Leveraging Administrative and Governmental Policies to Improve PrEP Utilization

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Financial Relationships With Ineligible Companies (Formerly Described as Commercial Interests by the ACCME) Within the Last 2 Years:

Mr Crowley has served as an advisor to Gilead Sciences, Inc, and Merck & Co, Inc. His institution receives financial support from Gilead Sciences, Inc, Merck & Co, Inc, and ViiV Healthcare. (Updated 11/16/21)

Slide 2

KEY PrEP POLICY ISSUES

- Is PrEP safe and effective?
- Do people want it / will providers prescribe it?

- Can people access it? (i.e., available, affordable, all components of regimen covered, etc.)

- Is the PrEP regimen sustainable (for the user and the provider)?
- Is PrEP helping to achieve population-level impacts?

NOT AN EXCLUSIVE LIST AND THERE ARE MORE ISSUES THAN I COVER CAN IN TODAY'S SESSION

STRUCTURE OF THE PRESENTATION

1. Overview of US Health Care System and HIV Public Health Programs
2. PrEP Policy Initiatives
3. Ongoing and Future PrEP Policy Issues and Threats
4. Resources

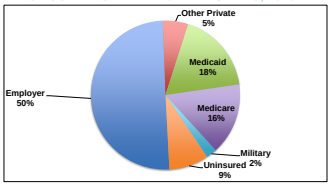
SECTION 1

OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

The United States has a complicated patchwork of health insurance programs

HEALTH INSURANCE COVERAGE IN THE UNITED STATES, 2020

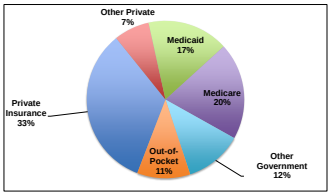


Source: Kaiser Family Foundation estimates based on Census Bureau's Current Population Survey (CPS: Annual Social and Economic Supplements), 2017-2021. Notes: Medicaid includes dual eligibles (who receive both Medicaid and Medicare) and children enrolled in the Children's Health Insurance Program (CHIP).

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

The United States spent 18% of GDP on health care last year

DISTRIBUTION OF US HEALTH CARE EXPENDITURES, 2020



Source: statista.com

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

Who and how many people do health insurance programs cover?

Private insurance coverage (Covered 216.5 million people in 2020): Covers roughly half of the population. Nearly all of this is employer sponsored coverage.

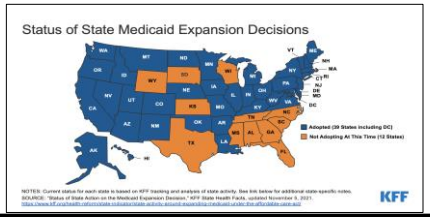
Medicare (62.6 million beneficiaries in 2020): Federal program for seniors (65+) and working age people with disabilities. Provides comprehensive acute care, not long-term care. For under 65, there is a 29-month waiting period. Because of Medicare, fewer than 1% of seniors are uninsured.

Medicaid (75.9 million beneficiaries in May 2021 + 6.9 million CHIP beneficiaries): Medicaid/CHIP enrollment is up 16% (11.5 million people) since the start of the COVID-19 pandemic. Feds set minimum standards and provide open-ended matching payments. States must cover defined "mandatory" populations and services but can exceed these minimum standards. Covers low-income children, parents, seniors, and people with disabilities. Largest payer for nursing home and community Long-Term Services and Supports (LTSS). 38 states plus DC have expanded Medicaid to citizens up to 138% of poverty.

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

12 states have not expanded Medicaid, most in the south

SOUTHERN US IS DISPROPORTIONATELY IMPACTED BY HIV



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Our complex health care financing systems consists of more than just insurance programs

DISCRETIONARY HEALTH PROGRAMS FILL IMPORTANT GAPS, BUT DO NOT OFFER A PROMISE OF GUARANTEED BENEFITS

- Health Centers Program
- Ryan White HIV/AIDS Program
- Indian Health Service
- Substance Abuse and Mental Health Services Administration
- Administration on Developmental Disabilities

This excludes other critical public health programs, but these programs either do not fund direct services or only do so in limited ways: Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Food and Drug Administration, etc.

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

People with HIV are equally likely to be insured, but more likely to be in Medicaid

THE AFFORDABLE CARE ACT HAS HAD A BIG IMPACT

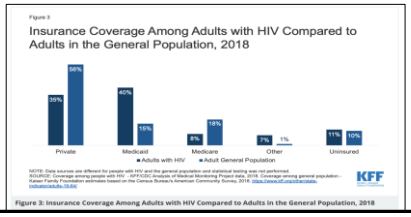

Figure 3: Insurance Coverage Among Adults with HIV Compared to Adults in the General Population, 2018

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Medicaid expansion is a structural intervention

PWHIV 3X MORE LIKELY TO BE UNINSURED IN NON-EXPANSION STATES

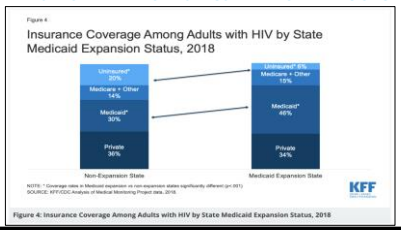

Figure 4: Insurance Coverage Among Adults with HIV by State Medicaid Expansion Status, 2018

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Most higher income PWHIV have private insurance

MOST LOW INCOME PWHIV HAVE MEDICAID

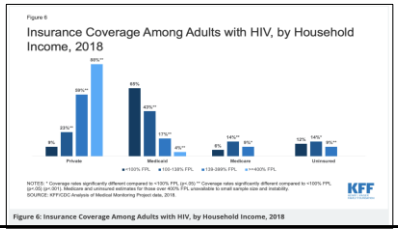

Figure 6: Insurance Coverage Among Adults with HIV, by Household Income, 2018

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Nearly half of PWHIV rely on Ryan White

SUPPLEMENTAL BACKSTOP FOR PERSONS WITH INSURANCE

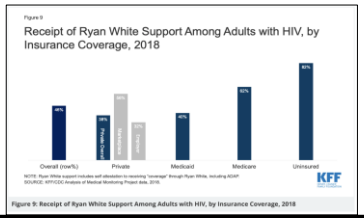

Figure 9: Receipt of Ryan White Support Among Adults with HIV, by Insurance Coverage, 2018

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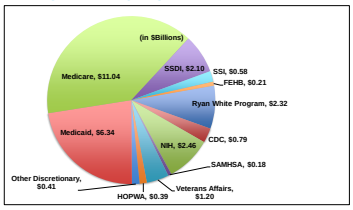
Federal funding for domestic HIV was $28 billion in FY 2019

MEDICAID AND MEDICARE MAKE UP MORE THAN HALF

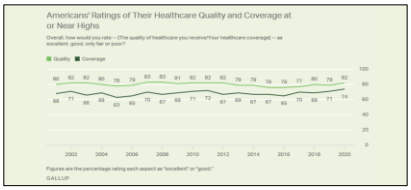


Source: Kaiser Family Foundation. *U.S. Federal Funding for HIV/AIDS: Trends Over Time*. March 2019. https://www.kff.org/global-health- policy/fact-sheet/u-s-federal-funding-for-hivaids-trends-over- time/.

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

This convoluted system is a mess. Why are we stuck with it?

MOST AMERICANS ARE SATISFIED WITH THEIR OWN COVERAGE

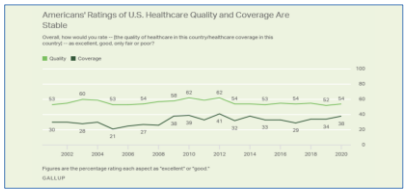


Source: https://news.gallup.com/poll/327686/americans-satisfaction-health-costs-new-high.aspx. Nationally representative sample of adults 18 and up in all 50 states plus Washington, DC.

LEVERAGING ADMINISTRATIVE AND GOVERNMENTAL POLICIES TO IMPROVE PrEP UTILIZATION

SECTION 1: OVERVIEW OF US HEALTH CARE SYSTEM AND HIV PUBLIC HEALTH PROGRAMS

EVEN AS THEY SEE PROBLEMS FOR THE COUNTRY AS A WHOLE



Source: https://news.gallup.com/poll/327686/americans-satisfaction-health-costs-new-high.aspx. Nationally representative sample of adults 18 and up in all 50 states plus Washington, DC.

LEVERAGING ADMINISTRATIVE AND GOVERNMENTAL POLICIES TO IMPROVE PrEP UTILIZATION

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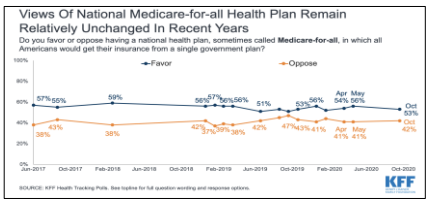
But lots of ideas are out there for a better way!!!

YET THERE IS A LACK OF CONSENSUS FOR NEW APPROACHES



SECTION 2

PrEP Policy Initiatives

SECTION 2: PrEP POLICY INITIATIVES

The Affordable CARE Act

2010 LAW HAS SEVERAL POLICIES THAT SUPPORT PrEP ACCESS

- Expanded health insurance coverage, new limits on out-of-pocket costs, and minimum benefit and network standards are all helpful
- Most significantly, the ACA allows for highly-rated screenings and prevention services to be provided without cost-sharing
- Requires an A or B (evidence-based rating) from the United States Preventive Services Task Force (USPSTF): **PrEP recieved an A rating**

THE USPSTF PrEP RECOMMENDATION CAN HELP TO INCREASE PrEP USE

WHAT IS THE USPSTF?	WHAT DID THE USPSTF CONCLUDE?	WHY THE PrEP RECOMMENDATION MATTERS
The United States Preventive Services Task Force (USPSTF) is an independent panel of national experts authorized by Congress and appointed by the Agency for Healthcare Research and Quality (AHRQ) within the Department of Health and Human Services (HHS). The task force reviews the scientific literature and makes evidence-based recommendations for the use of clinical preventive services such as screenings, counseling services, and preventive medications.	The USPSTF "found convincing evidence that PrEP is of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use." The USPSTF concluded "with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial."	Too few people in need of PrEP are receiving it due to both provider and patient barriers. These include lack of information regarding the evidence supporting PrEP's effectiveness and safety, as well as information on side-effects. Health insurance utilization management policies, including prior authorization and cost-sharing, have impeded access to PrEP. The requirement for the USPSTF to update its guidance, coupled with the recognition of strong evidence for its safety and effectiveness, could reduce barriers to PrEP delivery and access.

Source: O'Neill Institute, *Quick Take: The USPSTF PrEP Recommendation*, March 2020.

SECTION 2: PrEP POLICY INITIATIVES

The USPSTF Recommendation is important, but left several questions unanswered

DOES THE RECOMMENDATION REQUIRE COVERAGE OF MORE THAN THE DRUG?

The following is the closing excerpt of this *Quick Take*

> Before the USPSTF recommendation comes into force, the federal government should issue binding guidance that clarifies that the non-medication components of PrEP care must be covered without cost-sharing as part of the USPSTF recommendation and that standardizes coverage of PrEP medications to ensure comprehensive coverage and prevents plans from using drug coverage policies to deter enrollment of PrEP users.
>
> Models for such clarifying guidance associated with USPSTF recommendations include FAQs issued by CCIIO around polyp removal during colonoscopies, BRCA testing, and coverage of contraceptive methods.

Source: O'Neill Institute, *Quick Take: The USPSTF PrEP Recommendation*, March 2020.

SECTION 2: PrEP POLICY INITIATIVES

In July 2021, the US Departments of Health and Human Services, Labor, and Treasury issued FAQs to clarify coverage obligations WITHOUT COST-SHARING

STATE AND FEDERAL REGULATORS CAN TAKE ENFORCEMENT ACTIONS STARTING IN SEPTEMBER 2021

CRITICAL COMPONENTS OF THE FEDERAL PrEP GUIDANCE

Coverage of PrEP-related ancillary services without cost-sharing

See text box above for details.

Frequency of services must follow CDC guidelines and no restrictions on restarting PrEP

Plans must cover, free-of-charge, baseline and monitoring services that includes HIV testing every three months and sexually transmitted infection (STI) screening consistent with CDC guidelines.

Plans cannot restrict individuals from continuing or re-starting PrEP as long as their own health care provider determines that PrEP is medically indicated.

Access to medically appropriate PrEP medication without cost sharing, as determined by the individual's health care provider

Reasonable medical management is permitted to give preference to a specific PrEP medication, such as by offering one product without cost-sharing and imposing cost-sharing for other products. Plans are required, however, to accommodate any individual for whom a particular PrEP medication (generic or brand name) would be medically inappropriate, *as determined by the individual's own health care provider*. This requires plans to have a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.

Easy and timely exceptions process if plans limit PrEP services

If plans use medical management techniques to limit access to specific PrEP products or services, they must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual (or authorized representative) or provider. The FAQs provide the example of an exceptions process that allows for prescribing and accessing PrEP medications on the same day that an individual receives a negative HIV test and decides to start a PrEP regimen.

Source: O'Neill Institute, *Quick Take: Ensuring Compliance with New Federal USPSTF PrEP Guidance*, September 2021.

SECTION 2: PrEP POLICY INITIATIVES

FAQs specify required PrEP Services

REQUIREMENTS DEFER TO CDC CLINICAL PRACTICE GUIDELINES

REQUIRED PrEP SERVICES

Effective PrEP involves more than taking medication. Per federal guidance, most private plans and all Medicaid expansion plans **must provide the following care, without cost-sharing**, to insured persons. These standards reflect CDC clinical practice guidelines and help ensure safe and effective prescribing.

Office Visits: Office visits associated with each recommended preventive service when the primary purpose of the office visit is the delivery of the preventive service.

HIV Testing: Individuals must be tested to confirm that they are HIV negative before starting PrEP, and current guidelines call for repeat testing every 3 months while on PrEP.

Hepatitis B and C Testing: Individuals should be tested for Hepatitis B and C when initiating PrEP. Persons with an ongoing risk for Hepatitis C should be screened regularly.

Creatinine Testing and Calculated Estimated Creatine Clearance (eCrCl) or Glomerular Filtration Rate (eGFR): These tests of kidney function must be performed before starting PrEP and should be checked periodically.

Pregnancy Testing: Persons with childbearing potential must be tested before enrolling in PrEP and should be tested again periodically.

Sexually Transmitted Infection (STI) Screening and Counseling: All persons must be tested for STIs when starting PrEP and should be retested periodically. This includes testing for all symptomatic individuals. Sexually active adults and adolescents should be screened every six months. Asymptomatic gay and bisexual men at high risk for STIs should be screened every 3 months with 3-site specimen collection (i.e. pharyngeal, rectal, and genital/urine specimens).

Adherence Counseling: Individuals on PrEP must be offered regular behavioral counseling and adherence support.

Source: O'Neill Institute, *Quick Take: Ensuring Compliance with New Federal USPSTF PrEP Guidance*, September 2021.

SECTION 2: PrEP POLICY INITIATIVES

Providers have a role in enforcing the law

WE ALL HAVE A ROLE TO PLAY IN ENSURING COMPLIANCE

ACTIONS NEEDED TO SUPPORT COMPLIANCE AND ENFORCE THE LAW

PrEP USERS AND PROVIDERS

If patients or providers observe that a plan is not complying, they should bring the federal guidance to the attention of the plan or plan sponsor. In addition, they can contact the state and federal regulators indicated below.

Private-Employer Group Health/ERISA Plans: Persons with private employer group health plans can file a complaint with the Department of Labor Employee Benefits Security Administration (EBSA) at https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa or 1-866-444-EBSA (3272).

Non-ERISA Group Plans and Individual Plans: Persons with these kinds of plans (including persons with ACA marketplace plans) should contact their state insurance regulator. A directory is available from the National Association of Insurance Commissioners (NAIC) at https://content.naic.org/state-insurance-departments.

State and Local Government Employee Plans: In addition to state and local government oversight, HHS enforces federal requirements. Complaints can be emailed to NonFed@cms.hhs.gov.

Federal Government Employee Plans: The federal Office of Personnel Management (OPM) requires plans in the Federal Employees Health Benefits Program (FEHB) to provide ACA-required preventive services. Complaints can be made at 202.606.1800 or FEHB@opm.gov.

HEALTH DEPARTMENTS AND INSURANCE REGULATORS

State and local health departments and state and federal insurance regulators should develop compliance tools, education, and monitor activities to ensure plan compliance with federal rules. As regulators may be less familiar with the complexities of HIV prevention and clinical practices in PrEP services delivery, HIV experts in health departments can be an important resource for regulators in ensuring compliance with these requirements.

Audits, assessments, and enforcement actions should be released to the public, including any enforcement actions taken.

FEDERAL AGENCIES

The Centers for Medicare and Medicaid Services (CMS) should issue a State Health Officials Letter describing the critical importance of PrEP, these federal requirements, and ideas for compliance obligations of Medicaid programs and ACA marketplace health plans.

The FAQs rely heavily on Centers for Disease Control and Prevention (CDC) clinical practice guidelines. CDC should write to all health plans describing their clinical practice guidelines and how to use these guidelines to fulfill federal requirements. This could help to greatly increase the public health impact of PrEP.

Source: O'Neill Institute, *Quick Take: Ensuring Compliance with New Federal USPSTF PrEP Guidance*, September 2021.

SECTION 2: PrEP POLICY INITIATIVES

The 340B Drug Discount Program

AN IMPORTANT SOURCE OF REVENUE FOR SAFETY-NET PROVIDERS

Established in 1992 by Congress, the 340B program requires pharmaceutical manufacturers to sell drugs at a discount to eligible clinics and hospitals.

- **«Covered entities»** can receive reimbursement from third-party payer,s including Medicaid and private insurance, at the higher, usual and customary rate.
- The difference in what covered entities pay and receive in reimbursement is **«program income»** which may be used to invest in their programs and enhance services to uninsured patients.
- The use of program income must be consistent with the purpose of the 340B qualifying program.
- Eligible covered entities include Health Centers, Ryan White HIV/AIDS Program grantees, STI clinics funded under Section 318 of the PHSA, and Title X family planning clinics.

SECTION 2: PrEP POLICY INITIATIVES

340B includes a broad array of covered entities

RELATIVELY FEW HEALTH CENTERS AND RWHAP CLINICS PARTICIPATE

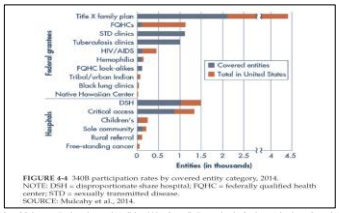


FIGURE 4-4 340B participation rates by covered entity category, 2014.
NOTE: DSH = disproportionate share hospital; FQHC = federally qualified health center; STD = sexually transmitted disease.
SOURCE: Mulcahy et al., 2014.

Source: National Academies of Sciences, Engineering, and Medicine 2021. Sexually Transmitted Infections: Adopting a Sexual Health Paradigm. Washington, DC: The National Academies Press. https://doi.org/10.17226/25995

SECTION 2: PrEP POLICY INITIATIVES

The 340B Program generates significant revenue that can support PrEP services

COVERED ENTITIES THAT QUALIFY SOLELY AS RWHAP CLINICS CANNOT USE PROGRAM INCOME FOR PrEP

- Health Centers, sexual health clinics, and others can and do use program income for PrEP services. This can include covering laboratory services, provding PrEP to the uninsured, offering case management and PrEP navigation services, and more.
- HRSA guidance does not permit program income from covered entities funded solely through the RWHAP to be used for PrEP services. Some have argued for a more expansive interpretation of the purpose of the program to encompass PrEP services as part of a cpmprehensive HIV response. While conceivable, it is unclear if this change could be made administratively and many places with the greatest PrEP services gaps also struggle with low rates of viral suppression raising questions of whether such a change is desireable

SECTION 2: PrEP POLICY INITIATIVES

Ending the HIV Epidemic and Health Centers

TRUMP ADMINISTRATION INITIATIVE SEEKS TO LEVERAGE HEALTH CENTERS FOR HIV PREVENTION AND CARE

- When the Trump Administration launched the Ending the HIV Epidemic (EHE) Initiative in 2019 with the goal of reducing new HIV transmissions by 90% by 2030, scaling up access to PrEP was a core strategy
- A critical part of the EHE is to invest new resources in Health Centers to increase their focus on both HIV prevention and care.
- Congress awarded $267 million for the EHE in FY 2020 of which $50 million was for Health Centers and $404.75 million for the EHE in FY 2021 of which $102.25 million was for Health Centers
- In March 2021, HRSA reported on the impact of the first awards to Health Centers. $54 million was awarded in supplementary funds to 195 Health Centers in 57 EHE jurisdictions:
  - 93% hired dedicated staff for a total of 389 FTEs;
  - 573,000 people were tested for HIV;
  - 2,260 were diagnosed and received follow-up within 30 days; and
  - **Nearly 50,000 people were prescribed PrEP at Health Centers**

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SECTION 2: PrEP POLICY INITIATIVES

Ready, Set, PrEP

TRUMP ADMINISTRATION PROGRAM TO COMPLEMENT THE ENDING THE HIV EPIDEMIC (EHE) INITIATIVE

- Announced as a partnership with Gilead Sciences, at the time, the sole manufacturer of FDA-approved PrEP medication. Gilead promised to donate up to 2.4 million bottles of medication per year through 2030 to CDC to distribute to uninsured people in the US who were at high-risk for HIV. Covers both Emtricitabine/Tenofovir Disoproxil Fumarate and Emtricitabine/Tenofovir Alafenamide.
- The intention of this partnership was to create a new pathway for extending access to PrEP for people without prescription drug coverage.

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Ready, Set, PrEP To Date

LIMITATIONS OF THE PROGRAM HAVE LIMITED ITS IMPACT

- It is estimated that this program, which is intended to serve up to 200,000 people, has had fewer than 2,000 participants.
- Time needed for program scale-up and COVID-19 fallout have hindered progress.
- Larger structural shortcomings, however, have limited the program's appeal. It is for people without prescription drug coverage, who are thus unlikely to have insurance. The program, however, only provides the drug for free and does not cover laboratory services or other aspects of the PrEP regimen. Gilead's patient assistance program also has been generous and may be a more attractive and accessible option.
- The program was structured to operate through commercial pharmacies and missed an opportunity to partner with Health Center and other public health pharmacies.
- Program improvements could increase its impact so that it becomes a valuable contributor to PrEP access.

SECTION 3

Ongoing and Future PrEP Policy Issues and Threats

SECTION 3: ONGOING AND FUTURE PrEP POLICY ISSUES AND THREATS

340B Reforms

MANUFACTURERS HAVE SOUGHT TO ELIMINATE OR NARROW 340B

- Pharmaceutical manufacturers have never liked the program and have sought ways to narrow its scope.
- As part of the ACA, Congress expanded 340B to cover more types of hospitals.
- In recent years, numerous efforts have been made to fundamentally alter the program, but so far, they have been unsuccessful.
- Following a court decision in August 2020, six manufacturers (AstraZeneca, Eli Lilly, Novartis, Novo Nordisk, Sanofi, and United Therapeutics) stopped providing discounted drugs through the program; in 2021, HRSA began enforcement action. Legal challenges have been raised over whether manufacturers can unilaterally put conditions on the drug discount program and whether HRSA can use its enforcement authority. These issues remain unresolved.
- Bipartisan legislation has been introduced the PROTECT 340B Act to protect 340B covered entities.

SECTION 3: ONGOING AND FUTURE PrEP POLICY ISSUES AND THREATS

Generic PrEP and Revenue Impacts for 340B Clinics

DEPENDENCE OF SAFETY NET PROVIDERS ON 340B PROGRAM INCOME COMPLICATES GENERIC PrEP ACCESS

- Safety net clinics do not receive the same level of program income from generics.
- Reasonable clinical debate may be warranted over which PrEP products to prescribe, but safety-net clinics most likely to serve most PrEP-eligible people could lose significant 340B program income by prescribing generics, thus prescribing decisions may not be based solely on clinical criteria
- Fears over impact on 340B may alter HIV stakeholder engagement in broader debate over drug pricing and price negotiation.

- **To enhance long-term sustainibility, the HIV community may need to step back and assess reliance on the 340B program income and whether alternative financing approaches are needed.**

SECTION 3: ONGOING AND FUTRE PrEP POLICY ISSUES AND THREATS

Looking ahead, new opportunities could be ahead

THE WHITE HOUSE IS EXPECTED TO RELEASE A NEW NATIONAL HIV/AIDS STRATEGY ON WORLD AIDS DAY

- A major challenge for the HIV community is keeping the American people and our elected officials invested in ending the HIV epidemic as the size of the epidemic decreases and the sense of threat recedes.
- Improving health equity in PrEP access and health outcomes must be a central focus of the HIV response and must guide all community policy decisions.
- Getting more PrEP and other services covered by mandatory programs (Medicaid and Medicare) and private coverage may increase sustainability.
- Emerging long-acting products for PrEP and treatment create new reasons for excitement.

SECTION 4

Resources

SECTION 4: RESOURCES

O'Neill Institute PrEP Resources

GO TO **http://bit.ly/USHIVpolicyproject**

- Kates, J., Dawson, L., Horn, T.H., Killelea, A., McCann, N.C., **Crowley, J.S**., and Walensky, R.P. **"Insurance coverage and financing landscape for HIV treatment and prevention in the USA,"** *Lancet*, published online February 18, 2021. doi.org/10.1016/S0140-6736(21)00397-4.
- *Quick Take: Ensuring Compliance with New Federal USPSTF PrEP Guidance*, September 2021
- *Quick Take: The USPSTF PrEP Recommendation*, March 2020
- Big Ideas: Achieving Sufficient Scale of PrEP Use is Critical to Ending the HIV Epidemic, *August 2019*
- *Expanding Access to Pre-Exposure Prophylaxis (PrEP) for Adolescents and Young Adults: Models for Addressing Consent, Confidentiality, and Payment Barriers*, by Sean Bland for amfAR, March 2019
- *Long-Acting HIV Prevention and Treatment are Coming: Preparing for Potential Game Changers* (4-document series), for amfAR, July 2018, https://www.amfar.org/long-acting-arv/

Question-and-Answer Session