



October 30, 2020

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Greg Walden
Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Alexander and Ranking Member Walden:

On behalf of Trinity Health and its 340B covered entities as well as those who benefit from the entities, following are comments on improving the 340B drug savings program in response to the October 9 request for input.

The 340B program is not only working, but working well. It supports safety-net hospitals that provide critical health services for low-income and rural patient populations, enabling these hospitals to ensure patients have continued access to care.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people in 92 hospitals across 22 states that span the full continuum of care. Committed to those who are poor and underserved, Trinity Health returns \$1.2 billion to our communities annually in the form of charity care and other community benefit programs. We are the leading health system participating in value-based care. Across the country, Trinity Health has (45) forty-five 340B programs supporting improved patient care, increased patient medication access and adherence, and decreased hospital readmissions.

340B is more critical than ever in light of the challenges and financial strain we have incurred in response to the COVID-19 pandemic. We do not believe legislation to change the 340B program is needed. However, the program could be strengthened if Congress were to use its oversight powers to ensure that the Department of Health and Human Services (HHS) is enforcing the 340B statute and using its existing authority to penalize manufacturers not meeting their 340B statutory obligations.

340B is a Success

Congress created the 340B program to help safety-net providers stretch their resources to reach more patients and provide more services. 340B program savings allow our hospitals to offer vital services despite challenges created by poor reimbursement and a weak payer-mix. If the 340B program were scaled back, reduced or saddled with costly administrative burdens, our 340B hospitals would lose the ability to provide the same services and benefits that the communities we serve currently rely on and expect. The 340B savings support and are tailored to diverse community needs. They enhance health, prevent morbidity and mortality, reduce readmissions, keep patient care close to home and help patients receive the care they need with dignity despite their financial and life circumstances.

Trinity Health's participation in the 340B program allows us to provide a direct benefit to our patients in the form of reduced-price and free medications.

The 340B program savings at MercyOne North Iowa Medical Center helps patients—who may not otherwise qualify for state assistance or afford insurance coverage—pay for their medications, thus resulting in better health outcomes. Mercy Health Saint Mary's in Grand Rapids, Michigan operates five community pharmacies, including the only ones centrally located in the city. These pharmacies provide free prescriptions to indigent patients and those with temporary financial need that amount to approximately \$3.7 million annually. This assistance protects patients from additional financial strain and disruption to their treatment regimens.

Participating in the 340B program also allows Trinity Health to provide a benefit to our communities and patients by funding services that we would otherwise be challenged to offer. The Springfield, Massachusetts Mercy Medical Center's Healthcare for the Homeless program identifies homeless persons in Western Massachusetts, assesses their needs and resources, delivers health and social services and evaluates the impact. In Boise, Idaho, Saint Alphonsus Regional Medical Center provides mobile outreach clinics that serve low-income neighborhoods with high levels of uninsured, undocumented and refugee patients. St. Francis Medical Center in Hartford, Connecticut has programs that focus on patients who typically have reduced access to care and are at high risk for health inequity. These programs have saved lives through early prostate cancer screening for underserved men, and ambulatory case management services to help patients navigate a complex web of community services. Several of our 340B hospitals offer behavioral health services. These are frequently the only behavioral health services available in the county or region, while also often running a negative financial margin.

Considering the many critical and valuable services that we are able to provide low-income and rural patients as a result of the 340B program, Trinity Health encourages Congress to preserve the program and protect the patients who benefit from it. Trinity Health further calls on Congress to ensure that HHS uses its existing authority to address the recent actions taken by drug companies that are in violation of the law and that seek to undermine the 340B program. These actions are outlined below.

Stop Manufacturers from Violating the 340B Statute

We remain extremely concerned that Eli Lilly, AstraZeneca and Sanofi recently began denying 340B pricing to hospitals for drugs dispensed through community pharmacy arrangements. These actions violate the law and jeopardize our ability to provide needed care to patients with low incomes. Manufacturers have a statutory obligation to offer drugs at 340B prices to all eligible hospitals, and there is no exception that allows manufacturers to deny pricing based solely on where the drugs are shipped. Allowing this to stand will encourage these and other drug companies to expand pricing restrictions to a wider range of vital drugs. Trinity Health urges Congress to ensure that HHS enforces the 340B statute by immediately using its existing authority to stop the unlawful actions of these manufacturers.

Prevent Turning 340B into a Rebate Program

There is also an effort by drug company representatives to overhaul the longstanding 340B discount model and replace it with a rebate system. This new system would make it significantly more difficult and expensive for all hospitals to access 340B savings and could result in denial of 340B pricing. For the program's entire history, pursuant to published Health Resources and Services Administration (HRSA) guidance, manufacturers have provided access to 340B pricing through discounts at the time of purchase, not back-end rebates.

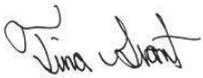
The new rebate model would require covered entities to pay exorbitant prices for drugs in the hope that they would receive a rebate at a later point in time. It would also give drug companies complete control over when and under what circumstances they will provide the statutorily required 340B discount. This effort will add to the administrative complexity of the program and make it more costly and burdensome for covered entities to participate, while failing to stretch scarce federal resources as far as possible, reach more eligible patients and provide more comprehensive

services. Trinity Health urges Congress to keep pressure on HHS to stop manufacturers from moving forward with a rebate model without prior approval or, at the very least, until guidance has been issued, subject to public notice and comment.

Given the importance of this critical program, Trinity Health urges Congress to continue protecting safety-net providers and their patients by supporting the 340B program. Without action to reverse the refusal of drug companies to comply with the law, it will cause long-term damage, forcing hospitals to reduce services at a time when our communities need them most.

Thank you for the opportunity to provide input regarding the 340B program. We appreciate your support of safety-net providers and thank you for your leadership. If you have questions on our comments, please feel free to contact Maggie Randolph, Director of Public Policy & Analysis, at Margaret.randolph@trinity-health.org.

Sincerely,



Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy
Trinity Health