



**CALIFORNIA
HOSPITAL
ASSOCIATION**

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Health Policy and Advocacy*

July 12, 2018

Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Ave., SW, Room 600E
Washington, DC 20201

RE: RIN 0991–ZA49; HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs – Section on the 340B Drug Pricing Program

Dear Secretary Azar:

The California Hospital Association (CHA), on behalf of our more than 400 member hospitals and health systems, appreciates the opportunity to submit comments on the 340B section of the Department of Health and Human Services' (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. While we appreciate the administration's focus on the issue of unsustainable drug prices, which threaten patient access to care, the focus on the 340B drug discount program as part of a plan to lower drug prices is misplaced. The questions raised by HHS in the request for information suggest that the 340B drug discount program might contribute to higher drug prices. However, drug manufacturers — not 340B entities — are solely responsible for setting list prices and determining subsequent price increases. Any effort to scale back this vital program would not lower drug prices, but instead would increase revenue for drug manufacturers — at the expense of vulnerable patients and the communities served by California's safety-net hospitals.

In California, 175 hospitals rely on savings from the 340B drug discount program to provide essential medications and access to health care for California's most vulnerable populations. Hospitals use these savings to fund vital patient care services including mobile health clinics, chemotherapy infusion centers, Hepatitis C treatment and inner-city primary care centers. Below are a few specific examples of how 340B savings are used to support patients, families and communities across California:

- Nearly 17 percent of Imperial Valley adults have been diagnosed with diabetes. Without intervention, they would be at risk for stroke, heart disease, renal failure, neuropathy and other serious conditions. Using savings from the 340B drug discount program, El Centro Regional Medical Center hired a certified diabetes educator and community educators to provide diabetes education programs, one-on-one consults and medication management guidance, and follow-up on patient progress. **The program has demonstrated significant positive results — in the last quarter of 2017 alone, nearly 4,000 patients benefited from the diabetes education services and the community experienced a significant reduction in diabetes-related morbidity.**
- University of Southern California's Keck Hospital found that a surprising number of discharged patients had not filled their prescribed medications. Knowing that 25 percent of readmissions

are medication-related, Keck launched the Meds-to-Beds program in its cardiac department, which serves high-risk patients whose costs of care can soar if recovery is challenging. Using savings from the 340B drug discount program, Keck Hospital hired pharmacists to work with the cardiac care and discharge teams to troubleshoot insurance authorizations so that patients leave with needed medications. **Ninety percent of patients in the cardiac program take advantage of the pharmacy services provided through 340B savings.**

- Orchard Hospital's emergency department (ED) saw an increase in homeless and underserved patients with oral abscesses and other serious dental issues. Without the means to afford dental care, oral health issues quickly turned into serious medical issues requiring ED treatment. Orchard Hospital came up with a creative solution. **Using savings from the 340B drug discount program, the hospital provided qualified patients with dental care vouchers for area dentists. With better access to dental care, patients are receiving the treatment they need and staying healthier, and ED visits for oral health issues have been reduced.**

The 340B drug discount program is a lifeline for vulnerable patients and diverse communities, as it extends the reach of precious health care dollars to best serve Californians. Efforts to scale back the program would have detrimental effects on access to care.

GROWTH IN THE 340B PROGRAM

HHS has asked how growth in the 340B drug discount program has affected list prices. Drug manufacturers inaccurately claim that programs such as 340B have driven them to raise prices to unsustainable levels, allegedly due to program growth. Although congressional action expanded the program to support more vulnerable communities, much of the program's growth can also be attributed to drug manufacturers' dramatic price increases for outpatient drugs and to medical advances that have enabled the provision of more care in the outpatient setting. In California, hospitals experienced a 5.3 percent increase in outpatient visits — compared to a 1.6 percent decrease in inpatient admissions — between 2012 and 2016. **While this 7 percent differential has certainly contributed to growth in the 340B program, 340B savings still account for less than 2 percent of overall manufacturer revenues. Furthermore, there is no evidence that reducing the level of discounts manufacturers provide to hospitals would result in manufacturers voluntarily lowering list prices rather than simply returning those profits to their respective companies and shareholders.**

As prescription drug prices continue to skyrocket, it is increasingly important that hospitals have access to the drug manufacturers' 340B ceiling price calculation methodology and that drug manufacturers are held accountable for overcharging providers. In 2010, Congress mandated that providers be given access to 340B ceiling prices but, more than eight years later, HHS has not provided that access. Last month, for the fifth time, HHS delayed the implementation of its final rule on 340B ceiling prices and civil monetary penalties for manufacturers until July 1, 2019. The 340B ceiling price and civil monetary penalties rule was intended to shine needed light on drug manufacturer price increases and hold drug manufacturers accountable for price overcharging. However, for more than seven years these provisions passed by Congress have not been implemented and, as a result, hospitals are unable to challenge drug manufacturers when they sell drugs above the 340B ceiling price. Effective enforcement of manufacturers' pricing obligations is key to containing drug costs, and we urge HHS to implement the final rule immediately.

PROGRAM ELIGIBILITY

HHS has asked whether several changes to the program, including the definition of a “patient,” are needed to “refocus the program toward its intended purposes.” The 340B program is working as Congress intended by enabling hospitals “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” This program allows hospitals to expand access to life-saving prescription drugs and comprehensive health care services to vulnerable communities across the country, including to low-income and uninsured individuals. Changes to the 340B patient definition or added regulatory burden that provide no benefit to taxpayers only put access to care for vulnerable communities at risk.

The current 340B patient definition is based on the relationship the eligible patient has with his or her hospital. It includes patients who receive health care services from a health care professional who either is employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. Changing the definition of patient, in the requirements governing covered entities, would significantly harm California hospitals and the patients they serve. Past proposals to narrow the patient definition would have effectively limited discharge prescriptions or infusion-only services, which could jeopardize hospitals’ ability to serve the most disadvantaged patients in their communities — including low-income patients, uninsured patients and patients receiving cancer treatments. For example, the Oncology and Hematology Center at El Centro Regional Medical Center uses savings from the 340B drug discount program to hire patient navigators to connect patients to much-needed services including medications, prosthesis, wigs and even transportation. The navigators also help educate patients about their illness and treatments. Since patient navigators came on board in late 2017, more than 110 patients have benefited from the services funded through savings from the 340B drug discount program. Satisfaction is high, and patients are exceptionally grateful for the support and assistance provided by the patient navigators.

CONCLUSION

California’s hospitals and health systems rely on drug therapies to save lives every day. Hospitals are deeply committed to ensuring that the patients they serve have access to the life-saving drugs they need. However, as major purchasers, hospitals cannot continue to sustain the high — and constantly rising — drug prices that have strained their budgets for decades. Far from contributing to higher drug prices, the 340B drug discount program has been a critical tool for hospitals to continue to care for their communities. If the 340B drug discount program is curtailed, patients and the local communities that hospitals serve will pay the price through more limited access to needed drugs and services.

We appreciate this opportunity to share our concerns, and we look forward to working with you and your staff to help safeguard this valuable program. If you have questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688 or my colleague Amber Ott, vice president, strategic financing initiatives, at aott@calhospital.org or (916) 552-7669.

Sincerely,

Alyssa Keefe
Vice President, Federal Regulatory Affairs