

The 340B Program Was Intended to Help Uninsured and Other Vulnerable Patients, Not For-Profit Pharmacies

- The 340B Program was created by Congress in 1992 to provide discounts on medicines to certain safety net providers that serve vulnerable and other populations.
- There is no statutory or regulatory requirement that covered entities share 340B discounts with patients.
- The Health Resources and Services Administration (HRSA), the federal agency that administers the 340B program, has issued guidance that indicates that covered entities may dispense 340B discounted drugs through contract pharmacies, and in 2010 removed the limitation on the number or reach of such arrangements.
- Since then, the number of contract pharmacies has grown from 193 in 2010 to more than 43,000 as of July 2020.ⁱ
- Over the years, many stakeholders, including the Government Accountability Office (GAO), and the Department of Health and Human Services Office of the Inspector General (OIG), have expressed concerns over the lack of transparency and oversight in the 340B program, including with respect to contract pharmacies.

Use of Contract Pharmacies in the 340B Program Has Grown Exponentially, Despite Providing Little or No Direct Benefit to Patients

- The average distance between a hospital covered entity and its contract pharmacies has grown from 34 miles in 2010 to 334 miles in 2020.ⁱⁱ In fact, some hospitals have as many as 400 contract pharmacies as far as 1,000 miles away.ⁱⁱⁱ
- Those contract pharmacies are dominated by national for-profit chain pharmacies, often integrated with large pharmacy benefit managers (PBMs), accounting for 60% of contract pharmacies though they represent only 35% of all pharmacies.^{iv}
- Notably, a record number of 340B sales was recorded in 2018 (\$24.3 billion), yet that same year the American Hospital Association reported uncompensated care by hospitals decreased by \$8.4 billion.^v

Actions Novartis Is Taking to Preserve the Sustainability of the 340B Program

We are taking a focused approach and establishing common-sense criteria that will help ensure that covered entities are serving the communities they are supposed to serve, consistent with the intent of the program.

- Ryan White clinics, community health centers, and other federal grantee covered entities will continue to receive 340B discounts exactly as they do today, as such grantees are subject to an established regulatory infrastructure that encourages them to share 340B program savings with the vulnerable populations that they serve.
- Our policy will continue to honor hospital contract pharmacy arrangements so long as the contract pharmacy is located within a 40-mile radius of the covered entity hospital, which is consistent with federal policy regarding hospitals and off-site affiliates.

- This policy will not restrict the number of contract pharmacies a hospital may establish within its own community (as defined by the 40-mile radius).
- If there are special circumstances, such as any involving rural hospitals, where a hospital does not have its own pharmacy and is left with no contract pharmacy as a result of this policy, we will work with the affected institution to ensure it has appropriate access to a contract pharmacy.
- We're also working to increase transparency within the program. We encourage all covered entities to voluntarily upload their claims data to the Second Sight Solutions 340B ESP™ platform to increase transparency and mitigate instances of duplicative discounts.

This Policy Will Not Harm Patients Access to Medicines

- Patients of covered entities will still be able to acquire the same medicines from their pharmacy.
- Nothing here impacts the ability of hospitals to share 340B discounts with patients, if they choose to do so.

Reform Is Needed

- Novartis continues to firmly support the intent of the 340B program to serve the uninsured and other vulnerable patients.
- While these actions do not fully resolve all concerns under the current contract pharmacy model, they are important, common-sense steps toward ensuring that the communities served by these covered entity hospitals are the beneficiaries of the 340B program and that the program itself is sustainable.
- We recently responded to the letter^{vi} from House Energy and Commerce Committee Ranking Member Walden (R-OR) and Senate HELP Committee Chairman Alexander (R-TN) with constructive proposals on ways to improve the 340B program.
- We will continue to work alongside all stakeholders to advocate for the transparency, oversight, and accountability reforms necessary for the 340B program to continue its vital mission as intended.

ⁱ Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program," October 2020, https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

ⁱⁱ Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program."

ⁱⁱⁱ GAO, "Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," June 2018, <https://www.gao.gov/assets/700/692697.pdf>.

^{iv} GAO, "Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement."

^v Drug Channels, "EXCLUSIVE: The 340B Program Reached \$19.3 Billion in 2017—As Hospitals' Charity Care Has Dropped," May 2018, <https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html>

^{vi} House Energy and Commerce Committee, "Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program," October 2020, <https://republicans-energycommerce.house.gov/news/walden-and-alexander-ask-for-input-on-modernizing-340b-drug-pricing-program/>.