Ryan White Clinics for 340B Access

Retrospective 340B Determinations by Manufacturers Threaten Ryan White Clinics

A Pharma Tactic to Shrink the 340B Program

Drug manufacturers including Johnson & Johnson, Bristol Myers Squibb, Eli Lilly, and Sanofi, and the information technology company Kalderos, are advancing unilateral policies to require 340B entities, including Ryan White Clinics, to obtain 340B discounts via a rebate model – a dangerous idea that will devastate the 340B safety net.

Imposing a rebate model means that manufacturers have **exclusive power** to determine whether a covered entity qualifies for a 340B discount and **delays** the 340B discount to after the point of sale. This action will result in **fewer discounts**, **increased administrative costs**, and **less resources** for covered entities to provide care to their patients.

THE MECHANICS OF 340B SAVINGS: UPFRONT VS REBATE DISCOUNTS

UPFRONT DISCOUNT

1. Patient of covered entity (CE) fills a prescription at an in-house or contract pharmacy.
2. CE receives drug from manufacturer/wholesaler **at discounted 340B price.**
3. CE bills patient's insurance (if applicable) at usual/negotiated rate.
4. Drug is dispensed to patient at in-house or contract pharmacy.
5. **CE receives the statutory set price, difference in price is the "340B savings."**
6. **340B savings is immediately available to CE to provide patient discounts or wrap-around services and supports.**

REBATE MODEL

1. Patient of covered entity (CE) fills a prescription at an in-house or contract pharmacy.
2. CE is **charged the full commercial price for the drug.**
3. CE bills patient's insurance (if applicable) at usual/negotiated rate.
4. Drug is dispensed to patient at in-house or contract pharmacy.
5. **CE must request a rebate from manufacturer.**
6. **Manufacturer has discretion to determine whether the CE is "eligible" for the rebate.**
7. **IF manufacturer deems the CE eligible, manufacturer will issue a rebate of the difference between the commercial price and the discounted 340B price.**
8. **CE receives 340B savings at an undetermined time, long after the drug was dispensed to patient.**

REBATE MODELS ARE HARMFUL TO PUBLIC HEALTH BECAUSE THEY. . .

Delay Access to Discounts and Care

- **Delay the 340B discount** from the point of sale when the patient picks up the prescription at the pharmacy counter to an undermined point of time at the manufacturer's discretion.
- ***Strip covered entities' immediate access to lower cost medications*** *which can be passed on to patients at the point of sale when they need it most*

Usurp HRSA Authority, Give Exclusive Power to Drug Makers

- **Give drug manufacturers the exclusive power** to decide IF it will provide a covered entity a 340B discount contrary to the 340B statute, that gives discretion to the Secretary of Health and Human Services, not manufacturers.
- ***Force covered entities to will bear the burden*** *of filing a petition for denied savings through the often costly and time-extensive administrative dispute resolution process.*

Increase Administrative Costs, Divert Covered Entity Resources

- **Force covered entities to invest time, money and energy** into designing, implementing and managing a system to track rebate requests at a time when they already face significant funding and budgetary pressures.
- ***Disproportionately harm small and under-resourced RWCs*** *that do not have the funds to absorb increased cash flow and budgetary demands. The high cost of HIV medications will make cash flow difficulties particularly severe for RWCs.*

Reduce Patient Pricing Transparency

- **Financially harm covered entities** because will lack the cash flow to offer discounts at the point of sale and will instead have to devise a way of adjusting patient charges retroactively.
- ***Make reduced pricing less transparent*** *to patients and makes patient financial relief contingent on the ability of the covered entity to collect rebates.*

Increase Costs for State Medicaid Programs

- **Force many covered entities to "carve out" all Medicaid claims** from the 340B program due to increased administrative burdens.
- ***Increase rebates that states must request*** *under the Medicaid Drug Rebate Program, increasing state pharmacy costs.*

Undermine Progress in Controlling AIDS Epidemic

- **Undermine RWC progress in controlling the AIDS epidemic**.
- ***Reduce 340B program savings and income*** *that RWCs rely on to provide comprehensive HIV care, much of which is not covered by insurance.*

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