

Congress of the United States
Washington, DC 20510

March 5, 2012

Ted Slafsky
Executive Director
Safety Net Hospitals for Pharmaceutical Access
1101 15th Street, NW, Suite 910
Washington, DC 20005

Dear Mr. Slafsky:

We are writing to you to request information to enable Congress to improve its oversight over the 340B drug discount program. We raise this issue as an area of mutual concern given the significant expansion of the program's scope in recent years and the risks of improper diversion and poor oversight identified by the Government Accountability Office (GAO). Specifically, we are interested in understanding the role that the Safety Net Hospitals for Pharmaceutical Access (SNHPA) plays with respect to the 340B program.

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program that ensures that certain providers, known as covered entities, within our nation's health care safety net have access to outpatient drugs at or below statutorily defined ceiling prices.¹ The original intent of the program was to extend the Medicaid drug discount to the most vulnerable of patients at Public Health Service clinics, those who are mostly, "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."²

The GAO report issued in September 2011 notes an inadequate level of oversight by the Health Resources and Services Administration (HRSA) and a lack of necessary direction on program requirements. Of greatest concern is the GAO finding that, "the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater."

¹ 42 U.S.C. 256b.

² Public Health Clinic Prudent Pharmaceutical Purchasing Act, Committee Report to Accompany S. 1729, 102-259, Senate Committee on Labor and Human Resources, March 3, 1992.

As the GAO notes in its report, “the number of covered entity sites has nearly doubled in the past ten years to over 16,500” -- with most of the new covered entities, hospitals, belonging to your organization.

As part of your mission statement SNHPA claims to help its members “...increase the affordability and accessibility of pharmaceutical care for the underserved in this nation.”³ Your website goes on to say that, “SNHPA is dedicated to educating its members and others about the 340B program and creating new opportunities for members to save on pharmaceuticals and improve access to pharmaceutical care.”

Because of your important and increasing role in educating the fastest growing category of covered entities in the 340B program, we respectfully request more information regarding your interpretation of the program’s original intent, program requirements, and thoughts on how to improve oversight of the program going forward. Specifically, we ask that you provide the following documents and respond to the below inquiries in writing by March 15, 2012:

1. All documents provided to SNHPA members regarding:
 - a. The definition of a 340B patient.
 - b. The eligibility of outpatient sites of participating hospital covered entities to acquire drugs at 340B discounts.
 - c. Inventory replenishment or virtual inventory programs.
 - d. Contract pharmacies.
2. All documents SNHPA has provided to members regarding Accountable Care Organizations (ACOs) and their interaction with the 340B program.
3. All documents that are provided to members related to the “On the Bubble” discussions, which targets hospitals that are at the cusp of the 340B disproportionate share hospital (DSH) eligibility threshold. For example, your website notes a recent teleconference where, “participants listened with interest as one provider described how it converted a portion of its psychiatric-unit beds into acute-care beds and how that change allowed the hospital to qualify for the 340B program.” Please include in your response minutes from that teleconference and any additional teleconference conducted as part of the “On the Bubble” program.
4. All program guidance documents provided in the Members only section of your website.
5. All materials provided by your organization to covered entities in preparation for and during the 340B conferences held in the past three years.

³ About Safety Net Hospitals for Pharmaceutical Access, available at <http://www.snhcpa.org/public/about.cfm>

6. Does SNHPA recommend organization and administrative changes to members for the purposes of maximizing the 340B program benefits? If so, please provide examples of such changes and related documentation.
7. How often does SNHPA communicate with the Office of Pharmacy Affairs at HRSA to coordinate 340B education services for covered entities?
8. What conflict of interest policies are in place for SNHPA leadership, outside consultants, and legal counsel?
9. Does SNHPA coordinate advocacy activities between SNHPA hospital members and other Federal grantees participating in the 340B program? If so, please explain.
10. Does SNHPA track member utilization of the revenues/savings generated by the 340B program? If so, please provide such information and how such funds are being used to serve the medically uninsured.
11. Does SNHPA provide guidance to members on how to best stretch scarce resources within the 340B program? If so, please provide the related documentation.
12. Does SNHPA have a protocol for identifying non-compliant 340B entities and a process under which you submit such information to HRSA for additional oversight? If so, please provide a list of those covered entities and which ones you have submitted to HRSA as potentially non-compliant?
13. Please provide any materials you are able to access through the 340B University offered through the prime vendor program.

Maintaining the integrity of the 340B program is of the utmost importance, and we trust that you share our concerns. If you have any questions regarding this request, please contact Heidi Stirrup with the Energy and Commerce Committee at (202) 225-2927, or Erika Smith with the Senate Judiciary Committee at (202) 224-5225, Riley Swinehart and Melissa Pfaff with the Senate Health, Education, Labor, and Pensions (HELP) Committee at (202) 224-6770 or Hayden Rhudy and Kimberly Brandt with the Senate Finance Committee at (202) 224-4515.


Sincerely,



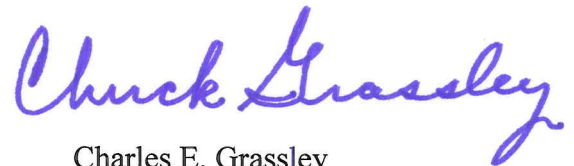
Joe Pitts
Member of Congress



Michael Enzi
U.S. Senator



Orrin G. Hatch
U.S. Senator



Charles E. Grassley
U.S. Senator

cc: Ranking Member Frank Pallone
Health Subcommittee
House Energy and Commerce Committee

cc: Chairman Max Baucus
Senate Finance Committee

cc: Chairman Patrick Leahy
Senate Committee on the Judiciary

cc: Chairman Harkin
Senate Health, Education, Labor, and Pensions Committee