

24 Aug 2022 | Analysis

340B Contract Pharmacy Restrictions Slowed Program's 2021 Spending Trajectory, But Not Much

by Cathy Kelly

Manufacturer restrictions on discounts to contract pharmacies may have depressed sales for 340B-discounted diabetes drugs in 2021. But sales in other categories, including oncology, immunology and arthritis drugs, were up by 20% to 40%.

Health care provider expenditures on discounted outpatient drugs purchased under the 340B program reached \$43.9bn in 2021, up 15.6% from the year before, according to the US Health Resources and Services Administration.

The vast majority of the spending, \$34.3bn, was by hospitals, HRSA reports. The data was confirmed by HRSA after it was first reported by Drug Channels Institute CEO and consultant Adam Fein, who obtained the figures through a Freedom of Information Act request. HRSA does not generally release spending data from the program to the public.

The 15.6% increase demonstrates the continued rapid expansion of the program, which is intended to provide Medicaid-level discounts to safety net hospitals and other providers serving needy patients. The program has ballooned over the years and now is larger than Medicaid and second only to Medicare Part D in terms of drug spending.

“The 340B Drug Pricing Program is now unambiguously the second-largest government pharmaceutical program, based on net drug spending,” Fein said in a [15 August post](#) on his Drug Channels blog. “But unlike such programs as Medicare Part D and Medicaid, 340B lacks a regulatory infrastructure, well-developed administrative controls, and clear legislation to guide the program.”

The biggest discounts available in Medicaid (and in 340B) come from drugs with significant price increases over the years because of the inflation penalty rebate. In fact, a number of blockbuster drugs are so heavily rebated because of the inflation penalty that they are available to providers for pennies. [AbbVie Inc.](#)'s Humira and [Amgen, Inc.](#)'s Enbrel are two prominent examples.

Sales of 340B-discounted diabetes drugs fell 7.4% in 2021 compared to 22% growth in 2020, "due in large part to contract pharmacy restrictions," IQVIA said.

While significant, the 15.6% increase in 340B spending represents a slow-down in growth compared to previous years. (See box.) That likely reflects moves by a number of major manufacturers to restrict 340B discounts to multiple pharmacies dispensing drugs under contract with providers, which began in the fall of 2020.

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In 2021, six drug companies had restrictions on 340B discounts for contract pharmacies in place for the whole year and three more added restrictions late in the year. Nine manufacturers have added restrictions in 2022 for a current total of 18. (See list below.) (Also see "[340B Snapshot: Janssen's Discounts In US Program Have Risen 220% Over Past Five Years](#)" - Pink Sheet, 18 Apr, 2022.)

So far HRSA has sided with 340B providers in the controversy over contract pharmacy restrictions and has threatened manufacturers with enforcement action and civil monetary penalties. (Also see "[US 340B Discount Restrictions By Pharma: HRSA Will Continue To 'Walk The Walk' In Opposition](#)" - Pink Sheet, 2 Aug, 2022.)

Several lawsuits over the issue are underway, but so far decisions have been mixed. (Also see "[340B Court Ruling Offers Manufacturers Short-Term Reprieve In Contract Pharmacy Dispute](#)" - Pink Sheet, 3 Nov, 2021.)

A recent analysis by IQVIA found that 340B sales for specialty drugs including targeted oncology, immunology and anti-arthritis agents continued to increase at rates of 20% to 40% in 2021. However, diabetes drugs showed a reverse trend, falling 7.4% in 2021 compared to 22% growth in 2020, "due in large part to contract pharmacy restrictions," IQVIA said.

Diabetes drugs were “disproportionately” impacted by those restrictions because more than half of 340B sales for some of the largest diabetes products “were penny priced, and their manufacturers were among the first to implement contract pharmacy restrictions,” IQVIA explained. (Also see "[Pharma Manufacturers Mobilize Against 340B Discounts At Contract Pharmacies](#)" - Pink Sheet, 20 Aug, 2020.) Penny priced drugs offer a larger potential margin between what a provider pays and what they get in reimbursement payments.

340B Drug Sales Through Pharmacy Chains Fell 5%

Retail and mail sales of 340B-discounted drugs marketed by the nine manufacturers who had contract pharmacy restrictions in place for some or all of 2021 fell 32% and 20%, respectively, [IQVIA found](#). In contrast, sales in those channels of 340B drugs for all other manufacturers rose 16% and 44%, respectively. Sales of 340B drugs through pharmacy chains fell 5%.

340B sales in the hospital and clinic channels were similar for manufacturers with and without restrictions in place. However, 340B sales in the mass merchandiser channel fell 60% for manufacturers with restrictions in 2021, “which explains in part why this same channel was down 30% for 340B sales overall,” IQVIA said.

High Drug Prices Contributing To Growth, Provider Group Maintains

Critics of the 340B program claim that lax government oversight has allowed hospitals and major retail chains to inappropriately cash in on the lucrative margins available under the program. In a statement on the 2021 data, the Pharmaceutical Research and Manufacturers of America said, “It is of no surprise that the 340B program grew yet again in 2021, and disappointingly, this growth doesn’t mean more patients are benefiting from the program.”

Without “proper program oversight and accountability measures, we are concerned hospitals, pharmacies, [pharmacy benefit managers], and insurers, among others, will increase their bottom lines instead of helping patients affordably access medicines,” the group continued.

“If 340B dollars were always being used to help vulnerable patients and communities, this growth wouldn’t be cause for alarm – but that isn’t the case,” PhRMA said. “Policymakers need to revisit this program before it engulfs the entire pharmaceutical market, further driving up costs for all Americans.”

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But hospitals push back on those assertions. “Sales of 340B drugs are affected by a number of factors including the very high prices set for new drugs on the market, increases in prices for existing drugs beyond inflation, and the continued shift of care from the inpatient to the outpatient setting,” a spokesperson for the advocacy organization 340B Health told the *Pink*

Sheet.

“The other thing to be aware of is the amount of sales does not reflect the size of 340B. Those are the dollars drug companies are being paid,” the spokesperson pointed out. “The discounts are a smaller percentage of that total.”