Ryan White Clinics 340B for 340B Access

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RWC-340B – Who We Are and Our Patient-Centric Mission

RWC-340B Overview

Ryan White Clinics for 340B Access (RWC-340B) is a national association of HIV/AIDS health care clinics and providers serving on the frontlines of the HIV/AIDS epidemic. Our members receive funding under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which provides support for entities that primarily render services to low-income, underinsured, and/or uninsured people living with HIV/AIDS. Because they receive these grants, Ryan White providers are eligible to participate in the federal 340B drug pricing program (340B program).

340B Works, As Intended

Under the 340B program, safety net providers like Ryan White clinics purchase drugs at discounted prices, dispense or administer those drugs to their patients, and, if the patient has insurance, bill the payer for the drugs. Because the drugs cost less through the 340B program than they would otherwise cost, Ryan White clinics are able to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

Comprehensive Services Are Key

The comprehensive services that Ryan White clinics provide range from free or discounted medications to critical wrap-around support services for people living with HIV including case management, dental and behavioral health, and housing assistance. Because Ryan White clinics often receive no insurance payments for these services, they depend on the 340B program to underwrite the cost of providing this care to their patients. Importantly, the 340B program allows Ryan White clinics to provide these expanded services without any cost to taxpayers. RWC-340B strongly opposes any attempts to restrict the reach of the 340B program. The 340B program enables Ryan White clinics to maximize their resources to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression.

340B Drives Viral Suppression, Integral in Fight to End HIV

Data shows Ryan White clinics are extremely successful in helping patients achieve sufficient viral suppression so that they cannot transmit HIV. In fact, in 2021, 89.7% of Ryan White clinic clients receiving HIV care were virally suppressed, exceeding the national average of 66%. The clinics' higher rate of success is directly attributable to their participation in the 340B program. RWC-340B is committed to protecting the 340B program so that its members may continue to provide life-saving treatments to those who need it most. The 340B program is essential to RWC-340B's mission of caring for low-income and vulnerable patients living with HIV/AIDS and ending the transmission of HIV.

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Discriminatory Practices Undermine the Healthcare Safety Net

PBMs/Other Payers Discriminating Against 340B Safety Net

Increasingly, pharmacy benefit managers (PBMs) and other third-party payers are usurping the benefit of the 340B drug discount program. They do so by offering Ryan White clinics and other 340B covered entities lower reimbursement rates on drugs than those offered to non-340B entities or forcing health care providers to use only selected (and sometimes financially tied) pharmacies. These discriminatory practices are a direct attack on the 340B program because they take the benefit of the 340B program from covered entities for the financial benefit of PBMs and private insurers.

Discriminatory reimbursement undermines and contradicts the purpose of the 340B program. The 340B program's drug discounts are intended to provide safety net providers with additional financial resources to deliver more comprehensive services to more patients, without increasing the federal budget. The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program. The 340B program was not enacted to benefit private insurers and PBMs, especially those that are for-profit. This usurping of 340B savings to communities will mean new costs to state and federal taxpayers.

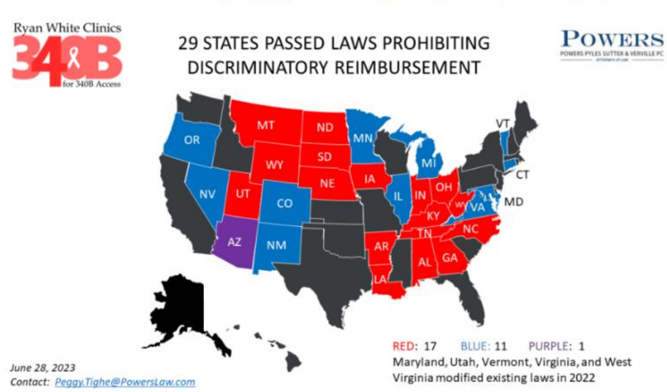
Harm to Patients

Ultimately, discriminatory reimbursement harms the low-income and medically vulnerable patients that 340B providers serve. Health care providers in the 340B program use 340B savings in numerous ways to benefit the patients they serve, including offsetting losses incurred from treating some patients, maintaining existing pharmaceutical and clinical services, lowering drug costs for low-income patients, serving more patients, and providing new services – such as patient outreach and housing and food assistance – to facilitate access to appropriate care.

States Leading the Way

PBMs must be prohibited from making reduced payments for 340B drugs and other discriminatory practices that result in siphoning off necessary 340B savings. At least twenty-nine states have enacted laws that protect 340B covered entities from discriminatory payer practices. At the federal level, the PROTECT 340B Act of 2023, H.R. 2534 (the "PROTECT Act") would prohibit discriminatory reimbursement, along with other PBM predatory contracting practices. Passage of the PROTECT Act is urgently needed to protect the 340B program and its participants.

State Laws Prohibiting Discriminatory Reimbursement



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340B Program Intent

Congressional Intent: Clear and Effective

The 340B program is a carefully constructed policy solution to the high cost of drugs for clinics and hospitals that, due to their mission of serving any patient regardless of ability to pay, are highly dependent on taxpayer support. Congress specifically identified these safety net providers in the statute, called "covered entities," and required drug manufacturers to give them deep discounts on outpatient drugs as a condition of Medicaid and Medicare Part B covering such drugs. Access to the discounts means that covered entities lose less money on dispensing or administering drugs to uninsured or underinsured patients and make more money on fully insured patients. The net financial benefit, according to the program's legislative history, "enables *covered entities* to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992) (emphasis added).

340B Serves Public Health

Congress was wise in realizing that the best way to support underserved and medically vulnerable patients was to provide more resources to the safety net clinics and hospitals that are on the front lines of caring for these individuals, at no cost to taxpayers. Since 1992, the 340B program has served as a critical component of this nation's public health infrastructure. In many communities – particularly low-income areas – safety net providers and the contract pharmacies upon which they rely for dispensing medications offer the only viable pathway to affordable health care for underserved populations. Most covered entities provide medications to needy patients at little or no cost, often below the 340B acquisition cost. But using the program for the sole purpose of lowering patient drug costs would do a grave injustice to patients. The high cost of drugs is just one of many obstacles vulnerable patients face in accessing clinically appropriate health care. The 340B program allows safety net providers to use drug savings to address and mitigate multiple barriers to care that are unique to their patients and communities.

Revising Program Intent Would Take Away Community Control

Restructuring the 340B program as merely a patient drug assistance program would deprive safety net providers of program savings needed to provide more comprehensive care to vulnerable patients, shifting the burden of uncompensated care back to taxpayers. Congress must continue to allow safety net providers to determine the most effective use of their 340B program savings so that they can address their local communities' unique needs, rather than turning the 340B program into a federally determined, one-size-fits-all patient assistance program.

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Contract Pharmacy Arrangements Are Critical to the 340B Safety Net

Contract Pharmacies = Improved Access to Medications

Many 340B clinics and hospitals do not operate their own outpatient pharmacies. For these providers, contract pharmacy arrangements are the only way they can fill their patients' prescriptions with 340B drugs. Many Ryan White clinics are among the safety net providers unable to fill prescriptions for their patients without "expend[ing] precious resources to develop their own in-house pharmacies."[1] Recognizing this fundamental barrier to 340B participation, the Health Resources and Services Administration (HRSA), which is the federal agency charged with administering the 340B program, issued guidance reminding 340B providers of their right under state law to dispense 340B drugs through an agent, in this case an independent pharmacy under contract with the provider to receive, dispense and bill 340B drugs on the provider's behalf. The pharmacy receives 340B drugs through a bill to/ship to arrangement, collects reimbursement for the drugs from the patient's third-party payer (if any) and remits the collected reimbursement to the covered entity. The covered entity, in turn, pays the pharmacy a fee for dispensing and billing services. Every administration, Republican and Democrat, has consistently interpreted the 340B statute as allowing contract pharmacy arrangements.

Contract Pharmacy and HIV

The ability to access 340B drugs through contract pharmacies is especially important for persons living with HIV/AIDS. The preparation, dispensing and management of antiretroviral medications and other HIV-related drugs often requires special expertise and support that Ryan White clinics can only offer through contract pharmacy arrangements. By partnering with contract pharmacies, Ryan White clinics can augment important social work and linkage services that ensure that people living with HIV are able to access and stay in care.

Manufacturers Unilaterally and Illegally Changed the Rules

For approximately 26 years, every drug manufacturer participating in the 340B program honored contract pharmacy arrangements. That practice changed abruptly in July 2020, when manufacturers began to significantly restrict distribution of 340B drugs ordered through contract pharmacy arrangements. These unilateral and unlawful policies are dramatically reducing resources available to safety net providers and harming their ability to meet the needs of vulnerable patients, only to boost manufacturer profits. Two states – Arkansas and Louisiana – recently enacted laws prohibiting drug manufacturers from restricting access to contract pharmacies, but covered entities in the rest of the country enjoy no such protection.[2] RWC-340B actively advocates to protect these state laws and for Congress to recognize covered entities' right to use contract pharmacy arrangements.

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[1] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

[2] Ark. Code Ann. § 23-92-604(c); La. Stat. Ann. § 40:2884.

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Drug Shortages Are the Result of Manufacturer Actions

No Link Between Drug Shortages and 340B Program
The root causes of drug shortages are almost always driven by manufacturer conduct. While the 340B program is a small percentage of drug spend in the United States, 340B program critics allege – with little to no supporting evidence – that 340B is a cause. The FDA found three primary causes for drug shortages, none of which involve 340B: 1) inadequate incentives for manufacturers to produce more affordable drugs; 2) no market reward for manufacturers that implement systems focused on early detection of supply chain issues; and 3) regulatory and logistical challenges that impede the market's ability to recover from a disruption.[3] Further, to the American Society of Health System Pharmacists (ASHP) found no link between 340B and drug shortages.

Penny Pricing Is Not the Cause of Drug Shortages
The 340B statute imposes an inflationary penalty on manufacturers that raise the price of their drugs faster than the rate of inflation. The amount by which the drug's average price exceeds the inflation rate is deducted from the 340B ceiling price. Sometimes manufacturers raise prices so quickly that the inflationary penalty drives the 340B price to a zero or near-zero price. In that case, manufacturers are directed to charge no more than a penny for the 340B drug. Critics allege that penny pricing contributes to drug shortages as a result of "potential stockpiling" by covered entities, a position that the Health Resources and Services Administration has unequivocally refuted.[4] If ANY pharmacy orders excess stock, it is only AFTER there's a shortage, and it's due an attempt to ensure an uninterrupted supply, and not by the purchase price. More importantly, manufacturers can avoid penny pricing by simply exercising greater restraint when raising their prices.

Drug Shortages Threaten HIV Care/Narrowing 340B Eligibility Is the Wrong Answer
RWC-340B is bracing for imminent drug shortages caused by recent decisions by manufacturers to discontinue certain drugs. For example, a lead manufacturer of HIV/AIDS drugs announced that several treatment options will be discontinued at the end of 2023: formulations of Epzicom (abacavir sulfate, lamivudine), Lexiva (fosamprenavir calcium), Selzentry (maraviroc), Tivicay (dolutegravir), Trizivir (abacavir sulfate, lamivudine, zidovudine), and Ziagen (abacavir sulfate). As a result, people living with HIV will be forced to change medications and they may not be able to tolerate their new therapies. Critics have proposed creating 340B exemptions for drugs in short supply as a way to address the problem. But such proposals would have little impact and would lead to more serious consequences by undermining the ability of safety net providers to meet the needs of their patients. For Ryan White clinics, the proposal could impede the clinics' fight against the HIV epidemic. While RWC-340B continues to advocate for Congressional solutions to the drug shortage problem, any such solution must target the real source of the crisis – manufacturers.

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[3] Drug Shortages: Root Causes and Potential Solutions, FDA (Mar. 11, 2020) Report | Drug Shortages: Root Causes and Potential Solutions | FDA.
[4] *Id.*

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340B Reporting Requirements Are Unwarranted

Transparency Claims Meant to Shrink 340B Program

Critics of the 340B program allege that the program lacks transparency and that program participants, called "covered entities," should report both the amount of their 340B savings and how they use 340B savings for patient care. Critics fail to understand, however, that federal grantees, which make up 11 of the 14 categories of entities authorized to participate in the program, are already subject to rigorous reporting requirements to ensure transparency and accountability. The real motivation for these allegations is to discredit the 340B program and to justify its reform.

Grantee Transparency: Detailed and Regulated

Federal grantees must submit detailed budgets with their grant applications and comply with those budgets. They must also report the income received as a result of the grant – called "program income" – and how such income is used. Importantly, federal grantees must use program income consistent with the purposes of their federal grant.[5] Ryan White grantees are also required to submit a Ryan White HIV/AIDS Program Services Report with client-level data and an allocations and expenditures report. Like other federal grantees, Ryan White clinics are subject to audits to ensure compliance and are required to perform internal monthly audits of prescriptions. Thus, federal regulators already have the data they need to validate proper use of 340B savings by Ryan White clinics. Most of that information is publicly available.

340B Eligibility, Existing Oversight Creates Transparency

Congress carefully limited 340B program eligibility to safety net providers that are already subject to transparency requirements. In addition to federal grantees, 340B-eligible hospitals must be nonprofit and show that they serve a disproportionate share of low-income individuals. Imposing another layer of reporting requirements on covered entities would create undue burden and expense, diverting their limited resources away from patient care.

Ryan White Clinics Use 340B to Effectively Control HIV

Tellingly, Ryan White clinics are making important strides in controlling the HIV epidemic through use of their 340B savings. In 2021, 89.7% of Ryan White clinic clients receiving HIV care were virally suppressed, exceeding the national average of 66%. Ryan White clinics are clearly using their 340B savings to meet the needs of HIV patients. RWC-340B urges Congress to refrain from adding new reporting requirements to the 340B program because, simply put, they would subject covered entities to unnecessary and harmful burden.

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[5] 45 C.F.R. § 75.307(e)(2).

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Duplicate Discounts and Common-Sense Solutions

Duplicate Discounts Explained

Manufacturers are required to pay rebates to state Medicaid programs on outpatient drug claims reimbursed by Medicaid. Federal law protects manufacturers from providing a Medicaid rebate and 340B discount on the same drug, known as a "duplicate discount."[6] Duplicate discounts occur more often on drug claims paid by a Medicaid managed care organization (MCO) than traditional Medicaid.[7]

Carve-Out of Pharmacy Benefit from Managed Care Threatens 340B & Public Health

Some states have implemented policies that are detrimental to 340B covered entities to avoid duplicate discounts. For example, California and New York recently carved out the pharmacy benefit from their Medicaid MCO programs to administer the benefit under traditional Medicaid. Because traditional Medicaid (unlike a Medicaid MCO plan) reimburses retail pharmacy drugs at the drug's acquisition cost, the pharmacy carve-out policy eliminates any financial benefit to covered entities for dispensing 340B drugs to Medicaid beneficiaries. Virginia and Louisiana prohibit contract pharmacies from dispensing 340B drugs to Medicaid MCO beneficiaries. These state carve-out strategies are particularly problematic for Ryan White clinics and the patients they serve. Individuals with HIV already face intense barriers to HIV care. In 2021, over a quarter of Medicaid enrollees with HIV did not receive one or more critical services – medical visits, viral load tests, and antiretroviral therapies. MCO carve-out policies will exacerbate these problems.

Solution is Clear and Achievable

RWC-340B agrees that measures are needed to protect manufacturers from duplicate discounts, but states or their MCO contractors should not be permitted to usurp the benefit of the 340B program. Neither the plain meaning nor the legislative history of the 340B statute indicates that Congress enacted the 340B program to save money for Medicaid. At the state level, RWC-340B supports the use of the *retrospective claims identification process* pioneered by the Oregon Medicaid program.[8] Under this model, covered entities and contract pharmacies submit 340B claims data to a Medicaid vendor so the vendor can remove 340B claims from the Medicaid agency's rebate requests to manufacturers. At the federal level, RWC-340B supports passage of the PROTECT 340B Act of 2023 (H.R. 2534). The PROTECT Act would require Health and Human Services to contract with a neutral third-party clearinghouse to identify and prevent duplicate discounts nationally. RWC-340B strongly supports these best practices to avoid duplicate discounts. Both address duplicate discounts while maximizing the 340B savings covered entities use to care for patients in their communities.

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[6] 42 U.S.C. § 256b(a)(5)(A)(i) (traditional Medicaid); 42 U.S.C. § 1396r-8(j)(1) (Medicaid MCOs).

[7] One mechanism for avoiding duplicate discounts is for a pharmacy to apply a modifier on a claim for drugs that were purchased with 340B discounts, thereby notifying the state Medicaid agency to forgo a rebate. But Medicaid MCO plans are often administered by payers that offer private insurance plans and the insurance cards for the Medicaid plan and private plan are virtually identical, making it difficult for a pharmacy to identify a Medicaid MCO beneficiary to apply the modifier.

[8] This Medicaid MCO identification model is one of the "best practices" recognized by the Centers for Medicare and Medicaid Services (CMS). CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid at 6 (Jan. 8, 2020).