



July 28, 2023

The Honorable John Thune
U.S. Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
U.S. Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
U.S. Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
U.S. Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
U.S. Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
U.S. Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran and Cardin:

Thank you for the opportunity to provide input on 340B Drug Pricing Program. Our comments reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health integrated care delivery systems in the nation, serving diverse communities that include more than 30 million people across 26 states. We advocate for public policies that promote care for the common good and advance our mission, including fair payment, a strong workforce, coverage for all that bridges social care, and total cost of care payment models.

The 340B Drug Pricing Program helps manage the rising cost of prescription drugs by providing cheaper drugs to eligible hospitals and clinics that serve low-income and rural patients. Savings from the program provide essential resources that are critical to helping 340B hospitals comprehensively serve the most vulnerable and improve the health of communities. Health services provided through 340B savings do not cost taxpayers any money. The services are paid for with the money saved through the price discounts from drug companies.

Trinity Health has forty-one 340B programs operating in 14 states that support programs to improve patient care, increase patient medication access and adherence and decrease hospital readmissions. We support efforts to ensure that the 340B program meets the objective set by Congress “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” At Trinity Health, 41% of revenue comes from Medicare and 18% from Medicaid and uninsured patients.

In recent years, there have been efforts to scale back, significantly reduce the benefits of or expand the regulatory burden of the 340B program. Drug companies suggest that 340B places an unsustainable burden on their business. In fact, 340B discounts represent a small share of the discounts and rebates drug companies voluntarily pay to participate in commercial payer networks and they still operate with double digit profit margins. In contrast, cuts to the 340B program take

resources away from patient care. This is especially outrageous considering health systems are facing record-high inflationary cost pressures and drug companies are generating record profits.

Please find our detailed comments on the request for information questions below.

What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

The Health Resources and Services Administration (HRSA) is responsible for administering the 340B program. HRSA has been successfully enforcing its statutory authority for years. It implemented the patient definition guidelines in 1996 that is still being followed today. HRSA conducts at least 200 covered entity audits per year with a low number of findings requiring repayment to drug companies.

HRSA allows covered entities the ability to contract with community and specialty pharmacies (contract pharmacies) to dispense drugs on their behalf. As participation with contract pharmacies increases, drug companies assert the program has strayed from its original intention. In response, many drug companies have taken action to limit or deny access to 340B pricing at contract pharmacies. They claim HRSA does not have authority to regulate these arrangements. Congress and both the Trump and Biden administrations maintained these actions by drug companies violate the 340B statute. Drug companies responded with lawsuits against the Department of Health and Human Services (HHS).

Trinity Health believes HRSA needs explicit statutory authority to prohibit drug company and payer actions related to 340B pricing that adversely affect the program and patients. Congress should strengthen the 340B statute by granting authority to ensure:

- Drug companies are required to offer and sell 340B eligible drugs to covered entities at the 340B price without regard to how the covered entity makes the drugs available to eligible patients.
- Drug companies are prohibited from refusing to deliver or interfering with the delivery of eligible 340B drugs as requested by a hospital or other provider, including to community and specialty pharmacies.
- Drugmakers are prohibited from placing conditions on a hospital's or other 340B covered entity's ability to access 340B pricing for eligible drugs, including those dispensed through community and specialty pharmacies.
- HHS has the authority to impose civil monetary penalties on a drugmaker that refuses to offer, sell, or deliver eligible 340B drugs as requested by a hospital or other 340B covered entity, including through community and specialty pharmacies.

Trinity Health believes that the current definition and understanding of an eligible 340B patient (providing broad access to 340B pricing) should be included in any legislation that grants HRSA additional authority. The definition of which patients are eligible is the bedrock of the program. The current definition and understanding allows covered entities to truly meet the stated intent of "stretching scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Hospital covered entities are concerned that accommodations by HRSA to continue the program in the face of opposition from drugmakers could adversely affect the program and reduce the benefits to patients and the ability of health care providers to meet patients' needs.

Given the extreme importance of the 340B program to safety net hospitals all over the United States, we request inclusion of requirements to demonstrate that any changes to the 340B program do not result in significant cuts to 340B savings, impacting both hospitals, other covered entities and patients.

What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Contract and specialty pharmacies serve as an extension of Trinity Health providers and allow patients to access their medications in the convenience of their local community pharmacy or through the mail (i.e., mail-order pharmacy). For health systems like Trinity Health, these arrangements allow us to ensure that our patients can access the drugs they need when they need it, especially as patients rely more heavily on specialty drugs many of which are in limited distribution. For patients, these arrangements make it easier to access their needed drugs without having to travel to our hospitals to receive the drug. The 340B savings generated from these arrangements allow Trinity Health to better serve our vulnerable communities by increasing access to more affordable health care services.

Trinity Health suggests Congress consider policies that require the insurers and drug distributors who have created narrow distribution networks to contract with covered entities for access to 340B pricing for patients eligible at the covered entity. A narrow network arrangement should not be permitted via a wholesaler or a specialty pharmacy to exclude drugs from 340B for covered entities. Narrow distribution network models and the associated “white bagging” of prescriptions filled at the designated pharmacies have negative impacts including delays in patient care and disruptions in care when coordination and care planning is essential. Cancer therapies is an important example. Requiring patients to collect and transport their infusion drugs to an infusion site puts the patient at risk for harm.

Congress should consider policies that empower the 340B covered entities to choose contract pharmacies that will meet the needs of patients even if distant from the covered entity. Many drug companies currently restrict contract pharmacies to a 40 mile radius from the covered entity, this restricts access in rural communities. Contract pharmacies are particularly important in rural hospitals, many of which do not have their own in-house pharmacies, and therefore solely rely on a network of contracted community and specialty pharmacies to ensure their patients have access to the drugs they need. Many of Trinity Health’s critical access hospitals in rural markets rely on contracts with pharmacies in communities that are more than 40 miles from the 340B critical access hospital.

Specialty pharmacies provide critical services and can serve a national scope. Yet, specialty pharmacies are regularly excluded from narrow networks. This should not be allowed.

The contract pharmacy restrictions imposed by drug companies over the past three years have impacted Trinity Health’s ability to access drugs at 340B pricing, decreasing our savings by approximately 50%. This restricts financial resources available for critical community services. And this comes at a time when health systems are already struggling with increased costs including a 24% increase in drug costs.

Policies regulating contract pharmacy arrangements should be established by HRSA, not the drug companies.

What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

340B savings are intended to benefit covered entities and the patients and communities they serve. Policy change can protect these savings. In contract pharmacy arrangements, retail pharmacies benefit from charging the partnering covered entity fees. Contract pharmacies have increased these fees and retained payments for 340B dispensed drugs. There is great variation in the pharmacy fee among retail pharmacies.

HRSA should be authorized to limit fees charged by pharmacies for dispensing and other services. Confidentiality of drug payment pricing can be assured via aggregate pass-through amounts and other protections.

Payers and pharmacy benefit managers (PBMs) are implementing discriminatory policies that harm 340B providers, such as by paying less for 340B drugs than they pay for non-340B drugs or requiring burdensome identification of 340B claims. Discriminatory reimbursement rates transfer the 340B financial benefit from safety-net providers to for-profit payers, harming the ability of providers to serve their patients and communities.

Trinity Health encourages Congress to pass legislation prohibiting discriminatory actions against 340B providers and pharmacy partners by a PBM, group health plan, health insurance issuer offering group or individual health insurance, or sponsor of a Medicare Part D prescription drug plan based on the providers' status as 340B entities. The legislation should authorize civil monetary penalties against PBMs that implement discriminatory policies. Many of the provisions in the PROTECT Act (H.R. 2534) would address these concerns.

What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

Duplicate discounts happen when both 340B discounts and Medicaid rebates are provided by a drug company for the same drug. Current statute does not specify whether the state Medicaid program, Medicaid managed care organization (MCO) or covered entity is responsible for ensuring duplicate discounts do not occur. Trinity Health fully supports efforts to prevent duplicate discounts, including provisions in the proposed rule to update the Medicaid Drug Rebate Program from the Centers for Medicare and Medicaid Services (CMS). The proposed rule would update the standard MCO contract to require Medicaid MCOs to use unique, Medicaid-specific codes and group numbers on beneficiary insurance cards. These identifiers would help ensure 340B discounts and Medicaid rebates are provided appropriately.

Drug companies have alleged that contract pharmacies' participation in 340B has resulted in duplicate discounts. Some drug companies will allow unlimited purchases of 340B drugs through contract pharmacies in exchange for claims data provided to a software vendor, 340B ESP. 340B ESP is a proprietary platform that allows 340B covered entities to upload claims data through an interface and then links it to Medicaid and commercial rebate data maintained by drug companies. Participating covered entities are notified by 340B ESP of any instances of duplicate Medicaid rebates to support corrective actions. Data now is available to payers and PBMs to prevent duplicate discounts and rebates.

Trinity Health and other covered entities have concerns about the potential risk of sharing claims data with 340B ESP. We support ways to prevent duplicate discounts but believe drug companies need to submit pass-through payment information, as well. Trinity Health suggests that a neutral clearinghouse, potentially within HRSA or another independent third party, is more appropriate to manage the process of identifying duplicate discounts. The clearinghouse would collect rebate data from states and 340B claims data from covered entities directly. Oregon provides a model that is showing success.

What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

The current program integrity requirements are strong and are supported by substantial resources from the covered entities. Hospitals participating in the 340B program expend significant resources on compliance with program requirements and changes, including the yearly-recertification process and

required randomized audits. Hospitals also submit annual Medicare Cost Reports, disclosing all revenue and expenses, by category, as well as utilization data, cost and charges by cost center, and statistical data regarding the volume of services (e.g., patient days and discharges) for Medicare and Medicaid. 340B hospitals must annually report detailed information to the IRS using Form 990 Schedule H, including for services that benefit the community, based on a mandatory community health needs assessment and implementation strategy.

Current legislative proposals in Congress that would require reporting of detailed data by service line would be incredibly onerous without a clear benefit to program integrity. Trinity Health's current 340B system would not accommodate reporting data for each line of service by location where the service is provided (i.e., child sites). This type of reporting also goes against the stated purpose of the program. 340B savings from one location may be used in a different location to support services needed by the community. Collecting detailed data by location falsely suggests that 340B savings are restricted to the specific department where the drugs are used.

Trinity Health urges common sense reform of HRSA's child site registration policy. Under current HRSA policy, hospitals are required to register offsite hospital locations by line of service, resulting in many registrations for a single hospital building. Also, though HRSA follows Medicare policy for registration of most hospital locations, it does not follow Medicare policy with respect to registration of new hospital locations that have not yet appeared on a filed Medicare Cost Report. Offsite hospital locations should be registered by building, not individual service, and hospitals should not have to wait until the next Medicare Cost Report filing to register new hospital locations.

Trinity Health encourages elimination of the group purchasing organization (GPO) prohibition to reduce administrative burdens and assure access to drugs. The GPO prohibition requires DSH hospitals to purchase covered outpatient drugs at higher prices when the hospital is unable to use 340B pricing for the drug. For example, if a hospital does not use 340B for a Medicaid patient (carves out to avoid duplicate discounts), the hospital cannot purchase those drugs at the GPO price and must purchase at the usually much higher wholesale acquisition cost (WAC). This increases the cost of drugs for safety net providers. Prior to a policy notice issued by HRSA in 2013, hospitals routinely purchased such drugs through their GPO, and then replenished those that were dispensed to 340B patients through their 340B account. Eliminating this prohibition would help hospitals keep drug costs low and eliminate a program audit burden for the covered entity and for HRSA auditors.

In 2023, Trinity Health made the difficult decision to participate in 340B ESP. Many drug companies have made it a requirement for covered entities to send data to 340B ESP to get access to 340B pricing for contract pharmacy arrangements. Despite concerns over sharing pharmacy claims data, Trinity Health joined out of necessity. Trinity Health has hired a consulting firm and two employees to manage the extensive reporting requests at an estimated cost of \$700,000. Trinity Health is managing this new work on behalf of all of our covered entities. However, entities that are not part of a system must each hire their own data manager. This is just one example of administrative waste imposed by drug companies with no statutory authority. We are in need of commonsense policy solutions.

What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

The 340B program is intended to broadly support patient care, as well as help cover the burden of under-payment from public programs. A true benefit of the program is that it is not too specific on how savings can be used. Instead, the program allows for flexibility to provide services that benefit specific community needs. Requiring data on use of 340B savings for specific and narrow areas has the potential to undermine the program's intentions. The program's flexibility is critical to supporting the health care safety net and allowing providers to maintain strong health care facilities for their communities. We urge avoidance of policy that seeks to define eligible uses of 340B benefit as such

policy will likely have unintended adverse effect on the health and wellbeing of the patients that the program seeks to benefit.

Some have suggested that the 340B program has led to consolidation in the health sector because access to 340B pricing incentivizes hospitals to vertically integrate with physician practices.¹ The suggested policy solution was to lower the scale of the 340B discounts. Our experience has been physicians are choosing to join health systems for help navigating their practices through increased costs and burdensome regulatory policies.

Other stakeholders have pointed to the 340B program, along with the Medicaid Drug Rebate Program, as drivers of drug shortages. There have been suggestions that the program's inflation penalties are pushing down prices for generic drugs to unsustainable levels.² Drug shortages have been an issue for decades. However, Congress only extended inflation penalties to generic drugs in 2017 and the trajectory of new drug shortages has not changed.³ In contrast, savings from the 340B program allow patients to receive services such as infusion and chemotherapy in their communities. Many of our covered entities use 340B savings to provide oncology services, and infusion access, for those who are uninsured and underinsured.

Trinity Health puts a high value on transparency. Covered entities across our health system have created impact profiles that describe their safety-net role and illustrate how 340B savings support services for patients and communities. Savings pay for unreimbursed services, such as Medication Access Coordinators, who help patients in obtaining free medications through patient assistance programs.

In Trinity Health communities across the country, 340B savings also support programs that address unique community needs, such as transportation services for primary care appointments that prevent avoidable hospitalizations. The savings also support care and education programs for patients and family members including heart health, chronic diseases, grief counseling, smoking cessation, diabetes management and prevention, ostomy and wound care. These services make a significant impact on patients, families and communities and would not be possible at the levels provided without the savings from the 340B program. Other examples include:

- Trinity Health Michigan's Pharmaceutical Access Program (PAP) provides more than 4,000 uninsured and underinsured patients annually with medication and supplies in West Michigan.
- Trinity Health Of New England's Health Care for the Homeless program delivers health and social services in Springfield, Mass.
- Saint Alphonsus' mobile outreach clinics serve uninsured, undocumented and refugee patients in Boise, Idaho.

Trinity Health is willing to serve as a resource as you consider ways to protect and strengthen the 340B program. Please reach out to Maggie Randolph, Director of Public Policy and Analysis, at margaret.randolph@trinity-health.org with questions.

¹ Cooper, Zach, PhD. *Written Testimony for Senate Committee on Finance Hearing: Consolidation and Corporate Ownership in Health Care*. 8 June 2023.

https://www.finance.senate.gov/imo/media/doc/20230605_sfc_testimony.pdf.

² Okon, Ted. *Written Testimony for House Committee on Energy and Commerce Hearing: Legislative Solutions to Bolster Preparedness And Response For All Hazards And Public Health Security Threats*. 11 Jun 2023.

https://democrats.energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/Ted%20Okon_Witness%20Testimony_06.13.23.pdf.

³ American Society of Health-System Pharmacists. *Drug Shortages Statistics*. <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly>.

Sincerely,

Damon Redding

Damon Redding
Vice President & Chief Pharmacy Officer
Trinity Health