



**National Coalition
of STD Directors**



De-mystifying 340B:

Why It Matters

When STI programs are introduced to 340B, they often perceive the program to be complicated and may feel overwhelmed about learning a new program. While there are several key compliance elements to monitor, it is important to understand why the 340B program is significant and how it impacts sexually transmitted infection (STI) prevention and control programming. This document attempts to de-mystify the complexities within 340B so that STI programs can feel confident explaining and utilizing the program with their counterparts.



The purpose of this document is to provide STI program staff with background information pertaining to the 340B Drug Pricing Program to increase understanding of the program and educate others about its value. This document complements other NCSD-produced 340B materials, such as the ABCs of 340B, 340B Basics and Beyond, and 340B and Ending the Epidemics webinars, the Syndemic Approach to STD 340B Correctional Facility Partnerships and Injectable Syphilis Treatment Delivery toolkits, and the 340B Glossary of Terms.

Introduction

The 340B program is a federal program authorized by Section 340B(a) (8) of the Public Health Service Act which enables covered entities to stretch scarce federal resources while providing outpatient medications at significantly reduced prices. These discounts are provided by drug manufacturers to eligible entities as a requirement of the manufacturers' participation in the Medicaid program. The 340B program is administered by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA).



Federal law defines which types of safety net programs may participate in the 340B program, including STI clinics and recipients of federal grants authorized under U.S. Public Health Services Act Section 318. All 59 jurisdictions funded under the Centers for Disease Control and Prevention (CDC) Division of Sexually Transmitted Diseases (STD) Prevention cooperative agreement (PS19-1901: Strengthening STD Prevention and Control for Health Departments, ([STD PCHD] 2019-2026) and their subrecipients are potentially eligible to participate in the 340B program based on 318 program actions, as well as the nature of the subrecipient and the services these entities provide with STD PCHD funds. This means that STI programs are in a unique position to protect the health of citizens, and ensuring access to reduced cost eligible sexual health-related medication in their jurisdictions is pivotal to fulfilling this role.



Discussion

While 340B may have compliance factors perceived as complicated, STI programs, clinics, people living with STIs, and those at increased risk for STIs all benefit from 340B programming that provides safety net services such as reduced medication costs to its covered entities. Let's demystify some of the aspects of 340B.

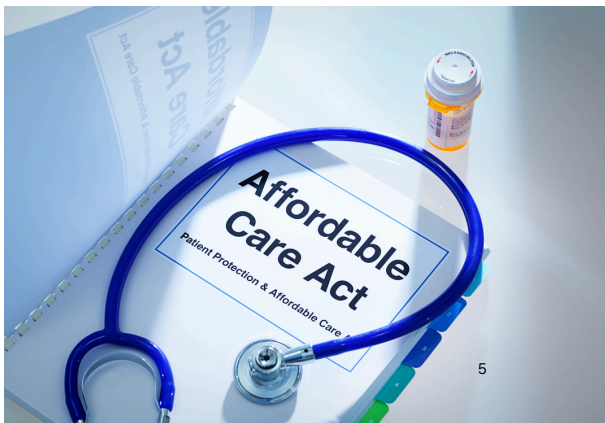
Reimbursement reinvestment

The 340B discounts on medications for covered entities can be significant, so it greatly benefits STI programs and their subrecipients to be a part of the 340B program to receive discounted medication. Additionally, covered entities that bill insurance can reinvest the difference between acquisition cost and reimbursement back into the clinic to further patient care. As non-340B medication costs increase, the amount available for reinvestment can increase as a result of the differences between the 340B cost and the reimbursed amount, which can benefit safety-net programs such as public health STI programs.



Because of the demands on safety-net clinics and their limited resources, many 340B covered entities, including STI clinics, rely on 340B savings to keep their operations going. The 340B discount is provided by drug manufacturers, so ensuring compliance with the 340B program is important for preventing potential perceptions of misuse.

Increased number of covered entities



Since the implementation of the Affordable Care Act (ACA) in 2012 and policy decisions made by OPA since that time, the number and type of covered entities have increased. Some of these decisions have been the ACA adding new covered entity types, OPA's efforts to ensure clinics are individually registered and not covered by large entities such as state health departments and updating the definition of covered entities in the 340B law.

Compliance

There are key points to remember when it comes to 340B compliance:

- ✓ only certain providers and patients are eligible
- ✓ an eligible entity must choose between either Medicaid & 340B or only 340B
- ✓ a covered entity must keep detailed records

Remember!

Formal Agreements



MOUs or other formal agreements with subrecipients can help ensure program compliance and that 340B savings are being funneled back to patient care. Ensuring covered entities are good stewards of the 340B program is an important role of STI programs as 340B-eligible entities.

Conclusion

Access to the 340B program is vital for STI programs and their local safety net providers. STI program staff play a key role in compliance and ensuring clinic partners have access to the program. As recipients of funding that can confer 340B eligibility, they are the custodians, champions and administrators of this program that is indispensable to reducing and controlling STIs to the benefit of the public's health.

For additional assistance, please refer to the NCSD 340B links above or contact NCSD's policy team at policyteam@ncsddc.org.

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