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The Honorable John Thune
Senator
United States Senate
Washington, DC 20510

The Honorable Tammy Baldwin
Senator
United States Senate
Washington, DC 20510

The Honorable Debbie Stabenow
Senator
United States Senate
Washington, DC 20510

The Honorable Jerry Moran
Senator
United States Senate
Washington, DC 20510

The Honorable Shelley Moore Capito
Senator
United States Senate
Washington, DC 20510

The Honorable Benjamin L. Cardin
Senator
United States Senate
Washington, DC 20510

Submitted electronically to Bipartisan340BRFI@email.senate.gov

April 1, 2024

Dear Senators,

On behalf of the University of California Health (UC Health), thank you for your continued work to strengthen and protect the 340B program. We appreciate this opportunity to respond to the Senate bipartisan 340B working group's request to provide feedback on the draft SUSTAIN 340B Act.

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 low-income 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.

Thank you for writing a draft bill that further codifies existing rules for contracts with community pharmacies and clarifies the authorities of the Health Resources and Services Administration (HRSA) to enforce those rules. The refusal of drug companies to offer 340B savings on drugs sold at our contracted community pharmacies has had significant negative financial impacts on all covered entities within UC Health. We also appreciate that the draft bill re-affirms that the Congressional intent of the program is to support safety net healthcare providers in stretching scare federal resources – a mission that is frequently misrepresented by critics of the program. We appreciate your efforts to create a mechanism for registering child sites outside of the Medicare Cost Report – reversing the return of the costly practice of HRSA requiring significant periods of time for child sites to be eligible for 340B savings. Finally, we appreciate your inclusion of provisions that end discriminatory payor policies for 340B covered entities. Those practices have the practical effect of transferring savings from the program to insurers and pharmacy benefits managers (PBMs) rather than the intended covered entities.

However, the draft bill also contains provisions that have the potential to dramatically increase regulatory burdens or reduce savings associated with the program – we urge you to reconsider these proposals. Finally, we are concerned that your RFI suggests significant limits on the program – including geographic restrictions on contract pharmacy and more limited definition of a patient. These changes have the potential to inflict ever greater losses in savings on the healthcare safety net. We ask you to be thoughtful about potential harms to safety net providers in these policy areas. These concerns are enumerated in detail below.

Contracts with Community Pharmacies

UC Health has significant concerns regarding any geographic restrictions on covered entities' use of contracts to dispense drugs and receive 340B savings through community pharmacies. Pharmaceutical manufacturers increasingly limit the dispensing of high-cost drugs to a single or small portion of specialty pharmacies– particularly ones that are only available via mail-order. If geographic limitations prevent covered entities from accessing these specialty pharmacies, then they will have the practical effect of cutting off savings for any drug that a manufacturer chooses to distribute in this way.

Notably, a contract with a community pharmacy only extends the ability of a covered entity to receive savings on drugs for *their* patients. These contracts do not entitle community pharmacies to receive savings on other patients. While a community pharmacy typically charges a fee to the covered entity for dispensing the drug, they do not otherwise reap financial benefit from the 340B program. A larger and more geographically diverse contract pharmacy network only produces financial benefits to the covered entity to the extent that they have patients in that geographic area who access that community pharmacy.

The draft bill requires hospitals to pass along financial assistance policies to our child sites and contracted community pharmacies. It's important to note that UC hospitals already apply their patient assistance policies to their outpatient departments and to their own in-house retail pharmacies. However, this requirement seems infeasible for our contracts with community pharmacies given the current design of the program. There is a significant verification process that must be undertaken to ensure that a patient is 340B eligible – including checking their relationship with the covered entity, checking that their provider is eligible and ensuring that their primary payer is not Medicaid. This qualification process largely occurs after a transaction at the pharmacy counter – making the determination too late to support contracted community pharmacies providing financial assistance at the time of purchase.

We are also concerned that the contract pharmacy section of the draft bill creates significant compliance burdens on covered entities and places mandates on HRSA that may result in the agency being unable to fulfill its new oversight roles envisioned by the bill. Please carefully consider whether annual registration, independent third-party audits, and HRSA review of all written agreements are necessary or

logistically feasible for the agency. Also, please consider maintaining the current statute related to drug manufacturer-initiated audits.

Patient Definition

UC Health respects the Senators' desire to codify a patient definition in law. However, any attempt to narrow the patient definition from the 1996 standard established by HRSA could harm safety net providers. The child site section of the draft bill includes language that implies that a drug is only eligible for 340B savings if the prescriber has clinical responsibility for healthcare services related to that drug. This provision implies a complex and far stricter definition of eligible patient than is currently in operation today. Implementing such a provision is operationally infeasible. Safety net hospitals typical qualify all outpatient drugs prescribed at their facilities for individuals who have visited their healthcare professionals. This restrictive definition overlooks the complicated nature of responsibility of care, such as when a condition is co-managed by multiple providers operating out of multiple clinics. Patients can and often do have multiple healthcare providers. There is no conflict with a patient receiving care at more than one facility or with more than one facility claiming that individual as an eligible patient. Each covered entity should receive 340B savings on the prescriptions written by their qualified health care providers.

UC Health recommends using the 1996 patient definition with the additional caveats that the prescription must be written from a visit at any covered entity owned and operated site by a covered entity health care provider or via telehealth from a covered entity healthcare provider. The Senators should also consider the American Medical Association's use of a 3-year time period for determining how recently an individual must have engaged with the covered entity to qualify as a patient.

Child Sites

Hospital systems use outpatient departments to be able to reach more patients and provide more comprehensive and integrated services – directly in line with the intent of the 340B program. Outpatient departments are part of a broader shift in the delivery of care towards less-costly and more convenient settings and community-based care sites. As a mechanism for supporting this delivery of care, child sites are a critical component of the 340B program.

The draft bill requires that child sites have a "meaningful range of clinical services" but does not define this term, which seems both vague and potentially problematic. Many child sites are specific to one line of service (such as cancer or cardiology), however that line of service is meaningful to patients in need of that care. This requirement seems to unnecessarily restrict the scope of the program, which will reduce savings for covered entities.

The child site section of the bill also contains a concerning suggestion that only the medical staff should be able to write prescriptions that are 340B-eliglble. Currently all prescriptions written by providers at the covered entity qualify for the program, so this dramatic reduction in eligible prescribers will reduce program savings for safety net hospitals. This proposed language also adds unnecessary complexity, when existing state and federal laws already carefully govern who can write a prescription within a hospital. The ability to have nurse practitioners, physician assistants, and advanced practice pharmacists see patients and write prescriptions where clinically appropriate supports important goals of increasing access.

Program Integrity Provisions

A national data clearinghouse on 340B should be focused on protecting the Medicaid program and ensuring that covered entities do not receive both a 340B discount and a Medicaid rebate on the same drug. This would conform to the current law's definition of a duplicate discount. Drug manufacturers

have sought to misconstrue and expand the definition of a duplicate discount to make it apply to business negotiations that do not impact Medicaid. There is no governmental interest in offering a national data clearinghouse to pharmaceutical manufacturers as a tool to enforce their contract negotiations with PBMs and insurers.

Transparency and Reporting

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 UCLA Health's webpage. 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.

It is important to remember that the 340B program produces savings not revenue, and efforts to measure those savings are primarily based on industry standards for how to account for those savings. For example, the draft bill computes savings as the difference between the 340B price and the Wholesale Acquisition Cost (WAC) price. However, that calculation fails to take into account that hospitals use group purchasing organizations (GPO) to buy many drugs and would not pay the WAC price absent 340B. They would pay a much lower price. To meaningfully measure savings and the impact those savings should be having on safety net healthcare providers, regulators should be calculating savings actually received by covered entities rather than an inflated value of what pharmaceutical companies calculate they are losing based off their much higher WAC price. It may not be practical for Congress to write a specific definition of savings into law. Rather, Congress should ask HRSA to work with covered entities to determine the best accounting of savings that represents the value of the program.

The draft bill also posits that hospitals should be able to provide a breakdown of charity care provided at individual child sites. There are a number of problems with this approach to transparency. Hospital outpatient departments (HOPDs) are – by definition – operationally connected to their parent hospitals, and the Medicare Cost Report has no mechanism for defining site-specific charity care. Likewise, data provided on the Medicare Cost Report does not align directly with the HRSA definition of a child site. It is possible to have multiple 340B child sites in a single HOPD. Most importantly, there are many ways that safety net hospitals can use 340B savings to expand patient access to critical services that do not qualify as charity care. It seems likely that this data would feed current misunderstanding about the allowable uses of 340B savings.

Similar concerns exist for proposals to collect racial, ethnic and financial data on patients at child sites. It is not clear that hospitals would be able to collect the data requested from all of our patients given the voluntary nature of that kind of data collection, and data collection would add significant burden to hospitals, their HOPDs and the patients they serve. For example, the bill requires covered entities to provide information on patients "eligible for financial assistance." However, hospitals do not determine eligibility for all their patients and would only have this data for the number of patients who applied or were granted assistance.

We would also note that the draft bill targets all reporting and auditing requirement at covered entities, despite the fact that the largest ongoing violation of HRSA's program integrity rules is the massive diversion of 340B savings by pharmaceutical manufacturers who are refusing to comply with HRSA's warning letters. The bill's sponsors should consider audit and transparency requirements for drug manufacturers that would similarly ensure their compliance with the program and provide assurance to the public that pharmaceutical manufacturers are not withholding critical financial resources Congress has intended to support safety net hospitals.

For over 30 years, the 340B program has successfully allowed safety-net providers to stretch scare 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.

Sincerely,

Tam Ma
Associate Vice President
Health Policy and Regulatory Affairs