

## Drug Pricing and Generics: Impact on Ryan White HIV/AIDS Programs

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Washington, DC

From T Horn, MS at New Orleans, LA, December 4-7, 2019, Ryan White HIV/AIDS Program CLINICAL CONFERENCE, IAS-USA.



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## Financial Relationships With Commercial Entities

Mr Horn has no relevant financial affiliations to disclose.  
(Updated 11/11/19)

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## Learning Objectives

After attending this presentation, learners will be able to:

- Describe the 340B Drug Pricing Program and its role in achieving cost containment and program income for Ryan White HIV/AIDS Programs
- Describe the challenges associated with high antiretroviral drug pricing
- Assess the impact of generic drugs on program cost containment and 304B program income

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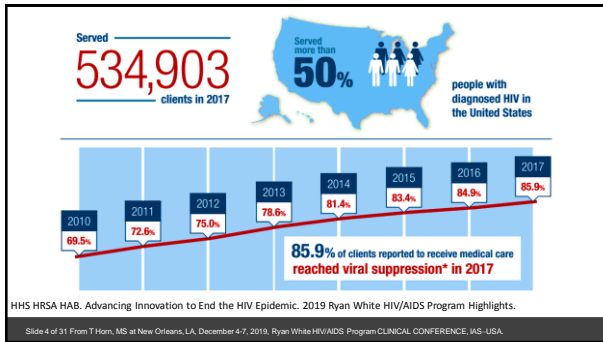
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### RWHAP Core Medical and Support Services

AIDS Drug Assistance Program Treatments + AIDS Pharmaceutical Assistance + Early Intervention Services (EIS) + Health Insurance Premium and Cost Sharing Assistance for Low-Income Individuals + Home and Community-Based Health Services + Home Health Care + Hospice Services + Medical Nutrition Therapy + Medical Case Management, including Treatment Adherence Services + Oral Health Care + Outpatient Ambulatory Health Services + Substance Abuse Outpatient Care + Child Care Services + Emergency financial Assistance + Food Bank/Home Delivered Meals + Health Education/Risk Reduction + Housing + Linguistic Services + Medical Transportation + Non-Medical Case Management Services + Outreach Services + Professional Services + Psychosocial Support Services + Referral for Health Care and Support Services + Rehabilitation Services + Respite Care + Residential Substance Abuse Services

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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

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## HIV Drug Cost Considerations

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**Rewire.News**  
HIV Drug Price Increase Brings 'Price Gouging' to the Forefront  
Erika G. Martin, Ph.D., M.P.H., and Bruce R. Scherman, Ph.D.

**HEALTH AFFAIRS BLOG**  
RELATED TOPICS: HIV/AIDS | PHARMACEUTICALS | ACCESS TO CARE | REUTERS  
Patient groups push back against Gilead's pricey HIV prevention treatment

**PrEP School: A Field Manual For The Battle Over HIV Prevention Drug Pricing**  
Rochelle P. Walensky, A. David Paltiel

**The New York Times**  
H.I.V. Drugs Cost \$75 in Africa, \$39,000 in the U.S. Does It Matter?  
Christian Antonio Urrutia James Kriegerstein Jan. 16, 2019

**TheBody**  
FINANCIAL ISSUES • VIEWPOINTS  
HIV Drug Prices Keep Rising. Why Is No One Talking About It?

**THE NEW ENGLAND JOURNAL OF MEDICINE**  
Treating and Preventing HIV with Generic Drugs — Barriers in the United States

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### ARS QUESTION 1

Over the past 10 years, list prices of DHHS Guidelines “preferred” single-tablet regimens have increased by how much?

- A. 10% to 50%
- B. 50% to 100%
- C. 100% to 150%
- D. 150% to 200%
- E. More than 200%

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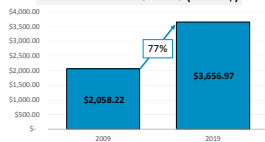
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## HHS-Preferred Regimen List Price Increases: 2009–2019

HHS-“Preferred” Regimens, 2009–2019

### ALL PREFERRED REGIMENS (MEAN \$)



2009	EFV/TDF/FTC	\$1,658	2019	BIC/TAF/FTC	\$3,707
	ATV/r + TDF/FTC	\$2,452		DTG/ABC/3TC	\$3,467
	DRV/r + TDF/FTC	\$2,466		DTG + TAF/FTC, TDF/FTC or TDF/3TC	\$53,295 – \$4,198
	RAL + TDF/FTC	\$1,655		RAL + TAF/FTC, TDF/FTC or TDF/3TC	\$53,095 – \$3,999

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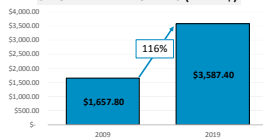
## HHS-Preferred Regimen List Price Increases: 2009–2019

HHS-“Preferred” Regimens, 2009–2019

### ALL PREFERRED REGIMENS (MEAN \$)



### SINGLE-TABLET REGIMENS (MEAN \$)



2009	EFV/TDF/FTC	\$1,658	2019	BIC/TAF/FTC	\$3,707
	ATV/r + TDF/FTC	\$2,452		DTG/ABC/3TC	\$3,467
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## Payer and Access Considerations

- Total undiscounted spending on ARVs in 2018: \$22.8 billion<sup>1</sup>
- HIV among the top five therapeutic classes in non-discounted spending in 2018, after medications for diabetes, autoimmune diseases, cancer and respiratory diseases<sup>1</sup>
- ARVs are No. 1 Medicaid outpatient drug expenditure (No. 5 and 4 for commercial and ACA plans, respectively)<sup>2</sup>
- Public and private payers: increasing formulary restrictions, utilization management (e.g., prior auth)
- Out-of-pocket spending is an issue; copay assistance programs in crosshairs

1. IQVIA. Medicine Use and Spending in the U.S. 2018 April.  
2. Express Scripts. Drug Trend Report, 2018.

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## Generic ARV Options (2019)

### Multi-Source "Generic" Drugs

- abacavir, abacavir/lamivudine, atazanavir, didanosine, fosamprenavir, lamivudine, nevirapine, ritonavir, stavudine, tenofovir disoproxil fumarate

### Multi-Source "Quasi-Generic Brand" Drugs

- Mylan: EFV/TDF/3TC, EFV(400)/TDF/3TC, TDF/3TC
- Celltrion: TDF/3TC

### Pending Generics

- September 2020: TDF/FTC
- Mid-2020s: darunavir, raltegravir

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## ARS QUESTION 2

Can generic drugs be used in DHHS *Guidelines*-recommended regimens?

- No
- Only "Initial Regimens in Certain Clinical Situations"
- Both "Initial Regimens for Most People With HIV" and "Initial Regimens in Certain Clinical Situations"

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## Generics in the HHS Guidelines

### Recommended Initial Regimens for Most People with HIV

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use.

**INSTI plus 2 NRTIs.**  
Note: For individuals of childbearing potential, see Table 4b before prescribing one of these regimens.

- **EFV/TDF/FTC (A1)**
- **DTG/TDF/FTC (A1)** **OR** **if HLA-B\*57:01 negative**
- **DTG plus [generic TDF](#) (A1)** **OR** for both TAF/FTC and TDF/FTC
- **NAC plus [generic TDF](#) (A1)** **OR** for TDF/FTC, B6 for TAF/FTC

\* [TDF](#) may be substituted for [TDF](#) or vice versa. [ABC/FTC](#), [TDF/FTC](#), [TDF/FTC](#) and [TAF/FTC](#) are available as combination, non-NRTI tablets, and they are also available as part of various [other](#) [formulations](#). [Cost](#), [access](#), and [availability](#) of [SIR](#) [formulations](#) are among the factors to consider when choosing between [TDF](#) and [TAF](#).

TAF and TDF are two forms of tenofovir approved by the FDA. TAF has fewer bone and kidney toxicities than TDF, while TDF is associated with lower lipid levels. [Safety](#), [cost](#), and [access](#) are among the factors to consider when choosing between these drugs.

### Recommended Initial Regimens in Certain Clinical Situations

These regimens are effective and tolerable but have some disadvantages when compared with the regimens listed above or have less supporting data from randomized clinical trials. However, in certain clinical situations, one of these regimens may be preferred (see Table 4 for examples).

**INSTI plus 2 NRTIs.**  
Note: For individuals of childbearing potential, see Table 4b before prescribing one of these regimens.

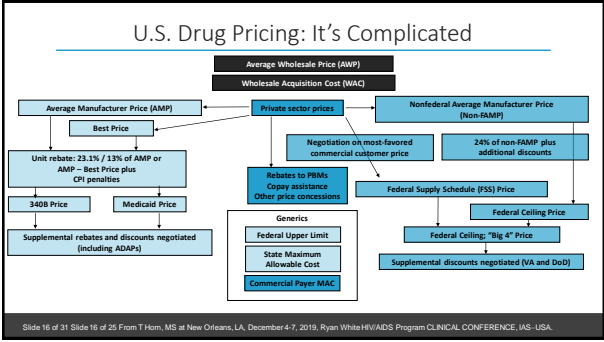
- **EVG/c/r/TDF/FTC (B1)** **OR** for both TAF/FTC and TDF/FTC
- **NAC plus [generic TDF](#) (B1)** **OR** if HLA-B\*57:01 negative and HIV RNA <100,000 copies/mL. Boosted [PI](#) plus 2 NRTIs (in general, boosted DRV is preferred over boosted ATV)
- **DRV/c/r or DRV/c plus [generic TDF](#) (B1)**
- **DRV/c or DRV/c plus [generic TDF](#) (B1)**
- **DRV/c or DRV/c plus [generic TDF](#) (B1)** **OR** if HLA-B\*57:01 negative (B1)

**INSTI plus 2 NRTIs.**  
• **DTG/TDF/FTC (B1)** **OR** for EFV 600 mg/TDF/FTC or EFV 600 mg/TDF/3TC, B6 for EFV 600 mg/TDF/FTC
- **RPV/TDF/FTC (B1)** **OR** if HIV RNA <100,000 copies/mL and CD4 cell count >200 cells/mm<sup>3</sup>

Regimens to Consider when ABC, TAF, and TDF Cannot Be Used or Are Not Optimal:

- **DTG plus [generic TDF](#) (C1)**
- **DRV/c plus [generic TDF](#) (C1)** **OR** if HIV RNA <100,000 copies/mL and CD4 cell count >200 cells/mm<sup>3</sup>
- **DRV/c or DRV/c plus [generic TDF](#) (C1)**

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**340B and the  
Ryan White HIV/AIDS Program**

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**340B Background**

- The 340B Drug Pricing Program was developed to allow manufacturers to continue offering discounted drugs to safety net entities, following the introduction of the Medicaid Drug Rebate Program
- Medicaid required manufacturers to calculate average and best prices for the Medicaid program, and any discounts to safety net entities would reduce Medicaid reimbursement
- The 340B Program was established to allow manufacturers to exclude these discounts from their Medicaid calculations

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## Manufacturers and 340B

- Why do manufacturers participate in 340B (and Medicaid)?
  - Manufacturers are not required to participate – they choose to participate and offer discounts
  - Participation is the only way to receive Medicare Part B and Medicaid reimbursement

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## 340B and RWHAP

- RWHAP grantees are essential public health care programs and therefore eligible for 340B Drug Pricing Program
- RWHAPs also subject to extensive restrictions on how 340B can be used: program-eligible PLWHIV, "additive" use consistent with grant terms
  - HRSA Policy Clarification Notice (PCN) 15-03
- Most RWHAP programs – or their contract pharmacies – access up-front **discounts**
- ADAPs, under RWHAP Part B, may choose up-front **discounts** and/or **rebates** paid by manufacturer
  - ADAP Crisis Task Force negotiates supplemental discounts/rebates with manufacturers – agreements with all ARV manufacturers on behalf of all ADAPs

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## 340B Discount and Program Income Basics

- 340B entities subject to a minimum discount of 23.1% off the Average Manufacturer Price; "Best Price" adjustment also possible
- When manufacturer takes a price increase that exceeds the Consumer Price Index for All Urban Costumers (CPI-U), an additional rebate – or "inflation penalty" – is added to base discount
- ✓ Achieves prescription drug cost containment
- ✓ Revenue, or "program income," is generated when clinics are able to purchase the drug at a discounted rate but are reimbursed by third-party payers at a higher usual and customary rate

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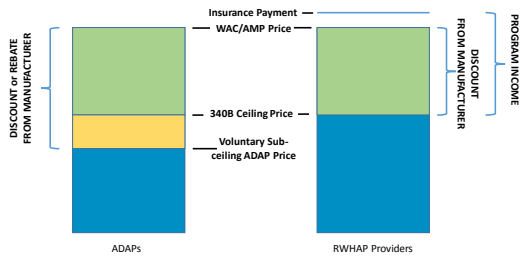
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### 340B Discount and Program Income Basics



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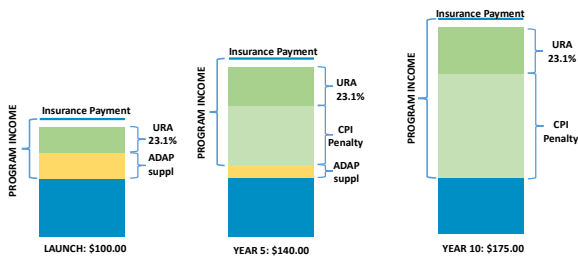
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### 340B Program Income Over Time



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### Challenges to 340B Program Income

- Any legislation or regulations that directly or indirectly lower "AMP" or "Best Price"
- Legislation or regulations that alter 340B Drug Pricing Program, including entity and patient definitions
- Legislation, regulations, or policies allowing payers to reimburse 340B discounted drugs at lower rates
- Competition that lowers list prices, AMP, or Best Price
- Patent cliffs and commercialization of generic drug products

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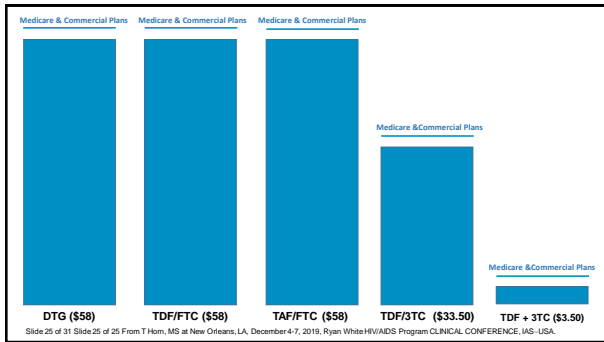
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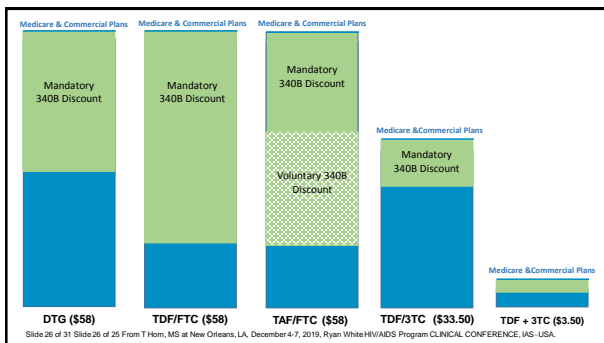
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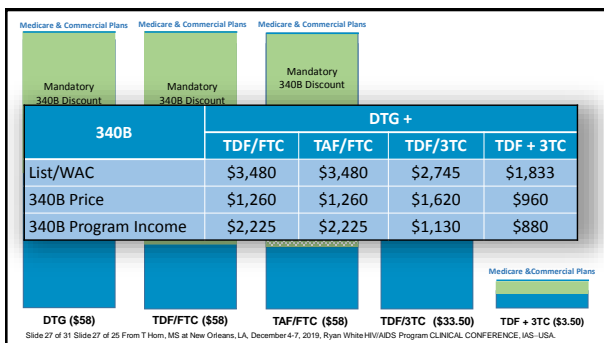
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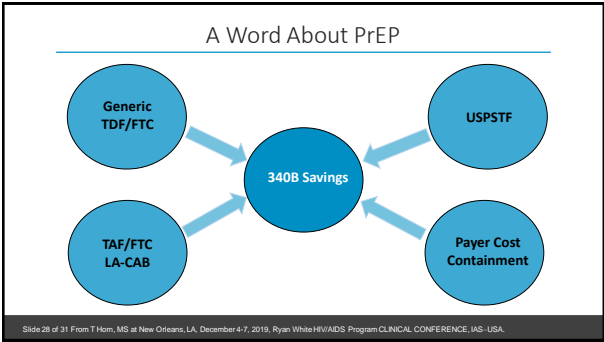
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- Summary
- The era of cost containment and generic competition has arrived; clinician knowledge/engagement increasingly important
    - Payers asking the same critical questions of data as clinicians: TAF vs. TDF, STRs vs. MTRs, added value of LA ARVs
  - 340B has been a lifeline to US HIV programs, including RWHAP clinics and AIDS Drug Assistance Programs (ADAPs)
  - ARV market (e.g., generics) and policy dynamics may impact 340B as savings source
  - The big question: How do we make lower drug prices work to the advantage of people with, or at risk for, HIV?
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THANK YOU!  
[thorn@NASTAD.org](mailto:thorn@NASTAD.org)

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## Question-and-Answer Period

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