February 10, 2021

U.S. House of Representatives
Washington, D.C. 20515

Dear Representative,

The Council for Citizens Against Government Waste (CCAGW) has long called for significant reforms to the 340B drug discount program. Created in 1992 to help uninsured, impoverished individuals obtain low-cost prescription drugs, 340B has grown exponentially since 2014 according to the Health Resources and Services Administration (HRSA), the agency that oversees the program. The blog *Drug Channels* reported in June 2020 that discounted 340B drug purchases reached $29.9 billion in 2019, an increase of 23 percent from 2018 and more than 232 percent since 2014.

CCAGW agrees with many of the conclusions in a January 2018 House Energy and Commerce Committee report, including Congress’s failure to clearly identify the intent of the program, especially the definition of a 340B patient, and require covered entities, like disproportionate share hospitals (DSH) and contract pharmacies, to report program savings and how they are used.

It is our understanding you have been asked to sign a letter intended for Health and Human Services (HHS) Secretary-designate Xavier Becerra and Acting Secretary Norris Cochran regarding actions several pharmaceutical companies have taken to restrict sales to certain 340B sites and contract pharmacies. Evidently these restrictions have arisen as a result of a January 2020 Government Accountability Office (GAO) report, “Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement,” which found continued weaknesses in HRSA’s oversight of contract pharmacies. The GAO found that, “federal law prohibits subjecting manufacturers to ‘duplicate discounts’ in which drugs provided to Medicaid beneficiaries are subject to both 340B Program discounted prices (i.e., are 340B drugs) and Medicaid rebates.” The GAO also found that, “unlike Medicaid fee-for-service, when duplicate discounts in Medicaid managed care claims are identified, HRSA does not require covered entities to address them or work with manufacturers to repay them. As a result, manufacturers may be subject to duplicate discounts for drugs provided under managed care. Given these limitations in federal oversight, HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts.”

On December 30, 2020, former HHS Secretary Alex Azar released an advisory opinion stating that manufacturers must provide the 340B discounts to contract pharmacies. The HHS press release noted that advisory opinions do not carry the force of law but describe the department’s
current views on a matter. Since then, some pharmaceutical companies have sued HHS and raised concerns that nothing in the 340B statute permits contract pharmacies and that the department’s actions violated the Administrative Procedures Act.

These events are emblematic of the continued problems with the 340B program that must be fixed by Congress. Currently, contract pharmacies number around 28,000, an amazing statistic considering the 340B statute does not authorize the use of contract pharmacies. They were created in a 1996 HRSA issue guidance allowing covered entities without an on-site pharmacy to contract with one off-site pharmacy. In 2010, ensuing guidelines removed the limitation on the number of contract pharmacies a covered entity can have.

The problem with the 340B program has not been the federal grantees, which have a regulatory structure that shares the savings in the 340B program with patients. These entities only represent 13 percent of total 340B sales, and many would have a need for a contract pharmacy. The issue has been with disproportionate share hospitals that are responsible for more than 81 percent of program sales and their numerous for-profit contract pharmacies that are enriching themselves off the program at the expense of patients, insurers, and taxpayers. An example of the abuse was demonstrated in a 2015 GAO report, which found, “per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis.” And a December 2017 study, “The Oncology Drug Marketplace: Trends in Discounting and Site of Care,” concluded that the 340B program has shifted oncology care from doctor’s offices for more favorable reimbursement at hospital outpatient settings. As a result, hospital outpatient facilities saw average profit margins increase from 40 percent in 2010 to 49 percent in 2015.

Congress has considered the need to reform the 340B program. Legislation has been introduced to preserve the program for what it was intended, helping indigent people get access to important medications, introduce more transparency, and not enrich hospitals or for-profit contract pharmacies. We urge you to refocus on this effort, which would make permanent changes in the 340B program, rather than signing the letter to Secretary-designate Xavier Becerra and Acting Secretary Norris Cochran and perpetuating the regulatory morass that has created many of the ongoing problems.

Sincerely,

Thomas Schatz