



CEDARS-SINAI®

September 29, 2017

House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Attention: The Honorable Greg Walden, Chairman, Committee on Energy and Commerce
The Honorable Tim Murphy, Chairman, Subcommittee on Oversight and Investigations

Re: 340B Drug Pricing Program

Dear Chairman Walden & Chairman Murphy:

Cedars-Sinai Medical Center ("***Cedars-Sinai***") is pleased to respond to your September 8, 2017 letter about our participation in the 340B Drug Pricing Program.

Cedars-Sinai is a California non-profit public benefit corporation based in Los Angeles, California. The hospital is one of the largest non-profit academic medical centers in the United States, with 886 licensed beds. Cedars-Sinai is the largest provider of Medicare in California and one of the largest private Medicaid providers in the state. Our Level I Trauma Center, designated to care for the most complex and critically-ill trauma patients in the region regardless of their ability to pay, is one of the few remaining trauma centers in Los Angeles County operated by a non-governmental entity.

Cedars-Sinai has participated in the 340B Drug Pricing Program since 2005 as a Medicare Disproportionate Share Hospital. In furtherance of the program's intent as stated in your Committee's 1992 report, Cedars-Sinai uses all of the savings generated from the 340B Drug Pricing Program "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. REP. No 102-384(II), at 12 (1992)). Participation in this program enables Cedars-Sinai to fulfill one of the key tenets of our organization's mission: striving to improve the health status of our community.

Please see our responses to the questions raised in your September 8, 2017 letter, below.

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;*

Calendar Year	Number of 340B Drugs Purchased (Units)
2012	5,757,450
2013	3,693,001
2014	1,612,930
2015	3,374,997
2016	5,884,725

We have defined the term “number of 340B drugs purchased” in the above chart as the number of individual units (i.e., pills, capsules, vials, etc.) of drugs purchased under the 340B Drug Pricing Program. Thus, for example, in the case of a drug that is sold in a quantity of 30 pills per bottle, there would be 300 “units” in 10 bottles. For this reason, the numbers in the chart above may seem higher than anticipated because the number of “units” likely will exceed the number of individual prescriptions, doses, or orders.

In calendar years 2012-2016, all 340B drugs were purchased by the covered entity. No 340B drugs were purchased directly by the covered entity’s child sites; however, our child sites utilized and dispensed 340B drug products from the covered entity’s 340B drug inventory during those years to patients of those child sites. All figures and calculations provided in this letter reflect 340B drugs used by the covered entity and all of our child sites.

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*

Calendar Year	Analgesics	Antidepressants	Oncology Treatment Drugs	Antidiabetic Agents	Antihyperlipidemic Agents
2012	14.4%	3.4%	1.3%	7.9%	6.6%
2013	18.3%	3.2%	2.1%	6.8%	5.7%
2014	22.1%	1.4%	5.4%	2.4%	1.7%
2015	28.8%	1.1%	3.0%	1.5%	1.2%
2016	24.2%	1.1%	1.8%	1.5%	1.4%



The above percentages were calculated based on the total volume of 340B drugs by units which were purchased during each of the above-referenced calendar years. In other words, approximately 88,271 of the 5,884,725 units of 340B drugs purchased in 2016 were antidiabetic agents. In the time available, we were not able to determine the number of 340B drugs in each of the above-referenced categories which were dispensed to patients in those years, due to the limited reporting capabilities of the outpatient pharmacy information system that we use to process prescriptions. Thus, the above data only reflects the percentage of 340B drugs which were purchased for each category.

- 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;*

Calendar Year	Number of 340B Drugs (Units) Dispensed to Medicare Beneficiaries*	Number of 340B Drugs (Units) Dispensed to Medicaid Beneficiaries **	Number of 340B Drugs (Units) Dispensed to Commercially Insured Individuals	Number of 340B Drugs (Units) Dispensed to Beneficiaries of Other Government Programs***
2012	195,744	179,660	2,944,466	2,735
2013	254,784	153,451	1,525,864	2,526
2014	295,807	144,948	667,543	7,494
2015	469,395	339,159	1,136,540	7,729
2016	869,728	632,593	2,085,452	4,602

* Medicare beneficiaries include individuals covered by the Medicare fee-for-service program and Medicare managed care plans, as well as individuals covered by Medicare who are eligible for both Medicaid and Medicare (dual-eligibles).

** Medicaid beneficiaries include individuals covered by the Medicaid fee-for-service program and Medicaid managed care plans.

*** "Other Government Programs" beneficiaries include individuals covered by other federal, state and local health insurance plans and programs including TRICARE, the Department of Veterans Affairs, the Civilian Health and Medical Program of the Department of Veterans Affairs, the California Healthy Families Program, the California Victim Compensation Board, and the Los Angeles County Trauma Program.

We have defined the term "number of 340B drugs dispensed" in the above chart as the number of individual units (i.e., pills, capsules, vials, etc.) of 340B-purchased drugs that were dispensed to insured patients. Please note that the numbers by category for each year will not add up to the total number of units purchased for that year provided in response to Question 1(a) for various



reasons; for example, in some cases, depending upon the dose of the drug prescribed, several units may be used to prepare one dispensed unit; some drugs purchased in a given year may not necessarily be dispensed in that same year; certain drugs may expire before they are dispensed; and some drugs may be wasted (i.e., discarded and not administered to a patient).

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

Calendar Year	Number of 340B Drugs (Units) Dispensed to Uninsured and Underinsured Patients
2012	531,644
2013	474,415
2014	238,241
2015	465,485
2016	1,225,387

As in our response to Question 1(c), above, we have defined the term “number of 340B drugs dispensed” in the above chart as the number of individual units (i.e., pills, capsules, vials, etc.) of 340B-purchased drugs that were dispensed to both uninsured and underinsured patients. We have defined “underinsured patients” here as insured patients to whom we provide free or discounted drugs for the following reasons: the patient does not have prescription insurance benefits, the patient’s insurance benefits do not cover the drugs actually prescribed, and the patient is unable to pay because his or her insurance deductible, is too high.

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;

Calendar Year	340B Cost “Savings”
2012	\$19,100,000
2013	\$21,100,000
2014	\$35,300,000
2015	\$42,100,000
2016	\$55,700,000



These figures were calculated by comparing the price that Cedars-Sinai paid for all purchases of 340B drugs during these years with the GPO price for the same drug. Please note that these numbers reflect Cedars-Sinai's *cost* savings for 340B drug purchases (e.g., the discount we received off of the GPO price). For at least two key reasons this estimate of cost "savings" should not be considered an estimate of additional revenue to Cedars-Sinai. First, with respect to 340B drugs dispensed to patients enrolled in California's Medicaid program, Cedars-Sinai passes on the cost savings attributable to its 340B drug purchases to the Medicaid program since Cedars-Sinai bills Medicaid an amount equal to our actual acquisition cost for any 340B-purchased drug (plus a nominal dispensing fee). Second, in the case of low-income uninsured patients for whom Cedars-Sinai provides free or significantly reduced cost care, the cost "savings" above translates into a reduction in Cedars-Sinai's uncompensated care costs, but not to any additional revenue.

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

Fiscal Year*	Amount of Charity Care Provided
2012	\$276,002,000
2013	\$269,155,000
2014	\$269,199,000
2015	\$207,300,000
2016	\$229,357,000

*Cedars-Sinai's fiscal year runs from July 1 through June 30; "Fiscal Year 2012" refers to the period commencing on July 1, 2011 and ending on June 30, 2012.

Charity care is defined here as the uncompensated costs of providing care to indigent patients, including Medicaid patients, patients eligible for both Medicaid and Medicare (dual-eligibles), commercially insured patients whose costs of care exceed the reimbursement received (in fiscal year 2016 these unreimbursed costs totaled approximately \$11,000,000), and uninsured patients. Such uncompensated costs are determined by calculating the difference between the actual costs of providing care to these patients and the actual amounts of reimbursement received (if any) for such care. Both inpatient and outpatient care is included in this figure.



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

Fiscal Year	Number of Patients That Received Charity Care
2012	150,672
2013	126,198
2014	130,803
2015	129,269
2016	126,968

These figures include Medicaid patients, patients eligible for both Medicaid and Medicare (dual-eligibles) and uninsured patients. Please note that the number of uninsured patients in California and the U.S. began dropping significantly starting in 2013 with the implementation of the Affordable Care Act.

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?*

Cedars-Sinai calculates the amount of cost savings generated through participation in the 340B Drug Pricing Program by comparing the price paid for purchases of 340B drugs with the GPO price for the same drug. Cedars-Sinai has regularly tracked our program cost savings using this methodology since we began participating in the 340B Drug Pricing Program in 2005.

We do not currently directly track the amount of money that Cedars-Sinai receives when an insured patient's insurance reimbursement exceeds the 340B price paid for the drug and it would be extremely difficult to calculate this exact figure. First, while different commercial payers and plans reimburse outpatient drugs differently, reimbursement for outpatient drugs is typically driven by the terms of our contracts with payers, not by the 340B price of the drug. Thus, for a given outpatient drug, we would receive the negotiated reimbursement amount set forth in the contract, regardless of our participation in the 340B Drug Pricing Program. At present, Cedars-Sinai does not track any difference (whether higher or lower) between that reimbursement amount and the 340B price paid for the drug. Rather, our patient accounting system evaluates whether the reimbursement we receive reflects any contracted rate we have negotiated; the patient accounting system does not estimate whether the reimbursement covered the "cost" of the provided services, drugs, or supplies. Although Cedars-Sinai does perform certain cost accounting to review whether we are covering our costs, we generally do this through review of entire service lines (e.g., all outpatient surgeries, all outpatient diagnostic services, etc.). Additionally, it is important to note that in some cases, the insurance reimbursement



payments received by Cedars-Sinai may not cover the cost of all services, drugs, and supplies actually provided.

While we do not specifically track the amount of money received when an insured patient's insurance reimbursement exceeds the 340B price paid for the drug for the reasons described above, we can estimate the portion of the total 340B cost "savings" (as defined in response to Question 1(e)) that is attributable to drugs dispensed to commercially insured patients. We estimate, based on an allocation of our gross charges for outpatient pharmacy services in our most recent fiscal year, that approximately 55% of the total 340B cost "savings" is attributable to such patients.

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

As mentioned above in response to Questions 1(e) and 2, Cedars-Sinai calculates the "cost savings" that we realize through participation in the 340B program by comparing the price paid for 340B drugs with the GPO price for those same drugs. However, for reasons explained above, that "cost savings" figure is not equivalent to additional "revenue" generated for Cedars-Sinai. Nevertheless, as reflected in response to Question 1(f), the amount of charity care that Cedars-Sinai provides each year far exceeds even these estimates of Cedars-Sinai's "cost savings."

In addition to providing traditional charity care, Cedars-Sinai also provides hundreds of millions of dollars each year to community benefit activities that reflect our longstanding commitment to helping those in greatest need. In fiscal year 2016, Cedars-Sinai spent a total of \$695,634,000 on community benefit activities, which include, among other things, programs and services that increase access to medical care for individuals and families who live in poverty or are uninsured or underinsured, and that enable people of all ages to lead healthier lives. This figure includes our charity care costs, as defined in our response to Question 1(f), above. Such community benefit activities include the following programs and services:

- COACH for Kids and Their Families: To help bring free health care to children and their families in some of the most vulnerable communities of Los Angeles, Cedars-Sinai operates two mobile medical clinics staffed by bilingual nurse practitioners, registered nurses, social workers and other healthcare professionals. The COACH mobile clinics provide a range of preventive services, including well-child and immunization clinics for children, treatment for minor illnesses, dental screenings, blood pressure screenings for adults, and linkages to additional health services and social service resources. The COACH program provides healthcare services at family homeless shelters, public housing developments, Head Start centers, elementary, middle and high schools, and community-based organizations.
- Healthy Habits: Cedars-Sinai's Healthy Habits program provides nutrition education and obesity prevention programs at elementary and middle schools in vulnerable areas where



75% or more of the students are eligible for free or reduced-price lunch programs. Our trained health educators not only teach these students, but also conduct educational programs for their parents. In fiscal year 2016, the Healthy Habits program taught 1,217 individual lessons and workshops for a total of 27,297 participant encounters.

- Community Grants: We also provide grants to support local, regional, and national partners whose missions closely align with Cedars-Sinai's. Through our Community Clinic Initiative, for example, Cedars-Sinai bolsters the effectiveness of community clinics that comprise the Los Angeles region's safety net and which collectively serve over 750,000 low-income individuals each year; in fiscal year 2016, 91% of eligible clinics benefitted from this initiative. Another example is Cedars-Sinai's Community Mental Health Grant program, which made awards to 13 organizations located in underserved areas of Los Angeles in fiscal year 2016 to support the provision of direct mental health services to uninsured and underinsured adults, children and families. Cedars-Sinai has also awarded grants for such initiatives as the Los Angeles Fire Department Foundation's Nurse Practitioner Response Unit and United Way's Home for Good regional effort to help end chronic homelessness in Los Angeles.

Additional information regarding Cedars-Sinai's charity care and community benefit programs can be found in Schedule H to Cedars-Sinai's IRS Form 990 for fiscal year 2016, attached as Exhibit A, and Cedars-Sinai's Community Benefit Update and Plan for fiscal year 2016, attached as Exhibit B.

- 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 explained above, Cedars-Sinai's estimate of our 340B "cost savings" in response to Question 1(e) does not equate to "revenue" generated for Cedars-Sinai and includes "cost savings" that Cedars-Sinai directly passes on to the Medicaid program. Thus, Cedars-Sinai's estimate of its 340B "cost savings" likely overstates the "funds derived from" the 340B program contemplated by this question. Nevertheless, in each year since 2012, Cedars-Sinai's investment in charity care has significantly exceeded even the "cost savings" estimates provided in response to Question 1(e). For example, in calendar year 2016, Cedars-Sinai estimates that the "cost savings" associated with its 340B drug purchases were \$55,700,000; during fiscal year 2016, Cedars-Sinai recognized \$229,357,000 of uncompensated costs for the provision of care to indigent patients. Cedars-Sinai funds the costs of providing uncompensated care to uninsured and underinsured patients through operating income. Finally, as explained in response to Question 3 above, Cedars-Sinai also invests hundreds of millions of dollars each year in additional community benefit activities that go beyond traditional charity care.



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

In fiscal year 2016, our charity care costs comprised 8.7% of Cedars-Sinai's total patient care operating costs, which we have defined as total hospital operating costs excluding the costs of research and medical education. We are excluding the costs of research and medical education from this figure because we consider these to be community benefit activities which are not related to direct patient care operations. Charity care is defined here as the uncompensated costs of providing care to indigent patients, including Medicaid patients, patients eligible for both Medicaid and Medicare (dual-eligibles), commercially insured patients whose costs of care exceed the reimbursement received, and uninsured patients.

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.

Cedars-Sinai provides free emergency supplies of prescribed medications to discharged patients who have no insurance or means to pay, in accordance with the policy titled "Discharge Prescriptions (MM.07.01.01d) Procedure: Medication Management," a copy of which is attached as Exhibit C. We are able to provide these free medications due to the cost savings we generate through our participation in the 340B Drug Pricing Program.

In addition, consistent with Cedars-Sinai's charitable mission and as required by California law, Cedars-Sinai bills the Medicaid program an amount equal to our actual acquisition cost for any 340B-purchased drug, plus a nominal, statutorily-mandated dispensing fee. This is described in the policy titled "Billing 340B Drugs to the Medi-Cal Fee-for-Service Program and County Organized Health Systems," a copy of which is attached as Exhibit D.

Cedars-Sinai also provides services without charge, or at significantly reduced prices, to eligible patients who cannot afford to pay for part or all of their care in accordance with our financial assistance policy, a copy of which is attached as Exhibit E. Under this policy, Cedars-Sinai provides automatic discounts of 40% off billed charges to self-pay patients receiving outpatient services, and 65% off billed charges for self-pay patients receiving Emergency Department outpatient services, regardless of the patient's ability to pay. Patients with low- to moderate-incomes receive additional discounts off of those charges or, in some cases, receive their services for free. Please note that our financial assistance policy is more generous than what is required under California law, which obligates hospitals to set eligibility for participation in their charity care or discount payment policies at no less than 350% of the federal poverty level; Cedars-Sinai provides financial assistance to patients with income up to 450% of the federal poverty level. (In 2017, 450% of the federal poverty level for a family of four is \$110,700.)

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.



CEDARS-SINAI

The Honorable Greg Walden
The Honorable Tim Murphy
House of Representatives Committee on Energy and Commerce
September 29, 2017
Page 10

Cedars-Sinai currently has 51 child-sites registered to participate in the 340B Drug Pricing Program. A list of all child-sites, which includes the location of the child-site and the date it began participating in the 340B Drug Pricing Program, is attached as Exhibit F.

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

Cedars-Sinai does not utilize any contract pharmacy arrangements to provide services in connection with our participation in the 340B Drug Pricing Program.

* * * * *

We look forward to meeting with members of the Committee to discuss the responses provided in this letter. In the meantime, if you have any questions, please contact my office at (310) 423-5711.

Sincerely yours,

CEDARS-SINAI MEDICAL CENTER

Thomas M. Priselac
President & Chief Executive Officer

cc: The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Brighton Haslett

Brittany Havens

Natalie Turner