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## **HOSPITAL GROUPS FILE LAWSUIT TO SHINE NEEDED LIGHT ON DRUG COMPANY PRICING AND OVERCHARGING**

**WASHINGTON, DC** (September 11, 2018) – Today, four national organizations representing hospitals and other stakeholders in the 340B Drug Pricing Program sued the federal government over its delay of regulations that would require pricing transparency for drug manufacturers and penalties for overcharging covered entities in the program.

The American Hospital Association (AHA), the Association of American Medical Colleges (AAMC), America's Essential Hospitals, and 340B Health filed their lawsuit against the U.S. Department of Health and Human Services (HHS) in the U.S. District Court for the District of Columbia.

At issue is a years-long delay in implementation of final regulations requiring drug companies to disclose the maximum per-unit, or "ceiling," price that can be charged to 340B providers for outpatient drugs. The delayed regulations would also give the government the ability to levy civil monetary penalties (CMP) against drug companies for knowingly and intentionally overcharging 340B providers.

The lawsuit asks the Court to declare HHS's delay in issuing these rules unlawful and to order HHS to make the January 2017 340B regulation effective in 30 days. The associations are joined in the suit by hospital plaintiffs: Rutland Regional Medical Center in Rutland, Vt.; Genesis HealthCare System in Zanesville, Ohio; and Kearny County Hospital in Lakin, Kan.

"As prescription drug prices continue to skyrocket, the 340B program is as crucial as ever in helping hospitals and health systems provide access to health care services for vulnerable patients and communities," said Rick Pollack, president and CEO of the AHA. "Our lawsuit will ensure that drug companies provide the transparency and accuracy that the government has found lacking and hold price gouging drug companies accountable."

“The continued success of the 340B program must rely on compliance by all parties, including drug manufacturers. Providers need access to the information that Congress said they are entitled to,” said AAMC president and CEO Darrell G. Kirch, MD. “The final regulation provides important transparency for this vital program. Delaying implementation of that rule ultimately harms vulnerable patients and the teaching hospitals they rely on for care.”

“While hospitals routinely meet rigorous requirements for accountability in the 340B program, the government has failed to hold manufacturers to the same standard,” said Bruce Siegel, M.D., MPH, president and CEO of America’s Essential Hospitals. “We must have a level playing field to ensure this program works as Congress intended, which is to help hospitals and other covered entities give vulnerable patients greater access to affordable drugs and health care services.”

“Congress required manufacturer transparency around 340B pricing after a federal watchdog agency documented widespread overcharging,” said Maureen Testoni, 340B Health interim president and CEO. “Here we are eight years later, with no evidence that the overcharging has abated, no transparency around prices, and providers still in the dark as to whether they are being overcharged. Moving forward with these requirements is critical to ensuring that manufacturers provide the 340B discounts they are required by law to provide. Doing so will strengthen the 340B program’s goal of helping providers that treat low-income patient populations.”

In response to Office of Inspector General (OIG) reports documenting numerous instances of drug company overcharges to hospitals and other providers, in 2010, Congress provided HHS with new authority to ensure the accuracy and transparency of ceiling prices and impose CMPs on drug companies for overcharging 340B participants. By January 2017, the agency issued a final rule on CMPs, ceiling prices, and internet posting. The current administration has since delayed the effective date of the new rule five times. This lawsuit challenges the most recent delay of the final rule on the grounds that the delay is arbitrary and capricious and an unreasonable delay in violation of the Administrative Procedure Act (APA).

For more than 25 years, the 340B program has enabled hospitals and other organizations that care for many low-income and uninsured patients to purchase certain outpatient drugs from pharmaceutical manufacturers at discounted prices. The program allows participating hospitals to use the savings from the discounts to provide an expanded range of comprehensive health services to their local communities, such as increased access to care, clinical pharmacy services, community outreach programs, free vaccines and transportation to follow-up appointments. An analysis released earlier this year by the AHA showed that 340B tax-exempt hospitals provided more than \$50 billion in total benefits to their communities in 2015 alone, the most recent year for which data is available.

For additional information, a copy of the complaint can be found by visiting [HERE](#).

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**About the American Hospital Association**

The AHA is a not-for-profit association of health care provider organizations and individuals that are committed to the improvement of health in their communities. The AHA is the national advocate for its members, which include nearly 5,000 hospitals, health care systems, networks and other providers of care. Founded in 1898, the AHA provides education for health care leaders and is a source of information on health care issues and trends. For more information, visit [www.aha.org](http://www.aha.org).

**About the Association of American Medical Colleges**

The Association of American Medical Colleges is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in

the biomedical sciences. Additional information about the AAMC and its member medical schools and teaching hospitals is available at [www.aamc.org](http://www.aamc.org).

### **About America's Essential Hospitals**

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to the highest-quality care for all people, regardless of their financial or social status. We support our 325 members with advocacy, policy development, research, and education. Communities depend on essential hospitals for primary care through trauma care, disaster response, health professionals training, public health programs, and other vital services. Essential hospitals innovate and adapt to lead the way to more effective and efficient care. Learn more at [essentialhospitals.org](http://essentialhospitals.org).

### **About 340B Health**

340B Health is a not-for-profit association of more than 1,300 hospitals and health systems that participate in the 340B drug pricing program. We are the leading advocate and resource for hospitals that serve their communities through participation in the 340B drug pricing program. Learn more at [www.340bhealth.org](http://www.340bhealth.org).