*Please add your letterhead and signature.*

*Feel free to incorporate information about your organization and your reasons for supporting.*

*Please email a copy to* *advocacy@healthplusadvocates.org**.*

***DEADLINE FOR SUBMISSION: September 21, 2020***

<INSERT DATE>

<INSERT ADDRESS OF YOUR CONGRESSIONAL REPRESENTATIVE>

**Re: Manufacturer Attacks to the 340B Program**

Dear <INSERT CONGRESSIONAL REPRESENTATIVES NAME>:

**[INSERT ORGANIZATION NAME]** would like to request your assistance in addressing recent actions by drug manufacturers that seriously threaten health center’s on-going ability to provide our low-income and medically vulnerable patients with access to affordable medications and other critical services.

CHCs are the backbone of the care delivery system in California, ensuring access to medical, behavioral, oral health, and social services for California’s most vulnerable populations, including 1 out of every 3 Medi-Cal beneficiaries. California CHCs provide healthcare services to underserved populations, with 68 percent of CHCs patients at or below 138% of the Federal Poverty Level (FPL) and more than 70% of patients being people of color. By mission CHCs focus on providing culturally and linguistically diverse services to low income and non-English speaking communities regardless of their ability to pay and immigration status. Since FQHCs adopt a patient-centered medical home framework, patient treatment is coordinated through their care team to ensure patients receive the necessary care when and where they need it, in a manner that they can understand.

[INSERT ORGANIZATIONS NAME] is committed to provide health care service that meet the patient where they are at to ensure patients receive the right care at the right time.[INSERT ORGANIZATIONS NAME] provides healthcare services to California’s most vulnerable populations, [INSERT INFORMATION ABOUT CHC – SUCH AS DEMOGRAPHIC DATA ABOUT YOUR PATIENT POPULATION & SERVICES PROVIDED]. We provide care to more than [INSERT NUMBER OF MEDI-CAL PATIENTS] Medi-Cal lives including lifesaving wrap around services and care coordination that is largely funded by 340B savings. The savings acquired from the 340B program are used to support [INSERT INFORMATION ON 2-3 SERVICES YOUR CHC OFFERS WITH THESE SAVINGS – FOCUS ON SERVICES THAT EXPAND HEALTH CARE ACCESS TO PATIENTS].

As a covered entity, we are eligible to participate in the 340B drug discount program.  The 340B program requires drug manufacturers who participate in Medicaid and Medicare to provide discounts on the price of outpatient pharmaceuticals purchased by “safety net” providers, such as [INSERT ORGANIZATIONS NAME] and other CHCs.  The 340B program is central to our ability to offer affordable pharmaceuticals to our low-income patients who are uninsured or underinsured; by reducing how much we would otherwise spend on drugs, it frees up other funds to support critical services such as [INSERT EX OF ACTIVITES YOU FUND W 340B SAVINGS]*.*

In early July, drug manufacturer Eli Lilly announced that it would no longer allow certain drugs purchased at the 340B price by 340B-eligible providers to be delivered to contract pharmacies, meaning pharmacies that are not owned by the 340B provider.  A few days later, drug manufacturer Merck sent a letter to all 340B providers instructing them to submit extensive data bi-weekly on all Merck drugs dispensed by contract pharmacies.  Soon after, drug manufacturer Sanofi & Novartis, announced that effective October 1, it will refuse to allow any drugs purchased at the 340B price by 340B-eligible providers to be delivered to contract pharmacies, unless the 340B provider submits the same type of data that Merck is requesting.  Most recently, AstraZeneca has informed covered entities that beginning October 1, they will no longer provide 340B drug discounts to contract pharmacies. We anticipate that there will be more manufacturer requests like these if action is not taken to prevent these practices. In response to these developments, the Health Resources and Services Administration (HRSA) in HHS announced that it lacks the authority necessary to stop the manufacturers’ actions.

These manufacturer actions violate both Section 330 and Section 340B of the Public Health Service statute. More importantly, these actions fundamentally threaten health centers’ ability to continue providing our medically underserved patients with access to affordable pharmaceuticals and other services*.*Specifically:

* Eli Lilly, Sanofi, AstraZeneca, and Novartis refusal to ship 340B-priced drugs to contract pharmacies violates both the 340B statute and the health center authorizing statute. The 340B statute requires manufacturers to see 340B-priced drugs to all eligible providers, regardless of where they are shipped. The health center authorizing statute (Section 330 of the Public Health Service Act) explicitly states that health centers may provide services -- including pharmacy services -- via contract.
* These manufacturers are threatening the ability of health center patients to access affordable pharmaceuticals at contract pharmacies. Health centers rely on contract pharmacies to make pharmaceuticals more accessible to their patients, both geographically and in terms of hours of operations.  [IF YOUR CHC HAS A CONTRACT PHARMACY INSERT EXAMPLES OF WHY YOU USE CONTRACT PHARMACIES, SUCH AS MORE ACCISSIBLE FOR PATIENTS IN REMOTE LOCATIONS]. Nationally, roughly half of drugs that FQHCs dispense to their nearly 30 million medically underserved patients are dispensed via contract pharmacies. If allowed to proceed, these manufacturers’ actions will force health centers to completely stop offering services through contract pharmacies.   The end of contract pharmacies will dramatically decrease the ability of health center patients to access affordable medications and other services.
* Manufacturer requests for data on Medicare and privately insured patients:
	+ **Are intended to save the manufacturer money, rather than ensure 340B compliance.** These manufacturers state that they will use the requested data to avoid paying discounts to Pharmaceutical Benefits Managers (PBMs) for drugs purchased under 340B.   However, manufacturer discounts to PBMs are completely independent from 340B and are offered on an entirely voluntary basis, generally as an incentive to increase the PBMs’ purchases of a particular drug. It is inappropriate to force health centers to undertake an onerous reporting process, completely unrelated to 340B compliance, simply to save manufacturers money.
	+ This request will strip health centers of the 340B savings benefit mandated by Congress, undermining their ability to provide affordable pharmaceuticals and other services to their low-income patients. Providing this data will almost certainly cause health centers to lose the benefit the 340B discounts that Congress intended for them.  In recent years, FQHCs have faced a dramatic and worrisome expansion of “discriminatory contracting” – meaning practices used by third parties, such as PBMs and insurers, to effectively transfer the benefit of 340B savings from the FQHC to themselves.  (For example, a PBM will pay the FQHC only its actual purchase price for a drug – thereby capturing the benefit of the 340B savings for itself at the expense of the health center.) The manufacturers have been clear that they will use this data to deny voluntary discounts to PBMs – and recent history is clear that PBMs will respond to this “shortfall” by reducing reimbursement for to the health center. Thus, complying with the manufacturers request for data on Medicare and commercial patients will strip the 340B benefits away from health centers, undermining their ability to continue providing affordable pharmaceuticals and other services for their low-income, vulnerable patients while these benefits are then transferred to industry. Meaning that the savings that were intended to support care costs by safety-net providers will now go to large corporations and NOT to patients as Congress intended.

In addition to the manufacturer concerns, just today Kalderos announced a new technology platform that would allow manufacturers to decide if they will be providing covered entities with 340B drug discounts or instead provide the state with a rebate. This translates to manufacturers deciding if they will be providing covered entities, such as CHCs, with 340B drug discounted drugs or not. This is extremely concerning, since CHCs will likely NOT be provided 340B discounted drugs on many of their drugs, meaning that our patients will now receive these drugs without the 340B discount. This will undoubtedly impact patient access to pharmaceuticals since CHCs may not have the funds to buy these drugs at full cost, limiting the drugs options CHCs can offer to their patients. Additionally, we do not believe manufacturers can unilaterally mandate the use of a rebate model instead of providing the 340B discount to safety net providers at initial purchase under current law and the current Pharmaceutical Pricing Agreements between [the U.S. Health and Human Services Department] HHS and manufacturers. However, this is yet another example of the attacks that WILL keep occurring if Congress does not act.

**On behalf of the [INSERT ORGANIZATIONS NAME] and its [INSERT NUMBER OF EMPLOYEES] employees caring for [INSERT NUMBER OF PATIENTS] of patients we respectfully ask your support in helping to express to your colleagues and industry contacts the implications of big pharma’s actions to covered entities, like CHCs.** Please also engage via letter or phone call anyone with whom your office has a contact at Merck, Eli Lilly, Sanofi, AstraZeneca, Novartis, and Pharma to express your concern about the risk of their actions on your community’s low-income and vulnerable populations.

Health center doctors, nurses, and other staff do the best we can with what we have. This unprecedented attack from industry and certain others is unfair, unwarranted, and harmful to the needs of vulnerable patients and the safety-net who cares for them.

We hope we can count on you to follow through on these points above. Please let us know what you are willing to do and contact me if I can answer any questions. I can be reached at [INSERT CONTACT INFORMATION].

Sincerely,

[INSERT SIGNITURE LINE]