



## Safety Net Hospitals for Pharmaceutical Access

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### **SNHPA Statement on Drug and PBM Industry Funded Study on 340B Program**

February 12, 2013—A coalition of pharmaceutical manufacturers, large pharmacy benefit managers, and other industry groups released a report today on the 340B drug discount program. While we agree with some of their recommendations, many of their findings are wrong or misleading.

Safety Net Hospitals for Pharmaceutical Access (SNHPA), which represents hospitals that participate in 340B, concurs with the industry coalition's finding that "340B is important today and going forward for the many patients who are dependent on this program." Congress has chosen on a number of occasions to expand 340B to new entities on a bipartisan basis, including to rural and children's hospitals.

This new report, however, is full of misinformation and contains many unsubstantiated assertions.

For instance, we are deeply dismayed that the report includes unfounded insinuations that some hospitals are putting patients in harm's way to maximize 340B savings. This is an affront to the integrity of safety-net caregivers across the country.

Also, today's report is off-base in stating that 340B has an extremely narrow purpose that is limited to helping "uninsured indigent patients gain better access to prescription drugs." The program's benefits are intended for a wider category of patients than only the indigent and uninsured. Moreover, the legislative history makes clear that it is intended to improve all types of health care services, not just access to prescription medicines. For two decades, 340B has helped give safety-net health care facilities the ability to continue serving large numbers of low-income and otherwise vulnerable patients. Federal regulators, Congressional committees, individual members of Congress, and government investigatory agencies have made it clear that the 340B program's actual purpose is to enable safety net health care providers to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Congress created 340B in response to escalating drug costs that were reducing the resources available to safety-net providers and limiting the level of services and number of vulnerable patients they were able to serve. 340B discounts reduce these providers' operating costs and enhance resources available for patient care.

Hospitals do, in fact, use program savings to improve care for eligible patients—exactly as Congress intended. A June 2011 study ([http://www.snhpa.org/public/documents/pdfs/340B\\_Value\\_Report\\_06-29-11.pdf](http://www.snhpa.org/public/documents/pdfs/340B_Value_Report_06-29-11.pdf)) found that 340B hospitals pass their program savings on to their indigent patients in a number of ways. Examples include reducing the price of drugs to low-income patients, serving more patients, increasing patient access to pharmacy services, increasing the choice of drugs available to patients, and enhancing pharmacy and other health care services.

The 340B program saves money not just for patients, but for all taxpayers. Analyses by the Congressional Budget Office have consistently projected that expansion of the program generates savings for the federal government. 340B saves rather than costs money for taxpayers.

SNHPA agrees that the Health Resources and Services Administration (HRSA), which oversees the 340B program, should be adequately funded and that continued oversight of 340B is needed. We applaud HRSA for the steps it has taken to increase program oversight.

We also agree with the call for increased transparency to help advance the program's goals. Many integrity initiatives that were enacted by Congress still have not been implemented. Among them are improved transparency of 340B prices, selective auditing of manufacturers, and establishment of a meaningful dispute resolution process. HRSA has never audited a manufacturer. This is alarming in light of the longstanding problem of manufacturers overcharging 340B covered entities. The HHS Office of Inspector General (OIG) has issued a series of reports documenting the 340B overcharge problem. In 2006, for instance, the OIG sampled pricing over the course of a month and found that 14 percent of total purchases were overcharges. 340B providers have complained about overcharging for two decades and the complaints continue today. The Government Accountability Office's 2011 report on 340B included a discussion of how HRSA's lack of program oversight may be resulting in manufacturers "charging covered entities more than the 340B price for drugs which would limit the benefit of the program for these entities." Although manufacturers are authorized to audit covered entities, covered entities have no way of auditing manufacturers.

SNHPA agrees that a clearer, more specific definition of "patient" is needed for the 340B program. We also believe that use of 340B should not be limited to patients based on their insurance status. The GAO report clearly recognized that covered entities "are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of patient, whether or not they are low income, uninsured, or underinsured." If Congress had intended to limit the definition of patient based on insurance status, it would have done so.

SNHPA is pleased that many hospitals, community health centers, and other clinics have developed mutually beneficial relationships with independent and retail pharmacies. While we know that many of these arrangements have resulted in improved access to care and better health outcomes, we want to ensure that these partnerships benefit all patients regardless of their ability to pay. Therefore, we agree it is time to evaluate the 340B contract pharmacy program to determine whether it is meeting its goals of stretching resources while increasing pharmaceutical access to indigent patients.

Policymakers should also consider the impact of Medicaid expansion on 340B and evaluate the effect it will have on program growth. Nonetheless, even after health insurance expansion, close to 30 million Americans will still lack health coverage and tens of millions will be underinsured.

Finally, we agree on the need for HRSA to issue formal regulations. While we recognize that the agency has used an informal notice and comment process for many of its past guidances, we believe formal regulations will ensure open and transparent rulemaking and will provide greater clarity concerning program requirements.

SNHPA looks forward to working with Congress, HRSA, and other 340B stakeholders to improve the 340B program.

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*Safety Net Hospitals for Pharmaceutical Access (SNHPA) is an association of nearly 1,000 hospitals with a mission to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. For more information about SNHPA and the 340B program, visit [www.snhpa.org](http://www.snhpa.org).*