

Submitted electronically to [Bipartisan340BRFI@mail.senate.gov](mailto:Bipartisan340BRFI@mail.senate.gov)

July 28, 2023

The Honorable John Thune  
United States Senate  
511 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Tammy Baldwin  
United States Senate  
141 Hart Senate Office Building  
Washington, DC 20510

The Honorable Debbie Stabenow  
United States Senate  
731 Hart Senate Office Building  
Washington, DC 20510

The Honorable Jerry Moran  
United States Senate  
521 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Shelley Moore Capito  
United States Senate  
172 Russell Senate Office Building  
Washington, DC 20510

The Honorable Benjamin L. Cardin  
United States Senate  
509 Hart Senate Office Building  
Washington, DC 20510

Dear Senators,

On behalf of University of California Health (UC Health), thank you for the opportunity to respond to the Senate bipartisan 340B working group's request to provide feedback on the 340B program. UC Health plays a leading role in California's health care safety net as the state's second largest provider of Medicaid inpatient services, and the largest provider of care to Medicare patients. UC Health includes six public Medicare and Medicaid disproportionate share hospitals, as well as a separate, private non-profit children's hospital, each of which participate in the 340B program as "covered entities." Government payors comprise two-thirds of our payor mix, with 35 percent of inpatient days at UC hospitals devoted to caring for Medicaid patients, and 36 percent of inpatient days devoted to caring for Medicare patients. While UC Health represents five percent of the hospital beds in the state of California, we provide an outsized amount of complex tertiary and quaternary care to patients across the state. Through our academic health centers, UC Health provides more than one million inpatient days and nearly 10 million outpatient visits to patients annually. The 340B program is essential to the work we do to provide world class healthcare to Californians with limited means and limited access to care.

In fiscal year (FY) 2021-2022, UC Health's hospitals and faculty practices provided a total of \$4.4 billion in community benefits, including more than \$1.1 billion in unreimbursed costs for providing care to Medicaid patients and \$1.95 billion in unreimbursed costs for providing care to Medicare patients at UC hospitals. In alignment with the 340B program's original congressional intent to "stretch scarce federal resources as far as possible to reach more eligible patients and provide more comprehensive services," UC's 340B hospitals use savings from the program to support access to care for low-income patients. Because of the large volume of Medicaid and low-income Medicare patients we serve, every UC hospital has a disproportionate share adjustment percentage that is significantly greater than the minimum eligibility requirements of the 340B program.

It is important to note that – along with Medicaid -- the 340B program is one of the core components of safety net hospital financing. The financial support of the 340B program has allowed UC hospitals to deliver on our safety net mission of providing access to complex care for low-income patients and

providing services and programs that respond to the unique needs of the communities each hospital serves. Savings realized through participation in the 340B program supports efforts by UC hospitals to make otherwise financially nonviable clinical services available and accessible to vulnerable and underserved patient populations, including but not limited to:

- Underwriting the cost of promising new treatments, such as CAR T-cell therapy for cancer and autoimmune disease;
- Providing discounted or free home infusion drugs and nursing services to patients who qualify for financial assistance;
- Partnering locally with the U.S. Department of Veteran Affairs to provide in-kind medical and behavioral health services to veterans and their families, and to help address the problem of chronic homelessness among veterans;
- Providing fresh produce at food pantries and transportation via taxi vouchers for needy patients; and,
- Subsidizing chemotherapy and immunotherapy for Medicaid and uninsured patients at on-site infusion centers and clinics.

***Community pharmacy restrictions have serious financial consequences on covered entities' ability to provide care to the safety net***

The 340B statute requires pharmaceutical manufacturers to offer their drugs at or below the 340B ceiling price for qualified patients of our hospitals regardless of the method or mechanism for dispensing drugs to those patients. In keeping with longstanding Health Resources and Services Administration (HRSA) guidance, UC's hospitals rely on contracts with community pharmacies to ensure our patients can pick up prescriptions at a pharmacy that is most convenient to them. Contract pharmacies are an important tool for advancing the goal of the 340B program and extending access to 340B savings for covered entities and eligible patients. Mounting restrictions by pharmaceutical manufacturers prevent UC hospitals from receiving the 340B price when drugs are dispensed through community pharmacies. These restrictions have serious financial consequences for UC hospitals and the patients we serve. We currently estimate the restrictions implemented by manufacturers as of today will reduce 340B savings at UC hospitals by more than \$150 million annually.

Efforts by pharmaceutical manufacturers to deny 340B savings to covered entities contracting with community pharmacies are a clear violation of the 340B statute and HRSA guidance and call out for meaningful enforcement. Congress should not allow manufacturers to dictate terms and set preconditions on a program required by federal law and should oppose all unilateral restrictions on covered entities accessing the 340B price. The manufacturers' coupling of unilateral restrictions on community pharmacies with distribution restrictions that limit the availability of drugs to specific specialty pharmacies are particularly harmful. Integrated specialty pharmacy operations at UC hospitals provide a much higher quality of care that is necessary to support patients participating in clinical trials. For example, pharmacy team members can be embedded in hospitals and other clinics to improve continuity of care. UC Health is also concerned about Pharmacy Benefit Managers' use of discriminatory pricing practices that could reduce 340B savings for safety net providers.

UC Health supports congressional efforts to clarify HRSA's existing statutory authority to allow covered entities to employ an unlimited network of contract pharmacies to distribute covered outpatient drugs. Drug manufacturers should be required to offer discounted prices on covered outpatient drugs to covered entities participating in the 340B program and to sell and deliver 340B drugs to covered entities when requested irrespective of the method through which a drug is dispensed. Clarifying the 340B statute would protect the core mission of the 340B program.

### ***340B program compliance and oversight***

UC hospitals have led the way on 340B oversight and transparency by investing significant resources to ensure compliance with the 340B statute and program guidance published by the HRSA's Office of Pharmacy Affairs. On an annual basis, each academic health center posts a public reporting of their 340B savings on their websites as well as the community and patient benefits that these savings have financed as shown in this example from UC Davis Health's [webpage](#)<sup>1</sup>. The UC academic health centers have each signed the [American Hospital Association's \(AHA\) 340B Good Stewardship Principles](#), which include commitments to communicate the value of the 340B program, to disclose 340B estimated savings that are calculated using a standardized method, and to continue rigorous internal oversight of our participation in the program.

UC hospitals publicly disclose the total 340B savings for each academic health center to ensure that everyone – from policy makers to patients – can understand the critical role that the 340B program plays in financing the health care safety net and supporting access to care for the communities we serve. Although UC public hospitals are exempt from requirements to file the IRS Form 990 and Schedule H, UC Health voluntarily prepares an annual report based on these requirements to provide transparency of our community benefit across California in a standardized format. Together, disclosure of UC hospital 340B savings and community benefit activities provides important context for the important role the 340B program plays in financing our safety net activities.

Each of the UC's 340B hospitals has a dedicated team to support program operations and ensure compliance with all applicable 340B program guidance and implementation of best practices. Each hospital has adopted robust 340B program policies and procedures and performs routine monitoring of drug purchases and claims data daily in addition to monthly and quarterly audits to verify that 340B drugs are dispensed only to eligible patients and that 340B do not duplicate Medicaid discounts. As required by the California Department of Health Care services, the state's Medicaid agency, UC hospitals and in-house pharmacies apply specific modifiers on claims submitted for 340B drugs dispensed or administered to Medicaid patients in order to prevent duplicate discounts. UC hospitals also have retained an independent external auditor that reviews each hospital's compliance with program requirements each year.

### ***Protecting the core elements of the 340B program is essential for UCH and other safety net providers***

As Congress considers changes to the 340B program, we ask that you preserve the program's flexible financing that is not tied to a specific location, service line or function, maintain clear statutory authority for hospital outpatient departments or "child sites" to administer 340B drugs to hospital patients, and avoid imposing restrictions on hospitals' ability to use 340B savings to support their operations and community benefit activities at all of their locations. Hospital outpatient departments (HOPDs) are a key component of how hospitals reach more patients and provide more health care services to patients closer to their homes and in under-resourced communities. To be eligible for registration as a child site, HOPDs must have adequate financial integration with the main hospital so there is no need to limit the use of 340B program savings to the particular HOPD location. UC Health is concerned that any restrictions on the movement of 340B savings from one child site to another could ultimately limit hospitals' ability to dedicate resources to the locations where they are needed most. UC also asks that you oppose proposals by pharmaceutical manufacturers that would limit contract pharmacies to being located within a geographic area or in low-income areas. Such restrictions on the location of contract pharmacies would curtail the benefit of the program to hospitals and patients and not result in meaningful oversight of the use of 340B savings.

---

<sup>1</sup> <https://health.ucdavis.edu/news/public-reporting/340b-program>

For over 30 years, the 340B program has successfully allowed safety-net providers to stretch scarce federal resources to better serve low-income, underserved patients and communities. In the face of rising drug prices and costs of living, the 340B program is especially important in providing access to care for the most vulnerable Americans. UC Health sincerely appreciates the opportunity to submit a response to the request for information and looks forward to continuing to work with you developing bipartisan policy solution that address the challenges faced by the program. If you have any questions, please contact Kent Springfield at (202) 993-8810 or [kent.springfield@ucdc.edu](mailto:kent.springfield@ucdc.edu).

Sincerely,

*Tam Ma*

Tam Ma  
Associate Vice President  
Health Policy and Regulatory Affairs