

Congress of the United States
Washington, DC 20510

March 5, 2012

Chris Hatwig
Vice President
Apexus, Inc.
125 E. John Carpenter Freeway
Irving, TX 75062-2354

Dear Mr. Hatwig:

We are writing to you to request information to assist Congress in 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 recently identified by the Government Accountability Office (GAO).

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 patients receiving services at Public Health Service clinics, including individuals who are, "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."²

Your organization's website notes the mission of Apexus, Inc.' is to leverage unique resources, "and expertise in delivering maximum value to its 340B stakeholders, through the promotion of program integrity, compliance..." As you may know, the program's integrity has become increasingly questioned over the past several months.

The GAO report issued in September 2011 outlined several findings related to the 340B program that are concerning to us. The GAO also stated that Federal oversight of the program is "inadequate" to ensure that covered entities and manufacturers are in compliance with program requirements. With the reliance on self-policing among participating manufacturers and covered entities and the increase in the number of new settings in which the program is offered, the risk of improper purchases or diversion of 340B drugs has significantly increased. The problems

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.

identified by the GAO as it relates to the oversight responsibilities of each party and the expansion of the program need resolution.

Therefore, to better understand how the program operates as it relates to these risks, to facilitate Congressional oversight over this important program, and to ensure that it is operating within the parameters of the law, we respectfully request that you please respond to the below inquiries in writing by March 15, 2012:

1. When does the latest Apexus, Inc., contract with the Office of Pharmacy Affairs (OPA) at Health Resources and Services Administration (HRSA) expire?
2. Your website notes that the original prime vendor contract went to Provista. What organizational changes occurred when Provista became Apexus, Inc.? Did HRSA rebid the contract when Provista turned into Apexus, Inc.? How many times has HRSA renewed Apexus, Inc.'s contract?
3. Your website notes that one of the roles of the Prime Vendor Program is to provide "other value-added products and service" above and beyond negotiating drug prices and establishing distribution solutions. Please explain what "other value-added products and services" are provided by your organization.
4. What role, if any, does your organization have in assisting covered entities in determining eligible 340B patients?
5. What process does Apexus, Inc. have in place to verify a covered entity's eligibility? How often does Apexus, Inc. verify a covered entity's eligibility for the program?
6. Has Apexus, Inc. reviewed or helped develop split billing software systems, which some covered entities use to replenish their 340B inventories? If so, has your organization raised any concerns regarding such systems with HRSA? Do you believe HRSA should provide guidance on the use of split billing software systems?
7. What role does Apexus play in assisting entities in becoming 340B eligible?
8. Is Apexus, Inc. aware of any potential violations by covered entities in using group purchasing organization (GPO)? If so, has such information been provided to HRSA?
9. When did Apexus, Inc. establish the 340B University? Which 340B stakeholders currently have access to the University and its educational materials? Does your HRSA contract cover the cost of developing and implementing the 340B University?
10. What scope of information is provided through the 340B University educational materials?
11. Do you have 340B University user fees for covered entities and/or manufacturers? If so, what are the fee schedules for each user?

Further, we ask that you please provide the following documents:

1. Documents provided by Apexus to covered entities that speak to the definition of a patient or 340B eligible customer.
2. Documents provided by Apexus to HRSA regarding any concerns of drug diversion or program misuse.

3. Documents provided to 340B stakeholders as part of the 340B University.

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, 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 Kim Brandt with the Senate Finance Committee at (202) 224-4515.

Sincerely,



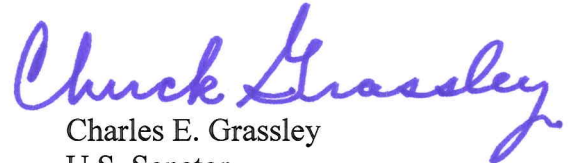
Joe Pitts
Member of Congress



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