

Testimony of Dr. Charles Daniels
House Energy and Commerce Committee
340B Oversight Hearing, July 11, 2018

Introduction

Good morning, Chairman Burgess and Chairman Walden, Ranking Member Green, and Ranking Member Pallone. Thank you for this opportunity to share my experience with the 340B Drug Pricing Program. I want to also want to say hello to Congressman Peters, my own Congressman, who serves on this Committee, along with Congresswoman Matsui, who represents the people of our sister institution UC Davis Health. I have been able to personally share with Congressman Peters and Congresswoman Matsui the value of the 340B discount to UC San Diego Health patients, as well as patients seen throughout UC Health System. My name is Dr. Charles Daniels, and I serve as Pharmacist-In-Chief for the University of California San Diego's academic medical center, referred to as UC San Diego Health. As Pharmacist-In-Chief, I oversee UC San Diego Health's administration and use of the 340B Program.

Who is UC San Diego Health?

UC San Diego Health is a public academic medical center serving the people of San Diego and surrounding communities. The medical center's service imprint extends over 100 miles into remote El Centro in Imperial County. Our mission is to deliver outstanding patient care through commitment to the community, groundbreaking research, and inspired teaching. UC San Diego Health, a premier provider of tertiary and quaternary services, is comprised of three major inpatient facilities, the Hillcrest Medical Center, the Jacobs Medical Center, and the Sulpizio Cardiovascular Center, along with the region's only National Cancer Institute (NCI)-designated Comprehensive Cancer Center. We provide the region's first Level I Trauma Center and its only Regional Burn Center, serving San Diego, Imperial, and Riverside Counties, as well as portions of Arizona. UC San Diego Health also houses two Comprehensive Stroke Centers, multi-organ transplant programs, and California's only advanced certification program for chronic kidney disease care.

UC San Diego Health includes two professional schools, the UC San Diego School of Medicine and the Skaggs School of Pharmacy and Pharmaceutical Sciences, where close to 1,694 faculty, including myself as an Associate Dean of the School of Pharmacy, educate close to 3,021 students, residents, fellows and post-docs. Our faculty advance patient care through their contributions to biomedical research. In fiscal year (FY) 2017, UC San Diego Health faculty received \$659 million in faculty research awards, including \$424 million from the National Institutes of Health (NIH). UC San Diego Health has been a formidable leader in innovating the use of precision medicine and initiating discoveries in brain, central nervous system, and cancer research.

UC San Diego Health's medical center is eligible for the 340B program because it is a state-owned "disproportionate share hospital" or "DSH" hospital, meaning that it serves a disproportionate share of low income Medicare and Medicaid (referred to in California as "Medi-Cal") patients, as measured using a complex statutory formula set out in the Medicare

statute.¹ While the minimum DSH adjustment percentage required for eligibility to participate in the 340B program is 11.75 percent, UCSD's DSH adjustment percentage is 34.77 percent. UC San Diego Health's Hillcrest Medical Center also qualifies as a Medi-Cal DSH hospital under federal and state law, based on the high percentages of Medi-Cal patient days that the hospital provides and Medi-Cal revenue that the hospital receives.

UC San Diego Health is deeply committed to serving patients and communities in San Diego, Riverside, Imperial counties, and beyond. In FY 2017, UC San Diego Health provided nearly \$17 million in charity care and more than \$155 million in uncompensated care, the vast majority of which was provided to Medi-Cal patients. As the Committee may know, the Affordable Care Act's Medicaid expansion resulted in nearly 3.7 million low-income individuals in California getting health care coverage from the Medi-Cal program. San Diego has no county hospital. That function is largely served by UC San Diego Health, which treats a significant number of Medi-Cal patients. Currently, nearly 40 percent of the patients that UC San Diego Health's medical center treats (measured in patient days) have Medi-Cal coverage. It's important to understand that California has one of the lowest Medicaid provider reimbursement rates in the country and that for many Medi-Cal patients, the costs of providing the specialty services that UCSD Medical Center offers are much higher than the Medi-Cal reimbursement that UC San Diego Health receives for those services. As a result, UC San Diego Health incurs tens of millions of dollars in uncompensated costs for providing care to Medi-Cal patients, including more than ten million in uncompensated costs for cancer care provided in the hospital inpatient setting and several million dollars more in uncompensated costs for cancer care provided in the outpatient setting. UC San Diego Health also serves a significant number of Medicare patients: 34 percent of UC San Diego Health's patient days are provided to individuals with Medicare coverage.

Intent of the 340B Program

Congress enacted the 340B Drug Pricing Program in 1992, and from the beginning, included public DSH hospitals that meet certain criteria, like UC San Diego Health's medical center, as "covered entities" that are eligible to participate in the program. UC San Diego Health has been a 340B provider, or "covered entity," since the program's inception. The program was designed to support qualifying safety net providers, such as UC San Diego Health, so they could stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. From the 340B program's birth to the present day, the 340B drug discount is furnished entirely by participating drug manufacturers.

UC San Diego Health Services to Low-Income and Uninsured Patients

UC San Diego Health fulfills the intended purpose of the 340B Drug Discount Program by using savings generated from the program to provide a variety of services for the uninsured, low-income uninsured, and other vulnerable patient populations in San Diego, Riverside, and Imperial counties. For example, UC San Diego Health pharmacies provides discounted or free outpatient drugs following a case-by-case evaluation process to patients who meet standard financial need criteria and who are not able to afford their medications. An example of such a

¹ UC San Diego Health does not purchase covered outpatient drugs through a group purchasing organization (GPO), and therefore it satisfies all three criteria to be eligible to participate as a "covered entity" in the 340B Drug Pricing Program.

patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health's help supplementing the drug's cost.

UC San Diego Health also uses its 340B savings to provide other necessary medical services to the underserved. For example, presently, UC San Diego Health invests savings it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County residents lived in poverty, and Imperial County residents' median household income was \$42,560.

UC San Diego Health also runs one of the most successful HIV/AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS Program and takes a whole-person care approach to treating patients with HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a “meds to beds” program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients' medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration's (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use the savings to serve the unique needs of its underserved patient populations.

Ensuring Compliance with 340B Program Rules

Because the 340B drug discount provides critical support for so many of UC San Diego Health's programs and services offered to our patients, we take very seriously our responsibility to be good stewards of the program and to comply with 340B program rules. We have put into effect numerous practices to promote compliance with the 340B program rules.

For example, at UC San Diego Health, we employ dedicated pharmacy staff to conduct internal audits each month of a random sample of 340B transactions from our hospital facilities and child sites. Audits include both in-house pharmacies and contract pharmacies, to verify that those prescriptions meet all of the HRSA requirements to be eligible for a 340B discount. The results of those internal audits are formally reported to the pharmacy department leadership on a quarterly basis and to the Executive Steering Committee for UC San Diego Health, at least twice

per year. This is done to ensure that any detected discrepancies or deficiencies are investigated and corrected in a timely way, and that any safeguards needed to prevent re-occurrence of any incident are put into place. UC San Diego Health also routinely hires an outside auditor to conduct an annual review of our 340B Program compliance. We also regularly provide continuing education on 340B rule clarifications to our 340B compliance staff and pharmacy personnel who work directly with patient prescriptions at the prescription counter.

Additionally, UC San Diego Health requires that any contract pharmacies that we work with meet the same standards for compliance. We have mapped out where our patients go to fill their prescriptions, have entered into contract pharmacy arrangements with pharmacies located within zip codes that are accessible to most of our patients. For example, Hillcrest Pharmacy, one of UC San Diego Health's contract pharmacies is located in a neighborhood accessible to many of our HIV patients. The Hillcrest Pharmacy offers services that are highly valued by our HIV patients. UC San Diego Health also does not accept "all in" contractual clauses from pharmacy chains which would require us to contract with any future pharmacy erected in the chain's San Diego area network, regardless of whether these new pharmacies are typically used by UCSD patients. This is a statement on our commitment to follow HRSA rules and protect access to the 340B program.

Qualifying A Prescription for the 340B Drug Discount

To further underscore UC San Diego Health's commitment to complying with the 340B program rules, I thought it would be helpful to explain the process for determining whether a particular drug dispensed to a UC San Diego Health patient is eligible for the 340B discount. The fact that UC San Diego's hospital meets the eligibility criteria for being a 340B covered entity is not sufficient for claiming the 340B discount on an outpatient drug; rather, it's only the first of many steps. There are multiple other requirements that must be satisfied, including all of the elements that HRSA has specified to define which patients are eligible for the 340B discount. (See the flowchart attached as Exhibit 1).

For example, HRSA requires the covered entity to have an established relationship with the patient. The treatment history for the patient must be maintained in the covered entity's medical records. It must go beyond the provider simply writing a prescription for the patient. Also, the patient must be treated by someone who is employed by or contracted with the covered entity, such that the covered entity retains responsibility for the patient's care. Further, the prescription must be written based on an encounter within the covered entity at one of its facilities or registered child sites. Additionally, to be eligible for the 340B discount, the prescription must be filled at the hospital's in-house pharmacy or contract pharmacy. Only after all of these requirements are met, does the covered entity receive the 340B drug discount on an eligible outpatient prescription.

Conclusion

The 340B Program helps safety net healthcare providers like UC San Diego Health to invest private dollars up front, in the unique needs of underserved patients, so that federal and state dollars need not later be expended for more costly care. UC San Diego Health, like the other medical centers in the UC Health system, uses the benefits from the 340B program to provide not only medications, but also a comprehensive array of high quality primary care and specialty

care services to patients in underserved communities across the state of California. I am very concerned that the financial impact of the nearly 30 percent cut in Medicare Part B reimbursement to DSH hospitals for drugs purchased under the 340B program will restrict UC San Diego Health's ability to provide some of the services we offer our underserved patient communities throughout San Diego, Imperial, and Riverside Counties. Any efforts in rulemaking or legislation to scale back the 340B Drug Pricing Program would be detrimental to our patients, and the patients of so many safety net providers across the country. I welcome this opportunity to answer your questions. Thank you.