



October 21, 2020

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

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Alexander and Ranking Member Walden:

On behalf of National Taxpayers Union, the nation's oldest taxpayer advocacy organization, I write in response to your request for input on modernizing the 340B Drug Pricing Program.¹ We appreciate your commitment to ensuring this program fulfills lawmakers' original intent, reflects the complex nature of our modern American health care system, and operates in a manner that respects the extraordinary taxpayer stake in the successful operation of all federal and state health programs.

Recent growth in the 340B program has underscored the need for updates and reform. As you both note:

340B program participation has grown substantially since the program's inception. For example, since 2005, the number of active hospitals and associated sites participating in 340B has increased by nearly 3,000 percent. In 2005, there were approximately 432 active hospitals and 594 associated sites; in 2020, there are now roughly 2,541 active hospitals and 26,641 associated sites.

From 1996 to 2010, 340B-participating hospitals and clinics that did not have an in-house pharmacy were allowed to contract with one outside pharmacy to make certain patients could access discounted 340B prescriptions. In 2010, the Obama Administration, through guidance, removed this cap and allowed such entities to contract with an unlimited number of outside pharmacies. Since that time, the number of contract pharmacies has spiked from 1,300 at the beginning of 2010 to over 25,000 in 2020.²

Yet the 340B program is still operating under unclear and confusing rules, designed for a much smaller program that was first created in 1992. Numerous independent audits and investigations have found that the Health Resources and Services Administration (HRSA), which oversees the 340B program, not only lacks the authority to conduct necessary and proper oversight and enforcement of 340B rules but also falls short on its *existing* oversight responsibilities.

¹ Energy and Commerce Committee Republicans. (October 9, 2020). "Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program." Retrieved from: <https://republicans-energycommerce.house.gov/news/walden-and-alexander-ask-for-input-on-modernizing-340b-drug-pricing-program/> (Accessed October 14, 2020.)

² *Ibid.*

For years, NTU has advocated for 340B reform. We will review some of our prior recommendations below, and we stand by them today. However, it is clear that lawmakers can also go above and beyond NTU's recommendations alone, and for that reason we concur in part with recent proposals offered by the nonpartisan Government Accountability Office (GAO), by Energy and Commerce (E&C) Committee Republicans in a 2018 report on the program, and by Rep. Bruce Westerman (R-AR) in his recently-introduced Fair Care Act. We will review these recommendations below as well.

Overall, it is clear that recent growth in the 340B program has presented unique challenges to consumers and taxpayers that Congress can and should remedy. We look forward to sharing our findings and reviewing your recommendations for modernizing the program.

NTU's Stake in Prescription Drug Policy

NTU's advocates and experts have been stakeholders for prescription drug policy for decades. Policymakers in Washington, D.C. and in the states exercise significant leverage over whether a drug is approved or not, how it may be marketed, and (in the case of Medicare, Medicaid, and the 340B program) how that approved and marketed drug is priced. While we seek limited government interference in the development, approval, marketing, and pricing of prescription drugs, NTU works actively with Congress, federal agencies, and state capitals to craft pro-taxpayer, pro-consumer, and market-oriented prescription drug policy.

NTU's Prior Recommendations for the 340B Program

In March 2018, NTU President Pete Sepp and Council for Citizens Against Government Waste (CCAGW) President Thomas Schatz submitted a statement on the 340B program to the Senate Health, Education, Labor, and Pensions (HELP) Committee.³

Sepp and Schatz identified several concerns with the program that have been echoed by stakeholders and nonpartisan watchdogs for years:

Due to vague language in the law and unclear regulations, like a well-defined description of what constitutes a 340B patient, this is not happening. CCAGW and NTU believe there is evidence that many hospitals are abusing the 340B program by purchasing the deeply discounted drugs, providing them to patients with health insurance, and boosting their profits by pocketing the substantial difference when reimbursed by the patients' co-pays and insurance. There is also evidence that this practice adversely impacts Medicare.

Even though proponents contend that the program has no cost to taxpayers, waste in 340B payments could certainly contribute to cost-shifting or duplicate payments in other government-funded health programs. All of this impacts taxpayers. Among the recommendations Sepp and Schatz shared with the HELP Committee are:

- Codifying a “**clear definition of a 340B patient**” into law, which “must include that the patient is uninsured and has a low income;”

³ Sepp, Pete. “Perspectives on the 340B Drug Discount Program Hearing.” National Taxpayers Union, March 18, 2018. Retrieved from: <https://www.ntu.org/publications/detail/perspectives-on-the-340b-drug-discount-program-hearing>

- Instituting “an audit or tracking system for how 340B hospitals utilize their pharmaceutical savings and make sure it is in line with the law’s intent;” and
- **Re-evaluating whether disproportionate share hospitals (DSH) should be automatically eligible for the 340B program;** since the program is meant to help primarily *uninsured* Americans, using DSH status, which is based on “the number of days Medicare and Medicaid patients have been in the hospital,” to determine 340B eligibility may not make sense. Instead, Sepp and Schatz write, lawmakers should consider having HRSA evaluate eligibility based on “[h]ow much uncompensated care a hospital provides to uninsured, indigent patients [and/or] the financial condition of the hospital.”

Also in 2018, NTU endorsed a bipartisan bill from Reps. Larry Bucshon (R-IN) and Scott Peters (D-CA) that “would [put in] place a two year moratorium for new enrollees into the 340B program.”⁴ The bill, the “340B Protecting Access for the Underserved and Safety-net Entities (PAUSE) Act” (H.R. 4710 in the 115th Congress⁵) would also require the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the GAO “to conduct a review of operations and costs” in the program.

We stand by our recommendations above and by our endorsement of the 340B PAUSE Act, but valuable information shared by GAO, E&C Republicans, and other stakeholders in the years since these publications point the way toward further reforms and adjustments to the 340B program.

More Recent Information on the 340B Program

GAO released two important reports on the 340B program around 10 months ago. One concerns hospital eligibility to participate in 340B,⁶ while the other concerns duplicate discounts - when manufacturers pay both the Medicaid Drug Rebate Program (MDRP) discount and a 340B program discount on the same drug.⁷ While all nine recommendations GAO made across the two reports were directed to either the Administrator of HRSA or the Administrator of the Centers for Medicare and Medicaid Services (CMS), the open status for seven of nine recommendations as of summer 2020 (and HHS disagreements with three of those seven remaining recommendations) points to the need for Congress to step in and apply the explicit instructions, timeline, and -- if necessary -- resources necessary for HHS to expeditiously address GAO’s concerns.

To address hospital ineligibility,⁸ Congress should:

⁴ Arnold, Brandon. “NTU Endorses Bill to Fix the 340B Drug Discount Program.” National Taxpayers Union, July 9, 2018. Retrieved from: <https://www.ntu.org/publications/detail/ntu-endorses-bill-to-fix-the-340b-drug-discount-program>

⁵ Congress.gov. (Introduced December 21, 2017). “H.R.4710 - 340B PAUSE Act.” Retrieved from: <https://www.congress.gov/bill/115th-congress/house-bill/4710> (Accessed October 14, 2020.)

⁶ Government Accountability Office. (December 2019). “340B DRUG DISCOUNT PROGRAM: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements.” GAO-20-108. Retrieved from: <https://www.gao.gov/assets/710/703128.pdf> (Accessed October 14, 2020.)

⁷ Government Accountability Office. (January 2020). “340B DRUG DISCOUNT PROGRAM: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement.” GAO-20-212. Retrieved from: <https://www.gao.gov/assets/710/703966.pdf> (Accessed October 14, 2020.)

⁸ All references in the subsequent bullet points on hospital ineligibility are sourced from: Government Accountability Office. (December 2019). “340B DRUG DISCOUNT PROGRAM: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements.” GAO-20-108. Retrieved from: <https://www.gao.gov/assets/710/703128.pdf> (Accessed October 14, 2020.)

- **Require HRSA to conduct an evaluation of “the reliability of the data for verifying nonprofit status” of 340B hospitals, and to report their findings to the HELP and E&C committees (and to the public) within a specified timeframe.** GAO wrote that HRSA is satisfied with the reliability of its information “because hospital administrators attest to its accuracy,” but GAO also noted in its report that “HRSA uses Medicare cost report data from CMS to determine whether hospitals are nonprofit, but these data may not be sufficiently reliable for this purpose.” Any evaluation Congress requires HRSA to conduct should, at minimum, seek to examine and address GAO concerns that relying on self-reported Medicare cost report data may create “a risk that for-profit hospitals could receive discounted pricing for which they are not eligible.”
- **Require HRSA to verify that all nongovernmental hospitals participating in 340B have a contract with a state and local government, and require HRSA to implement a permanent system to re-verify contract status at least once per year.** This is the only one of six GAO recommendations that HHS did not agree with, but GAO’s counterargument to HHS is compelling: “HRSA already requires hospitals to maintain copies of their state or local government contracts. Therefore, it is unclear how implementing a process to verify the existence of those contracts would represent a significant burden.” We also believe it is prudent to continually verify the existence of state and local contracts with 340B-eligible providers, and believe re-verification should occur at least once annually. HRSA could conduct these re-verification checks all at once or on a rolling basis, depending on the agency’s capacity and preference. If HRSA insists that additional resources are absolutely necessary to conduct these checks, Congress could consider appropriating redirected or new funds for this explicit purpose.
- **Require HRSA to issue more specific guidance to 340B program auditors on ensuring provider contracts with state and local governments stipulate “the provision of health care services to low-income individuals.”** GAO left this recommendation to HRSA open because, while HRSA updated its audit guidance their documents “do not contain any specific guidance on how auditors are to evaluate whether contracts require these services.” It is clear that more specific guidance is necessary, and Congress should step in and require this of HRSA within a specified timeframe.
- **Prohibit HRSA from accepting “retroactive contract documentation” from participating providers, and strengthen sanctions for providers that lack a contract with a state or local government as required by the program.** GAO noted that HRSA *must* “show that it has ceased accepting retroactive contract documentation.” This troubling trend -- allowing a provider to correct for the lack of a contract with a state and local government after the provider has been determined not to have one -- “effectively allows hospitals to avoid audit findings,” according to GAO. Congress could explicitly prohibit HRSA from allowing a provider to avoid adverse audit findings or program sanctions by merely “accepting new contracts that are retroactive.” Hand in hand with that recommendation, in GAO’s estimation, is applying “consistent and appropriate consequences when auditors find that nongovernmental hospitals did not have contracts in effect prior to the beginning of their audit periods.” We defer to Congress and the HRSA on the proper consequences. Although NTU is sensitive to the need for the cautious exercise of sanction and enforcement powers with any federal agency -- and appropriate safeguards/appeal mechanisms -- it is clear that this area of program administration needs strengthening.

To address duplicate discounts, Congress should:⁹

⁹ All references in the subsequent bullet points on hospital ineligibility are sourced from: Government Accountability Office. (January 2020). “340B DRUG DISCOUNT PROGRAM: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement.” GAO-20-212. Retrieved from: <https://www.gao.gov/assets/710/703966.pdf> (Accessed October 14, 2020.)

- **Authorize HRSA to promulgate regulations aimed at preventing duplicate discounts for 340B providers.** GAO recommended that HRSA “incorporate assessments of covered entities’ compliance with state Medicaid programs’ policies and procedures regarding the use and identification of 340B drugs into its audit process,” but HHS responded that HRSA “does not have regulatory authority related to the prevention of duplicate discounts for covered entities” even though they have requested such authority. Congress should answer HRSA’s call and provide the agency with requested regulatory authority. Lawmakers should also require HRSA to promulgate regulations within a specified timeframe, and conduct oversight to ensure HRSA regulations are consistent with Congressional intent. If HRSA insists that additional resources are absolutely necessary to promulgate and enforce these new regulations, Congress could consider appropriating new or redirected funds for this explicit purpose.
- **Require HRSA to issue guidance on avoiding duplicate discounts directed to Medicaid managed care providers (and not just Medicaid fee-for-service [FFS] providers), and require HRSA to both collect information on Medicaid managed care claims and urge providers to work with manufacturers on repayment in the case of duplicate discounts.** HHS disagreed with this GAO recommendation because “HRSA does not have guidance for covered entities related to Medicaid managed care claims.” This is a gaping hole in HRSA oversight; “[a]ccording to analysis from the Medicaid and CHIP Payment and Access Commission [MACPAC], in fiscal year 2018, 61 percent of Medicaid gross spending for drugs and 71 percent of Medicaid drug prescriptions were in managed care.” HRSA should have guidance for providers related to Medicaid managed care claims, and it appears Congress will need to explicitly instruct HRSA to issue such guidance. Congress should go two steps further: it should 1) require HRSA to collect information on Medicaid managed care claims as they pertain to the 340B program;¹⁰ and 2) require HRSA to work with Medicaid managed care providers on repayment to manufacturers when HRSA or a state has certified that a managed care provider received a duplicate discount.

Recent HRSA audit data indicates that duplicate discounts continue to be a significant problem in the 340B program. Of 152 providers subject to program integrity audits from HRSA in fiscal year (FY) 2020, 17 (or 11 percent) received duplicate discounts and were instructed to repay manufacturers.¹¹ Of 199 providers subject to program integrity audits in FY 2019, 23 (or 15 percent) received duplicate discounts and were instructed to repay manufacturers.¹²

NTU also concurs with the following recommendations from E&C Republicans’ 2018 report on the 340B program:¹³

¹⁰ Congress could require Medicaid managed care providers to register with the Medicaid Exclusion File (MEF) when they “carve in 340B drugs for Medicaid managed care.” Currently the MEF is only used for Medicaid FFS claims. If this option is untenable, Congress could instead require HRSA to certify that the 13 states that use the MEF “exclusively to identify and exclude Medicaid managed care drugs” have an additional, non-MEF process in place for verifying Medicaid managed care claims data.

¹¹ Health Resources & Services Administration. (Updated September 15, 2020). “Program Integrity: FY20 Audit Results.” Retrieved from: <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-20-results> (Accessed October 14, 2020.)

¹² Health Resources & Services Administration. (Updated September 15, 2020). “Program Integrity: FY19 Audit Results.” Retrieved from: <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results> (Accessed October 14, 2020.)

¹³ Energy and Commerce Committee Republicans. (January 10, 2018). “Review of the 340B Drug Pricing Program.” Retrieved from: https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf (Accessed October 14, 2020.)

- **“Congress should give HRSA sufficient regulatory authority to adequately administer and oversee the 340B program**, including the ability to improve program integrity, clarify program requirements, monitor and track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program.” (This broad point overlaps with several of the recommendations that stem from the GAO reports above.)
- **“Congress should establish a mechanism to monitor the level of charity care provided by covered entities**. This should include a clear definition of charity care such that the data can be used to fairly compare care provided across entities.” (If properly calibrated to reflect administrability and paperwork burden concerns, this dovetails well with the first two recommendations Sepp and Schatz shared with the HELP Committee in 2018.¹⁴)
- **“Congress should equip HRSA with more resources and staff** to conduct more rigorous oversight and more effective management of the 340B program.” (As noted above, we believe that any additional appropriations from Congress to HRSA should come with explicit instructions for how to use the funds, which would preferably come from redirected resources; a generic increase in authorization levels or appropriations will not suffice.)

We also believe Congress should enact into law two provisions concerning the 340B program in Rep. Bruce Westerman’s Fair Care Act:

- Section 329: “This section requires participating 340B entities to **report to HHS the number of individuals dispensed drugs under this program**, whether they belong to Medicare, Medicaid or other insurance, the total costs incurred and reimbursements received. This data will be made public on the HHS website and the OIG, GAO and Comptroller General will provide subsequent reports based on the data.”¹⁵ (While the HHS OIG and GAO have conducted excellent research on deficiencies in the 340B program, these analyses are often more qualitative than quantitative. Hard data are necessary to determine whether more significant reforms to the program are needed.)
- Section 330: This section “require[s] participating 340B entities to **report to HHS the low-income utilization rates of specific outpatient hospital services**. Additionally, the Health Resource Services Administration (HRSA) will provide a report based on the data.”¹⁶ (This dovetails well with E&C Committee’s 2018 recommendation to “monitor the level of charity care provided by covered entities.”)

Lastly, we believe Congress can take steps in some manner to help **resolve the ongoing disputes between manufacturers and 340B providers over contract pharmacies**. For example, two manufacturers recently announced they have “restrict[ed] sales of drugs discounted under the 340B program to contract pharmacies, escalating a war with hospitals.”¹⁷

¹⁴ 1) Codifying a “clear definition of a 340B patient” into law, which “must include that the patient is uninsured and has a low income,” and 2) Instituting “an audit or tracking system for how 340B hospitals utilize their pharmaceutical savings and make sure it is in line with the law’s intent.” See: Sepp, Pete. “Perspectives on the 340B Drug Discount Program Hearing.” National Taxpayers Union, March 18, 2018. Retrieved from:

<https://www.ntu.org/publications/detail/perspectives-on-the-340b-drug-discount-program-hearing>

¹⁵ Congressman Bruce Westerman. (October 2020). “Title, Subtitle and Section Summary for The Fair Care Act of 2020.” Retrieved from: <https://westerman.house.gov/sites/westerman.house.gov/files/The%20Fair%20Care%20Act%20Section%20Summary.pdf> (Accessed October 14, 2020.)

¹⁶ *Ibid.*

¹⁷ King, Robert. “Eli Lilly to halt sales of 340B drugs to contract pharmacies with exception of insulin.” *Fierce Healthcare*. September 2, 2020. Retrieved from:

<https://www.fiercehealthcare.com/hospitals/eli-lilly-to-halt-sales-340b-drugs-to-contract-pharmacies-exception-insulin> (Accessed October 14, 2020.)

Manufacturers insist that the skyrocketing use of contract pharmacies in the 340B program has caused the program to significantly drift from its intended purpose, sending resources to large pharmacies instead of patients in need of support.¹⁸ Providers argue that manufacturers deciding to restrict sales for 340B purposes are “in violation of the 340B statute.”¹⁹ Congress could step in and help end this dispute, specifically by offering clarity on 340B providers’ use of contract pharmacies.

Absent more data, or a study from GAO or HHS OIG, we cannot definitively determine what restrictions on providers or contract pharmacies are appropriate (if any). However, Congress should more closely examine these troubling trends.

Conclusion

To summarize, NTU supports:

- A temporary moratorium on new 340B enrollees while Congress, GAO, and HHS OIG conduct oversight of program deficiencies;
- Changes to the 340B statute that clarify the definition of a “340B patient;”
- A re-evaluation of whether DSH hospitals should participate in 340B based on DSH status alone;
- Enhancements to HRSA’s regulatory, enforcement, and data collection capabilities so that the agency can better monitor hospital eligibility, duplicate discounts, and more;
- Targeted additional resources to HRSA to enable them to fully oversee the 340B program, monitor compliance, and enforce sanctions on entities that break the rules;
- Additional reporting from 340B entities to HHS, to clarify who benefits from the program, at what level, and how those trends change over time; and
- A careful study of how large, national contract pharmacies may or may not benefit from the 340B program.

NTU appreciates your commitment to modernizing and reforming the 340B program. We certainly do not believe the above recommendations are an exhaustive list of potential reforms, and we look forward to reading and reviewing the proposals of other stakeholders in the weeks and months ahead. We also look forward to working with you on a potential reform package for lawmakers. Thank you for your consideration of our proposals, and should you have any questions please do not hesitate to contact me at alautz@ntu.org.

Sincerely,

Andrew Lautz
Policy and Government Affairs Manager

¹⁸ Vandervelde, Aaron; Erb, Kevin; Hurley, Lauren. “For-Profit Pharmacy Participation in the 340B Program.” Berkeley Research Group, LLC, October 2020. Retrieved from: https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf (Accessed October 14, 2020.)

¹⁹ 340B Health. “Protect Patients. Stop 340B Cuts!” Retrieved from: <https://www.stop340bcuts.org/> (Accessed October 14, 2020.)