United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

March 27, 2013

VIA ELECTRONIC TRANSMISSION

Mary K. Wakefield, BSN, MS, PhD
Administrator
Health Resources and Services Administration
Parklawn Building
5600 Fisher's Lane, Room 14-05
Rockville, MD 20857

Dear Administrator Wakefield:

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program that ensures that certain providers within our nation's health care safety net (covered entities) 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]

Legislation and administrative orders over the past three years, including the American Recovery and Reinvestment Act (ARRA), the Patient Protection and Affordable Care Act (PPACA) and administrative sub-regulatory guidance related to contract pharmacies, has resulted in exponential growth in the number of covered entities utilizing the program, yet the agency has conducted virtually no oversight. In fact, the U.S. Government Accountability Office (GAO) reported that the number of covered entities participating in the program has grown by 183 percent since 2005.

In addition, the uncertainty surrounding the definition of "patient" was highlighted in a recent report from GAO that found "guidance on [340B] program requirements often lacks the necessary level of specificity to provide clear direction."[3] GAO also found that "the 340B

[1] *See generally* 42 U.S.C. 256b.
[2] Pub. Health Clinic Prudent Pharmaceutical Purchasing Act, Comm. Report to Accompany S. 1729, 102-259, S. Comm. on Labor and Human Resources at 6 (1992).
[3] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-836, DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT at 22 (2011).

program has increasingly been used in settings . . . where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients."[4] Because hospitals who participate in the 340B program have broad discretion as to whom to sell their deeply discounted 340B drugs, hospitals can elect to sell all of their 340B drugs to only fully insured patients while not passing any of the deeply discounted prices to the most vulnerable, the uninsured. This is contrary to the purpose of the 340B program since much of the benefit of the discounted drugs flows to the covered entity rather than to the vulnerable patients that the program was designed to help.

For these reasons, in September 2012, I wrote to three North Carolina hospitals regarding their participation in the 340B Program. Specifically, I requested the three hospitals share how much revenue they earn by participating in the 340B Program, the breakdown of the 340B payer mix, and how they reinvest those 340B dollars back into serving the most vulnerable patients. In light of these findings, below is a summary of the findings and additional questions for the Health Resources and Services Administration (HRSA) regarding program oversight.

First, all three North Carolina hospitals provided a summary of revenue generated by participating in the 340B program from 2008. Below is a revenue summary of Duke University Health System, University of North Carolina Hospital, and Carolinas Medical Center:

Carolinas Medical Center	UNC	Duke
2008: $12,970,012	2009: $33,087,329	2009: $88,953,570
2009: $16,697,500	2010: $38,451,076	2010: $109,700,404
2010: $16,910,956	2011: $52,580,763	2011: $131.759.091
2011: $21,065,620	2012: $65,391,050	2012: $135,539,459

These are not small amounts.

[4] *Id.* at Study Findings.

Second, all three North Carolina hospitals provided a breakdown of their "340B patients." Below is a chart that illustrates 340B patients with respect to the three North Carolina hospitals:

Hospital	Medicare	Medicaid	Self-pay	Commercial
UNC	2009: 27.5% 2010: 16.8% 2011: 23.1% 2012: 32.9	2009: 10.3% 2010: 7.2% 2011: 9.7% 2012: 12.5%	**2009: 20.0%** **2010: 10.3%** **2011: 12.0%** **2012: 13.7%**	2009: 27.9% 2010: 28.0% 2011: 22.6% 2012: 29.6%
Carolinas Medical Center	2009: 24.2% 2010: 24.4% 2011: 25.6% 2012: no data	2009: 18.5% 2010: 18.2% 2011: 18.3% 2012: no data	**2009: 11.5%** **2010: 11.3%** **2011: 11.3%** **2012: no data**	2009: 42.2% 2010: 42.6% 2011: 41.9% 2012: no data
Duke	2009: 14% 2010: 17% 2011: 19% 2012: 19%	2009: 7% 2010: 10% 2011: 8% 2012: 9%	**2009: 5%** **2010: 5%** **2011: 4%** **2012: 5%**	2009: 74% 2010: 69% 2011: 68% 2012: 67%

These numbers paint a very stark picture of how hospitals are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread. For example, only 5 percent of the patients who received discounted drugs under Duke University Hospital's 340B program were uninsured. The vast majority of the remaining patients who received discounted drugs paid Duke University Hospital full price through private insurance. As the GAO points out in its September 2011 report, "most [covered entities] reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers."[5]

Third, I asked the North Carolina hospitals how they were reinvesting their 340B revenue. Duke University Healthcare uses 340B revenue to provide, "primary care wellness clinics within four Durham [North Carolina] public schools."[6] According to Duke, "These, clinics operate during the school year and provide medical and mental health services, including medical coverage during weekends and school holidays."[7] Carolinas Medical Center reinvests its 340B revenue to offer free and low-cost medications in addition to providing, "access to its cancer infusion centers for Medicare, Medicaid and uninsured patients who cannot access private freestanding infusion options in the region."[8] UNC Healthcare reinvests 340B resources into

[5] *Id.* at 14.
[6] Letter from Mark D. Gustafson, Deputy Gen. Counsel for Health Affairs, Duke Univ. Health Sys., to Senator Grassley at 2 (Oct. 23, 2012).
[7] *Id.*
[8] Letter from Joseph G. Piemont, President and Chief Operating Officer, Carolinas HealthCare Sys., to Senator Grassley at 4 (Oct. 12, 2012).

maintaining its Medicaid Assistance Team, which "helps patients obtain co-pay assistance, and in some cases, obtain free branded medications from manufacturers."[9]

HRSA needs to have an understanding of where 340B dollars are being reinvested to ensure that covered entities are fulfilling their mission. As the agency overseeing the 340B program, it is critical that you collect information from covered entities regarding their participation in the program given the level of revenue generated from participation.

To help me better understand HRSA's oversight of the 340B program, please answer the following questions by April 22, 2013:

1. Does HRSA currently collect data on how much revenue covered entities receive by participating in the 340B program?
2. Does HRSA currently collect data on the payer-mix for 340B drugs broken down by Medicare, Medicaid, self-pay, and commercial insurance?
3. Does HRSA currently collect data on how covered entities are reinvesting their 340B revenue?
4. If HRSA does not collect this kind of data, then how does it determine whether covered entities are meeting 340B goals and obligations?
5. What, if anything, prevents HRSA from requesting this type of data from covered entities?
6. Since there appears to be no statutory prohibition on collecting such data from covered entities, why does HRSA not collect it?

Maintaining the integrity of the 340B program is of the utmost importance. If you have any questions regarding this request, please contact Erika Smith with the Senate Judiciary Committee at (202) 224-5225.

Sincerely,

Charles E. Grassley
Ranking Member

[9] Letter from William L. Roper, Chief Executive Officer, Univ. of N. Carolina Health Care Sys., to Senator Grassley at 5 (Oct. 17, 2012).