## Weekly Checkup

# He’s a Growing (340B)oy

**JOHN WALKER | MAY 24, 2024**

**Earlier this month, IQVIA released its yearly study of the size and growth rates of the 340B Drug Pricing Program across 2023. The findings were troubling.** Growing at a cumulative 129.4 percent in the past five years and reaching a year-end total of $124 billion in wholesale acquisition cost sales for 2023, the 340B program continues to expand at an unmanageable rate. **Let’s dive into the study to better understand the 340B Program and how its longstanding issues with transparency, eligibility, and enforcement put the program on the wrong path.**

As a quick refresher, 340B is a federal program that was created in 1992 in response to the faulty best price calculation originally implemented in the Medicaid Drug Rebate Program. Under 340B, manufacturers must provide discounts on outpatient drugs to eligible health care providers, which may then resell the drugs to patients or be reimbursed by payers at higher rates, in theory creating a revenue stream for charity care. IQVIA’s research provides a deeper dive into 340B, focusing on its growth across a variety of disease areas and the larger impacts of manufacture contract pharmacy restrictions. **The key takeaway from the study is that even when manufacturing restrictions force 340B-covered medication sales back into the hands of hospitals and clinics, and away from larger distribution networks such as retail and mail pharmacies, 340B drug sales continue to grow, with the 340B program experiencing roughly 16.5 percent year-over-year growth in 2023**. Considering pharmacy restrictions are implemented with the intention of cooling 340B drug sales, this increase in growth signals that current regulatory controls are no longer sufficient to effectively manage the program.

**Due to a lack of detail in its original statute, the 340B program has three critical problems, which will only continue to worsen as the program grows.** First, hospitals are not required to publicly disclose where their 340B savings are being used or even pass on the savings directly to qualifying patients. Second, current eligibility requirements produce gross misclassification of who is an eligible patient, while also allowing for

considerably more drugs to be obtained at a discount than originally intended. Third, due to a lack of funding, staff, and minimal enforcement mechanisms for violations, the Health Resources and Services Administration (HRSA) is unable to reasonably enforce the rules of 340B.

**While the 340B program may have been authored with good intentions, its execution was wrought with transparency, eligibility, and enforcement issues.** As it continues to grow, with states litigating away contract pharmacy restrictions and the courts removing more of HRSA's dwindling authority to enforce the program's provisions, these larger issues will only become more apparent, stressing 340B's already unstable construction to its breaking point. As my Weekly Checkup predecessor put it, "Congress has only just begun working on it, so there is much more to be done."