## Congress of the United States Mashington, DC 20510

April 18, 2013

Charles A. Stark, FACHE President and Chief Executive Officer Columbus Regional Healthcare System 710 Center Street Columbus, GA 31901

Dear Mr. Stark:

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.<sup>1</sup> 340B discounts are available for outpatient drugs only. Drugs used in the inpatient setting do not qualify for savings under the 340B program. The original intent of the program was to extend the Medicaid drug discount to the most vulnerable of patients at PHS Clinics, those who are mostly "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."<sup>2</sup>

In its September 2011 report on the 340B program, the Government Accountability Office (GAO) notes an inadequate level of oversight by the Health Resources and Services Administration (HRSA)<sup>3</sup> and a lack of necessary direction on program requirements.<sup>4</sup> 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."<sup>5</sup> As the improper use of the 340B program increases, so does the financial liability to the federal government. The intent and design of the program is to help lower outpatient drug prices for the uninsured. It is not intended to subsidize covered entities for providing inpatient services to those who are covered by private insurance, Medicare, or Medicaid. As such, we have been examining the 340B program.

<sup>&</sup>lt;sup>1</sup> 42 U.S.C. 256b.

<sup>&</sup>lt;sup>2</sup> Public Health Clinic Prudent Pharmaceutical Purchasing Act, Comm. Report to Accompany S. 1729, 102-259, Senate Comm. on Labor and Human Resources, Mar. 3, 1992.

<sup>&</sup>lt;sup>3</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-836, DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT 21 (2011).

<sup>&</sup>lt;sup>4</sup> Id. at 22.

<sup>&</sup>lt;sup>5</sup> Id. at Highlights.

Columbus Regional Healthcare System participates in and receives savings through the 340B Drug Discount Program. Notably, during his recent appearance on FOX Business, Columbus Regional Healthcare System's Director of Pharmacy and Clinical Research, Dr. Burnis Breland, asserted "There is not a windfall of profits in this program at all. The lower drug costs that we incur with the 340B program help us reduce our losses that we incur in treating indigent patients."<sup>6</sup> Dr. Breland also stated "The savings we get from the 340B go right back in to care for these patients that are unreimbursed services that we provide."<sup>7</sup> Nonetheless, we understand that Columbus Regional Healthcare System, an entity that receives drugs at a discounted price, subsequently receives reimbursements from Medicare and insurance companies for the same drugs at the full price.

To help better understand the Columbus Regional Healthcare System's participation in the 340B program, please provide the following documents and respond to the below inquiries in writing by May 2, 2013:

- 1) Please provide a summary of all revenue received from participating in the 340B program since 2008, broken down by year.
- 2) Please explain whether, to what extent, and how Columbus Regional Healthcare System has reinvested 340B savings for the benefit of uninsured patients.
- Please provide data and documentation that demonstrates this revenue was directly reinvested to provide care for indigent patients since 2008, broken down by year.
- 4) Please provide the payer mix for all 340B drugs from 2008-2012. Please list the price at which Columbus Regional Healthcare System purchased each 340B drug, and the price at which it sold the drug, per payer mix.
- 5) Please describe and provide documentation on Columbus Regional Healthcare System's indigent care population and composition.
  - a. What is Columbus Regional Healthcare System's policy on charitable care?
  - b. Please provide documents on Columbus Regional Healthcare System's charitable care policies.
- 6) Please provide the amount of indigent care Columbus Regional Healthcare System has provided since 2008, broken down by year.

<sup>&</sup>lt;sup>6</sup> MONEY with Melissa Francis: Concerns Hospitals are Abusing Discount Drug Program (FOX Business television broadcast Feb. 15, 2013). <sup>7</sup> Id.

- 7) Has the Health Resources and Services Administration ever audited Columbus Regional Healthcare System's 340B program?
  - a. If so, please provide all documentation related to such audits (reports requested by and communications with HRSA, etc.).

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 Erika Smith of the Senate Committee on the Judiciary at (202) 224-5225 or Courtney Lawrence of Congressman Cassidy's staff at (202) 225-3901.

Sincerely,

Charles E. Grassley, Ranking Member Committee on the Judiciary U.S. Senate

sid y

Bill Cassidy, M.D. // Committee on Energy and Commerce U.S. House of Representatives