

# PrEP Pricing, Access, and Sustainability

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# PrEP is Comprehensive

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Laboratory Services ☐ Scheduling ☐ Follow Up  
Monitoring ☐ TelePrEP ☐ Office Visits ☐ PrEP  
Navigation ☐ Social Work ☐ Case Management ☐  
Billing ☐ Referral Services ☐ Housing Support ☐  
Mental Health Counselling ☐ Outreach ☐ Education  
☐ Awareness Campaigns ☐ Adherence Education  
and Counselling ☐ PrEPDAP programs

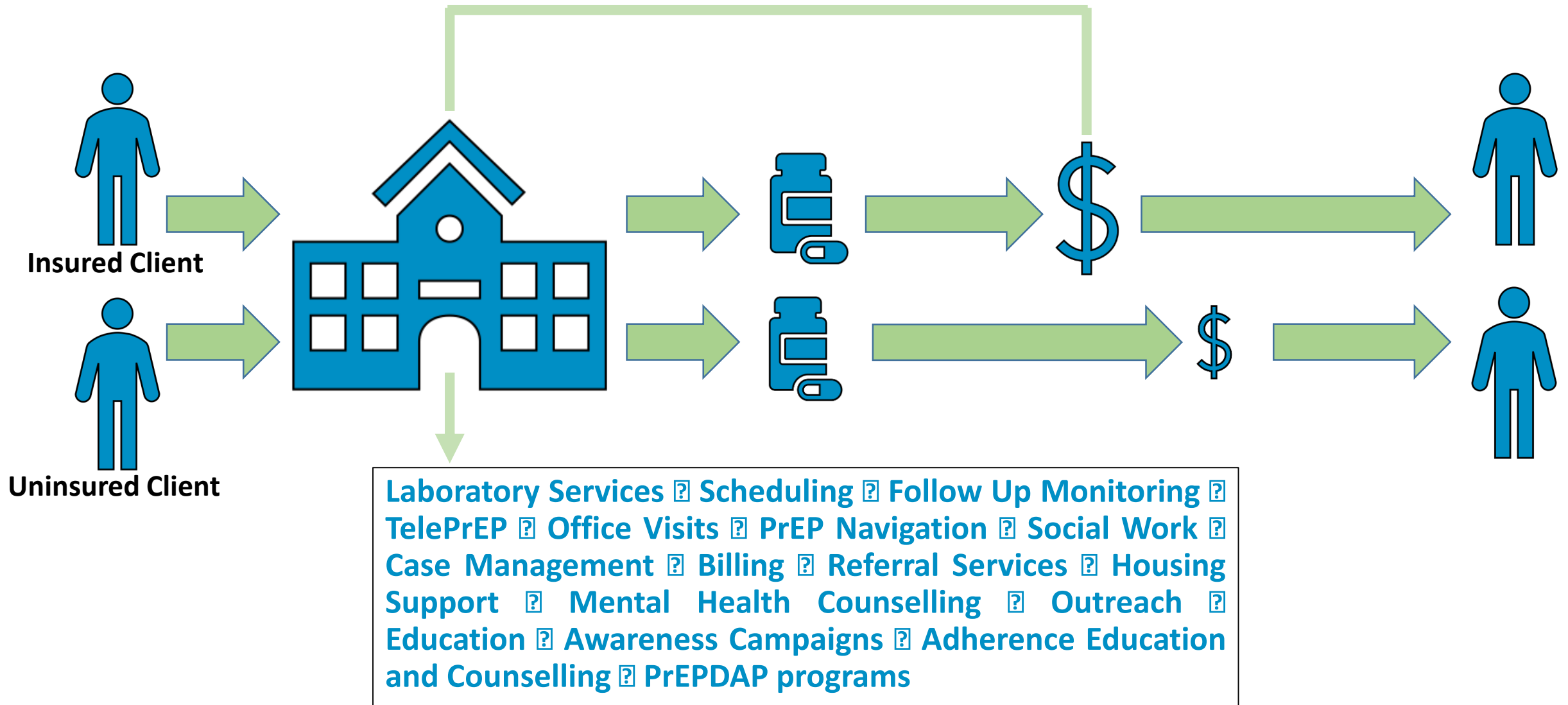
# PrEP is Comprehensive

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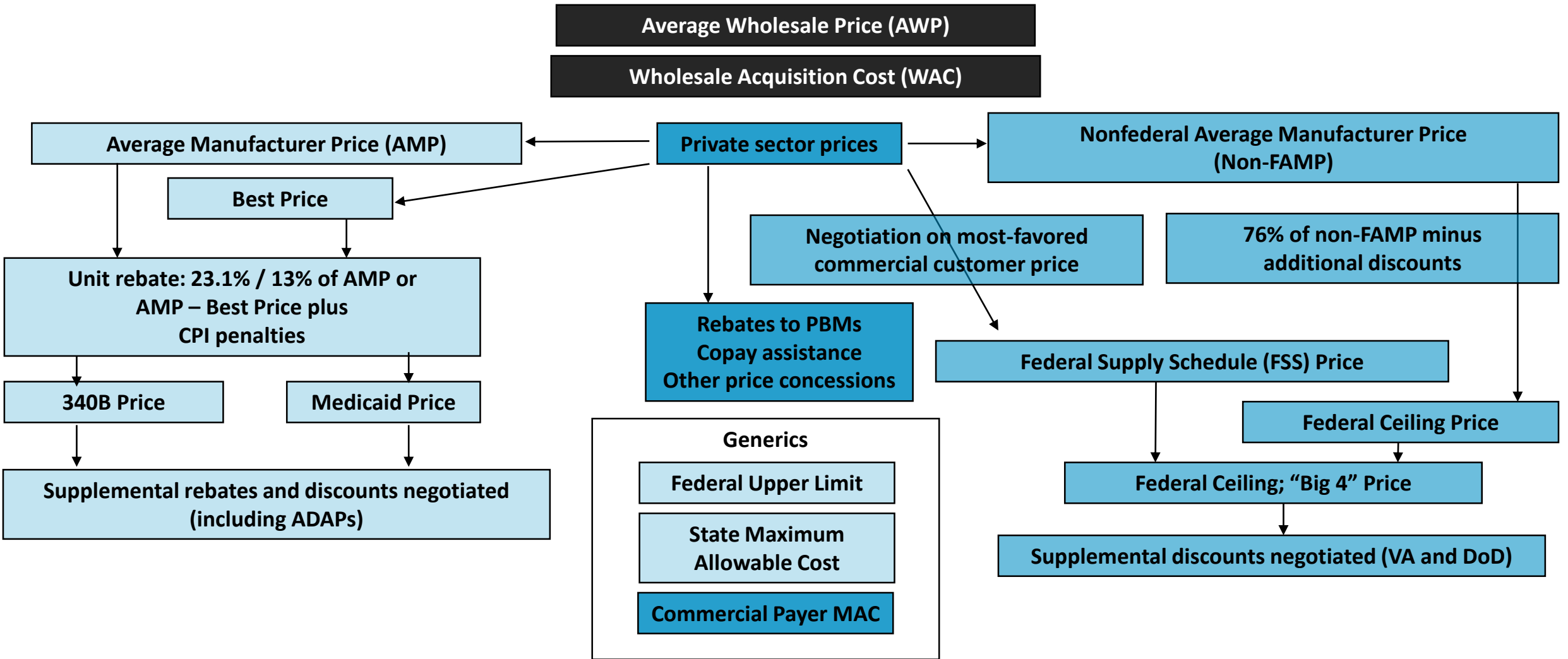
Laboratory Services [?] Scheduling [?] Follow Up  
Monitoring [?] PrEP  
Navigation [?] Payment [?]  
Billing [?] Support [?]  
Mental [?] Education  
[?] Awareness [?] Education  
and Counseling [?] PrEP/DAI programs

The 340B Drug Pricing Program helps Ryan White HIV/AIDS Programs, including ADAPs, to achieve both **cost containment** and **revenue** “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

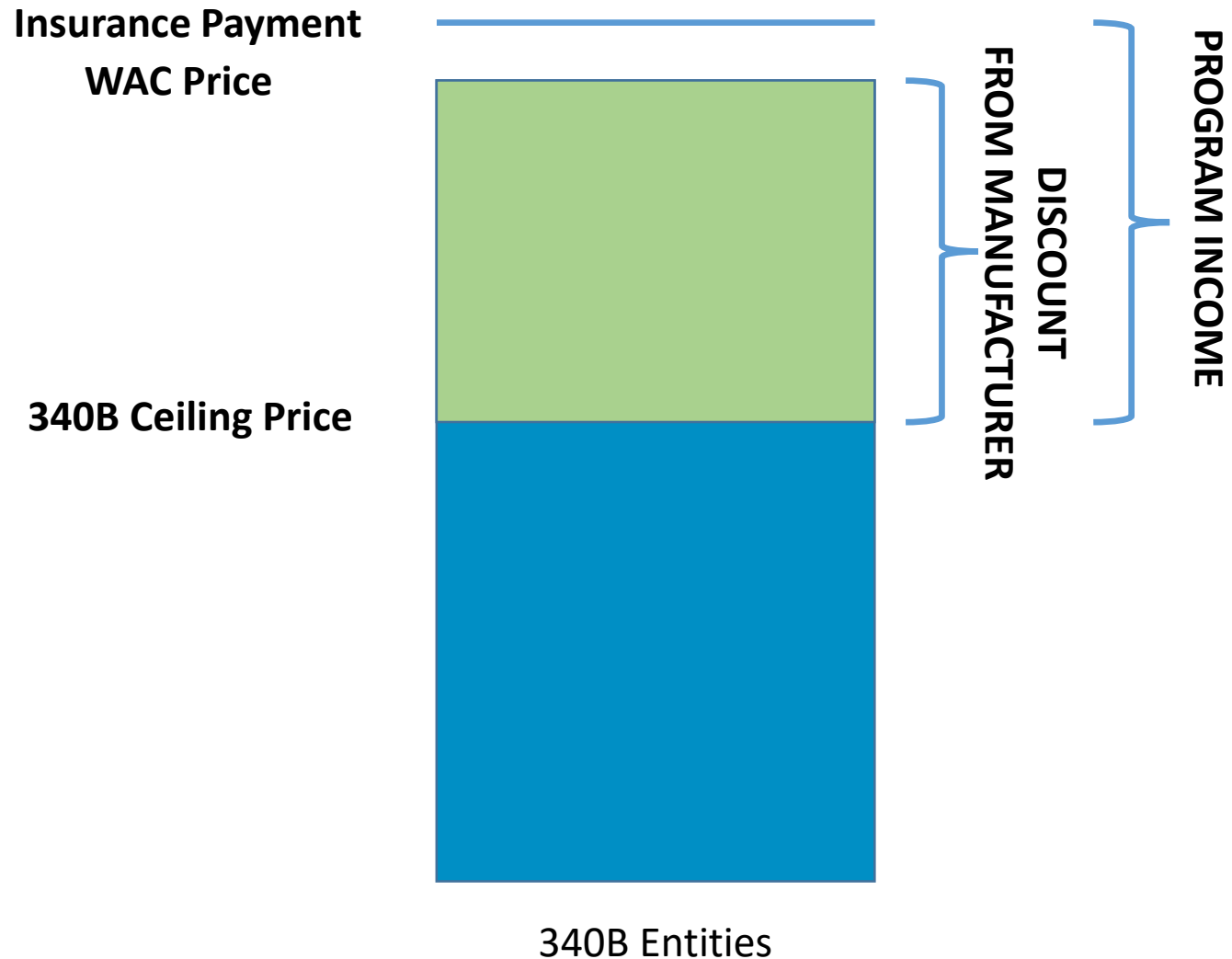
–H. R. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session



# U.S. Drug Pricing: It's Complicated



# 34B Discount and Program Income Basics



# 340B: Covered Entities

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## Health Centers

- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

## Hospitals

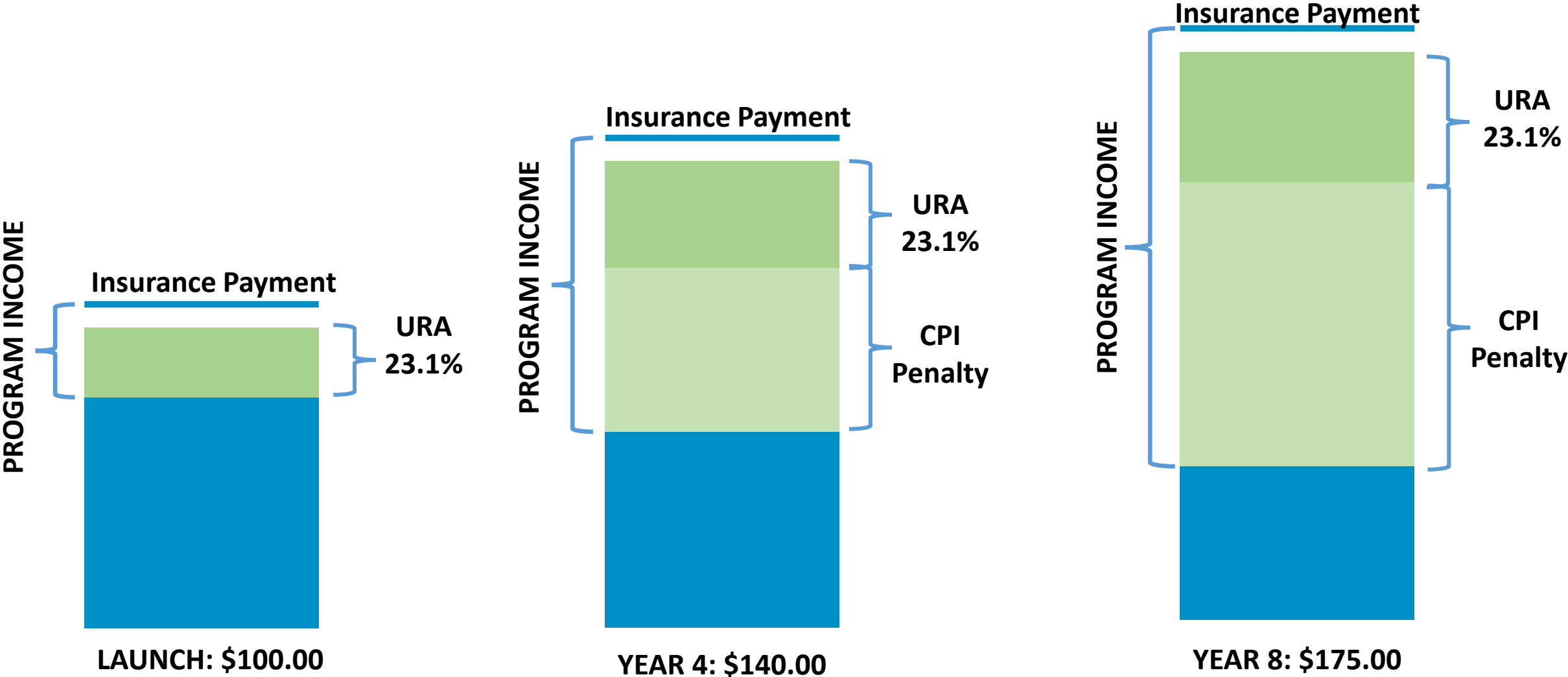
- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

## Ryan White HIV/AIDS Program Grantees

### Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- STD Clinics and 318 Grantees
- Tuberculosis Clinics

# 340B Program Income Over Time





# Challenges to 340B Program Income

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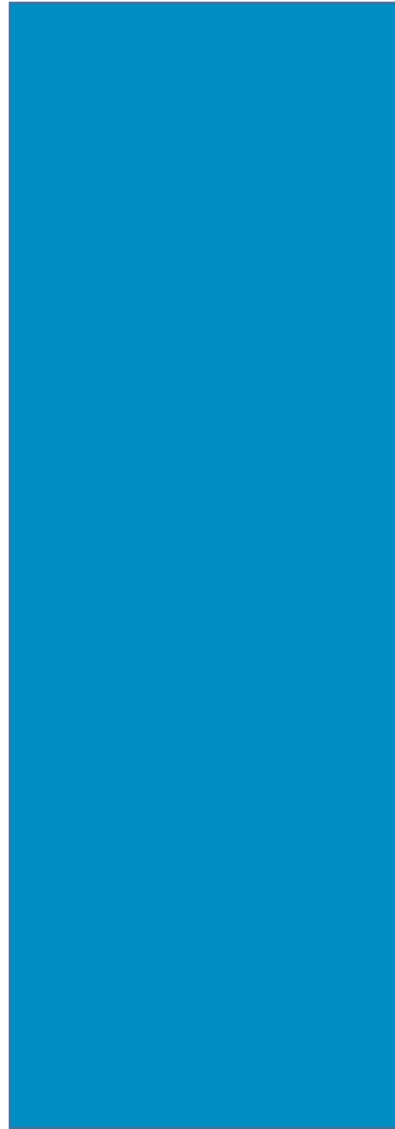
- Any legislation or regulations that lowers list prices and prices in private market
- Legislation or regulations that alter 340B Drug Pricing Program, including entity and patient definitions
- Legislation or regulations allowing payers to reimburse 340B discounted drugs at lower rates
- Competition that lowers prices
- Patent cliffs and commercialization of generic drug products

Medicare & Commercial Plans



**TDF/FTC (\$58)**

Medicare & Commercial Plans



**TAF/FTC (\$58)**

Medicare & Commercial Plans



**TDF/3TC (\$33.50)**

Medicare & Commercial Plans



**TDF/FTC (\$52)**

Medicare & Commercial Plans



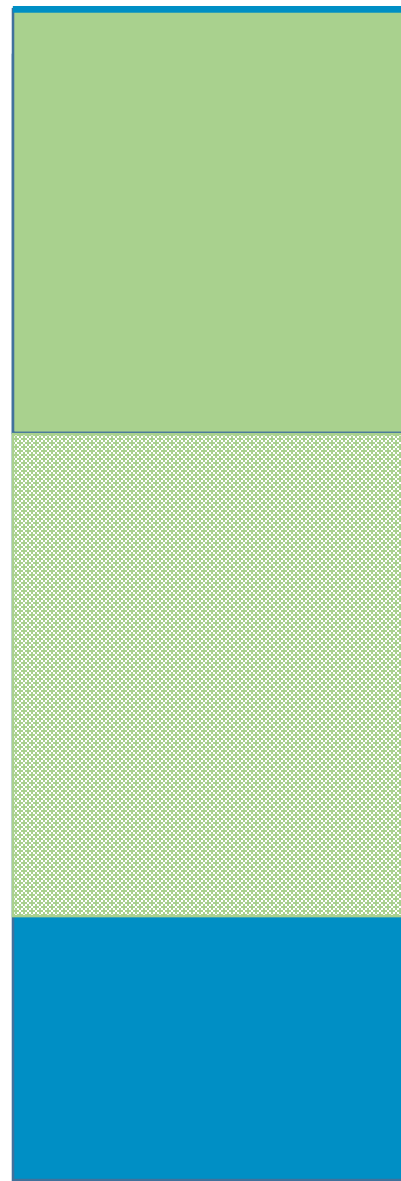
**TDF/FTC (\$3.50)**

Medicare & Commercial Plans



**TDF/FTC (\$58)**

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**TAF/FTC (\$58)**

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**TDF/3TC (\$33.50)**

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**TDF/FTC (\$3.50)**

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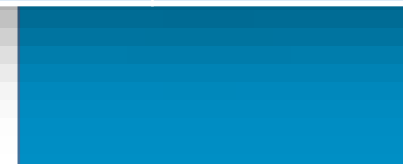
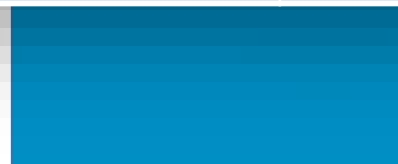
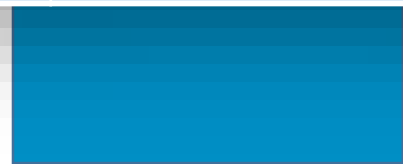
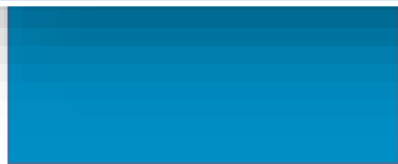
Medicare & Commercial Plans

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Medicare & Commercial Plans



	TDF/FTC	TAF/FTC	TDF/3TC	TDF/FTC (single source)	TDF/FTC (multi-source)
List/WAC	\$1,757	\$1,757	\$1,005	\$1,580	\$105
340B Price	\$415	\$415	\$772	\$1,374	\$91
340B Program Income	\$1,347	\$1,347	\$238	\$211	\$19



TDF/FTC (\$58)

TAF/FTC (\$58)

TDF/3TC (\$33.50)

TDF/FTC (\$52)

TDF/FTC (\$3.50)

# USPSTF Draft Grade A Recommendation

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition	A

- ACA mandates that private insurance plans and Medicaid expansion programs cover preventive services with a USPSTF A or B rating **at no cost**
- Plans must adopt in the plan year that begins at least one year following the final USPSTF recommendation (for PrEP that means **January 2021** for most plans and Medicaid)

# Implementation Considerations

## Access to the medication

- Competition in the PrEP medication space; individuals need access to clinically recommended regimen, but may not be appropriate to push for open formulary
- Potential for UM to be used in discriminatory ways (e.g. prior authorization to determine risk should be prohibited)

## Access to PrEP services beyond medication

- Lab tests and clinical visit costs at initiation and every three months should be covered without cost sharing, but are not explicitly included in USPSTF recommendation

# Next Steps for USPSTF Implementation

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- Advocates have asked CMS/CCIIO and CMS/CMCS to issue guidance to private insurance plans and state Medicaid agencies about appropriate implementation
- Advocates are asking state insurance regulators to issue bulletins and guidance to plans (e.g., NY Department of Insurance Bulletin on non-discriminatory practices for PrEP coverage)
- Provider and consumer education is critical to ensure that USPSTF and CDC guidelines are being followed and to ensure consumers know about new cost-sharing protections

# PrEP Donation

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- Gilead has committed to provide the PrEP medication for up to 200,000 people a year for up to 11 years
- Commitment to donate Truvada and Descovy
- Gilead bears the cost for the medication itself. Specifically, Gilead must reimburse pharmacies for (or back fill) PrEP medication that the pharmacies distribute to eligible patients



# PrEP Donation Program

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- Gilead has been awarded a \$6 million six-month contract to provide Truvada to 4,250 uninsured patients
  - Optional six-month extension for a total of 10,000 people in Year 1 of program
  - During the six-month period, HHS will hold a full and open competition to select a longer-term contractor or contractors.
- HHS will cover the cost of verifying eligibility, enrollment, building a network of participating pharmacies, dispensing medication to uninsured patients, etc.
- HHS has announced webinar on **November 15<sup>th</sup>** to provide more information about the program, which is expected to launch in the next month

# PrEP Donation Program

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- To qualify, patients must:
  - Lack health insurance coverage for outpatient prescription drugs
  - Have a valid “on-label” prescription
  - Have appropriate testing showing that the patient is HIV-negative
  - Patients who are currently enrolled or have been enrolled in the last 12 months in the Gilead Medication Assistance Program **CANNOT** enroll in the HHS program
- Any provider with a qualified patient can access the program
- Eligible patients can enroll in the program and receive donated medication through the mail or at a pharmacy
- Nationwide rollout with initial focus on Phase 1 ETE jurisdictions
- HHS awarded a contract to Brunet-Garcia to develop an education and awareness campaign to maximize the impact of the PrEP donation program. The awareness campaign will focus its efforts on Phase 1 EtHE jurisdictions.

# Financing Models for PrEP: A Patchwork of Funding and Delivery Mechanisms

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	Drug Access	PrEP Clinical Visits & Lab Costs	Counseling and Linkage
<b>Uninsured</b>	<p>Manufacturer Patient Assistance Program</p> <p>HHS/Gilead Donation Program</p> <p>PrEP Drug Assistance Programs or “PrEP DAPs” (state funded)</p> <p>CHCs; Family Planning Clinics; STD Clinics using 340B savings</p>	<p>PrEP DAPs (state funded)</p> <p>CDC prevention funds to pay for HIV/STD testing</p> <p>CHCs; Family Planning Clinics; STD Clinics using 340B savings</p> <p><b>?? CDC EtHE NOFO flexibility??</b></p>	<p>PrEP DAPs (state funded)</p> <p>CDC prevention grants and 340B savings</p> <p>CHCs; Family Planning Clinics; STD Clinics using 340B savings</p>
<b>Insured</b>	<p>Covered by payers; co-pay assistance through manufacturer assistance program</p>	<p>Largely covered, but with patient co-pays; some state programs cover co-pays with state funds</p>	<p>Not well covered by public or private insurance</p>

# Summary

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- Generic TDF/FTC poses new opportunities to contain individual and health care system costs of a critical biomedical prevention tool
- Generic competition poses important challenges to many PrEP program financing models dependent on 340B Program Income
- Implementation of USPSTF recommendation must balance maximized access with cost-conscious formulary design
- TAF/FTC must be available with the same cost-sharing protections for individuals for whom it is indicated based on clinical judgment and grounded in clinical guidelines

THANK YOU!  
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