TOOLKIT

340B Rebate Models — A Guide for Covered Entities and Advocates

Overview

Increasingly, drug manufacturers are advancing unilateral policies to require 340B entities to obtain 340B discounts via a rebate model. Rebate models give manufacturers exclusive power to determine whether a covered entity qualifies for a 340B discount and delays the 340B discount to after the point of sale.

The 340B Drug Pricing Program was created by Congress to enable safety-net providers – known as covered entities – to stretch scarce federal resources, expand services, and improve access to care for vulnerable and underserved patients. For decades, the 340B program has been a lifeline for rural hospitals, community health centers, and clinics serving those most in need.

Allowing manufacturers to impose rebate models – no matter how limited, time-boxed, or vendor-managed – shifts risk and cost onto the safety net, diverts resources from patient care, and contradicts the purpose and function of the 340B drug discount program – for the sole benefit of drug company profits.

This toolkit includes the following:

- An analysis of rebate models and their impact on 340B and patient care
- Action items for advocacy and engagement
- Sample talking points for advocacy and public engagement

Analysis

Threat to Patient Access and Public Health

Rebate models will directly harm patients and undermine public health by stripping away the immediate access to lower-cost medications that covered entities currently provide at the pharmacy counter. Further, covered entities use 340B savings to provide comprehensive care outside of simply a prescription.

Instead of offering discounts at the point of sale, providers would be forced to wait for rebates and then devise complicated retroactive adjustments, making discounts less transparent and harder for patients to access. This delay leaves patients and safety net providers at the mercy of manufacturers to choose when and if to reimburse, leaving vulnerable patients exposed to higher out-of-pocket costs when they need care most. Rebate models reduce the savings that rural and

safety-net providers rely on to serve uninsured and underinsured patients, draining resources from the very programs designed to protect community health. The result is a system that prioritizes manufacturer control over patient needs, causing real financial harm and threats to public health in communities least able to bear it.

Concentration of Power in Manufacturers' Hands

Imposing a rebate model gives manufacturers exclusive power to determine whether a covered entity qualifies for a 340B discount and delays those discounts until after the point of sale. This model will reduce discounts, raise administrative costs, and deplete resources for providers to care for their patients. Safety net providers would face denied discounts and be forced into costly, time-consuming dispute resolution. This shift also opens the door to discriminatory reimbursement, as manufacturers control terms, timelines, and data access, using discounts as leverage. Ultimately, it allows some of the wealthiest corporations in the world to dictate access to 340B savings, putting safety-net providers and the communities they serve at serious financial risk and harm to public safety and health.

Administrative Burden

Rebate models create heavy new administrative burdens for the stretched thin healthcare workforce. Drug companies have spent years restricting contract pharmacy arrangements, forcing providers to spend scarce time and resources just to maintain access to 340B discounts. Many now also require use of 340B ESP, a manufacturer-run platform riddled with technical problems, inaccurate data, and long delays, which only adds to providers' workloads and slows access to lawful savings. Rebate models would exacerbate these same problems, requiring entities to manage yet another system just to receive benefits guaranteed by law – pulling resources away from patients and undermining the core purpose of the 340B program.

Cash Flow Delays

Rebate structures create dangerous cash flow risks for covered entities, especially in rural and underserved communities. Providers may be required to wait weeks or months for payment on drugs they've already purchased and dispensed, tying up enormous sums – particularly for high-cost drugs. This delay forces safety-net providers to shoulder the cost, threatening their ability to stock needed medicines, meet payroll, and sustain patient care. Meanwhile, manufacturers hold on to funds that rightfully belong to providers, effectively profiting at the expense of the safety net.

Data Privacy & Security Risks

Rebate models often require covered entities to submit patient-level prescription data to manufacturer-run platforms, raising serious concerns about privacy, HIPAA compliance, and the misuse of protected health information. Providers have already seen the risks of this data collection through systems like 340B ESP, which suffer from unclear security safeguards, serious data errors, and burdensome processes. Handing sensitive claims data to manufacturers or their vendors increases the risk of breaches and gives drug companies access to prescribing patterns and patient populations – information that could be used to impose new restrictions or disadvantage safety-net providers. Without strict safeguards, these models put patient privacy and provider security at risk while offering little real benefit.

Attempts to soften rebate models with "guardrails" do not solve the models' core problems. Some models attempt to soften the inherent harm through limits on the drug list, promises of faster processing times, choices in hosting platforms, giving interim payments, or starting as voluntary models. A rebate model—by design—delays value, increases overhead, and compromises privacy.

Action Items

To help protect 340B and ensure patients continue to receive affordable and comprehensive care, covered entities and stakeholders can take the following actions:

1. **Submit Comments** – Provide formal feedback during regulatory or public comment periods on proposed rebate models.
2. **Engage Policymakers** – Meet with local, state, and federal representatives to share concerns about how rebate models impact patient access, safety-net providers, and public health.
3. **Educate Your Team** – Train staff and leadership on the implications of rebate models, so everyone can advocate effectively and understand operational risks.
4. **Join Advocacy Networks** – Participate in regional or national groups like CV340B to stay informed, coordinate advocacy efforts, and amplify your voice.
5. **Share Patient Impact Stories** – Collect and communicate real-world examples of how rebate models could affect patient care, particularly for rural and underserved communities.

6. **Engage the Press** – Draft press releases, pitch stories to local media, and provide interviews to raise awareness about the risks of rebate models in your community. Use clear, straightforward language, include a strong headline and key quotes from local advocates or providers, highlight patient impact and financial challenges, provide contact info for reporters to follow up.
7. **Leverage Social Media** – Use platforms like X (formerly Twitter), Facebook, and LinkedIn to share news, comment on developments, and amplify key messages using hashtags like #Defend340B or #Reject340BRebates.
8. **Monitor and Track Policy Developments** – Keep up to date with legislation, regulatory proposals, and manufacturer practices to respond quickly and strategically.

Sample Talking Points

Use these talking points to clearly communicate the risks of rebate models, highlight patient and community impacts, and make a persuasive case to policymakers and stakeholders – but the most important thing is to share your story and speak from your experience."

My name is [your name], and I am a [role: patient/provider/community member/etc.] in [city/state].

I am deeply concerned about rebate models in the 340B program because they will:

- Strip away immediate patient access to lower-cost medications at the pharmacy counter.
- Impede safety net providers' ability to provide comprehensive care to patients in need.
- Threaten efforts to protect public health, prevent disease prevention and transmission, improve nutrition, engage and keep people in care.
- Increase administrative burdens and divert staff time away from patient care.
- Delay or reduce 340B savings, threatening the financial stability of safety-net providers.
- Create serious cash flow risks, forcing providers to pay for expensive drugs upfront.
- Require submission of patient-level data to manufacturer platforms, raising privacy and HIPAA concerns.
- Make patient financial relief contingent on manufacturer reimbursement.
- Concentrate power in the hands of manufacturers, undermining the statutory intent of the 340B Program.
- Open the door to discriminatory reimbursement against covered entities.

- Disproportionately harm rural and underserved communities, reducing funding for programs that serve uninsured and underinsured patients.
- Undermine timely, affordable access to care for the most vulnerable patients.

In my community, 340B savings help fund [specific program/service]. If these savings are reduced or delayed, [describe harm: *e.g.* reduced medication access, closure of community programs, fewer appointments, etc.].

I urge policymakers to reject rebate models and protect the intent of the 340B program: ensuring access to care for the most vulnerable patients.