October 28, 2020

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor, and Pensions Committee
Washington, D.C. 20510

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
Washington, D.C. 20515

Dear Chairman Alexander and Ranking Member Walden,

On behalf of the millions of taxpayers our organizations represent, we are responding to your October 9, 2020 request for comments on modernizing the 340B drug pricing program. We agree with your statement that the program has "evolved and grown exponentially over the past 15 years, underscoring the need for clarity. For too long, 340B has been governed by guidance and other sub-regulatory actions that do not carry the weight of law."

The most significant reform of 340B would be to provide a clear definition of a 340B patient. They should be only those who are indigent, uninsured, and not eligible for Medicaid. This measure alone would ultimately correct through market forces the reported abuses of the program that have developed, particularly those that have purportedly been associated with certain contract for-profit pharmacies.

Congress also needs to take a closer look at the types of hospitals that are eligible for the program. Rather than using the standard disproportionate share hospital (DSH) statutory formula of Medicaid and Medicare patient rates, eligibility should be based on the number of indigent, uninsured patients who are served and the amount of charity care a hospital provides.

Like federally qualified health centers that must operate within the rules of their federal grants, strict and clear rules for hospitals and their contract pharmacies should be created. Although 340B is not a federal grant program, its maladministration can create cost bubbles that are squeezed toward federal health programs that are directly taxpayer supported. The change should be accompanied by an audit system to track how hospitals utilize their 340B savings.

The original intent of the 340B program was to provide significant discounts to health providers, like certain DSH hospitals and federally funded facilities like community health centers, black lung clinics, and hemophilia centers.

The cost reductions of between 20 to 50 percent are supposed to be used to "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" but due to unclear legislation, legally questionable guidance by the Health Resources and Services Administration (HRSA), which oversees the program, and expansion under the Patient Protection and Affordable Care Act, the program has grown

exponentially and is vulnerable to abuse. As noted in the January 10, 2018 House Energy and Commerce Committee report, "Review of the 340B Drug Pricing Program," while HRSA prohibits diversion and resale of 340B drugs to ineligible patients, "a large percentage of HRSA's audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016."

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. An October 2020 Berkeley Research Group (BRG) report, "For-Profit Pharmacy Participation in the 340B Program" found that, "more than 27,000 individual pharmacies (almost one out of every three pharmacies) participate in the 340B program as contract pharmacies" and that "hospitals now account for over 44 percent of all contract pharmacy arrangements, up from 2 percent in 2000." From 2010 to 2020, contract pharmacy arrangements increased 4,228 percent. That is an astonishing number considering the 340B statute does not authorize the use of contract pharmacies.

Supporters of the current 340B structure like to say that the program is not paid for by tax dollars. But a June 2015 Government Accountability Office report, "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" found that Medicare Part B drug spending per beneficiary was substantially higher at 340B hospitals than non-340B hospitals due to being prescribed more drugs or more expensive drugs. Taxpayers and consumers are paying for those "savings" either through higher premiums or out of pocket copays. An April 2016 study commissioned by the Community Oncology Alliance, "Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014," found that cancer care is moving from lower-cost physician offices to higher-cost hospital outpatient settings. When a 340B hospital purchases a physician's office, it can administer their heavily discounted drugs to its newly acquired patients that have insurance, charging the insurers the full reimbursable price and pocketing the difference.

Similar results were seen in a December 2017 BRG report, "The Oncology Drug Marketplace: Trends in Discounting and Site of Care," which found that the "shift in site of oncology care from the physician office to the hospital outpatient setting has continued unabated since 2008, and almost 50 percent of 2016 Medicare Part B chemotherapy drug administration claims occurred in the hospital outpatient setting – up from just 23 percent in 2008" and "average profit margins on Part B-reimbursed physician-administered oncology drugs purchased at a 340B price increased from 40 percent in 2010 to 49 percent in 2015 and have created substantial financial incentives for 340B hospitals to expand oncology services, despite overall healthcare costs increasing as a result of this shift in site of care."

Providing a clear statutory definition of a 340B patient, changing the definition of eligible hospitals, and refocusing the program on patient affordability will help to make sure that 340B fulfills its original mission of helping indigent Americans get access to important medicines, rather than contributing to heavier burdens on taxpayers.

Thank you for your consideration of our views on the 340B program.

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