

340B Federal Policy Recommendation: A Path to Directly Benefit Patients

Under the 340B drug pricing program, pharmaceutical manufacturers participating in Medicaid and Medicare Part B are required to provide reduced pricing on outpatient drugs to eligible hospitals and certain “safety-net” clinics. These providers, also referred to as “covered entities,” can include disproportionate share hospitals (DSHs), critical access hospitals, sole community hospitals, and federal grantees. The 340B program reduces drug costs for these entities, with the expectation that they will use at least a portion of these profits to increase access to affordable medicines for low income and medically underserved patients. However, the program has no requirement that patients directly benefit from reduced 340B prices to decrease what they pay for their medicine.

Since the 1990s, the number of 340B covered entity sites has grown substantially, increasing from approximately 1,000 in 1992 to approximately 60,000 in 2024.¹ Furthermore, the share of pharmacies participating in the program as contract pharmacies has expanded from less than 1% of US pharmacies to over 40% between 2010 and 2022.²

Despite the growth of the program, it does not appear that reduced 340B prices are being used to lower drug costs for patients. A 2020 analysis found outpatient drug spending for commercially insured patients at 340B hospitals was, on average, 150% higher than prescriptions at non-340B hospitals.³ With the vast networks of contract pharmacies dispensing 340B medicines, and covered entities and contract pharmacies at times charging uninsured patients the full cost of the medicine, patients who are meant to benefit from the program may end up bearing much of the cost themselves.

Policy Issue & Proposal: Sliding Fee Scale for Cost Sharing on 340B Medicines

Studies have shown that the prolific growth of the 340B program has not led to a commensurate benefit to patients.^{4,5,6} In fact, evidence suggests the 340B program has led to increased health care costs for patients and the healthcare system as a whole. **A sliding fee scale that would lower the costs of medicines for low income privately insured and uninsured patients receiving care at a 340B covered entity location would help to ensure that many underserved patients directly benefit from this safety net program and better align system-wide incentives.**

To understand the potential savings from a sliding fee scale for patients, the policy contemplated in the 340B ACCESS Act was used to model patient out-of-pocket costs under a sliding fee scale compared to actual median annual spending on medicines among low income privately insured and uninsured patients. The sliding fee scale included in the 340B ACCESS Act for hospital covered entities would eliminate cost sharing on 340B medicines for privately insured and uninsured patients below 100% of the federal poverty level (FPL), limit cost sharing on these medicines for privately insured and uninsured patients between 100% and 199% FPL to the lesser of 20% of their applicable cost-sharing or \$35, and limit cost sharing for uninsured patients at or above 200% FPL to the lesser of 30% of their applicable cost-sharing or \$50.

Results

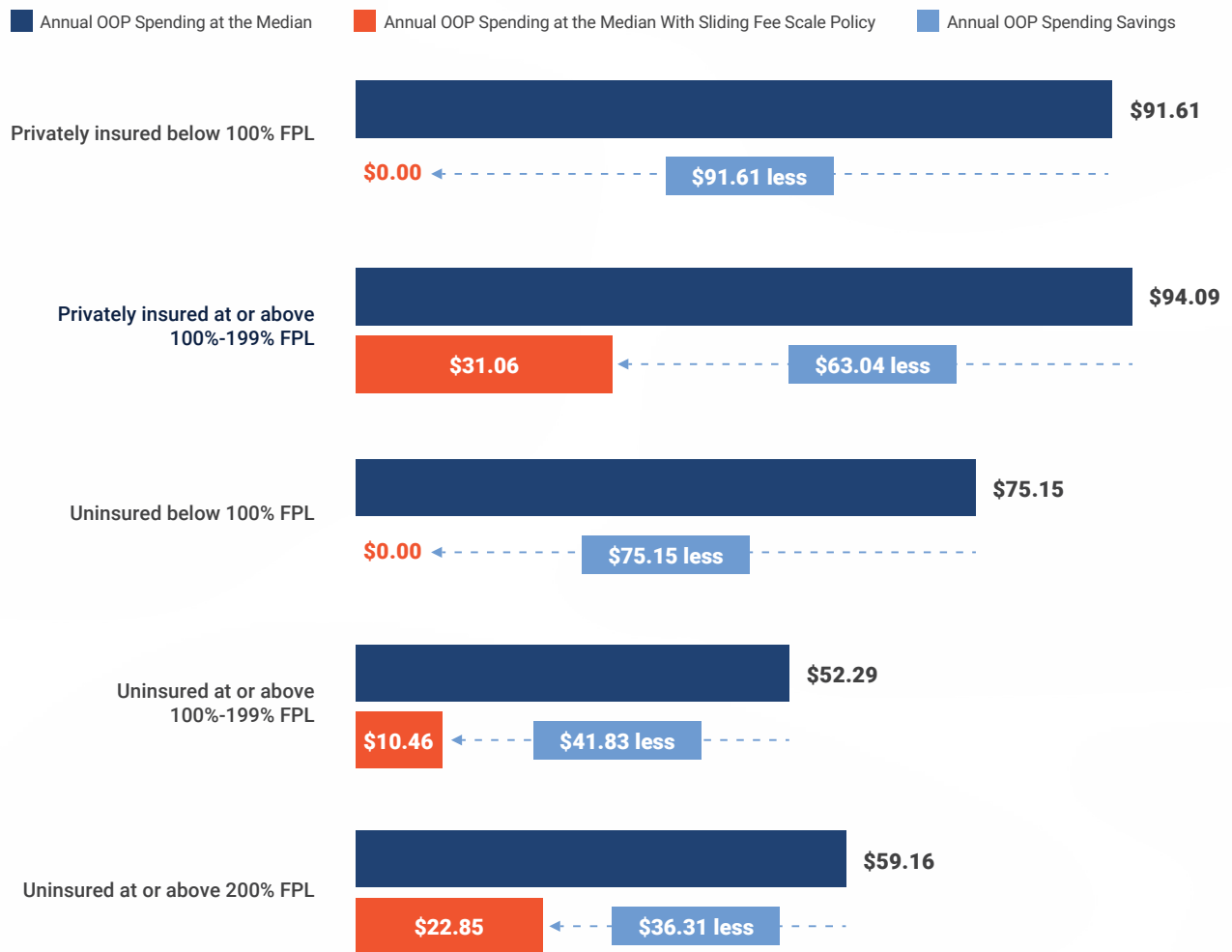
Privately insured patients below 200% FPL and uninsured patients were estimated to have annual median out-of-pocket costs on medicines of \$93.34 and \$59.08, respectively. Had the sliding fee scale been in effect:

- Privately insured patients below 200% FPL would have saved 93.6%, or \$87.39, in annual out-of-pocket spending at the median
- Uninsured patients would have saved 82.3%, or \$48.63, in annual out-of-pocket spending at the median

340B ACCESS Act Sliding Fee Scale Policy for 340B Hospitals:

- Privately insured and uninsured patients <100% FPL: \$0
- Privately insured and uninsured patients ≥100%-199% FPL: lesser of 20% of applicable cost-sharing or \$35
- Uninsured patients ≥200% FPL: lesser of 30% of applicable cost-sharing or \$50

National Savings From 340B ACCESS ACT Sliding Fee Scale Policy for 340B Hospitals



Note: The uninsured analysis using MEPS included prescription claims only. The privately insured analysis using closed claims data included prescription and medical claims in the hospital outpatient setting.

Implementing the sliding fee scale policy included in the 340B ACCESS Act could significantly reduce patient out-of-pocket spending on outpatient drugs subject to 340B program pricing. Significant savings were seen for both low income privately insured and uninsured groups. Variations between groups were driven by a combination of differences in the total number of prescriptions per patient and the types of drugs they most commonly used.

Policy Considerations

Despite significant growth in the 340B program over the last several decades, many uninsured and low income privately insured patients continue to struggle to afford their medicines. Yet, covered entities are not required to use their 340B profits to subsidize patients' out-of-pocket drug costs. As a result, profits generated through the 340B program may be diverted to other priorities by some covered entities. Policymakers should consider legislation that would require 340B covered entities to implement a sliding fee scale for prescription drugs for low income privately insured and uninsured patients. Passing a share of program profits on to vulnerable patients in the form of lower medicine costs would better align incentives in the program and ensure patients seeking care at safety net providers are able to access and afford the medicines they need.

Beyond the implementation of a sliding fee scale, policymakers should consider legislation to require covered entities to spend a minimum portion of their 340B profits on charity care, including providing uncompensated care to underserved patient populations. Use of 340B profits should be more heavily scrutinized by regulators to ensure the benefits of the 340B program are reaching patients most in need.

Methodology

Real-world medical and pharmacy drug utilization data was used to estimate how a 340B sliding fee scale policy could change out-of-pocket costs for low income privately insured and uninsured patients. Patients were grouped based on their income relative to FPL guidelines. For each patient group, out-of-pocket costs under their respective sliding fee scale policy scenario were compared to actual out-of-pocket costs to estimate the impact of the policy on patients. Drug costs were standardized to 2024 dollars using the US Bureau of Labor Statistics' Consumer Price Index for All Urban Customers (CPI-U).

Commercial Data Source

Magnolia Market Access' Data Repository for Innovation and Value Evidence (DRIVE), which includes closed claims and social determinants of health (SDOH) databases. All patients with 12 months of continuous medical and prescription drug coverage in 2022 with claims and SDOH survey data were included in the analysis.

Uninsured Data Source

The Medical Expenditure Panel Survey (MEPS) database's 2021 Full-Year Consolidated Data files and 2021 Prescribed Medicines files.

Limitations

The analysis uses median annual out-of-pocket spending regardless of where a patient filled their prescription. The analysis is not limited to prescriptions eligible for 340B. Rather, the analysis uses overall spending data to estimate the potential savings if a patient were to receive care at a 340B hospital with a sliding fee scale policy in effect.

Privately Insured Analysis Using Closed Claims

This analysis does not account for benefit design parameters for privately insured patients. As such, patients may or may not have reached their maximum out-of-pocket threshold under each proposed policy, which would have an impact on their out-of-pocket costs on a per claim basis and could result in over- or underestimating annual out-of-pocket savings.

Uninsured Analysis Using MEPS Data

The MEPS database does not include physician-administered drug information, and therefore, uninsured patients' out-of-pocket costs for physician-administered drugs are not included in the analysis. The results applied the full-year person-level weights so that the patient counts are nationally representative.

Table 1. Annual Patient OOP per Patient for 340B Eligible Drugs (National, by Insurance Type and FPL Group)

	Median Annual OOP Cost	Median Annual OOP Cost With Sliding Fee Scale Policy	Savings From Sliding Fee Scale Policy (\$)	Savings From Sliding Fee Scale Policy (%)
Privately Insured <100% FPL	\$91.61	\$0.00	-\$91.61	-100.0%
Privately Insured ≥100%-199% FPL	\$94.09	\$31.06	-\$63.04	-67.0%
Uninsured <100% FPL	\$75.15	\$0.00	-\$75.15	-100.0%
Uninsured ≥100%-199% FPL	\$52.29	\$10.46	-\$41.83	-80.0%
Uninsured ≥200% FPL	\$59.16	\$22.85	-\$36.31	-61.4%
Total Privately Insured Patients <200% FPL	\$93.34	\$5.95	-\$87.39	-93.6%
Total Uninsured	\$59.08	\$10.46	-\$48.63	-82.3%

Note: The uninsured analysis using MEPS included prescription claims only. The privately insured analysis using closed claims data included prescription and medical claims in the hospital outpatient setting.

Table 2. Annual Patient OOP per Patient for 340B Eligible Drugs (by US Region and Insurance Type)

	Privately Insured Patients <200% FPL				Uninsured Patients <200% FPL			
	Median Annual OOP Cost	Median Annual OOP Cost With Sliding Fee Scale Policy	Savings From Sliding Fee Scale Policy (\$)	Savings From Sliding Fee Scale Policy (%)	Median Annual OOP Cost	Median Annual OOP Cost With Sliding Fee Scale Policy	Savings From Sliding Fee Scale Policy (\$)	Savings From Sliding Fee Scale Policy (%)
Northeast	\$83.42	\$9.00	-\$74.42	-89.2%	\$22.69	\$3.00	-\$19.69	-86.8%
Midwest	\$99.10	\$9.00	-\$90.10	-90.9%	\$91.38	\$3.00	-\$88.38	-96.7%
South	\$108.37	\$6.00	-\$102.37	-94.5%	\$60.62	\$3.00	-\$57.62	-95.1%
West	\$74.99	\$6.00	-\$68.99	-92.0%	\$40.45	\$3.00	-\$37.45	-92.6%
Total Patients	\$93.34	\$6.00	-\$87.34	-93.6%	\$56.70	\$3.00	-\$53.70	-94.7%

Note: The uninsured analysis using MEPS included prescription claims only. The privately insured analysis using closed claims data included prescription and medical claims in the hospital outpatient setting.



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