New Report Pinpoints Drivers of Rapid Growth in the 340B Program

Predicts More Than $16 Billion in 340B Purchases by 2019

WASHINGTON, D.C. (December 3, 2014) – A new white paper released today by the Berkeley Research Group and funded by the Alliance for Integrity and Reform of 340B (AIR 340B) projects the 340B program will continue to rapidly expand in coming years, fueled in large part by the participation of Disproportionate Share Hospitals (DSH) and despite a continuing decrease in the number of uninsured due to the Affordable Care Act.

“The 340B program has grown tremendously in the past ten years, and it’s concerning to see projections that continue this unsustainable trajectory,” said Stephanie Silverman, spokesperson for AIR 340B, a coalition of patient, clinical and manufacturing interests. “Some entities use the program responsibly; however, 340B already lacks sufficient oversight for generating profits for well-funded hospitals that don’t primarily serve the uninsured as the program intended. Now is the time to establish needed oversight for the program.”

Congress created the 340B Discount Drug Program in 1992 to help entities serving large numbers of uninsured, indigent and vulnerable patients provide outpatient medicines to those populations. However, a variety of legislative, regulatory and behavioral factors have contributed to dramatic growth of the 340B program and led to an increase in total purchases from $1.1 billion in 1997 to more than $7.0 billion by 2013. Total purchases are expected to grow to more than $16 billion (at the discounted 340B price) by 2019.

The paper explores four historical drivers of substantial growth in the 340B program that will continue to underpin future expansion during the next five years, including:

- **Increase in 340B Enrolled Disproportionate Share Hospitals (DSH):** Largely as a result of the Medicare Modernization Act in 2004 altering the DSH calculation for certain hospitals, hundreds of new hospitals enrolled in the 340B program. From 2003 to 2013, the number of DSH hospitals enrolled in the program increased from 185 entities to approximately 1,000. Newly enrolled DSH hospitals have been the biggest single driver of growth in the program, accounting for an estimated half of total 340B drug spending in 2013. DSH entities purchase the vast majority (more than 80 percent) of 340B drugs.

- **DSH Hospital Acquisition of Satellite Clinics:** There have been at least 140 instances of DSH hospitals acquiring community oncology practices between 2009 and 2012, and an almost 120 percent increase in 340B oncology drug utilization following these acquisitions. This has contributed to 340B purchases at DSH hospitals almost doubling from 2010 to 2013. Research projects the trend will continue, along with new acquisition targets, contributing to an additional $1.5 billion in 340B purchases by 2019.

- **Contract Pharmacy Arrangement Expansion:** In 2010, the Health Resources and Services Administration (HRSA) issued guidance allowing 340B entities to contract with an unlimited number of pharmacies to provide 340B purchased drugs to eligible patients. As a result, almost two-thirds of all 340B DSH hospitals currently have at least five contract pharmacies and many have more than fifty.
• **Impact of the Affordable Care Act (ACA):** The ACA established new eligibility categories in the 340B program for pediatric hospitals, critical access hospitals, sole community hospitals, rural referral centers and freestanding cancer centers. To date, more than 1,100 of these entities have enrolled in the 340B program and remain active. Further, new hospitals could become eligible due to Medicaid expansion increasing the DSH percentage above the 340B eligibility threshold for some hospitals. This could result in incremental 340B purchases of more than $1.4 billion by 2019.

“As 340B continues to expand, there must be more transparency, oversight and resources to keep the program focused on benefiting uninsured patients,” concluded Silverman.

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**The Alliance for Integrity and Reform of 340B (AIR 340B)** is a coalition of patient advocacy groups, clinical care providers, and biopharmaceutical innovators and distributors dedicated to reforming and strengthening the 340B program to ensure it directly supports access to outpatient prescription medicines for uninsured indigent patients. [www.340Breform.org](http://www.340Breform.org)

**Contact:** (202)449-8385, info@340bBreform.org