EMORY
UNIVERSITY
HOSPITAL
MIDTOWN

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September 29, 2017

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

The Honorable Tim Murphy
Chairman
The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairmen Walden and Murphy and Ranking Members Pallone and DeGette,

On behalf of Emory University Hospital Midtown (EUHM), a 531-bed academic community hospital in the heart of midtown Atlanta, I am formally submitting the following information in response to your September 8, 2017 questions regarding EUHM's participation in the 340B Program. Thank you for allowing EUHM the opportunity to describe the positive impact that the 340B Program has on our patients and the communities that we serve.

The 340B Program Helps EUHM Provide Meaningful Community Benefits:

Our mission at EUHM is to care for patients and their families with concern not only for their illnesses, but also for their mental, emotional and spiritual well-being. EUHM is part of Emory Healthcare, an integrated academic healthcare system committed to providing the best care for our patients, educating health professionals and leaders for the future, pursuing discovery research in all of its forms, including basic, clinical, and population-based research, and serving our community.

not afford to sustain such high levels of Medicaid and other under/uncompensated care while facing substantial drug price increases.

EUHM is proud to serve as a safety net hospital open to all patients in our region. We reflect that pride in the services we perform on an emergency, uncompensated, and charity care basis. We discuss each of these examples as part of our substantive responses to your questionnaire, but we highlight them here to give you a sense of the role EUHM plays in our community:

- EUHM sees over 173 daily patient encounters in its Emergency Department, providing life-saving emergency care that is frequently uncompensated.
- In 2016, EUHM provided $16.5 million in charity care and $9.2 million in uncompensated care resulting in total of over $ 25.6 million in free or discounted care to our community;
- In 2016, EUHM opened a retail pharmacy on campus expressly to serve underinsured and uninsured patients. Even with 340B savings on the drugs dispensed from this location, the pharmacy operated at break-even for FY2017 and at a loss since opening.
- EUHM offers various patient assistance programs to assist patients under the federal poverty level who cannot afford to fill their prescriptions.

The benefits of the 340B Program do not just exist in abstract figures; the EUHM 340B Program affects the lives of EUHM patients. Here are just a few examples of personal success stories made possible by savings from the EUHM 340B Program:

- *A Hepatitis C patient with terminal hepatocellular carcinoma required 200mg of spironolactone BID to manage her symptoms of ascites (a painful buildup of fluid in the abdominal cavity). She was uninsured and could not afford the drug given her annual income under $8,500. She was previously given a limited supply of spironolactone upon hospital discharge, but she had run out of this supply. If she had not been able to take spironolactone, she would have required more aggressive treatment, including large volume paracentesis and/or hospital admission. The generic drug costs the hospital $50/100 tablets. With the savings from the 340B Program, we were able to provide this medication to the patient without charge and she was able to remain compliant with her medication regimen. The expected results include a better quality of life for the patient and a lower risk of readmission.*

EUHM has relied upon the 340B Program to support the hospital's mission since we enrolled in the program in 2006. The 340B Program is a critical part of our efforts to provide world-class care to our community's most vulnerable patients. It is our consistent policy to provide emergency and/or other medically necessary care, without discrimination, to all patients regardless of ability to pay – including the 1.7 million Georgians without health insurance. As a Disproportionate Share Hospital (DSH) in a large urban area, we are constantly working to expand access to care and to provide our patients with access to cutting edge initiatives that we offer as part of an academic medical center.

As you know, Congress created the 340B Program in 1992 to allow safety net hospitals, such as EUHM, and other types of covered entities to purchase outpatient drugs at a discount from drug manufacturers in order to expand services that benefit vulnerable populations. The House Energy and Commerce Committee stated at that time:

> "In giving these "covered entities" access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

Today, EUHM uses 340B savings for the very purpose the Committee set forth twenty-five years ago. At almost no cost to taxpayers, the 340B Program has been a tremendous success in achieving Congress's stated intent, allowing EUHM and other safety net providers to treat large numbers of uninsured and underinsured patients and to continue to expand the care that we offer, rather than being forced to reduce access to patient care because of the cost of pharmaceutical and biological products. EUHM simply would not be able to provide the degree of access that it does without the 340B Program. EUHM uses savings achieved under the 340B Program to expand the hospital's health care services, including providing access to needed drugs for vulnerable populations.

The 340B Program represents one of the most efficient tools Congress has to support healthcare for low-income patients. The 340B Program is almost entirely self-sustaining from a taxpayer perspective; all financial support to participants derives from drug manufacturer discounts. The federal government only provides modest appropriations

[1] House Energy and Commerce Report on The Medicaid Drug Rebate Amendments of 1992 to the Veterans Health Care Act of 1992, P.L. 102-585, H.R. REP. 102-384(II), at 12 (1992).

for administration and oversight costs. Under the Program, drug manufacturers offer lower prices on covered outpatient drugs to eligible hospitals and other settings, enabling these eligible entities like EUHM to reinvest the difference in health care services for underserved and uninsured patients.[2]

It is important to note that the 340B Program does include some built-in limits. Drug manufacturers are only required to offer the 340B discount to entities under limited circumstances per statutory and regulatory guidance.[3] Consistent with the 340B statute, manufacturers are not required to offer and EUHM does not purchase 340B-priced products for inpatients. Also, EUHM may only obtain a 340B discount relative to outpatients that meet Health Resources and Services Administration, Office of Pharmacy Affairs' (HRSA) patient definition.

340B Allows EUHM to Provide Vital Patient Services at Reduced Cost:

EUHM is precisely the kind of hospital that the 340B Program was designed to support, acting as a true safety net for patients in a metropolitan area of over 5 million people. Some of Atlanta's poorest residents rely on the low to no-cost care they receive at EUHM. EUHM provides a particularly high amount of care to Medicaid patients. In 2016, Medicaid patients were 24.5% of total patient days at EUHM. EUHM's DSH percentage, a metric based in part on costly Medicaid inpatient days, is over 23%, well above the minimum qualifying DSH threshold of 11.75% and even higher than the 18% median DSH percentage for 340B-participating DSH entities. Congress created the 340B Program and clearly outlined the intent of the program – to provide access to price reductions to stretch scarce Federal resources - in recognition that safety net hospitals like EUHM could

[2] In addition to allowing individual covered entities to save costs on drug purchases, we believe the 340B Program is indirectly helping to keep drug prices lower in general. Due to the method by which drug manufacturers and the Centers for Medicare and Medicaid Services (CMS) calculate various drug prices, providing covered entities like EUHM with access to 340B pricing can actually help keep the price of drugs for the overall provider community (and their patients) at a lower level. If 340B covered entities had to purchase all pharmaceutical products in the open market, those purchases (at a higher price point) would be factored into drug pricing methodologies that could very well drive up the cost for all providers. This is an area that we urge the Committee and agencies like CMS to consider studying before proposing any changes to the 340B Program. Drug pricing benchmarks, like Average Sales Price (ASP), could increase, resulting in a direct cost increase to the Medicare program that bases reimbursement on ASP.

[3] *See* 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).

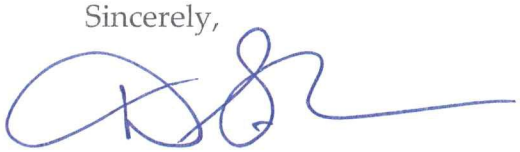
- *A kidney cancer patient was prescribed Pazopanib. He did not qualify for the drug company's assistance program, and they were going to avoid treatment. His previous attempts to obtain access to the medication with his community oncologist were unsuccessful. When this patient came to EUHM, our clinical pharmacy specialist performed a full benefit investigation for him, rather than letting him leave without life-saving medicine. EUHM's pharmacy, funded by savings from the 340B Program, played a crucial role in getting him medication before his condition progressed further. Today, the patient is doing well and is grateful to our pharmacy staff for helping get him access the drugs he needed.*

- *A EUHM patient was prescribed the medication Gleevec, but did not qualify for the Novartis program, even with dependents. The co-pay alone was in the thousands of dollars, an amount the patient simply could not afford. For this patient's specific melanoma, Gleevec is the only treatment; if he had not taken this medication his condition most likely would have worsened and ultimately claimed his life. EUHM's specialty pharmacy was able to provide the medication to the patient at an affordable, subsidized price, thanks to the savings from the 340B Program. This patient is doing well on treatment and is currently heading into his third month of treatment with positive evaluations at the most recent clinic appointment.*

We appreciate the opportunity to convey the importance of the 340B Program to EUHM and the communities we serve. We hope this information provides the Committee with greater insight into how the 340B Program operates at EUHM and how it benefits our community. We have worked tirelessly to produce the requested data, and we appreciate the extension of time to respond to the request. We look forward to working openly and collaboratively with you and your staff to provide any necessary supplemental documentation.

Please feel free to contact me or a member of my staff if you have any further questions.

Sincerely,



Daniel S. Owens

RESPONSE TO QUESTIONNAIRE

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.*

    See Appendix A.

    b. *The percentage of 340B drugs 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*

    See Appendix B.

    c. *The number of 340B drugs your organization purchased that were dispensed to insured patients, including: (i) Medicare beneficiaries; (ii) Medicaid beneficiaries; (iii) Commercially-insured individuals*

    See Appendix C.

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

    See Appendix C.

    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*

    See Appendix D.

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

    See Appendix E.

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

    See Appendix E

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?*

EUHM uses available metrics to measure the impact of the 340B Program at EUHM. HRSA does not currently require 340B hospitals to track the use of their savings distinct from their overall charity care and indigent care responsibilities. As you will see below, we have devoted millions of dollars to providing charity care and subsidized low income care to the community. We fund charity care and indigent care through a variety of cost savings measures, public health grant funds, and charitable contributions. While we do not track specific funding sources for each charity care and indigent care program, we note that our 340B savings supporting charity and indigent care represent 3.8% of the total operating expense budget for FY 2016.

For the purpose of the inquiry, savings were calculated by aggregating 340B purchases annually and comparing to the GPO cost for the drugs at the NDC level. To calculate the net savings from the 340B Program, we would take into account expenses incurred, such as annual Wholesale Acquisition Cost ("WAC") spend (for drugs dispensed in non-340B settings or patients not eligible for the 340B Program, calculated by the cost difference between drug purchases at WAC compared to the cost for the same drug at the GPO cost); fees paid to 340B software vendors related to use of software and account management; expenses related to our employees primarily responsible for the oversight and management of the 340B Program, and legal, consulting and audit fees necessary to comply with 340B Program requirements.

In our in-house retail pharmacies, the system we use from our pharmacy management vendor allows us to track the reimbursement and 340B drug cost of every 340B eligible dispense. Similarly, in our contract pharmacy operation, the systems we use from our 340B software vendors allows us to track the reimbursement and 340B drug cost of the 340B eligible dispenses. Due to the nature of reimbursement for hospital services and drugs administered within the hospital and its outpatient departments (i.e., non-retail drugs that are administered to the patient during a visit), however, we do not track the difference between insurance reimbursement and the 340B drug cost for 340B eligible dispenses in those settings. The reimbursement we receive from insurance carriers in

those settings often consist of bundled payments that include amounts for multiple services (e.g. pharmacy, laboratory, radiology, surgical services, miscellaneous supplies, etc.) a patient may receive during his or her encounter. Therefore, it is difficult, and many times impossible, to carve out which portion of each payment is for a particular drug.

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

As noted above, EUHM is not required to track the use of savings generated by the 340B Program; however, the 340B savings is accounted for in our operating budget and has several uses. Although we do not track the source directly, EUHM uses savings generated by the program for improving the needs of our community, including our uninsured and underinsured populations. We operate three separate charity and indigent care programs to help patients access affordable medication: the Emory Indigent Program (available at EUHM's outpatient retail pharmacy); the Emory Specialty Charity Care Program (available at EUHM's specialty care outpatient retail pharmacy), and the Emory Financial Assistance Policy (available to patients receiving outpatient medications during treatment). Below is a more detailed summary of the various ways in which EUHM is able to provide assistance to vulnerable populations with the assistance of the 340B Program:

- ***Patient Assistance at EUHM Outpatient Retail Pharmacies***

EUHM has two outpatient retail pharmacies that each provide financial assistance to patients. In 2016, EUHM opened a retail pharmacy (a project costing over $1 million in build-out, software, inventory, salary, and operating fees) expressly for the purpose of serving uninsured and underinsured patients. EUHM's Emory Indigent Program is managed by our Social Services department, and allows certain patients who qualify for the program to receive, on a sliding scale, discounted or free medications, or to receive assistance with co-pays when they fill their prescriptions at the pharmacy. Patients who have a financial need are referred to Social Services for financial consultation. Upon determining financial need, the Social Services department authorizes the pharmacy to dispense certain medications at no charge to the patient, or to assist with the

patient's co-pays. As of August 31, 2017, this pharmacy has filled 8,457 prescriptions for patients qualifying for assistance at no cost to the patient, representing $247,522.47 in charity care (based on acquisition costs and co-pay amounts). The 340B Program is critical to this program as it provides a mechanism to support free or significantly discounted prescriptions for patients in need.

In addition, EUHM operates a separate retail pharmacy location that provides specialty pharmacy services. The Specialty Charity Care Program is available to patients at that pharmacy who need assistance with co-pays for high cost medications, regardless of whether the patients are 340B-eligible. Patients can apply for financial assistance, which is determined based on the individual patient's financial status. In FY 2017, this pharmacy dispensed 257 prescriptions to patients requiring co-pay assistance, with a total sum of $302,254.17 of charity care for specialty medication co-payments. Again, the 340B Program provides critical support for this program.

The amount of financial assistance provided for by these programs is in addition to the overall charity and uncompensated care provided by EUHM as listed in Appendix E.

- ***Additional Financial Assistance for Outpatients***

EUHM also provides various forms of assistance to patients receiving outpatient medications at EUHM. EUHM adheres to the Emory Financial Assistance Policy, whereby patients that apply and qualify for assistance are eligible to receive free and discounted medications in the outpatient setting. During FY 2016 and 2017, EUHM provided $3.7 million and $4.3 million, respectively, in infusion indigent and charity care. Under the Financial Assistance Policy, certain qualifying EUHM patients may also receive assistance with co-payments as needed. Additionally, EUHM provides off-label medication assistance and drug replacement assistance for insured patients (including Medicare and Medicaid beneficiaries), where clinically appropriate, in cases where payors may not provide coverage for a particular drug.

- ***Addition of Clinical Pharmacy Specialists for Patient-Centered Care***

In addition to supporting uninsured and underinsured patients with access to unreimbursed medications, savings from the 340B Program have allowed EUHM to expand its network of clinical pharmacy specialists in EUHM's Hepatology, Hematology, Oncology, Neurology, and Gastroenterology clinics to assist patients undergoing treatment in those clinics. Adherence to pharmaceutical regimens is critical for value-based care, as it helps improve and maintain patient health and reduce unnecessary hospital readmissions. As noted below, the availability of specialty pharmacists is instrumental in creating a patient-specific approach that keeps patients on track with treatment.

This group of 11 clinical pharmacy specialists performs the following patient-centric care services:

Clinic

- Pharmacists participate in clinic by counseling patients on IV and oral medications (e.g. chemotherapy or protease inhibitors). The pharmacists will often create patient calendars and evaluate patient adherence to medications. They also collaborate with providers on the selection of treatment plans and utilize their knowledge to evaluate off-label medication use based on Phase I and Phase II studies.

Infusion

- Pharmacists help prepare infusion orders and review IV medication dosing for patients. These pharmacists take part in creating patient education handouts and calendars. They utilize their expertise to adjust medication dosing based on recent lab values, and consider patient specific factors such as nausea for determining pre-medications. Pharmacists devote substantial time and effort to ensure that patients are at the center of care and regimens are customized based on patient-specific factors.

Patient

- Pharmacists form a close relationship with patients, who obtain direct access to a board-certified pharmacist by phone. Pharmacists follow up with patients to make sure patients received their medication and know

how to accurately take it. Pharmacists also follow up with patients to perform a toxicity assessment and monitor patient-specific changes. In addition, pharmacists often must coordinate financial assistance through grants and manufacturer assistance programs to ensure patients do not have gaps in their treatment regimen. Patients are thrilled to have the same pharmacist they see in clinic available to help them by phone when needed.

Programs like those described above keep patients healthier and are possible only with the flexibility given to 340B covered entities to craft targeted and responsive models of indigent care with their 340B savings. If 340B savings were narrowed to merely passing on savings—often to patients who weren't in a position to pay in the first place—it would not be feasible for DSH hospitals like EUHM to provide these valuable programs that are so advantageous to patients' clinical care.

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.*

As noted above, EUHM tracks the aggregate amount of charity and uncompensated care that it provides to the community, but does not track the individual sources of funds specifically used for charity care. We fund charity care and indigent care through a variety of cost savings measures, public health grant funds, and charitable contributions.

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

In fiscal year 2016, EUHM provided nearly $16.5 million in unreimbursed charity costs to our community, totaling 2.5% of the operating expense budget. However, EUHM believes that this Committee should also seek information on how much uncompensated care 340B entities provide given its role in providing care to significant Medicaid populations. In fiscal year 2016, EUHM also provided $9 million in uncompensated care. Taken together, EUHM provided in excess of $25.5 million in care without reimbursement in fiscal year 2016 or 3.8% of the operating budget.

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.*

Please see the answer to Question 3, above, describing the Emory Indigent Program; the Emory Specialty Charity Care Program; and the Emory Financial Assistance Policy. These policies are available to patients based on financial need, regardless of whether or not they receive drugs purchased under the 340B discount program.

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.*

Please refer to **Appendix F** for a listing of all child sites. Applicable HRSA guidance requires EUHM to separately register each and every outpatient location covered under the hospital's cost report as a "child site," if it will be used to provide 340B drugs.[4] Further, HRSA guidance requires us to separately register all off-site hospital cost centers providing 340B drugs, even when they are located in the same building providing the same function.[5] For example, if a cardiology outpatient clinic resides in Suite A, but hospital breaks out the costs of the department on three different lines of the cost report, three separate registrations are required.

As a result, many of the separately-listed child sites provided in Appendix F are simply departments operating in a small number of hospital locations, and you will see addresses repeated several times (e.g., 1365 Clifton Road N.E., Building A, 4th Floor). Likewise, when a covered entity hospital operates a second hospital campus under the same Medicare provider number, HRSA requires the covered entity to register each and every outpatient department (by cost center on the Medicare cost report) individually. This can lead to numerous filings for a single address. We believe the above items lead to a consistent misunderstanding of the scope of child sites in general.

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[4] See e.g., 59 Fed. Reg. 47884, 47886 (September 19, 1994).

[5] See HRSA 340B Frequently Asked Questions, https://www.hrsa.gov/opa/updates/august-2014.html. "In order for off-site outpatient facilities to purchase 340B drugs and/or provide 340B drugs to its patients, they must be listed on the 340B database. All clinics, services or departments located off-site of the parent hospital, regardless of whether they are located in the same building, must register with OPA as child sites of the parent 340B-eligible hospital."

6. *How many pharmacies has your organization contracted with to dispense drugs purchased through the 340B Drug Pricing Program on your behalf?*

EUHM currently contracts with seven pharmacy chains to dispense drugs to eligible patients at 66 retail locations and via mail order.

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

No, not at the current time. Although EUHM continues to explore ways to effectively implement a system that would facilitate this, we do not currently have access to such a system. This is partly because our current contract pharmacy agreements – drafted to parallel HRSA guidance – do not require such redistribution of savings. In addition, it is often operationally impossible to link a patient's 340B eligibility and the availability of 340B drugs at the time of a patient's treatment.

HRSA has issued specific and detailed guidance on the required elements of 340B Program agreements between covered entities and contract pharmacies. We have used this guidance as a template for our agreements. However, these guidelines do *not* address the sharing of cost savings with patients.[6] Because our agreements are structured to follow the applicable federal guidelines on this point, EUHM's contract pharmacy agreements also do not contain such a requirement.

Further, from an operational perspective, there is often a significant delay between a patient's receipt of a medication and our determination of their eligibility for 340B drugs. Due to the regulatory requirements of the 340B Program, compliance and operational issues render it difficult, if not impossible, to pass along 340B savings in the retail setting directly to patients at the point of sale. Under the 340B Program, only certain patients of the covered entity are eligible to receive 340B drugs, and the responsibility for compliance

[6] See HRSA, Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10277-10279 (March 5, 2010).

remains with the covered entity at all times.[7] The determination of which patients are "eligible" to receive 340B drugs is complex.[8]

To ensure that 340B discounted drugs are not inadvertently diverted to patients who are not eligible to receive them, EUHM, like many covered entities, uses a retrospective "replenishment" model in its contract pharmacy arrangements. Under this model, using data about the patient's care at the hospital and data about the dispensing of the prescription, the covered entity makes determinations retrospectively regarding which patients filling prescriptions at the contract pharmacy were eligible to receive 340B drugs at the time of dispense. The covered entity then replenishes the contract pharmacy's inventory that was dispensed to those eligible patients with 340B drugs purchased by the covered entity and shipped to the pharmacy. Under the replenishment model, the determination of 340B eligibility is made by the covered entity only after the patient has purchased the drug at the contract pharmacy. Thus, neither EUHM nor the contract pharmacy is aware at the time of purchase that the patient is an eligible 340B patient. Again, the system was designed this way to use comprehensive hospital and pharmacy data to ensure 340B drugs are provided only to eligible patients consistent with 340B Program requirements.

Conversely, retail pharmacies bill payers using a point-of-sale (POS) system whereby they submit drug claims in real time, not knowing whether a particular prescription qualifies as a covered entity's 340B prescription. Covered entity and/or retail pharmacies utilize inventory management software that retrospectively identifies 340B dispensations by pulling in data from the pharmacy and the hospital's registration and electronic medical records systems. Since this process is managed retrospectively to comply with the replenishment concerns detailed above, pharmacies and 340B covered entities would need to develop an entirely new system that accurately identifies discount-eligible patients *prospectively* in order to share savings with beneficiaries.

While we continue to explore options to implement a prospective shared savings system, we have concerns about the viability of this approach under the replenishment rules.

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[7] 75 Fed. Reg. at 10277.

[8] As discussed above, EUHM's ability to acquire 340B-discounted drugs is limited. It must identify patients that meet HRSA's 340B patient definition.

Given the complexity of the determination of patient eligibility, requiring a contract pharmacy to prospectively identify a subset of patients for the purpose of applying a discount formula may not be operationally feasible. Further, this process may create significant risks of diversion of 340B drugs to patients who are not eligible to receive such drugs, in violation of HRSA's replenishment standards.

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

EUHM does not share 340B Program savings with contract pharmacies. Consistent with its not-for-profit status, EUHM is a good steward of its 340B savings. Likewise, consistent with applicable 340B contract pharmacy guidance and other federal and state laws (such as fraud and abuse), EUHM is required to and does pay its contract pharmacies a fair market value dispensing fee to compensate those pharmacies for their services in dispensing 340B drugs to eligible EUHM patients and, in some cases, in assisting with the administration of EUHM's 340B inventory. Such an arrangement is expressly permitted by 340B guidance issued by HRSA.[9] Like rent, legal fees, and other overhead, fair market value service fees paid to contract pharmacies represent the cost of doing business.

[9] See 75 Fed. Reg. at 10277 ("[T]he covered entity is free to negotiate how it chooses to use any such [340B] funds as it sees fit. For example, the covered entity is free to choose to use those dollars to pay contract pharmacies for their services or for extra services such as delivery.").

Appendix A

Question 1 (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.*

We note that the "number of drugs" may be measured differently by different covered entities. We calculated the "number" of 340B drugs purchased by using the total number of packages purchased for each drug (using specific National Drug Code or NDC) for each year multiplied by the number of units per package i.e. Package Quantity (e.g. 100 units of Tylenol 500mg tablets in each package). The numbers listed here will not be directly comparable to other covered entities if these entities simply reported the number of packages.

Please note that this table of retail purchase history reflects management by an outside vendor from FY 2012-2013. In FY2014 management of retail pharmacy was returned in-house and all 340B purchases were held until appropriate software management could be put into place to ensure program integrity. 340B purchases were re-initiated in FY2015. This explains both the zero units purchased by the retail pharmacy in 2014 and the relatively low volume in 2015.

Time Period (Fiscal Year - Sep. 1 through Aug. 31)	1A			
	Total 340B purchases (# units)	340B Purchases-Covered Entity (# units)	340B purchases-Child sites (# units)	340B Purchases-Retail (# units)
2012	345,513	65,970	202,710	76,833
2013	863,963	531,063	294,670	36,230
2014	862,749	437,112	425,637	0
2015	748,953	431,453	310,872	6,628
2016	939,788	445,019	376,430	118,339

Appendix B

Question 1 (b): *The percentage of 340B drugs 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*

Time Period (Fiscal Year - Sep. 1 through Aug. 31)	**% Analgesics**	**% Antidepressants**	**% Oncology Treatment Drugs**	**% Antidiabetic Agents**	**% Antihyperlipidemic Agents**
2012	18.6%	0.3%	14.3%	0.3%	0.3%
2013	13.5%	1.2%	5.1%	0.7%	1.4%
2014	14.9%	0.2%	6.2%	0.2%	0.3%
2015	17.1%	0.2%	5.8%	0.1%	0.5%
2016	17.4%	0.4%	6.2%	0.4%	0.6%

List of Therapeutic Classes used to determine number of drugs purchased under each of the requested categories:

Therapeutic Class Code	Therapeutic Class Name	Category
12200000	SKELETAL MUSCLE RELAXANTS	Analgesics
12200400	CENTRALLY ACTING SKELETAL MUSCLE RELAXANTS	Analgesics
12200800	DIRECT-ACTING SKELETAL MUSCLE RELAXANTS	Analgesics
12201200	GABA-DERIVATIVE SKELETAL MUSCLE RELAXANTS	Analgesics
12209200	SKELETAL MUSCLE RELAXANTS, MISCELLANEOUS	Analgesics
28080000	ANALGESICS AND ANTIPYRETICS	Analgesics
28080400	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	Analgesics
28080408	CYCLOOXYGENASE-2 (COX-2) INHIBITORS	Analgesics
28080492	OTHER NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	Analgesics
28080800	OPIATE AGONISTS	Analgesics
28081200	OPIATE PARTIAL AGONISTS	Analgesics

28089200	ANALGESICS AND ANTIPYRETICS, MISC	Analgesics
28160400	ANTIDEPRESSANTS	Antidepressants
28160412	MONOAMINE OXIDASE INHIBITORS	Antidepressants
28160416	SELECTIVE SEROTONIN- AND NOREPINEPHRINE-REUPTAKE INHIBITORS	Antidepressants
28160420	SELECTIVE-SEROTONIN REUPTAKE INHIBITORS	Antidepressants
28160424	SEROTONIN MODULATORS	Antidepressants
28160428	TRICYCLICS AND OTHER NOREPINEPHRINE-REUPTAKE INHIBITORS	Antidepressants
28160492	MISCELLANEOUS ANTIDEPRESSANTS	Antidepressants
68200000	ANTIDIABETIC AGENTS	Antidiabetic agents
68200200	ALPHA-GLUCOSIDASE INHIBITORS	Antidiabetic agents
68200300	AMYLINOMIMETICS	Antidiabetic agents
68200400	BIGUANIDES	Antidiabetic agents
68200500	DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS	Antidiabetic agents
68200600	INCRETIN MIMETICS	Antidiabetic agents
68200800	INSULINS	Antidiabetic agents
68201600	MEGLITINIDES	Antidiabetic agents
68202000	SULFONYLUREAS	Antidiabetic agents
68202800	THIAZOLIDINEDIONES	Antidiabetic agents
68209200	ANTIDIABETIC AGENTS, MISCELLANEOUS	Antidiabetic agents
36260000	DIABETES MELLITUS	Antidiabetic agents
10000000	ANTINEOPLASTIC AGENTS	Oncology Treatment Drugs
24060000	ANTILIPEMIC AGENTS	Antihyperlipidemic agents
24060400	BILE ACID SEQUESTRANTS	Antihyperlipidemic agents
24060500	CHOLESTEROL ABSORPTION INHIBITORS	Antihyperlipidemic agents
24060600	FIBRIC ACID DERIVATIVES	Antihyperlipidemic agents
24060800	HMG-COA REDUCTASE INHIBITORS	Antihyperlipidemic agents
24069200	ANTILIPEMIC AGENTS, MISCELLANEOUS	Antihyperlipidemic agents

Appendix C

Question 1 (c): *The number of 340B drugs your organization purchased that were dispensed to insured patients, including: (i) Medicare beneficiaries; (ii) Medicaid beneficiaries; (iii) Commercially-insured individuals*[10]

Question 1 (d): *The number of 340B drugs your organization purchased that were dispensed to uninsured patients*

1(c) & 1(d)	FY12	FY13	FY14	FY15	FY16
Total 340B Purchased Drugs (NDC Units)	345,513	863,963	862,749	784,953	939,788
MEDICARE	149,262	391,375	400,316	346,016	435,122
MEDICAID	40,425	111,451	106,981	87,628	105,256
COMMERCIAL	124,730	309,299	308,001	277,862	356,180
UNINSURED	30,751	52,702	48,314	37,448	42,290

The number of 340B drugs purchased were calculated using the total number of packages purchased for each drug (using specific National Drug Code or NDC) for each year multiplied by the number of units per package i.e. Package Quantity (e.g. 100 units of Tylenol 500mg tablets in each package). Note that different covered entities may have calculated the "number" of drugs differently (e.g., by supplying the number of packages).

[10] The number of 340B drugs dispensed by payor type was estimated by taking overall Emory University Hospital Midtown payor mix percentage for each fiscal year and multiplying it by the number of 340B purchases for the respective fiscal year. Payor mix percentages are based on percentage of revenue by each payor category at the end of each fiscal year.

Appendix D

Question 1 (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*

Time Period (Fiscal Year - Sep. 1 through Aug. 31)	***1(e)***
	Amount of Savings in Dollars compared to GPO cost
2012	$39,017,232
2013	$38,907,913
2014	$44,726,034
2015	$39,618,918
2016	$44,072,375

To calculate 340B savings we deducted 340B cost per invoice records from GPO cost of the drug.[11] For years 2012, 2013, 2014 and 2015, we used wholesaler GPO cost as of Oct. 2015. We switched wholesalers in Oct. 2015, therefore, for 2016, we used the GPO cost from our current wholesaler as of the current date.

[11] Certain aspects of the program require 340B hospitals to incur higher costs than non-340B facilities for some drugs, including the 340B Program patient definition and the group purchasing organization (GPO) prohibition. Covered entities do not have unlimited access to 340B discounts. In fact, a substantial portion of the products that 340B entities purchase are not acquired at the 340B discounted rate – rather, they are acquired at GPO or wholesale acquisition cost (WAC) prices that can be significantly higher than the cost that non-340B hospitals pay for the same products. While we have provided responses to your questions below contrasting 340B and GPO pricing, we note that the rules described here mean WAC pricing (when the 340B price is not an option) may be a more relevant comparison.

Appendix E

Question 1 (f): *The amount of charity care (in dollars) that your organization provided*

Question 1(g): *The number of patients that received charity care from your organization*

Time Period (Fiscal Year - Sep. 1 through Aug.31)	1f. Amount of Charity Care	Net Amount of Uncompensated Care	Total Charity & Uncompensated Care	1g. Number of Patients that received charity care
2012	$19,392,174	$8,824,047	$28,216,221	15,658
2013	$19,392,174	$2,438,612	$21,830,786	19,856
2014	$21,293,481	$5,859,430	$27,152,911	19,586
2015	$15,674,117	$1,444,666	$17,118,783	10,925
2016	$16,596,543	$9,084,171	$25,680,714	15,788

The amounts of charity care and uncompensated care reconcile with the EUHM Medicare Cost Report.

Appendix F

Emory University Hospital Midtown Child Sites Listing:

Participating Start Date	Entity Sub-Division Name	Address 1	Address 2	City	State	Zip
1/1/07	Winship Cancer Institute Infusion Center at Clifton Road Campus	1365 Clifton Rd NE, Bldg C, Plaza Level		Atlanta	GA	30322
1/1/07	Winship Cancer Institute Infusion Center at EUHM Campus	550 Peachtree Street NE	Medical Office Tower, 16th Floor	Atlanta	GA	30308
4/1/12	Infusion Center Non-Oncology at Clifton Road Campus (A3)	1365 Clifton Road NE, Bldg A, 3rd Floor		Atlanta	GA	30322
4/1/12	Internal Medicine at Emory Endocrinology	1365 Clifton Road, N.E.	Building A-4th floor	Atlanta	GA	30322
4/1/12	Infusion Center Non-Oncology at Clifton Road Campus (B1)	1365 Clifton Road NE, Bldg B, 1st Floor		Atlanta	GA	30322
4/1/13	Winship Cancer Institute Infusion Center at EJCH Campus	6335 Hospital Parkway	Physicians Plaza, 1st Floor	Johns Creek	GA	30097
4/1/13	Winship Cancer Institute Infusion Center at ESJH Campus	5665 Peachtree Dunwoody Rd	Erb Specialty Center - 1st floor	Atlanta	GA	30342
7/1/14	Infusion Center Non-Oncology at EUHM Campus	550 Peachtree Street NE	Medical Office Tower, 7th Floor	Atlanta	GA	30308
7/1/14	Internal Medicine at Emory Nephrology	1365-A Clifton Road NE	Building A-4th floor	Atlanta	GA	30322
7/1/14	Internal Medicine at Emory Pulmonary Infusion	1365-A Clifton Road NE	Building A-4th floor	Atlanta	GA	30322

7/1/14	Southern Heart Cardiac Imaging at Fayetteville	115 Sumner Road		Fayetteville	GA	30214
7/1/14	EUHM Southern Heart Cardiac Technicals at Locust Grove	4899 Bill Gardner Parkway		Locust Grove	GA	30248
7/1/14	Southern Heart Cardiac Imaging at Stockbridge	1050 Eagle's Landing Parkway	Ste. 102	Stockbridge	GA	30281
7/1/14	Southern Heart Cardiac Imaging at Riverdale	6507 Professional Place		Riverdale	GA	30274
7/1/14	Emory Heart and Vascular Imaging at EUHM Campus	550 Peachtree Street NE	Medical Office Tower, 6th Floor	Atlanta	GA	30308
7/1/14	Emory Heart and Vascular Imaging at Decatur	2801 N Decatur Rd	Suite 295	Decatur	GA	30033
7/1/14	Emory Heart and Vascular Imaging at Eastside	1608 Tree Leaf Lane	Professional Center #101	Snellville	GA	30078
7/1/14	Emory Heart and Vascular Imaging at Hillandale	5461 Hillandale Dr	Suite 100	Lithonia	GA	30058
7/1/14	Emory Heart and Vascular Imaging at Rockdale	1400 Wellbrook Circle NE	Suite 103	Conyers	GA	30012
7/1/14	Emory Heart and Vascular Imaging at Villa Rica	401 Permian Way	Ste. A	Villa Rica	GA	30180
7/1/14	Emory Heart and Vascular Imaging at Smyrna	3903 South Cobb Drive SE	Suite 110	Smyrna	GA	30080
7/1/14	Radiology - Buford Imaging Center	3276 Buford Drive, Suite 200		Buford	GA	30519
7/1/14	Radiology - McDonough Imaging Center	249 Jonesboro Rd		McDonough	GA	30253
7/1/14	EUHM Radiology (CT) - Medical Office Tower	550 Peachtree Street NE	Medical Office Tower, 8th floor	Atlanta	GA	30308

7/1/14	EUHM Radiology (General Diagnostics) - Medical Office Tower	550 Peachtree Street NE	Medical Office Tower, 8th floor	Atlanta	GA	30308
7/1/14	EUHM Radiology (PET) - Medical Office Tower	550 Peachtree Street NE	Medical Office Tower, 8th floor	Atlanta	GA	30308
7/1/14	Internal Medicine at MOT Rheumatology	550 Peachtree Street NE	Medical Office Tower	Atlanta	GA	30308
4/1/15	Emory Transplant Center Hepatitis C Clinic and Transplant Infusion	1365 Clifton Rd NE, Bldg B, 6th Floor		Atlanta	GA	30322
4/1/15	Winship Cancer Institute BMT Clinic at Clifton Road Campus	1365 Clifton Rd NE, Bldg C, Plaza Level		Atlanta	GA	30322
4/1/15	Winship Cancer Institute Hematology Clinic at Clifton Road Campus	1365 Clifton Rd NE, Bldg C		Atlanta	GA	30322
4/1/15	Winship Cancer Institute Medical Oncology Clinic at Clifton Road Campus	1365 Clifton Rd NE, 2nd floor		Atlanta	GA	30322
4/1/15	Winship Cancer Institute Hematology / Oncology Clinic at EUHM Campus	550 Peachtree St NE	Medical Office Tower, 18th floor	Atlanta	GA	30308
4/1/15	Winship Cancer Institute Hematology / Oncology Clinic at ESJH Campus	5665 Peachtree Dunwoody Road	Erb Specialty Center, 1st floor	Atlanta	GA	30342
7/1/16	Winship Cancer Institute Hematology / Oncology Clinic at EJCH Campus	6335 Hospital Parkway	Physicians Plaza, 1st Floor	Johns Creek	GA	30097
4/1/17	Winship Cancer Institute Hematology and Medical Oncology Clinic-Buford	3276 Buford Drive		Buford	GA	30519

4/1/17	Winship Cancer Institute Infusion Center at Buford	3276 Buford Drive		Buford	GA	30519
4/1/17	EHM Smyrna / Ancillary services-Imaging	3949 South Cobb Drive		Smyrna	GA	30082
4/1/17	EHM Smyrna / Observation	3949 South Cobb Drive		Smyrna	GA	30082
4/1/17	EHM Smyrna / Respiratory	3949 South Cobb Drive		Smyrna	GA	30082
7/1/17	EUHM Heart Failure Center-Arrythemia	550 Peachtree St. NE	Medical Office Tower, 4th floor	Atlanta	GA	30308
7/1/17	EUHM Radiology (MRI)-Medical Office Tower	550 Peachtree St NE	Medical Office Tower	Atlanta	GA	30308