Weekly Checkup

Let's Address the 340B Elephant in the Room

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The 340B Drug Pricing Program, administered by the Department of Health and Human Services' Health Resources and Services Administration (HRSA), is designed to support certain providers by enabling them to purchase outpatient medications at significantly reduced prices to "stretch scarce federal resources." **The program aims to ensure these providers, known as covered entities (CEs), can access pharmaceuticals meant for vulnerable populations. This is not always how the program operates, however.** Because it lacks transparency and accountability measures, CEs can theoretically use these funds for anything, creating a tax-advantaged account to leverage. **Recent policy developments and energetic moves by industry have made it an opportune time to revisit this issue.**

First, a brief primer on how the 340B Program is structured. Manufacturers, as a condition of participating in other government-funded health programs, must provide discounts on drugs sold to CEs for drugs they dispense, ranging from 25 to 50 percent. CEs can then either dispense these medications themselves at in-house pharmacies or contract with external pharmacies to dispense them – by either giving or selling them to patients – and the CEs recoup their spending. Simple, right? Wrong. **The cost savings realized from 340B pricing are *intended* to be directly reinvested in patient care. But there aren't guardrails on this program.** Many hospitals, rather than reinvesting money generated from 340B discounts on patient care, use the money to sustain their operations.

The 340B Program faces deserved scrutiny – particularly as other sweeping changes in health care finance are enacted to impact various forms of prescription drug spending. Issues with transparency, accountability, and eligibility have dogged the program in recent years, especially as its related spending has grown exponentially, as documented in the chart below. In large part, due to several compounding factors including

the expansion of covered entities, new participants in Medicare and Medicaid, and a pronounced shift to outpatient care, **growth in the program has far outstripped other prescription drug spending.**

This is an un-budgeted, off-the-books style program, mandating that certain companies sell their goods for one price and allowing other companies to resell them for whatever price fits their needs. **The ability to leverage** spread pricing (a practice that drives industry crazy when pharmacy benefit managers do it), **the massively** inefficient wealth transfer between taxable and non-taxable groups**, and the lack of price transparency and auditing opportunities by various members of the 340B relationship create a black hole of a program.**

Various attempts to reform the 340B Program have been lackluster, piecemeal, or both. Individual states have led legislative efforts aimed at prohibiting manufacturers from limiting 340B discounts through contract pharmacy arrangements. HRSA has issued rules attempting to streamline the dispute resolution process and increase program accountability, but they have failed to address the program's structural concerns. While there have been a handful of bipartisan congressional efforts at reform, none has seen floor action.

As the 340B Program's problems continue bubbling to the surface, there is reason to believe there will be increased pressure to address them. HRSA's new administrator Tom Engels, who is familiar with the agency having already led it once, is primed to tackle improvements in the program focusing on transparency and accountability. Moreover, Senator Bill Cassidy (R-LA), now chair of the Senate Committee on Health, Education, Labor, and Pensions, intends to introduce legislation directly addressing the misuse of savings from the program, which would create opportunities for a reimagination of the current rebate model and develop one with more equity and accountability. Finally, ongoing court action has created opportunities for a reimagination of the current rebate model and develop one with more equity and accountability.

With various parts of the ecosystem aligning at the right time, some optimism for finally reforming the 340B Programs may be warranted. Of course, as with anything in health policy, nothing is done until it's done. Simultaneous reforms to the vast health care world always introduce uncertainty, and given the list of reforms working their way around town, the 340B Program might lose out to other issues. **But the second largest federal drug program by spending deserves the attention its market share commands.**

340B PROGRAM CONTINUES TO OUTPACE MEDICAID DRUG SPENDING

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Growth in the 340B Program has accelerated rapidly in recent years, raising concerns about the scope of the program and if its participants, known as covered entities, are taking advantage of the program for financial gain. Measuring the growth of 340B drug purchases in relation to Medicaid drug rebate spending provides crucial context to the evaluation of 340B policy, as both programs aim to serve uninsured or underinsured communities.

In 2023, covered entities purchased $66.3 billion in prescription drugs, which amounts to 15 percent of the entire national health expenditure on prescription drugs. By purchasing volume, 340B is the second largest federal prescription drug program in the United States.

As the chart below shows, covered entity purchases of prescription drugs are expanding at a far greater rate than the net expenditures of the Medicaid Drug Rebate Program. With covered entities receiving discounts on prescription drugs greater than or equal to what Medicaid can receive in rebates, it is raises the question of why covered entities are outspending Medicaid on the same drugs with approximately the same utilization.

