

September 22, 2017

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

The Honorable Tom Murphy
Chairman
Subcommittee on Oversight and Investigation
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Walden and Chairman Murphy,

Thank you for your letter of September 8, 2017 requesting specific information regarding NYU Langone Health's participation in the 340B Drug Pricing Program (the "Program"). NYU Langone Health is pleased to respond to questions related to this important Program which provides extremely valuable resources for us to satisfy the health care needs of our community, particularly the most vulnerable members of our community. The medical center strongly supports the Program and its original intent to provide a means for hospitals to maintain vital services and meet community need. NYU Langone Health is extremely proud of our on-going efforts to improve access for the underserved and provide the highest quality healthcare for all populations.

NYU Langone Health is the integrated academic medical center jointly operated by NYU Langone Hospitals ("NYULH") and NYU School of Medicine (a division of New York University) serving patients throughout New York City and the broader metropolitan area. NYULH owns three acute care inpatient facilities in Manhattan and Brooklyn and over thirty ambulatory facilities in Manhattan, Brooklyn, Queens and Long Island. Two of the inpatient facilities (Tisch Hospital and NYU Langone Orthopedic Hospital) are located in Manhattan and the third, NYU Langone Hospital-Brooklyn (formerly Lutheran Medical Center) in the Sunset Park section of southwest Brooklyn, was acquired in 2016. Before we acquired Lutheran Medical Center, it was a financially distressed, safety-net hospital and the principal provider of healthcare services for residents of one of New York City's poorest neighborhoods. With more than 85,158 Medicaid beneficiaries, the Sunset Park area¹ has the highest Medicaid enrollment in New York State, with 86% of its population enrolled in Medicaid.

In addition to its inpatient and ambulatory facilities, NYULH operates in conjunction with Sunset Park Health Council, Inc. ("Sunset Park") one of the largest Federally Qualified Health Center networks in the nation. Family Health Centers at NYU Langone (the "Family Health Centers") is a network comprised of nine primary care sites throughout Brooklyn, 37 school-based health centers and dental clinics, four day care centers, twelve community medicine sites in homeless shelters and a family support center that offers educational, vocational and other social support programs. In CY2016, the Family Health Centers saw over 130,000 patients, with 807,000 visits annually (including 40,850 children and adolescents), 81% of whom are low

¹ Zip code 11220

income (below 200% of the Federal Poverty Level) and 73% identify as ethnic or racial minority. Some of the school-based clinics are located in public schools where the clinics provide the majority, if not all, of the healthcare the children receive.

Lastly, NYULH is the lead hospital in NYU Langone Hospital-Brooklyn PPS, a network of hospitals, primary care practices and other healthcare providers participating in the New York State Delivery System Reform Incentive Payment program ("DSRIP"). DSRIP is a federally funded initiative funded by the Center for Medicare/Medicaid Services which has invested over \$7 billion in New York State over five years, and is intended to stabilize the safety net system and reduce avoidable hospital use by 25% over the next five years.

In sum, the Program has been an important partner in assisting us in providing healthcare services to many communities and programs in our service areas.

Before we begin our responses, there are three important points to note:

1. NYULH submitted data and qualified on the basis of its own patient demographics in late 2015 and enrolled in the Program on January 1, 2016. On the same date, NYULH's full-asset merger with the former Lutheran Medical Center (now known as NYU Langone Hospital-Brooklyn), which had previously participated in the Program, became effective. Since the former Lutheran Medical Center did not have the systems in place to track Program reporting, all information presented herein with respect to the Program dates from January 1, 2016 forward.
2. NYULH's fiscal year ("FY") is September 1 to August 31 (following the academic year of its parent corporation, New York University), as opposed to a calendar year ("CY"). We have distinguished our responses to reflect FY versus CY as appropriate.
3. Pursuant to the New York State Department of Health's operating license, NYULH and Sunset Park are "co-operators" of the Family Health Centers, and jointly file cost reports. However, Sunset Park is a separate corporate entity with an independent Board of Directors and its own assets and liabilities. NYULH has continued the historical relationship NYU Langone Hospital-Brooklyn had with Sunset Park and is committed to doing so going forward. Since the merger with the former Lutheran Medical Center (now known as NYU Langone Hospital-Brooklyn), NYULH has provided more than \$10 million in funding annually to support operations and services at Sunset Park (and will continue to do so) and provided an additional \$2.2 million in 2017 (and will continue to do so) to fund the increase in charity care Sunset Park currently provides. (Please see the response to Question 1f.)

The following are responses to the specific questions:

1. In a chart or similar format, please list each of the following items for 2012, 2013, 2014, 2015 and 2016:

- a) *The number of 340B drugs your organization, and all associated sites and off-site outpatient facilities registered as child sites, purchased for that year. Please provide a breakdown of the number of these drugs that were purchased by the covered entity's child sites and the number directly purchased by the covered entity.*

Response: NYULHC purchased 769 340B unique drugs in CY 2016². (For details, please see *Attachment 1, Supplemental Documents*.) Of our 101 340B-eligible locations (100 child-sites and one parent location), only 51 have purchased 340B medications for clinic utilization.

- b) *The percentage of 340B purchased and dispensed that fall into each of the following categories:*
- i. *Analgesics*
 - ii. *Antidepressants*
 - iii. *Oncology treatment drugs*
 - iv. *Antidiabetic agents*
 - v. *Antihyperlipidemic agents*

Response: The percentage of 340B unique drugs purchased and dispensed in the below categories are as follows:

Pharmacological Class	Percentage
Analgesics	4%
Antidepressants	1.5%
Oncology Treatment Drugs	10.3%
Antidiabetic agents	1.1%
Antihyperlipidemic agents	1%

To calculate the percentages, we used the data from 1a and categorized each unique 340B purchased medication into 6 categories (five of them being the requested pharmacological classes and the 6th being other). The detailed breakdown per child site is in the accompanying spreadsheet. For each child site, the percentages are calculated based on the number of unique 340B drugs administered at that specific child site.

- c) *The percentage of 340B drugs your organization purchased that were dispensed to insured patients, including Medicare beneficiaries, Medicaid beneficiaries and commercially-insured individual.*

Response: The total number of 340B unique drugs purchased that were dispensed to insured patients is 769, broken down as follows:

- Medicare beneficiaries: 676 (88%)

² Our response is predicated on the number of unique drugs (i.e. active ingredients) used for the Program not individual NDC (National Drug Code).

- Medicaid beneficiaries: 629 (82%)
- Commercially-insured individuals: 687 (89%)

d) The Number of 340B drugs your organization purchased that were dispensed to uninsured patients.

Response: The number of 340B unique drugs purchased and dispensed to uninsured patients in FY2016 was 426.

e) The amount of savings (in dollars), as compared to the GPO price for the same drug, that your organization generated through participation in the 340B Drug Pricing Program.

2016 Gross Savings: GPO cost minus 340B cost = \$72,684,995

2016 Net Savings: GPO cost minus 340B cost minus WAC impact minus Program Cost = \$66,894,274

f) The amount of charity care (in dollars) that your organization provided.

Response: NYU Langone Health's Charity Care policy is one of the most comprehensive and generous policies in the nation, and reflects our strong commitment to providing comprehensive and high quality health care services to all of our patients. (See *Attachment 2, Charity Care-Financial Assistance Policy*.) Patients who are below 600% of the Federal Poverty Level (FPL) are not required to pay any out-of-pocket co-pays, deductibles, or hospital charges. Patients who are above that level and below the 800% FPL are eligible for a discount on co-pays, deductibles and charges based on a sliding scale. The total cost to NYULH to provide free care for patients eligible under its charity care policy for FY2016 totaled \$33.9 million. In addition, NYULH contributed \$2.2 million to Sunset Park to allow Sunset Park to raise the qualifying level for free care from 300% FPL to 600% FPL and contributed more than \$10 million to fund Sunset Park's operating costs. (See *Attachment 3, Family Health Centers at NYULH*.) Lastly, NYULH experienced a Medicaid program deficit of \$216 million for unreimbursed care in FY2016.

g) The number of patients that received charity care from your organization.

Response: The number of NYULH patients who received charity care in FY2016 was 36,450, and Sunset Park provided charity care to 87,827 patients of the Family Health Centers.

2. *How does your organization calculate the amount of savings it generates through participation in the 340B Drug Pricing program? How does your organization track the amount of money your organization receives when an insured patients' insurance reimbursement exceeds the 340B price paid for the drug?*

Response: The savings from the 340B program are calculated by subtracting the 340B price from the GPO price for Gross Savings and further subtracting the cost of purchasing medications at WAC price due to 340B requirements and Program administration costs to arrive at Net Savings. We do not track the money received from insurer reimbursement due to the fact that payor reimbursement methodologies vary. For example, medication reimbursement may be grouped with other services and not itemized as a stand-alone; in other instances reimbursement mechanisms do not provide sufficient detail to infer specific medication payments. For contract pharmacies, we utilize the Sentry software platform to calculate savings using the formula of Reimbursement minus Cost of Medication minus Dispensing Fee.

3. *How does your organization calculate the program savings to care for vulnerable populations? Are program savings used for any other purpose?*

Response: Please see the response to the preceding question regarding calculation of savings. The savings realized from the Program have been used to fund expanded services and programs for patients served by the NYU Langone Hospital-Brooklyn campus in the Sunset Park section of southwest Brooklyn. NYULH has made a major commitment to raise the quality and quantity of healthcare services and programs at the Brooklyn campus, including implementing the Epic electronic health record software throughout the hospital and its ambulatory facilities, expanding the Emergency Department, adding an observation unit, commencing construction of three multi-purpose units (interventional neurology, cardiac catheterization and interventional radiology), and expanding the Stroke Center, improving access and quality of healthcare services there by adding 90-95 physicians with skill sets and specialties not previously available at the Brooklyn facility, hiring additional nurses, physician assistants, social workers and patient transporters (with 70% of the new hires coming from the local community). (See *Attachment 4, NYU Langone Hospital-Brooklyn.*) While NYULH used, and will continue to use, its own resources to fund infrastructure and capital improvements, much of the programmatic expansion and improvements, such as the enhanced physician and healthcare staffing and outreach, will require funding on an on-going basis and would not have been—and will not be—possible without the 340B savings. Among the new clinical services that were not previously available at the Brooklyn campus, requiring patients previously to travel to Manhattan, and which have been added using the 340B savings, are robotic surgery, obstetrical safety officers, advanced oncologic gastro-intestinal surgery, advanced gynecological oncological surgery, advanced spine and neurosurgery, neurologic critical care, advanced endoscopy, interventional pulmonary, advanced airway surgery for children and adults, advanced urology including prostate cancer surgery and advanced breast reconstructive surgery. The 340B savings are critical to the continuation of these healthcare services for the Sunset Park and greater Brooklyn population, which is largely Medicaid or uninsured.

a) *Does your organization provide any additional charity care to uninsured and underinsured patients with funds derived from sources other than the 340B Drug Pricing Program? If so, please elaborate.*

Response: As noted above, NYULH has a comprehensive and generous charity care policy for all inpatient and ambulatory patients, which makes available free care to patients who are below 600% of the Federal Poverty level, and that provides a discount to patients who are below 800% of the Federal Poverty level. In addition, in 2016 NYULH contributed \$2.2 million to Sunset Park to allow Sunset Park to raise the qualifying level for free care from 300% FPL to 600% FPL. In April 2017, NYULH established a pharmacy liaison program and hired several pharmacy liaison(s) to help all patients (including 340B eligible patients), who have been prescribed specialty medications (i.e. high cost drugs) alleviate the financial burden deriving from the out of pocket cost of such medications.

b) *What percentage of total health care services provided by your organization is charity care?*

Response: In FY2016, 1.03% of total health care services provided as charity care.

4. *Does your organization have any policies to help ensure that uninsured and underinsured patients directly benefit from the program by receiving discounts on 340B drugs? If so, please elaborate.*

Response: NYULH does not have any specific policies to help ensure that uninsured and underinsured patients directly benefit from the Program by receiving discounts on 340B drugs, since this is not the way in which the Program is structured. As noted above, NYULH established a pharmacy liaison program and hired several pharmacy liaison(s) to help all patients (including 340B eligible patients), who have been prescribed specialty medications (i.e. high cost drugs) alleviate the financial burden deriving from the out of pocket cost of such medications. Moreover, we bill Medicaid and the Medicaid HMOs at the 340B cost rather than GPO rates, thereby generating savings for the Medicaid program that can be utilized to fund healthcare services for patients.

5. *How many child-sites does your organization have registered to participate in the 340B Drug Pricing Program? Please provide a list of all child-sites, including the location of the child-site and the date it began participating in the program.*

Response: NYULH has 100 child-sites registered to participate in the 340B Program. (See *Attachment 5, Child-sites.*) NYULH has embarked on a strategy of moving toward and enriching access to ambulatory and out-patient care for our patients in order to bring better healthcare to the communities we serve.

6. *How many pharmacies has your organization contracted with to dispense drugs purchased through the 340B drug pricing program on your behalf?*

Response: NYULH contracted with 12 unique pharmacies (38 specific pharmacy locations), although there were no transactions with or revenue from those pharmacies in 2016. Presently, in 2017, only 3 pharmacies are actively participating in the Program with NYULHC.

- a) *Do your contracts with these pharmacies require that program savings be passed on to the intended beneficiaries, including requiring that uninsured or underinsured patients received discounts on 340B drugs?*

Response: Our contracts do not require contract pharmacies to pass on Program savings to the intended beneficiaries because this is not the way the Program was structured and operationally a contract pharmacy does not know if a patient is a 340B-eligible patient at the time of dispensing the drug (i.e., at the point of sale). However, on a case by case basis, we regularly work with our contract pharmacies to assist patients who require financial assistance to pay for medications. Also, as noted above, in early 2017, we established a pharmacy liaison(s) program and hired several pharmacy liaison(s) to help all patients (including 340B eligible patients), who have been prescribed specialty medications (i.e. high cost drugs) alleviate the financial burden deriving from the out of pocket cost of such medications.

- b) *Does your organization share any program savings with these contract pharmacies? If so, please elaborate.*

Response: NYULH does not share the Program savings with its contract pharmacies. We pay a dispensing fee at fair market value to the contracting pharmacies, which varies depending on the type of medications and services provided to our patients.

Thank you for this opportunity to share our strong support for the 340B Program and to explain how this program benefits our patients and communities.

Sincerely,



Gilda Ventresca Ecroyd

cc: Brighton Haslett
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