safety net from the existential threat of unsustainable drug costs.

To understand our ardent support for the 340B program, you first must understand the patients and communities our hospitals serve. About half of our hospitals' patients are uninsured or Medicaid beneficiaries.² Nearly half of essential hospitals' discharges in 2015 were for racial and ethnic minorities.³ On average, each of our member hospitals cares for more than 17,000 inpatients annually, more than 67,000 emergency department (ED) patients, and more than 350,000 outpatients.⁴ In states represented

AMERICA'S ESSENTIAL HOSPITALS 401 Ninth St NW Ste 900 Washington DC 20004 by HELP Committee members, our hospitals saw 1.3 million inpatient discharges, 4.9 million ED visits, and 28 million non-emergency outpatient visits in 2016. In the context of 340B, it is important to note hospital outpatient clinic patients are nearly four times as likely as those treated at physician offices to be Medicaid, self-pay, or charity care patients, and almost twice as likely to live in high-poverty communities.⁵

The communities our hospitals serve are no less disadvantaged. They are home to an estimated 4.6 million families living below the federal poverty line and more than 21.5 million individuals without health insurance.⁶ Social determinants of poor health also loom large: Federal data show essential hospitals serve communities where more than 275,000 individuals struggle with homelessness and 8.5 million people have only limited access to healthful food.⁷

Essential hospitals work diligently not only to care for patients who face financial hardships, but also to help everyone in the community overcome social and economic factors that contribute to poor health. For example, they provide medical respite programs for the homeless and, for those living in hunger, food pantries, community gardens, and meal delivery services. Typically, they do these things on their own dime.

This dedication to mission and to reaching beyond their walls requires essential hospitals to commit resources always in short supply. Our hospitals operate with a margin of only 3.2 percent, less than half that of other U.S. hospitals.⁸ Many barely break even, and in many states—Colorado, Indiana, Louisiana, Utah, and Washington, for example—they operate at a loss. Our 325 hospitals represent only about 6 percent of all U.S. hospitals but bear nearly 17 percent, or about \$6 billion, of the nation's uncompensated care.⁹ Our average member sustains about \$61 million annually in uncompensated care—more than eight times that of other U.S. hospitals.¹⁰

Wide gaps often exist between those average uncompensated care costs and 340B savings at these hospitals. In Tennessee, for example, Regional One Health, in Memphis, reports uncompensated care costs eight times greater than its 340B savings. Grady Health System, in Atlanta, reported more than \$174 million in unreimbursed and uncompensated costs in 2015, more than four times its 340B savings. These gaps between uncompensated costs and 340B savings are not atypical, and collectively provide one example of how essential hospitals more than meet their responsibility to vulnerable patients as good stewards of the 340B program.

With these numbers in mind, it is not surprising our hospitals and the patients and communities they serve depend on every available source of support. These hospitals rely on a patchwork of federal, state, and local support, and losing any piece puts the whole at risk. The savings our members achieve through the 340B Drug Pricing Program is a key piece of that patchwork. The program is vitally important not only to providing vulnerable patients with affordable drugs, but to sustaining the many comprehensive services on which these people and their communities depend.

Congress envisioned 340B as supporting this broader mission, and lawmakers explicitly stated this as their intention for the program. In the 1992 House report that accompanied legislation establishing the 340B program, they wrote, "In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and *providing more comprehensive services.*"

I added emphasis to those last words to underscore a critical point: Congress designed the 340B program to do more than reduce drug costs for entities serving low-income patients. Lawmakers also intended for it to support a variety of *comprehensive services* consistent with the mission of safety-net providers, such as essential hospitals, and that our members provide daily.

We have few tools as effective as 340B for countering high drug prices. And we have no tools as cost-effective as 340B for the federal government and taxpayers: Support to hospitals comes from manufacturer discounts, not taxpayer dollars. In fact, restricting 340B likely would leave state and local governments picking up the tab for uncompensated care, or necessitate further federal investments.

How Essential Hospitals Use 340B Savings for Vulnerable Patients

Our hospitals' work to care for low-income patients and provide entire communities with high-intensity, lifesaving services—trauma care, burn units, disaster response, and others—reflects Congress' vision for the 340B program. The list of comprehensive services made possible by 340B savings is long: free clinics and community programs for primary and chronic condition care; cancer and transplant care, including costly chemotherapy and anti-rejection drugs; medical respite care for the homeless and case management for underserved patients; training for rural hospital partners in high-risk labor and delivery and other specialized care.

Not only do 340B savings support more services, they result in better care and better care outcomes. Boston Medical Center (BMC) fills more than 1 million prescriptions annually at its pharmacies, with three-quarters provided through the 340B program. The hospital's 340B savings support its successful Specialty Pharmacy Program for more than 1,000 cancer, HIV, and other patients. Patients enrolled in this and other BMC programs reliably have medications in hand thanks to 340B—95 percent receive their medication compared with only 40 percent communitywide.

Particularly impressive are the improvements to access and outcomes for the hospital's cancer and HIV patients due to 340B. BMC has decreased the time it takes patients to get cancer drugs from an average of 11 days using outside pharmacies to the same day, using the hospital's 340B-supported pharmacy. Medication adherence has improved significantly, too, through use of the hospital's pharmacy: More than 90 percent of oncology and HIV patients have and take their medications compared with previous rates of 50 percent to 70 percent. Better health outcomes have followed, such as those

for patients with hepatitis C. Patients who complete hepatitis C therapy have nearly a 100 percent chance of full recovery, and 340B has driven therapy compliance from a communitywide average of 60 percent to 99 percent at BMC.

Our hospitals across the country have similar patient stories of better access to care, better health, and cost savings through their participation in the 340B program, including these examples:

East Alabama Medical Center (EAMC), Opelika, Alabama—At EAMC, a patient mix that includes a high number of uninsured and Medicaid patients contributed to \$50 million in uncompensated care costs in 2016. Although falling well short of covering this gap, the 340B savings the hospital achieved—\$10 million that same year—helped EAMC make cancer treatment available to indigent, uninsured, and underinsured patients.

Hennepin County Medical Center (HCMC), Minneapolis—HCMC admitted a homeless, uninsured man nine times over four months at a cost of \$225,000, or more than \$56,000 a month. Pharmacists in a hospital medication therapy management program made possible by 340B savings taught the man how and when to take his medications. After regular clinic visits and improved care management, his medical expenses dropped to \$36,000—\$4,000 a month—in just nine months.

UK HealthCare, Lexington, Kentucky—UK HealthCare's 340B savings allow the health system to maintain dedicated pharmacy staff to help indigent, self-pay, and underinsured patients receive needed medications through copayment assistance and other financial support programs. The system, which lacks its own home infusion pharmacy, extends care through a contract home infusion pharmacy with the help of the 340B program.

Erlanger Health System, Chattanooga, Tennessee—Without its 340B savings—\$9 million in 2014, or about a tenth of its \$92 million in uncompensated care costs— Erlanger could not have provided some trauma, oncology, and stroke services programs to underserved patients. The health system's 340B savings also fully fund a pharmacy at its Dodson Avenue Community Health Center, which offers face-to-face counseling on medication therapy, adherence, and chronic disease management.

University of Utah Health Care, Salt Lake City, Utah— With its 340B savings, University of Utah Health Care provides an AIDS drug assistance program in which patients receive drugs at cost plus a minor fee. It also partners with rural hospitals to help them successfully care for patients with peripherally inserted central catheter lines or with high-risk pregnancies, increasing capacity for emergency and critical care and improving operating room procedures. This keeps patients in their communities and avoids costly transfers to other hospitals. **University of Virginia** (**UVA**) **Health System, Charlottesville, Virginia**—UVA Health System has one of the highest case mixes in the United States, evidence that it cares for many of the sickest patients. It also provides more than \$250 million in uncompensated care annually. The health system's 340B savings are vital to maintaining specialty services, such as home health and dialysis, and access to specialized pharmacy services for patients at high-risk of readmission.

VCU Health, Richmond, Virginia—Savings from the 340B program made possible the VCU Health Virginia Coordinated Care program, which contracts with primary care providers to offer a medical home for 23,000 low-income, uninsured people. The program has lowered ED use and costs and made medications available to the 80 percent of outpatients who otherwise lack prescription drug coverage.

Essential Hospitals as Good Stewards of 340B

Since its inception, the 340B program has incorporated rigorous requirements for how hospitals and other covered entities qualify for and use the program. Rules implementing the program control how hospitals procure and dispense 340B drugs, maintain 340B drug inventories, ensure only eligible patients receive discounted drugs, and avoid duplicate discounts through the Medicaid Drug Rebate Program.

The program also has adequate safeguards to prevent hospitals from diverting 340B drugs to ineligible patients and to ensure they make appropriate contractual arrangements with outside pharmacies to extend the reach of 340B discounts to more vulnerable patients and underserved communities.

In short, the 340B program is subject to substantial oversight and monitoring. The Health Resources and Services Administration (HRSA), the federal agency that oversees the program, conducts regular audits of hospitals and other covered entities to ensure compliance with program requirements. HRSA employs a comprehensive audit process, with pre-audit, onsite, and post-audit phases, an evolving notice and hearing process for findings, and a corrective action plan and repayment component. Since it began auditing covered entities in 2012, HRSA has conducted 825 audits, mostly of hospitals. Audit reports, including the agency's findings and corrective actions by covered entities, are publicly available on the HRSA website.

By contrast, HRSA has conducted only 11 manufacturer audits since 2012, the first year the agency began actively checking drug maker compliance. This stark disparity suggests a need for more work to bring parity to the audit process and protect hospital and their patients from overcharges and inappropriately denied discounts.

Our member hospitals and health systems undergo HRSA audits regularly to ensure their compliance with 340B program rules, and they provide substantial data and respond to many questions as part of these audits. When auditors find problems, essential hospitals diligently correct shortcomings in their programs and, if warranted, return savings to manufacturers. Our members work daily to be good stewards of the 340B program because they know their patients and communities depend on it.

340B: Necessary in 1992, Necessary Today

The 340B program grew from an urgent need for action after manufacturers responded to the Medicaid Drug Rebate Program with changes in discounting practices that caused drug prices to surge nationally. We are no less at risk today of unsustainable drug costs, and the 340B program remains our best hedge against high prices.

Again, stories from our hospitals illustrate the point. Without the 340B program, a UVA Health System patient with diabetes, hypertension, high cholesterol, and heart disease could not afford the high cost of insulin and 11 other medications necessary to treat the patient's chronic illnesses—medications that otherwise would cost \$24,000 a year, or well more than double the patient's annual income.

It is unfortunate that stories like this are more the rule than the exception at our hospitals. The patients our hospitals serve are those least able to afford the crushing cost of prescription medications and physician-administered drugs, especially those with cancer and other devastating diagnoses. Restricting access to affordable drugs through the 340B program would irrevocably harm care, destabilize hospitals on which millions of Americans rely, and put patients at risk—maybe gravely so.

America's Essential Hospitals and its members thank the committee for its interest in ensuring program integrity and transparency for the 340B Drug Pricing Program. We share those goals and stand ready to work with this committee and all stakeholders to strengthen the 340B program without restricting access to it by hospitals that care for our most vulnerable patients.

Thank you.

¹ Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. <u>www.essentialdata.info</u>. Accessed March 12, 2018.

² Ibid., 11.

³ Ibid., 10.

⁴ Ibid., 18.

⁵ Comparison of Cancer Patients Treated in Hospital Outpatient Departments and Physician Offices. KNG Health Consulting, LLC. November 2014.

⁶ Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. <u>www.essentialdata.info</u>. Accessed March 12, 2018.

⁷ Ibid., 12.

⁸ Ibid., 15.

⁹ Ibid., 14.

¹⁰ Ibid.