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Mark R. Laret
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October 6, 2017

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigation
U.S. House of Representatives
Washington, DC 20515

The Honorable Diana Degette
Ranking Member
Subcommittee on Oversight and Investigation
U.S. House of Representatives
Washington, DC 20515

Re: Committee on Energy and Commerce request for information about UC San Francisco (UCSF) Medical Center's participation in the 340B Drug Pricing Program

Dear Chairman Walden, Ranking Member Pallone, Chairman Murphy and Ranking Member Degette:

This letter is in response to your recent inquiry into UC San Francisco (UCSF) Medical Center's participation in the critically important 340B Drug Pricing Program administered by the Health Resources and Service Administration (HRSA). We thank you for your patience and flexibility as our team has worked diligently, while facing technical and logistical hurdles, to compile the requested information for the Committee.

We appreciate the opportunity to inform your investigation with the enclosed data and analysis, which explains how the 340B Drug Pricing Program allows UCSF to maximize access and clinical outcomes for low-income and underserved patients in our care.

As the Committee considers UCSF's response, we would like to draw your attention to the following points, which we believe provide critical context to our 340B Drug Pricing Program activities:

- Across California, the Affordable Care Act (ACA) Medicaid expansion resulted in 3.7 million low-income Californians acquiring health care coverage. Of those, a disproportionate share residing in the Greater Bay Area, Northern California, Central Valley and beyond, seek treatment at UCSF, which is one of the few medical centers that provides tertiary and quaternary care to California Medicaid enrollees suffering from highly acute medical conditions.
- With the increase in Medicaid enrollees in California it should be noted that California has one of the lowest Medicaid provider reimbursement rates in the country. Consequently, UCSF is only reimbursed for 64% of the costs it incurs treating Medicaid patients.
- UCSF does not operate its own outpatient pharmacies. Fewer than 10 outpatient prescriptions per day are filled directly by UCSF. Space at UCSF is at a premium and we must rely on local pharmacies to provide services to all of our patients.

We at UCSF believe that the 340B Drug Pricing Program allows us to accomplish our public service mission, which is at the core of all we do. We look forward to discussing our submission with you in more detail on October XX, 2017. If you have any questions before that date, please do not hesitate to contact Natalie Alpert, Director, Federal Government Relations (202.974.6315/natalie.alpert@ucsf.edu) or Ann Sparkman, UCSF Chief Medical Center Counsel (415.476.3186/ann.sparkman@ucsf.edu).

Respectfully,



Mark R. Laret
President and CEO
UCSF Health

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;**

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|---------------|---------------|---------------|---------------|---------------|
| Number distinct drug names | 466 | 1,444 | 1,734 | 1,480 | 1,541 |
| Total units of 340B drug purchased by UCSF | 80,553 | 236,339 | 348,951 | 314,140 | 327,904 |
| Notes: 1. All drugs are purchased directly by the covered entity 2. Methodology: All 340B purchases were aggregated by unique drug name and tallied by purchasing unit | | | | | |

- 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;**

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|--|---------------|---------------|---------------|---------------|---------------|
| i. Analgesics | | 4.0% | 1.6% | 2.7% | 3.3% |
| ii. Antidepressants | | 3.0% | 2.5% | 1.5% | 2.0% |
| iii. Oncology treatment drugs | | 1.2% | 1.3% | 1.5% | 1.8% |
| iv. Antidiabetic agents | | 4.9% | 4.4% | 3.9% | 4.6% |
| v. Antihyperlipidemic agents | | 2.7% | 2.9% | 2.1% | 2.4% |
| Notes: 1. UCSF implemented its electronic health record system (APeX) in June of 2012. FY2012 data requires reviewing paper records and legacy systems, and cannot be made available for this response date. 2. Methodology: All doses administered in eligible sites and all contract pharmacy prescriptions were sorted by payor type and year, and tallied to determine the percentages. | | | | | |

- 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;

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|--------|---------|---------|---------|---------|
| Medicare | 27,100 | 97,724 | 142,361 | 119,798 | 117,582 |
| Medicaid | 10,362 | 30,990 | 52,308 | 43,211 | 45,189 |
| Commercial | 41,447 | 103,732 | 147,298 | 142,876 | 153,526 |
| Notes: | | | | | |
| 1. The total units of 340B drugs administered were identified by payor for contract pharmacies and eligible outpatient clinics and areas. | | | | | |
| 2. Methodology: The total units of 340B drugs purchased were allocated by the percentage of orders for each drug by payor. | | | | | |
| 3. Medicaid includes Fee-For-Service for medications administered in eligible outpatient clinics and areas, and Managed Medicaid prescriptions in both the eligible out-patient clinics and areas and in the contract pharmacies. | | | | | |
| 4. Contract pharmacies in California cannot fill Medicaid Fee For-Service prescriptions with 340B drugs ("carved out"), reducing the percent of total prescriptions dispensed to UCSF Medicaid patients. | | | | | |

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

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|--|--------|--------|--------|--------|--------|
| Uninsured | 1,644 | 3,893 | 6,985 | 8,255 | 11,607 |
| Notes: | | | | | |
| 1. Methodology: The total units of 340B drugs purchased were allocated by the percentage of orders for each drug by payor. | | | | | |

- 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;

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|--|--------------|--------------|--------------|--------------|--------------|
| Annual 340B savings | \$17,172,846 | \$36,652,522 | \$37,696,245 | \$48,969,427 | \$82,931,835 |
| Notes: | | | | | |
| 1. Methodology: These figures were determined using the formula provided below in response to No. 2. | | | | | |

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

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|
| Medicaid Uncompensated Care Cost (Millions) | \$175.71 | \$205.93 | \$220.85 | \$267.72 | \$322.45 |
| Charity Care Cost (Millions) | \$7.51 | \$8.99 | \$14.59 | \$6.74 | \$9.25 |
| Total Charity Care (Millions) | \$183.23 | \$214.92 | \$235.44 | \$274.47 | \$331.70 |
| Notes: | | | | | |
| 1. Medicaid reimbursements cover only 64% of the costs UCSF incurs treating Medicaid patients. We consider the remaining uncompensated Medicaid costs to be a component of our charity care. | | | | | |
| 2. Methodology: For the purposes of responding to this inquiry, UCSF defines charity care as the total costs of uncompensated care to Medicaid patients and the costs UCSF waives per its Financial Assistance Policy to patients pursuant to California Health & Safety Code §127400 (Hospital Fair Pricing Act). | | | | | |

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

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|---------------|---------------|---------------|---------------|---------------|
| Medicaid Outpatient Visits | 124,612 | 139,466 | 154,160 | 215,146 | 254,005 |
| Medicaid Inpatient Days | 52,340 | 49,645 | 53,038 | 57,050 | 69,306 |
| Other Charity Care Patients | 2,788 | 3,167 | 3,387 | 1,772 | 2,146 |
| Notes: | | | | | |
| 1. Methodology: For the purposes of responding to this inquiry, UCSF defines number of patients receiving charity care as the total number of outpatient visits and inpatient days that accrued to Medicaid patients and patients whose care was waived per UCSF's Financial Assistance Policy to patients pursuant to California Health & Safety Code §127400 (Hospital Fair Pricing Act). | | | | | |

2. How does your organization calculate the amount of savings it generates through participation in the 340B Drug Pricing Program?

Formula: $A - B + C = \text{Approximate Annual 340B Benefit}$

Formula Description

(A) Estimated Acquisition Cost if UCSF Purchased the Same Drugs at Prices Outside of 340B
 (B) Actual Acquisition Cost for Drugs Purchased through 340B was determined by running the wholesale distributor 340B purchase data and adding in the direct from manufacturer purchase data.

(C) Benefit Derived from Contract Pharmacy Utilization: The 340B software vendor calculates the benefit UCSF receives from contract pharmacy utilization, which UCSF then audits monthly. This calculation is based on the total prescription receivable value (amount paid by patient and payer) minus the 340B cost of the drugs, any dispensing or administrative fees to the contract pharmacy, any processing or administrative fees to the 340B software vendor, any administrative or audit fees from UCSF

Note: All 340B savings for California Medicaid Fee-For-Service accrue to the State of California, and not to the institution.

How does your organization track the amount of money your organization receives when an insured patient's insurance reimbursement exceeds the 340B price paid for the drug?

HRSA does not require institutions to track individual patient payor reimbursements. Tracking is not feasible at the patient line-item level because reimbursement for care by payors is often made in the form of a global payment. Rather, UCSF tracks the 340B savings through its out patient clinics' cost accounting system and through monthly audits of its contract pharmacies.

3. How does your organization use program savings to care for the vulnerable populations?

UCSF takes seriously the stated intent of the 340B Drug Discount Program to "maximize scarce federal resources as much as possible," so that we "reach more eligible patients and provide care that is more comprehensive."¹

UCSF is a safety-net tertiary and quaternary care provider serving the greater San Francisco Bay Area, Northern California, Central Valley, and beyond. UCSF treats patients suffering from the most acute medical conditions, which are often associated with costly medications, regardless of their ability to pay. UCSF is San Francisco's largest provider of hospital care for Medicaid patients – who receive over 26 percent of our total patient services – and is among the largest Medicaid providers in Northern California.

As a self-supporting institution, that receives no operating funds from the State of California or the University of California system, UCSF Medical Center relies heavily on federally funded Medicaid DSH dollars, along with pharmaceutical manufacturers' 340B drug discounts.

Patients who come to UCSF for care often have overlapping vulnerabilities – both financial, and geographic. UCSF stretches its scarce federal resources by using the 340B program to focus on these areas of need, particularly uncompensated care incurred serving our pediatric patients (\$160 million loss in FY2016) and our cancer patients (\$41 million loss in FY2016).

UCSF's share of Medicaid patients has been steadily increasing, due to California's Medicaid expansion under the Affordable Care Act, which was fully implemented in 2014. However California, which has one of the lowest Medicaid reimbursement rates in the country, only reimburses UCSF approximately 64 percent of the cost of the specialty care our medical center

¹ H.R. Rep. No. 102-384 (II), at 12 (1992). The House report that accompanied the authorizing legislation for the 340B Drug Pricing Program stated, "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."

provides. As a result, UCSF incurred \$322.45 million in uncompensated care to Medicaid patients in 2016.

Medicaid reimbursements for expensive treatments, especially high-cost medication infusions, frequently fall short of the cost of providing care. As a result, other private medical practices and physicians are often unable or unwilling to care for these patients. In part due to the savings UCSF realizes through the 340B Drug Pricing Program, we are able to provide these services despite these unreimbursed costs.

For example, a ten-year-old girl from a remote area of Northern California was diagnosed with severe ulcerative colitis. Despite their best efforts, her family was unable to find a provider in their community who would accept their insurance, because it provided inadequate reimbursement for the infusions she required. At UCSF, however, she received infusions every other month to control her disease.

It is important to note that while California Medicaid paid UCSF for the actual 340B acquisition cost of the medication required for her infusions, minus any discount, it did not pay the additional cost UCSF incurred in compliance with CMS's Medicare Conditions of Participation. These conditions of participation require that the drug be prepared by a pharmacist and that it undergo a pharmacist-dosing review. In addition, the nursing care involved with the administration of the infusion was compensated at about 20% of actual cost. These uncompensated costs amounted to \$650 per dose. For this one patient, the losses amounted to \$4,000 per year, but the outcome was a 10-year-old who was able to excel academically and participate in soccer after school.

Another example is a 21-year-old student at a local college, who was diagnosed with acute leukemia. Although he had no insurance, UCSF assisted him in signing up for a California Medicaid plan. The medical team determined his best outpatient course of treatment was an expensive, non-formulary oral drug. His Medicaid plan did not initially cover the drug, so UCSF paid the cost of his first month of therapy at \$5,200 (340B acquisition cost), allowing him to appeal and receive ongoing coverage. Without 340B savings, this talented young man would have had to receive an inferior therapy and fail before he would be allowed to use the more effective drug.

UCSF also provides care for low-income patients who struggle to secure adequate care for serious or rare diseases in their local communities. UCSF pioneered fetal surgery that allows corrections of those spinal cord defects which cause spina bifida. After fetal surgery, these babies are significantly more likely to be able to walk and function without the medical and public health costs historically associated with these birth defects. This is not treatment that can be replicated in every community, and women come from all over the west coast for treatment at UCSF. 340B savings enables UCSF to treat these patients, regardless of their ability to pay.

Further, 340B savings allow UCSF to operate otherwise financially nonviable clinical services with the sole intention of ensuring necessary medical services can be delivered in closer proximity to vulnerable patient populations.

To illustrate, UCSF has a very active organ transplant program, including kidney, liver, heart, lung and pancreas. Many of our patients from California's Central Valley make the four-hour

drive to UCSF for their transplants. To improve outcomes, UCSF provides outreach to pre- and post- kidney and liver transplant patients in Fresno. Sending our clinicians to Fresno enables close follow-up for patients who reside in that medically underserved area. However, it is costly for UCSF to station highly skilled clinical personnel in remote locations, such as the Central Valley. 340B savings makes it possible to stretch our dollars, help absorb these costs and provide improved outcomes for patients.

These are just four of a long list of examples of how 340B savings allow UCSF to systematically provide a broad and deep range of life-changing care for our low-income patients. These examples also demonstrate UCSF's efforts—and commitment—to ensure all of our patients can access the same level of care, despite their financial circumstances. In sum, 340B savings allow UCSF to support its critical mission without regard to the severity of patients' illnesses, where they reside, or their level of income. 340B savings significantly help UCSF to:

- Ensure access for Medicaid and uninsured patients to UCSF specialty clinics that provide life-saving treatments for those in need of:
 - kidney, liver, heart, lung and pancreas transplants;
 - complex cancer care;
 - immunological care including bone marrow transplants;
 - neurological care, cardiovascular care; and
 - neurosurgery and cardiothoracic surgery.
- Provide specialized hospital and outpatient care for thousands of children with unique and life-challenging medical conditions, such as cancer, organ failure, genetic diseases, heart defects and epilepsy, roughly half of whom are covered by Medicaid.
- Ensure access for Medicaid and uninsured patients at UCSF clinics that provide treatments for such illnesses as HIV, Hepatitis C, and asthma, among others that disproportionately impact vulnerable patients.
- Subsidize costly chemotherapy and immunotherapy for Medicaid and uninsured patients at our on-site infusion centers and clinics.

Are program savings used for any other purposes?

No.

- 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, elaborate.**

Additional charity care provided to uninsured and underinsured patients in excess of savings generated from the 340B program is covered by operating funds.

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

The total health care services for charity care, as a percent of total care was 21.7% in FY2012 increasing to 26.5% in FY2016.

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.**

UCSF has a distinct community benefit program with certain contract pharmacies in which patients are able to purchase medications at the 340B cost plus a dispensing fee.

Contract pharmacies representing 75% of our contract pharmacy prescription volume participate in this community benefit program. We are working to achieve 100% participation with our contract pharmacies.

We do not retain any 340B savings or other revenue associated with prescriptions dispensed by our contract pharmacies to our patients without third party coverage for their prescriptions; in fact we incur expense. As required by 340B Program guidance, we exclude all Medicaid fee-for-service prescriptions from all of our contract pharmacy arrangements. Therefore, we are unable to pass along 340B discounts under contract pharmacy arrangements to that portion of our patient population.

In addition, UCSF's Financial Assistance Policy pursuant to California Health & Safety Code § 127400 (Hospital Fair Pricing Act) provides assistance to patients without financial means to pay for their drug expenses at UCSF's outpatient clinics. The policy states, "It is the policy of UCSF Medical Center to provide assistance to Financially Eligible Patients [statutorily defined term], who require medically necessary services, are uninsured, ineligible for third party assistance or have low income with high medical cost."

It should be noted that UCSF operates these programs to assist our vulnerable patients, yet at the same time as a Medicare and Medicaid provider, UCSF is required to comply with federal Medicare and Medicaid guidance which prohibits hospitals from waiving co-pays or providing free services as an inducement to federal healthcare program beneficiaries to return for other services (commonly known as the prohibition against inducement).

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.**

We have 333 child-sites registered to participate in the 340B Drug Pricing Program.

By way of context, all of UCSF's child sites are located at our three hospital sites and provider-based clinics on UCSF Medical Center's license, located at Parnassus, Mount Zion, and Mission Bay, serving patients throughout the Greater Bay Area, Central Valley and Northern California.

These sites include licensed specialty clinics that treat asthma, diabetes, HIV, hepatitis C and pediatric cancer patients, among others, as well as primary care clinics that primarily treat vulnerable and underserved patients.

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

We contract with thirteen pharmacy companies, reflecting 242 total contract pharmacy locations.

UCSF does not operate its own outpatient pharmacies. Fewer than 10 outpatient prescriptions per day are filled directly by UCSF. Space is at a premium and decisions made decades ago rely on the local pharmacies to provide services. The contract pharmacy arrangements have allowed UCSF to partner with businesses across the Greater Bay Area, Northern California, the Central Valley and beyond, to serve our patients without competing with them directly.

Since our patients come from many locations outside of San Francisco, we identify contract pharmacy opportunities based on our e-prescribing data. This allows patients, not UCSF, to choose pharmacy locations most convenient to them.

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

UCSF has a distinct community benefit program with certain contract pharmacies in which patients are able to purchase medications at the 340B cost plus a dispensing fee. Contract pharmacies representing 75% of our contract pharmacy prescription volume participate in this community benefit program. We are working to achieve 100% participation with our contract pharmacies.

We do not retain any 340B savings or other revenue associated with prescriptions dispensed by our contract pharmacies to our patients without third party coverage for their prescriptions; in fact we incur expense. As required by 340B Program guidance, we exclude all Medicaid fee-for-service prescriptions from all of our contract pharmacy arrangements. Therefore, we are unable to pass along 340B discounts under contract pharmacy arrangements to that portion of our patient population.

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

No, UCSF does not share any savings generated from participation in the 340B Program with any contract pharmacy.