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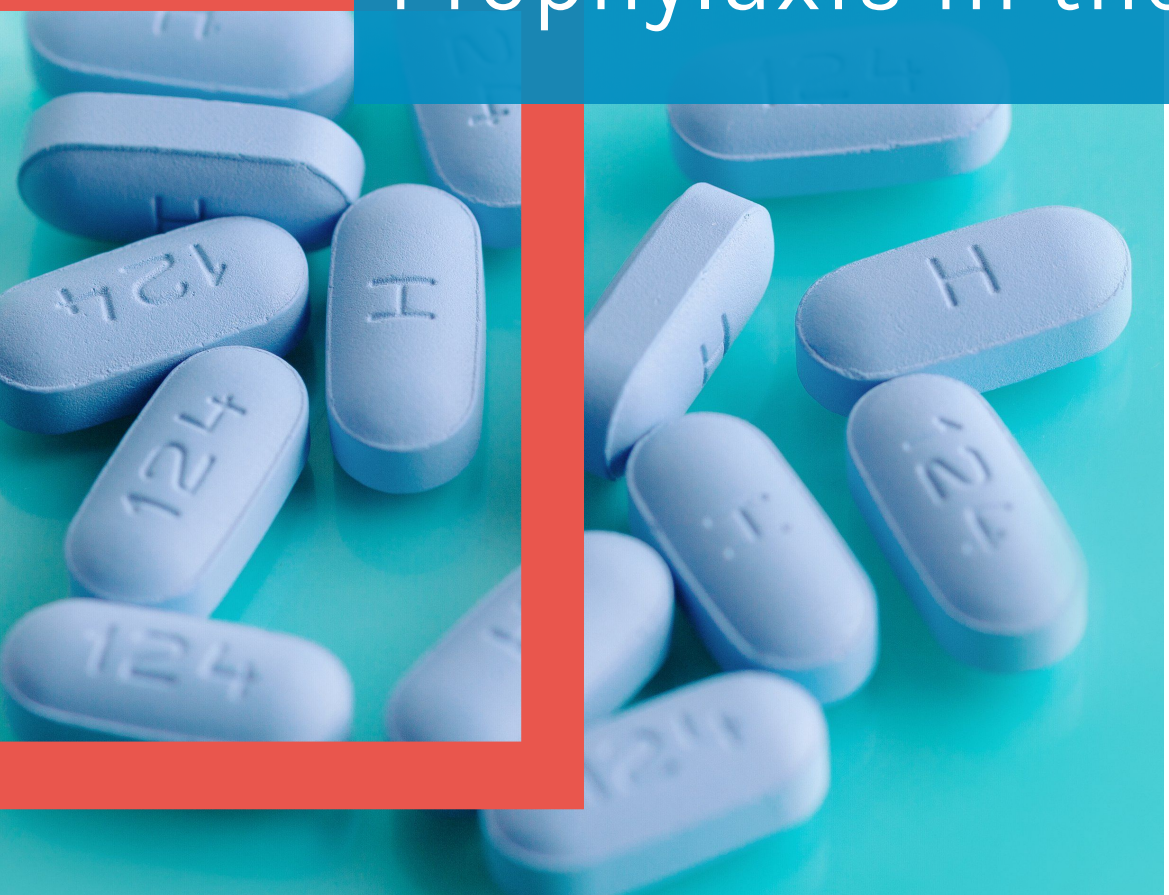
Financial Inaccessibility of HIV Pre-exposure Prophylaxis in the U.S.



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Disclaimer

The author conducted this study as part of the program of professional education at the Frank Batten School of Leadership and Public Policy, University of Virginia. This paper is submitted in partial fulfillment of the course requirements for the Master of Public Policy degree. The judgments and conclusions are solely those of the author, and are not necessarily endorsed by the Batten School, by the University of Virginia, or by any other agency.

Honor Pledge

On my honor as a University of Virginia student, I have neither given nor received unauthorized aid on this assignment.

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LIST OF ACRONYMS

AIDS: Acquired Immunodeficiency Syndrome

CDC: Centers for Disease Control & Prevention

EHE: Ending the HIV Epidemic

FDA: Food & Drug Administration

HHS: Health & Human Services

HIV: Human Immunodeficiency Virus

HRSA: Health Resources and Services Administration

MSM: Men Who Have Sex with Men

NASTAD: National Alliance of State & Territorial AIDS Directors

PrEP: Pre-exposure Prophylaxis

STI: Sexually Transmitted Infections

TDF/FTC: Tenofovir/Emtricitabine

USPSTF: United States Preventive Services Task Force

LIST OF FIGURES

EXECUTIVE SUMMARY

This report will focus on assessing policy alternatives for the National Alliance of State & Territorial AIDS Directors (NASTAD) to advocate for increased financial accessibility of pre-exposure prophylaxis (PrEP) and PrEP-associated costs at state and federal levels. HIV pre-exposure prophylaxis (PrEP) is a biomedical HIV preventive medication that reduces the risk of HIV acquisition by upwards of 90% for sexual encounters and 70% for injection drug use exposure. If widely used, PrEP has the potential to help end the HIV epidemic in the U.S. (Fauci et al., 2019). Despite the effectiveness of the drug, the uptake of PrEP remains low amongst high-risk groups – Black and Hispanic communities, people living in the South, men who have sex with men (MSM), cisgender women, and transgender women – due to high costs and limited access to financial resources to cover the cost of PrEP-associated medical visits and laboratory tests (Furukawa et al., 2020). Addressing these access barriers is crucially important to promote health equity and move the needle on ending the HIV epidemic in the U.S.

While many programs provide access to the PrEP medication, there are far fewer programs that address the ancillary services integral to PrEP intervention. As such, this report will focus on alternatives that help mitigate the cost of PrEP-related services, such as medical visits and laboratory tests. First, the literature points to the implementation of a public-payer of last resort model at a state or federal level as a method to alleviate out-of-pocket costs for patients and promote equity of access to preventive services across healthcare coverage. This is a novel approach in the U.S. and should be further explored in a comparative analysis of holistic public-payer models. Secondly, increasing regulation of cost-sharing practices could alleviate the burden of high out-of-pocket costs for patients across health insurance groups. Lastly, the expansion of CDC federal funding streams to cover PrEP-associated medical visits and laboratory costs could reduce financial barriers to PrEP amongst high-risk communities, but there is limited empirical evidence to assess the efficacy and feasibility of this intervention within the context of the CDC funding guidelines.

These findings inform the four policy options proposed in this report. Each alternative will be evaluated against a set of evaluative criteria: (1) reduction in cost barriers of PrEP-associated costs, (2) policy reach, (3) total cost of the program to key stakeholders, (4) administrative feasibility, and (5) equity.

This report ultimately recommends policy option #1, to expand the existing "Ready, Set, PrEP" program to cover PrEP-associated costs in addition to PrEP. This option ranked the highest for feasibility because of its nature as an existing program, as well as its policy reach and potential to improve equity. Despite the high cost, it requires the least amount of extensive program implementation for a significant gain in the financial accessibility of PrEP. With the EHE initiative and the current federal government's interest in health equity, this may be the right time to explore and advocate for increased financial accessibility for PrEP-associated costs and services, to help end the HIV epidemic in the U.S.

PROBLEM STATEMENT

HIV pre-exposure prophylaxis (PrEP) is a biomedical HIV preventive medication that reduces the risk of HIV acquisition by upwards of 90% for sexual encounters and 70% for injection drug use exposure. If widely used, PrEP has the potential to help end the HIV epidemic in the U.S. (Fauci et al., 2019). **Despite the effectiveness of the drug, the uptake of PrEP remains low amongst high-risk groups – Black and Hispanic communities, people living in the South, men who have sex with men (MSM), cisgender women, and transgender women – due to high medication costs and limited access to financial resources to cover the cost of PrEP-associated medical visits and laboratory tests** (Furukawa et al., 2020).

CLIENT OVERVIEW

NASTAD is a non-profit that represents public health officials who administer HIV programs in all 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and various other local jurisdictions (NASTAD, 2015). NASTAD works on issues of healthcare access and health systems policy and, through partnerships with federal and state health departments, acts as an advocate for empirically-based policy and program mobilization to improve health and HIV outcomes. Since this problem is focused specifically on the financial inaccessibility of PrEP-associated medical visits and laboratory tests, NASTAD is uniquely positioned to provide recommendations to the federal government, state health departments, peer advocacy groups (including the Federal AIDS Policy Partnership), and insurance companies regarding improvements to preventive HIV care access.

Access to PrEP is a key facet of NASTAD's prevention strategy over the past few years, but federal funding restrictions and variability of state resources have remained a salient barrier to the coverage of PrEP and PrEP-associated services (NASTAD, 2018). As such, this analysis of policy alternatives to leverage existing systems and funding streams for PrEP access is extremely relevant and timely to NASTAD's current advocacy efforts.

INTRODUCTION

Over one million Americans currently live with HIV and nearly 37,000 Americans were newly diagnosed in 2018 (Centers for Disease Control and Prevention, 2020). In 2016, the Centers for Disease Control and Prevention (CDC) estimated that approximately 1.2 million people were at high risk of getting HIV and had a clinical indication for PrEP (Centers for Disease Control and Prevention, 2020). The federal government currently spends approximately $20 billion in annual direct health expenditures for HIV prevention and care (HHS Press Office, 2018). One of the four pillars of the federal government's relatively new *Ending the HIV Epidemic* (EHE) initiative is increasing access to and use of PrEP (Furukawa et al., 2020) – in fiscal year 2021, $386 million was appropriated for the EHE initiative, of which $102 million was allocated to provide "HIV testing, linkage to care, and prescription of PrEP" (Office of Infectious Disease and HIV/AIDS Policy, HHS, 2020). Despite PrEP being approved by the United States Food and Drug Administration (FDA) in 2012 and the high effectiveness of the drug, less than 20% of those at high risk of getting HIV received a PrEP prescription in 2019 (Mayer et al., 2020).

BACKGROUND

In addition to taking the PrEP medication daily, ancillary laboratory tests and medical visits are key components of the PrEP regimen as outlined by CDC guidelines (Centers for Disease Control and Prevention, 2021), and patients cannot access PrEP without them. While many programs provide access to the PrEP medication, there are far fewer initiatives that address the ancillary services integral to PrEP intervention. The current high cost of PrEP-associated medical visits and laboratory tests remains one of the most salient barriers to PrEP access. According to data from FAIR Health, the cost of PrEP care for the initiation of PrEP is $2,666.90 for uninsured patients, of which roughly $1,000 is encompassed in laboratory tests and medical visits (Table 1). The cost of the branded drug tenofovir/emtricitabine (TDF/FTC) is $1,757.90 and the cost of the generic is $48.51 (NASTAD, 2018). Under these assumptions, the annual cost of PrEP-associated laboratory tests and medical visits amounts to a low-end estimate of roughly $3,000 for uninsured patients annually. These cost projections include the cost of the medication, primary care physician visits, and the essential tests that are recommended for most patients. Importantly, this does not factor in additional tests that would be recommended based on risk, such as Hepatitis C screenings or HIV RNA tests for patients who present with symptoms of acute HIV.

Table 1. Cost Data for PrEP Initiation (PrEP, Laboratory Tests, and Medical Services) for People without Insurance

Service	Cost
Medication	
Brand-name TDF/FTC	$1,757.90
Brand-name TAF/FTC	$1,806.41
Generic TDF/FTC	$48.51
Laboratory Tests	
Baseline HIV test (no copay)	$138.50
Hepatitis B Surface Antigen (no copay)	$53.00
Hepatitis B Surface Antibody (no copay)	$40.50
Hepatitis B core antibody IgM (no copay)	$91.50
Metabolic panel / creatinine test	$29.00
Gonorrhea & Chlamydia Screening (number of sites screened based on exposure) 1 site 2 sites 3 sites	 $123.00 $246.00 $369.00
Syphilis Screening (no copay)	$61.50
Pregnancy Test	$29.00
Medical Services	
Primary Care Physician Visit	$97.00

Of the 1.2 million adults estimated to have clinical indicators for PrEP, 86,300 (7%) are projected to need financial assistance for medical visits and lab tests alone; these costs would amount to an annual cost of $119 million (Smith et al., 2017). An additional 7,300 (<1%) need financial assistance for PrEP, medical visits, and laboratory tests, amounting to $88.9 million in annual costs (Smith et al., 2017). Because of the high cost-barrier, there is a lower uptake of PrEP in at-risk communities, thereby increasing the likelihood of transmission and prevalence of HIV in these communities and the necessity of HIV care (Anderson et al., 2012; Cottrell et al., 2016). Since the cost of HIV care is significantly greater than the cost of investing in widespread PrEP access, not addressing the low uptake of PrEP in the U.S. could lead to an outcome that is not cost-effective or preventive in scope.

COSTS & CONSEQUENCES OF FINANCIAL INACCESSIBILITY OF PrEP

PrEP as a cost-effective solution to ending HIV

There is a growing body of literature that suggests PrEP is a cost-effective intervention and an important component of ending the HIV epidemic. PrEP has been shown to reduce lifetime HIV risk in high-risk populations by almost 20% and, assuming 90% PrEP efficacy, it was also associated with significant reductions in lifetime HIV risk, dropping from 43.5% to 5.8% (Paltiel et al., 2009). In particular, price reductions could justify PrEP as a cost-effective measure for young or high-risk populations (Paltiel et al., 2009). PrEP is also shown to be a cost-effective measure amongst high-risk MSM with at least 2% HIV incidence in the US (Schackman & Eggman, 2012). One study estimating the cost-effectiveness of PrEP for all MSM and MSM at high risk of getting HIV demonstrated that even if only 20% of the MSM population initiated PrEP, over 60,000 new HIV infections would be prevented over the next 20 years (Juusola et al., 2012). Furthermore, this study found that targeting PrEP to 100% of high-risk individuals, who represent roughly 20% of the MSM population, prevents a larger number of infections at a lower cost as opposed to targeting PrEP to 20% of the MSM population as a whole (Juusola et al., 2012).

Scaling out to global interventions assessing the cost-effectiveness of PrEP, a cost-savings study conducted in Germany found that while PrEP could initially increase costs by a maximum of $171 million during the first 10 years of implementation, it has the potential to be cost-saving after year 10, as the costs of a lifetime of HIV care exceeds the cost of a PrEP regimen (van de Vijver et al., 2019). It is important to note that cost-effectiveness calculations are largely dependent on current HIV prevalence, viral suppression rates, and projected behaviors within a population – as such, given that this model was conducted in Germany, these findings may not be able to extrapolate to an American context.

Direct Costs of HIV Transmission

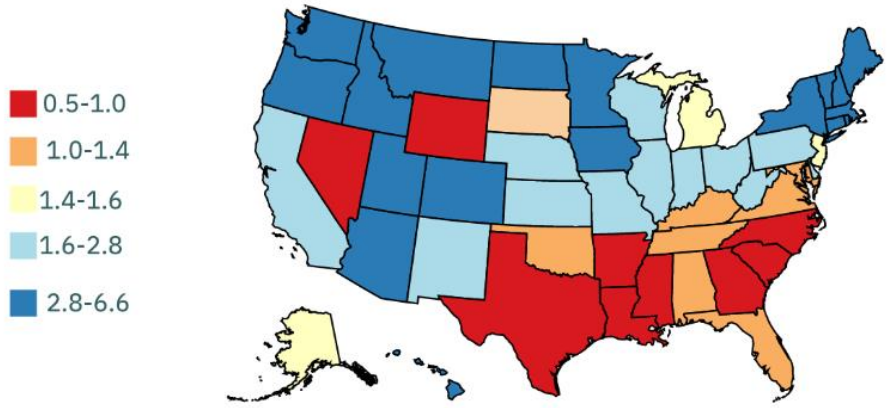
The federal government currently spends approximately $20 billion in annual direct health expenditures for HIV prevention and care (Office of Infectious Disease and HIV/AIDS Policy, HHS, 2020). Direct costs include outpatient visits to HIV specialists, medication costs, laboratory costs, hospitalizations, and other healthcare expenses. The total direct costs of HIV care are estimated to be around $41.2 billion over 40 years (Stephens, 2019). The cost averted by avoiding 1 new HIV transmission amounts to $400,000 in lifetime costs (Riddell et al., 2018). Discounted average lifetime costs for HIV patients ranged from $253,000 - $402,000 depending on the stage at which they enter care, and these cost estimates indicate that people living with HIV who enter care at an early stage incur greater lifetime costs, but experience greater clinical benefits and reduction in risk of HIV transmission (Farnham et al., 2013). Quantifying the externality cost for social and economic loss that a person incurs is more nuanced. Additionally, given that HIV is a transmittable disease, lack of access to PrEP has public health consequences. In failing to address the problem of access to biomedical

HIV prevention, we will continue to allow significant externalities to society to occur, by increasing the prevalence of HIV rather than ending the epidemic (Shah et al., 2016).

Equity Implications

There are disparities in PrEP uptake among at-risk groups across race and ethnicity, gender, age, and geographic location. Across all of these margins, counterintuitively, those that are most at-risk for contracting HIV are those with the lowest PrEP utilization. Black and Hispanic individuals are estimated to have higher rates of clinical indications for PrEP at 43.7% and 24.7% respectively. Despite this, in 2016, almost 70% of PrEP users were white, 11% were Black, and 13% were Hispanic (Huang et al., 2018). PrEP usage amongst women accounted for merely 4.7% of PrEP prescriptions in 2016, and uptake amongst men was roughly 14 times higher than uptake amongst women (Huang et al., 2018). People who are 25-44 years old were also more likely to be PrEP users than people in other age groups (Huang et al., 2018). Lastly, evidence suggests significant geographic disparities in PrEP access. The US-South accounted for more than half of new HIV diagnoses in 2016 but represents only 30% of all PrEP users (*Mapping PrEP*, 2018). Additionally, a recent study demonstrated that southern states had the lowest levels of PrEP utilization relative to need (Figure 1), measured by the proxy of 2016 HIV diagnoses (Siegler et al., 2018). Furthermore, Medicaid Expansion states have been found to have better PrEP uptake than states without Medicaid Expansion (Karletsos & Stoecker, 2021; Siegler et al., 2018).

Figure 1: PrEP utilization relative to 2016 HIV diagnoses (by state)



Data Source: Siegler et al., 2018

These disparities reveal an equity gap, where the people for whom the need for PrEP is most salient are the people that have the greatest difficulty in accessing it. HIV care and PrEP access are highly impacted by social and structural determinants of health. Moreover, these access issues disproportionately affect at-risk and underserved communities. The US-South has the highest annual new HIV diagnosis rates nationally (Reif et al., 2019) and has disproportionately higher rates of poverty, lack of insurance, and rurality relative to other regions (Desilver, 2014). Furthermore, in 2016, over 75% of people newly diagnosed with HIV in the South were either Hispanic or non-Hispanic

Black (Reif et al., 2019) and, once diagnosed, they were less likely to be linked to care, retained in care, or receive treatment (A. S. Johnson et al., 2013; Mugavero et al., 2009; Tripathi et al., 2011). People living with HIV in the South are also less likely to achieve viral suppression than those living in other geographic areas (Hanna et al., 2013). Social stigma, particularly in the South, associated with HIV diagnoses and queer identities, has resulted in higher rates of laws that criminalize HIV, which exacerbates barriers to PrEP (Arnold et al., 2017; Cahill et al., 2017; Kerr et al., 2014; Oldenburg et al., 2015; Sullivan et al., 2019). Lower accessibility to PrEP can be correlated with this social stigma, as providers in these areas may be less likely to openly prescribe PrEP (Mayer et al., 2020). Lack of access to PrEP will therefore increase the prevalence of HIV in these communities and subsequently amplify social stigma. These disparities in outcomes are likely to exacerbate prior socioeconomic inequities, as well (Pellowski et al., 2013).

LITERATURE REVIEW

A growing body of literature is striving to identify policies and programs that can increase financial accessibility of PrEP (Horberg & Raymond, 2013; Kay & Pinto, 2020; Smith et al., 2017), but less is known about financial barriers for PrEP-associated medical visits and laboratory tests. This literature review will explore four potential policy approaches to improve access and reduce financial barriers to PrEP-associated medical visits and laboratory costs: (1) Public-Payer Models for PrEP Financing, and (2) Cost-Sharing Regulation, and (3) the Expansion of CDC Federal Funding Streams. This review will identify the strengths and limitations of existing evidence, as well as what remains unknown, to evaluate potential policy options for reducing the cost associated with PrEP-related services to improve PrEP access.

Public Payer Models/Drug Assistance Programs

Insurance coverage status plays a critical role in PrEP financial accessibility. PrEP medication costs alone can exceed $17,000 per year (Horberg & Raymond, 2013), plus additional expenses for medical visits and laboratory tests. While the anticipation of high costs is a significant barrier to the PrEP uptake, PrEP implementation interventions ramped up after the passage of the Patient Protection and Affordable Care Act (ACA) in 2012. Studies indicate that the perception of the high cost of PrEP as a barrier was alleviated by industry-sponsored medication assistance programs such as Gilead Sciences, Inc., and non-profit medication assistance programs, such as the Patient Access Network (PAN) and Patient Advocate Foundation (PAF), as these programs pay for PrEP for those without insurance and assist with medication copayments for those who are insured (Smith et al., 2017). While the literature highlights medication assistance programs as mechanisms to make PrEP more affordable to people with lower incomes and underinsured individuals, the impacts of these programs are uncertain, especially as it relates to coverage of PrEP-associated costs (Horberg & Raymond, 2013). Additionally, even though PrEP is generally covered by state Medicaid programs along with the associated medical visits and laboratory tests, access to the drug is widely disparate, as many states in the South have not expanded Medicaid under the Affordable Care Act (Seiler, 2019).

A few states have begun to address this concern by moving to a public payer of last resort model for PrEP financing. According to the CDC, states have established PrEP patient assistance programs using non-federal and local funds, including California, Virginia, Massachusetts, New York, Washington state, and the District of Columbia (Centers for Disease Control and Prevention, 2020). In California, the office of AIDS provides financial assistance for PrEP medication and additional medical expenses including medical visits and laboratory tests (One Community Health, 2020). Eligibility criteria for the program includes having an income less than 500% of the federal poverty level, California residency, and not being fully covered by third-party payers. If a patient is uninsured, the program will pay for all medical costs including medical visits and laboratory tests. If a patient is insured, the program will pay for all PrEP-associated medical out-of-pocket costs and cover any medication costs not covered by the drug manufacturer's copay assistance program (One Community Health, 2020).

The public payer of last resort model could potentially be incorporated in the federal *Ending the HIV Epidemic* (EHE) "Ready, Set, PrEP " initiative at the federal level. Currently, to receive PrEP through this initiative, an individual must (1) test negative for HIV, (2) have a valid prescription from a healthcare provider for the medication, and (3) not have health insurance for outpatient prescription drugs. If a patient qualifies for this program, all medications are fully covered, but the costs of medical visits and lab tests vary depending on income (HHS Press Office, 2019). Despite extensive literature about the mechanisms of public payer models, there is limited evidence analyzing the causal effects of public payer models on PrEP accessibility, largely due to these programs being relatively novel. Additionally, these programs are limited in their dependency on state investment, because states are not permitted to use federal Ryan White funding for PrEP and the non-EHE CDC funds cannot fund medical visits and laboratory tests associated with PrEP (NASTAD, 2018). Further investigation of public payer model efficacy should scale to a comparative lens and assess global trends of PrEP accessibility with public payer models.

Regulation Prohibiting Cost-Sharing for PrEP

Much of the discourse surrounding HIV biomedical preventive service access and coverage is fragmented across private insurance, Medicare and Medicaid markets. The US Preventive Services Task Force (USPSTF) provides recommendations for a range of highly effective preventive services based on exhaustive review of clinical evidence. The ACA requires most insurance plans to cover USPSTF Grade A and B rated services without cost sharing (Horberg & Raymond, 2013). In June of 2019, the USPSTF finalized a Grade A recommendation for PrEP, meaning that PrEP must be covered by most private insurance plans without cost-sharing[1] beginning in January 2021(Hughes et al., 2019; Seiler, 2019). While the USPSTF recommendation for PrEP references the CDC guidelines, it does not explicitly mention the clinic visits and lab services that are integral to the PrEP intervention. This lack of specificity has meant that insurers vary on whether and what PrEP ancillary services they cover without cost sharing as part of the PrEP intervention (Kay & Pinto, 2020). In addition, USPSTF recommendations are not associated with coverage requirements for Medicare Part D, which covers prescription drugs, nor for traditional Medicaid programs outside of Medicaid expansion (Hughes et al., 2019).

Studies indicate that reducing cost-sharing for PrEP medication may help promote access to the drug (Seiler, 2019). However, if cost-sharing requirements for PrEP do not cover medical visits and laboratory tests, PrEP remains financially inaccessible. There are many limitations to the USPSTF policy due to its ambiguous scope. First, it is unclear whether the PrEP-associated medical visits and labs are also restricted from cost-sharing (Kay & Pinto, 2020). Since laboratory tests are often neglected in terms of coverage, this USPSTF recommendation should delve deeper into ensuring that the restriction on cost-sharing applies to related medical visits and lab testing as well as medication costs (Kay & Pinto, 2020). Similarly, ambiguities remain across first dollar coverage[2] requirements

[1] Cost sharing occurs when patients pay for a portion of healthcare costs that are not covered by health insurance

[2] Insurance policy where the insurer pays for all expenses once an insured event occurs without the use of a deductible

across payers for the cost-sharing restriction – while the initial medical visit to obtain PrEP must be covered without cost sharing, it is unclear whether the support for additional medical visits are entitled to the first dollar coverage (Hughes et al., 2019). Federal and state regulators could solve this problem by issuing regulations or sub-regulatory guidance requiring insurers to cover both the medication and PrEP ancillary services recommended by the CDC.

Some states have implemented mandates requiring insurers to cover both the medication and ancillary services for PrEP at no cost-sharing across to the USPSTF recommendations. A New York 2018 insurance guidance letter, for instance, advised that issuers cover any tests or services at no cost-sharing that are expressly recommended in the "USPSTF's Final Recommendation Summary to PrEP" – this includes ongoing follow medical visits, monitoring, HIV tests, and additional laboratory testing for recommended services such as kidney function and hepatitis B and C testing, STI screenings, and pregnancy tests (Johnson, 2020). While this policy expands financial access to clinical and laboratory services, it is contingent on cost-sharing regulation being enforced. Despite most health plans being required by law to cover PrEP with no cost-sharing, according to the HIV+Hepatitis Policy Institute, many insurers are failing to adhere to the guidelines due to a lack of enforcement of the regulation (Burke, 2020). As such, there is a lack of empirical evidence analyzing cost-sharing restrictions for PrEP accessibility due to all the aforementioned policy ambiguities. Further research is necessary to add nuance to state and federal payer regulation and enforcement measures.

CDC Federal Funding Streams

While PrEP is listed as an essential component of the CDC's funding package entitled the "Integrated HIV Surveillance and Prevention Programs for Health Departments," the CDC has a longstanding policy that these federal funds cannot pay for most medication, laboratory tests, and medical visits associated with PrEP (Centers for Disease Control and Prevention, 2020). However, in 2019, the CDC EHE implementation awards authorized the use of $4.5 million in federal funds to cover PrEP lab services in three "Jumpstart Sites" – East Baton Rouge Parish, LA, DeKalb County, GA, and Baltimore City, Maryland (Centers for Disease Control and Prevention., 2020). Through the expansion of CDC federal funding, The Open Health Care Clinic in East Baton Rouge Parish acquired a new lab site and increased PrEP laboratory testing capacities. DeKalb County's STD clinic implemented a PrEP awareness campaign and expedited their testing capabilities (Centers for Disease Control and Prevention., 2020). Given that these awards were recent and localized in scope, there are currently limited empirical analyses regarding the impact of federal funding expansion on PrEP financial access. This expansion of federal funding to include PrEP laboratory tests and medical visits could potentially be expanded across CDC funds, instead of solely EHE awards. For instance, the Notice of Funding for the fiscal year 2020 includes a strategy to accelerate efforts to increase PrEP use, particularly amongst high-risk populations. This notice details that CDC funds "may be used for laboratory costs for screening or monitoring PrEP per CDC Guidelines for uninsured or underinsured people receiving PrEP in not-for-profit or governmental clinics" (Centers for Disease Control and Prevention., 2020) This stipulation is vague and requires further analysis into the intricacies of the CDC guidelines and the types of settings in which CDC funds can be used to cover laboratory costs.

Additionally, there is limited literature, with the exception of evidence from the CDC, that discusses the expansion of federal funding streams to cover PrEP-associated costs. More empirical analysis is required to assess the efficacy of federal funding streams on increased financial access to PrEP.

Takeaways from the literature

While there is a growing body of literature on financing policy options for PrEP-associated medical visits and laboratory costs, there is limited empirical evidence assessing the validity of the options within the system at large. Firstly, the implementation of a public-payer of last resort model at a state or federal level could alleviate out-of-pocket costs for patients and promote equity of access to preventive services across healthcare coverage. This is a novel approach in the U.S. context, and needs to be further explored in a comparative analysis of holistic public-payer models. Secondly, increasing regulation of cost-sharing practices could also alleviate the burden of high out-of-pocket costs for patients across health insurance groups. Policy approaches could include prohibiting cost-sharing for preventive services such as PrEP, but ambiguities remain in terms of what aspects of the PrEP service model count under that restriction. Lastly, the expansion of CDC federal funding streams to cover PrEP-associated medical visits and laboratory costs could reduce financial barriers to PrEP amongst high-risk communities, but there is limited empirical evidence to assess the efficacy and feasibility of this intervention within the context of the CDC funding guidelines.

Future directions could include designing economic models to predict the impact of these potential policy solutions and exploring how these PrEP financing policy options fit into the larger socio-political considerations at play in the US. With the EHE initiative and the current federal government's interest in health equity, this may be the right time to explore and advocate for increased financial accessibility for PrEP-associated costs and services.

EVALUATIVE CRITERIA

To recommend a policy from the proposed list, I will use the following criteria:

Reduction in Cost Barriers of PrEP-Associated Costs

Effectiveness is defined by the reduction in the cost of PrEP-associated services for individuals in need of PrEP. This will be measured through a cost comparison of PrEP financial accessibility pre-intervention and post-intervention in dollar amount, using comprehensive data from similar interventions and cost estimates from FAIR Health. Policy alternatives will be assigned relative scores **ranging from 1-5** based on the dollar amount of cost-savings according to insurance status (i.e. cost-saving for insured patients, cost-saving for uninsured patients). Effectiveness will be rated slighter higher for cost-savings for uninsured patients relative to insured patients.

Policy Reach

This criterion measures how many individuals the policy option reaches and reduces cost-barriers for, in terms of the percent of the target population that is reached through the intervention. This will be operationalized by using proxies and estimates from similar interventions of the number of patients reached, with a particular focus on insurance rates to estimate reach. Policy alternatives will be assigned relative scores **ranging from 1-5** based on the percent of the target population and net number of people reached by this alternative.

Cost

This criterion measures the total cost of each intervention (in 2021 dollars) based on data of current funding streams and estimated total spending for each alternative. The total costs of each alternative will be valued and monetized, and will be multiplied by the total number of people reached. Cost estimates will also include a 10% administrative cost for program implementation, using a proxy from the Health Resources and Services Administration's (HRSA) guidelines for the Ryan White HIV/AIDS Program (Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program). Since NASTAD represents state and federal health departments, this analysis will primarily consider state and government costs. All cost calculations can be found in the appendix. Policy alternatives will be assigned relative scores in **reverse order on a scale of 1-3: high cost (1), medium cost (2), or low cost (3).** The strongest policy options in terms of cost will have the highest ranking for this criterion.

Administrative Feasibility

Federal and state funding for PrEP-associated medical visits and laboratory tests has not been at the forefront of the political agenda for HIV until relatively recently. This criterion will measure how likely the alternative is to be adopted across stakeholders, ranging from political stakeholders to insurance companies to medical providers. This will be measured by the number of steps it would take for the policy to be enacted, and could be gauged upon on metrics including the previous voting history of stakeholders, partisan view on the issue and the policy, insurance companies' reception of the

alternative, the makeup of the federal/state legislature, and emerging windows of opportunity. After compiling the number of steps and the other administrative factors of the alternative, it will be weighed on a rubric and given a **determined score of low (1), medium (2), or high (3).**

Equity

There are disparities in PrEP uptake among at-risk groups, particularly across race, gender, age, and geographic regions. Counterintuitively, those that are most at risk are those with the lowest PrEP utilization. This criterion measures the impact of the alternatives on reducing inequitable access to PrEP and PrEP-associated services. This criterion will use proxies of similar interventions' impact on (1) racial equity, (2) geographic equity, and (3) socioeconomic equity. It will be operationalized with a point system, with a maximum of **1 point assigned to each of the three pillars of the equity criteria, for a total possible score of 3 for equity**.

ALTERNATIVES & EVALUATION

All of the alternatives advocate for increased spending to cover the cost of PrEP and PrEP-associated costs, either through the form of expanding federal or state discretionary spending or the cost burden falling on insurance payers. Thus, most of these options entail some degree of the cost burden on either taxpayers or insurance payers, through channels such as income tax payments or potentially increased insurance premiums. This stipulation of the cost burden is an underlying phenomenon across all of the proposed alternatives, and while not explicitly an evaluative criterion, it must be accounted for in the analysis of the potential policy directions.

Policy Option #1: Expansion of "Ready, Set, PrEP" as a federal public payer to cover PrEP-associated costs

This alternative focuses on moving to a federal-level public payer of last resort model and patient-assistance programs for PrEP financing. A payer of last resort is the payer who covers care and services only if there are no other sources of payment available. By law, Medicaid has served as the public payer of last resort, where, if another insurance program has the responsibility to cover medical costs incurred by a Medicaid-eligible individual, that program is required to pay all or some part of the claim before Medicaid makes a payment (MACPAC, 2020).

Through this option, the public payer of last resort model could potentially be incorporated in the federal *Ending the HIV Epidemic* (EHE) "Ready, Set, PrEP " initiative. To receive PrEP through "Ready, Set, PrEP," an individual must (1) test negative for HIV, (2) have a valid prescription from a healthcare provider for the medication, and (3) not have health insurance for outpatient prescription drugs. If a patient qualifies for this program, all medications are fully covered, but the costs of medical visits and lab tests vary depending on income (HHS Press Office, 2019). This alternative would engage NASTAD's advocacy initiatives with the federal health department to expand "Ready, Set, PrEP" into a public payer of last resort model that covers PrEP-associated costs as well.

Furthermore, public payer models of last resort are geared towards increasing access for underinsured or uninsured individuals, so the scope of access effectiveness must be further evaluated. Funding for this alternative would likely come from budget appropriations at the state or federal level. Federally, this funding would come from Congress' federal budget appropriations for the EHE initiative to fund "Ready, Set, PrEP." In the fiscal year 2021, $386 million was appropriated for the EHE initiative, of which $102 million was allocated to provide "HIV testing, linkage to care, and prescription of PrEP" (Office of Infectious Disease and HIV/AIDS Policy, HHS, 2021).

Reduction in cost-barriers of PrEP-associated costs

According to data from FAIR Health, the projected cost of PrEP care for the initiation of PrEP is $2,666.90 for uninsured patients, of which roughly $1,000 is encompassed in laboratory tests and medical visits (NASTAD, 2018). Under these assumptions, the annual cost amounts to a low-end estimate of roughly $3,000 for uninsured patients for just the PrEP-associated laboratory tests and medical visits, and approximately $24,000 including the cost of

the branded Truvada drug. These cost projections include the cost of the medication, primary care physician visits, and the essential tests that are recommended for most patients. Importantly, this does not factor in additional tests that would be recommended based on risk, such as Hepatitis C screenings. While "Ready, Set, PrEP" covered the cost of medication fully, this intervention would expand the coverage to PrEP-associated medical visits and laboratory costs, which would allow **uninsured PrEP-recipients to save approximately $3,000 for PrEP-associated costs** and $24,000 for total PrEP costs (including the drug) annually. As such, this alternative will receive a **score of 4** for effectiveness, as it covers the cost of PrEP-associated services for uninsured patients.

Policy Reach

Gilead Sciences has donated enough Truvada to the federal "Ready, Set, PrEP" program to meet the goal of providing PrEP to 200,000 people annually, for a maximum of 11 years (*Ready, Set, PrEP*, 2021; Straube, 2020). Of the 1.2 million people with clinical indications for PrEP, 27.5% are uninsured (Smith et al., 2017) – as such, the uninsured population in need of PrEP is roughly 330,000 individuals and this policy could reach **200,000 of them, roughly 60% of the target population**. Given this, this alternative receives a **score of 4** for policy reach.

A collective of over 24,000 pharmacies have partnered with the federal program to donate medical dispensing services, representing almost half of the pharmacies in the U.S., Puerto Rico, and the U.S. Virgin Islands (Stein, 2020). This partnership allows program enrollees to fill prescriptions for PrEP at the participating pharmacies or by mail order – it can be assumed that if the "Ready, Set, PrEP" program were to be expanded to cover the cost of PrEP-associated services, similar partnerships would need to be established across not only participating pharmacies, but clinics and laboratory testing facilities.

This program has faced take-up limitations that need to be considered for policy reach. Despite the aim to increase access to 200,000 uninsured patients, according to data from Bloomberg Law reports, only 891 people were enrolled in 2020 (Stein, 2020; Straube, 2020). Cited reasons for low uptake include limited federal healthcare resources due to the COVID-19 pandemic and lack of coverage of PrEP-associated laboratory tests and medical visits (Straube, 2020). As such, this policy option could address a gap in access to PrEP through this program.

Cost

The annual cost to expand "Ready, Set, PrEP" to cover PrEP and PrEP-associated costs is **$704 million**, assuming a policy reach of 200,000 annually and 10% administrative costs. This is the highest cost of all alternatives, and thus receives a **score of 1**. This calculation is based on a projected cost of $3,000 annually per person for PrEP-associated costs (NASTAD, 2018) and an initial estimate of the federal government paying Gilead roughly $200 per bottle of

Truvada to cover the cost of the distribution and dispensing (Rodriguez, 2019). The 10% administrative cost cap is a proxy extrapolated from Health Resources and Services Administration's (HRSA) guidelines for the treatment of costs under the statutory 10% administrative cap for Ryan White HIV/AIDS Programs Parts A, B, C, and D (Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Parts A, B, C, and D, 2020). A full description of this cost estimate is found in Appendix I.

Administrative Feasibility

Funding for this alternative would likely come from budget appropriations at the federal level. This funding would come from Congress' federal budget appropriations for the EHE initiative to fund "Ready, Set, PrEP." In fiscal year 2021, $386 million was appropriated for the EHE initiative, of which $102 million was allocated to provide "HIV testing, linkage to care, and prescription of PrEP" (Office of Infectious Disease and HIV/AIDS Policy, HHS, 2020). This proposal must first be presented by HHS or the EHE for the expansion of federal funds to cost PrEP-associated costs to either the President or Congress. The President will submit an annual budget request to Congress, and Congress will then create a congressional budget resolution on total discretionary spending. HHS' Health Resources and Services Administration (HRSA) oversees the program "Ready, Set, PrEP" as well, so this funding expansion will be administered and executed by HRSA.

Provided the funding is approved by key stakeholders, the funding will be used to cover costs to Gilead for the drug and costs to participating clinics and laboratory testing facilities. Participating pharmacies act as vendors for the distribution of the medication, and it can be assumed that similar partnerships would need to be established across clinics and laboratory testing facilities, which may require additional time to develop. The government pays Gilead directly to cover the cost of the drug, but will likely need to move to a reimbursement model to cover the cost of clinical and laboratory services (Rodriguez, 2019).

With a shift to the Biden Administration and the ongoing COVID-19 pandemic, there is an emergency window of opportunity to expand coverage for infectious disease measures. The CARES Act has set a precedent for issuers covering all coronavirus preventive services, including ancillary services and this model could be scaled to a federal public payer model through "Ready, Set, PrEP." As such, this would rank **medium** for administrative feasibility and receive a **score of 2**.

Equity

The "Ready, Set, PrEP" initiative aimed to target communities that could benefit the most from access to PrEP – namely, Black and Latino MSM, transgender people, and Black women (Stein, 2020). However, uptake of PrEP through the program remains low, largely due to a lack of coverage of PrEP-associated costs. Thus, the expansion of "Ready, Set, PrEP" to cover associated laboratory tests and medical visits has the potential to increase equity across racial

lines, but there is limited empirical evidence to assess the effects of these interventions. HHS has indicated that the participation of certain independent pharmacies in "Ready, Set, PrEP" will increase access to PrEP in these traditionally underserved areas, provided that there is equitable access to participating clinics and pharmacies with the expansion.

Examining California's PrEP-AP initiative, cisgender women, young people from ages 18-24, Black individuals, and those living in rural areas were all under-enrolled in the program (Gallagher, 2020). Targeted interventions, such as telemedicine access in the Central Valley and confidentiality policies to combat social stigma have been implemented in California, but there is limited empirical evidence to assess the effects of these interventions. This trend will likely scale to the federal assistance programs level through "Ready, Set, PrEP" – as such, this option gains 0.5 points for racial equity and 0.5 points for geographic equity. Lastly, because this expansion covers the cost of PrEP and PrEP-associated services for uninsured individuals, it would increase equitable access to PrEP across socioeconomic lines. As such, it receives 1 point for socioeconomic equity, amounting to a total of **2 out of 3 points** for equity.

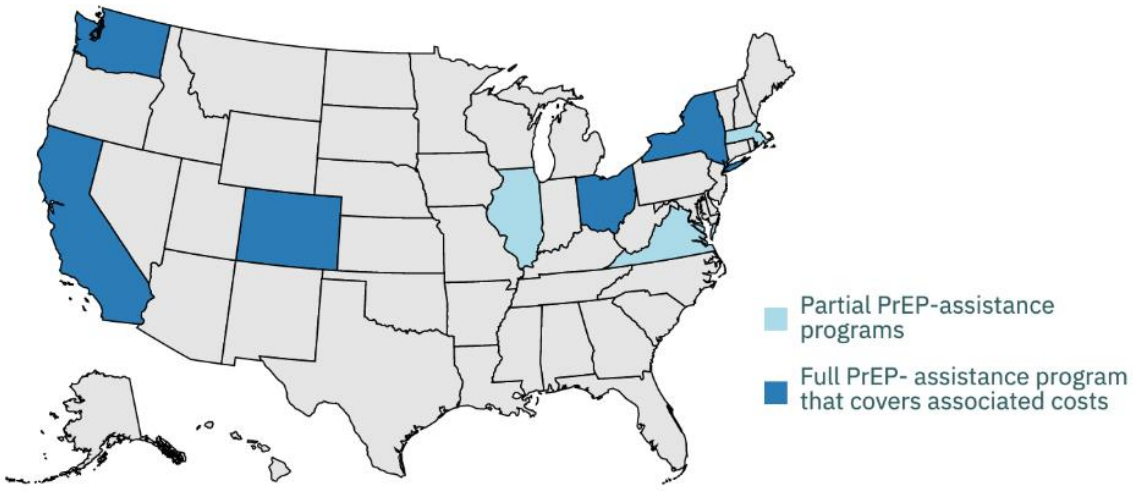
Option #1: Expansion of "Ready, Set, PrEP" as a federal public payer to cover PrEP-associated costs				
Effectiveness	***Policy Reach***	***Cost***	***Admin. Feasibility***	***Equity***
4 $3,000 annual reduction for uninsured	4 60% Up to 200,000 people annually	1 $704 million in annual program cost	2 Medium	2 0.5 – Racial Equity 0.5 – Geo. Equity 1 – Economic Equity **Total**: 2/3

Policy Option #2: State public payer models for PrEP financing

Similar to option #1, this option focuses on advocating for more states to adopt a public payer of last resort model and patient-assistance programs for PrEP financing. According to the CDC, a few states have established PrEP patient assistance programs using non-federal and local funds, including California, Colorado, Illinois, Massachusetts, New York, Ohio, Washington state, Virginia, and the District of Columbia (Centers for Disease Control and Prevention, 2020; NASTAD, 2018). For example, in California, the office of AIDS provides financial assistance for PrEP medication and additional medical expenses including medical visits and laboratory tests (One Community Health, 2020). Eligibility criteria for the program include having an income less than 500% of the federal poverty level, California residency, and not being fully covered by third-party payers. If a patient is uninsured, the program will pay for all medical costs including medical visits and laboratory tests. If a patient is insured, the program will pay for all PrEP-associated medical out-of-pocket costs and cover any medication costs not covered by the drug manufacturer's copay assistance program (One Community Health, 2020).

Through this option, NASTAD would advocate to the remaining state health departments to adopt PrEP drug assistance programs as a public payer of last resort for uninsured/underinsured individuals in need of PrEP. These programs are likely limited by their dependency on state investment because states are not permitted to use federal Ryan White funding for PrEP, and the non-EHE CDC funds cannot fund medical visits and laboratory tests associated with PrEP (NASTAD, 2018). PrEP-AP in California was authorized to implement the program through the 2016 California Budget Act, which makes appropriations for the support of the state government for the fiscal year of 2016-2017 (*SB-826 Budget Act of 2016.*, 2016). As such, funding for this alternative would likely come from budget appropriations at the various state levels.

Figure 2: States with PrEP-Assistance Programs (2019)



Source: NASTAD, 2018

Reduction in cost-barriers of PrEP-associated costs

Similar to policy option #1, according to data from FAIR Health, the projected cost of PrEP care for the initiation of PrEP is $2,666.90 for uninsured patients, of which roughly $1,000 is encompassed in laboratory tests and medical visits (NASTAD, 2018). Under these assumptions, the annual cost amounts to a low-end estimate of roughly $3,000 for uninsured patients for just the PrEP-associated laboratory tests and medical visits, and approximately $24,000 including the cost of the drug. The implementation of state drug assistance programs that cover the cost of PrEP-associated laboratory tests and medical visits allows **uninsured PrEP-recipients in those states to save approximately $3,000 for PrEP-associated costs** and $24,000 for total PrEP costs (including the drug) annually. As such, this alternative will receive a **score of 4** for effectiveness, as it covers the cost of PrEP-associated services for uninsured patients.

Policy Reach

This policy option will turn to pre-existing assistance programs implemented in other states to estimate policy reach. For example, from April 2018 to November 2019, enrollment in California's PrEP-AP increased to more than 3,000 clients, of which 58% were uninsured, 38% had commercial insurance, and 4% were on Medicare (Gallagher, 2020). If a patient is insured, the PrEP-AP will pay for all PrEP-associated medical out-of-pocket costs, as well as cover any medication costs not covered by the drug manufacturer's copay assistance program (One Community Health, 2020). If a patient is uninsured, PrEP-AP will pay for all medical costs including medical visits and laboratory tests. As such, roughly 58% of uninsured recipients of PrEP through CA PrEP-AP will have the full cost of their PrEP covered by the Assistance Program.

This metric will vary across states, especially across states that have not expanded their Medicaid programs. This report will use existing assistance programs, like the California PrEP-AP, as a proxy for other assumptions about policy reach. This report will assume that the priority will be to focus on states that have implemented drug assistance programs but do not currently cover PrEP-associated costs, such as Illinois and Virginia. In Virginia's case, there were 32,380 people at high risk of contracting HIV in 2018, but only 5% of them were prescribed PrEP (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2018) Since there is limited data on the insurance status of these individuals, using the assumption that roughly 58% of the target population in a state is uninsured, this policy could reach potentially 18,780 individuals in the state of Virginia. Similarly, in Illinois, there were 53,854 individuals at high risk of contracting HIV, and about 28% of them have received PrEP prescriptions (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2018). As such, using 58% reach as a proxy, this option can potentially reach 31,000 individuals in Illinois through expanding to cover PrEP-associated costs. In sum, expanding these programs in Virginia and Illinois would allow the policy to **reach 49,780 (15%) of the 330,000 uninsured individuals in need of PrEP in the U.S**. This policy alternative will receive a

score of 2 for policy reach, because of the variability in reach across states and the ambiguity in the data.

Cost

Assuming this policy option prioritizes targeting states that have preexisting drug assistance programs but do not currently cover PrEP-associated costs, the total cost of the state level programs is approximately $66 million in the state of Virginia and $110 million in Illinois, amounting to a **total across the two states of $176 million**. As such, this policy alternative will rank **medium** for cost and will receive a **score of 2.** This cost estimate assumes a policy reach of 18,780 individuals in Virginia annually and 53,854 individuals in Illinois as a proxy, and 10% administrative costs. This calculation is based on a projected cost of $3,000 annually per person for PrEP-associated costs (NASTAD, 2018) and an initial estimate of the cost of the drug, utilizing the proxy of the federal government spending of roughly $200 per bottle of Truvada (Rodriguez, 2019). A full description of this cost estimate is found in Appendix I.

Administrative Feasibility

PrEP-AP in California was authorized to implement the program through the 2016 California Budget Act, which makes appropriations for the support of the state government for the fiscal year of 2016-2017 (*SB-159 HIV: Preexposure and Postexposure Prophylaxis*, 2019) and the funding source of the program is a supplemental rebate. As such, funding for this alternative would likely come from budget appropriations at the various state levels. This alternative would rely on advocating to individual state health departments to implement medication assistance programs at the state-level and likely negotiate supplement rebates with drug companies to drive down cost (Waldrop & Calsyn, 2021). This option will likely be contingent on the state's political, social, and cultural interest regarding HIV/AIDS, and their willingness to appropriate additional funding to cover PrEP-associated costs. As such, this option will rank **low** for administrative feasibility and receive a **score of 1**, as passing legislation on a state-by-state basis will likely be more cumbersome than legislation at the federal level.

Equity

Similar to policy option #1, examining California's PrEP-AP initiative, cisgender women, young people from ages 18-24, Black individuals, and those living in rural areas were all under-enrolled in the program (Gallagher, 2020). It is likely that this trend of underutilization would scale to various other state assistance programs, so this option does not gain points for racial equity. Implementing assistance programs at the state level has interesting promise for increasing access at a local level, but access is largely dependent on the state that a patient lives in – it is less likely that states in the US-South or states that have not expanded Medicaid will implement PrEP-assistance programs, hindering access to geographic regions with the highest need for PrEP. As such, this option does not gain points for geographic equity. Conversely, since this option expands access to cover the cost of PrEP and PrEP-associated services for uninsured individuals, it would increase equitable access to PrEP across socioeconomic lines.

As such, it receives 1 point for socioeconomic equity, amounting to a total of **1 out of 3 points** for equity.

Option #2: State public payer models for PrEP financing				
Effectiveness	***Policy Reach***	***Cost***	***Admin. Feasibility***	***Equity***
4 $3,000 annual reduction for uninsured patients	2 15% 49,780 patients across VA/IL	2 $66 mil: VA $110 mil: IL $176 mil total	1 Low	1 0 – Racial Equity 0 – Geo. Equity 1 – Economic Equity **Total**: 1/3

Policy Option #3: Prohibiting cost-sharing with private insurers & Medicaid for PrEP-associated costs

This policy alternative recommends that states implement additional cost-sharing mandates requiring insurers to cover PrEP and PrEP-associated services at no cost-sharing across to the USPSTF recommendations, including ongoing follow medical visits, monitoring, HIV tests, and additional laboratory testing (Johnson, 2020). While this policy alternative expands financial access to clinical and laboratory services, it is contingent on cost-sharing regulation being enforced. Starting in January 2021, ACA Qualified Health Plans and Medicaid Expansion Plans were required by law to provide PrEP without cost-sharing according to USPSTF recommendations – despite this, according to the HIV+Hepatitis Policy Institute, many insurers are failing to adhere to the guidelines due to a lack of enforcement of the regulation (Burke, 2020), which may pose an implementation challenge for this policy alternative.

From a legal standpoint, this alternative would suggest passing a state-level enforcement of the federal regulation outlining PrEP as an "A" rated recommendation that should be covered at no cost-sharing. This option could also include outlining supplemental guidance to issuers that highlight PrEP's status as an "A" rated drug, similar to the New York Insurance Law additional mandate (Johnson, 2020). This alternative is focused on implementation at a state-level and targets the intervention for those with private insurance or Medicaid under Medicaid expansion. Importantly, USPSTF recommendations are not associated with coverage requirements for Medicare Part D, which covers prescription drugs, nor for Medicaid plans that are not covered under Medicaid expansion (Hughes et al., 2019).

Reduction in cost-barriers of PrEP-associated costs

Copayments for the drug and PrEP-associated costs vary across private insurance and Medicaid payers. While Truvada and associated clinical and lab work is generally covered by state Medicaid programs (Andrews, 2019), private insurance co-payments historically ranged from $400-$750 monthly for both the drug and PrEP-associated costs (Andrews, 2021). As such, this policy alternative to prohibiting cost-sharing for PrEP-associated costs could potentially **reduce costs of PrEP for individuals with private insurance by $4,800-9,000** per year. As such, this alternative will receive a **score of 3** for effectiveness, as it covers the cost of the co-payment for PrEP-associated services, but only targets individuals with insurance.

Policy Reach

Of the 1.2 million people with clinical indications for PrEP, **52.6% had private insurance** (Smith et al., 2017), meaning this policy option could potentially reduce costs of PrEP for **631,200 individuals** with indications for PrEP. One study estimates that amongst 93,600 adults in need of financial assistance to cover PrEP-associated costs or PrEP and PrEP-associated costs, 90% were uninsured and 10% were insured (Smith et al., 2017). Furthermore, among those that are insured but whose coverage denies payment, 67% of those individuals

have private insurance and 33% have public insurance (Smith et al., 2017). As such, this alternative receives a **score of 3** for policy reach.

Cost

The cost estimates for this policy option are slightly nuanced – because the intervention is focused on implementing additional mandates and enforcement regulation at the state level to prohibit cost-sharing for PrEP, the **state governments will not incur the costs of this option,** with the exception of minor potential costs of hiring or training new individuals to enforce regulation. Since this estimate is not well documented, this analysis assumes the cost of this policy alternative to be **$0 or negligible** to state governments, and ranks this option with a **score of 3** for cost.

Assuming a low-end annual cost of PrEP co-payments of $4,800 and a high-end estimate of $9,000, the total cost of covering co-payments for all individuals with clinical indications for PrEP with private insurance ranges from $3-5 billion. This burden would not fall on the taxpayers or the government, but rather the insurance companies that are mandated to cover costs with no cost-sharing. There is a concern that insurance companies might increase private insurance premiums to make up the loss, but evidence on the subject is limited.

Administrative Feasibility

This alternative has some legal precedence already because of the USPSTF guidelines that require health plans to provide PrEP without cost-sharing, but many insurers are failing to adhere to these protocols (Burke, 2020). For this option, administrative feasibility centers around the protocol for enforcing these regulations, as it is. This option is contingent on enforcing a federal regulation at a state-level, lowering the administrative feasibility within NASTAD's jurisdiction. NASTAD may advocate and work with state health departments to issue insurance laws explicitly outlining this regulation and its extension to cover laboratory testing and medical visits with no cost-sharing, or guidance letters similar to that of New York State (Johnson, 2020). Ultimately, without adequate regulations and enforcement at the state-level, payers may continue to fail to adhere to the protocols, especially as it extends to PrEP-associated costs. There is also a potential concern that these payers may raise premiums to make up the cost. As such, this option ranks **low** on administrative feasibility and receives a **score of 1**.

Equity

The USPSTF recommendation specifically identifies "persons at high risk of HIV" as "sexually active gay or bisexual men, heterosexual men or women, sex workers, and transgender people" who have a behavior risk factor (i.e. having a partner who is living with HIV or inconsistent condom use), or are individuals with injection drug use (IDU) (USPSTF, 2019). As cost-sharing is viewed as a substantial access barrier to PrEP that perpetuates disparate outcomes across race and gender, this option has the potential to increase access

across these lines and earns 1 point for racial equity. On the other hand, because this enforcement is implemented on a state-by-state basis, there will likely be geographic disparities due to states' jurisdiction – as such, it earns no point for geographic equity. This option is specifically targeted at individuals with private insurance or Medicaid under Medicaid expansion – as such, it will not cover those who fall in the coverage gap and are uninsured. Thus, this option receives no point for socioeconomic equity, amounting to a total of **1 out of 3 points** for equity.

Option #3: Prohibiting cost-sharing with private insurers/Medicaid for PrEP-associated costs				
Effectiveness	***Policy Reach***	***Cost***	***Admin. Feasibility***	***Equity***
3 $4,800-9,000 annual reduction for insured patients	**3** 52.6% Up to 631,200 individuals with private insurance	**3** $0 - cost borne government or taxpayers $3-5 billion for insurance payers	**1** Low	**1** 1 – Racial Equity 0 – Geo. Equity 0 – Economic Equity **Total**: 1/3

Policy Option #4: Expansion of CDC EHE federal funds for PrEP-associated costs

In this alternative, NASTAD would advocate to the federal health department for the expansion of federal funding to include PrEP laboratory tests and medical visits could potentially be expanded across CDC funds, instead of solely EHE awards. For instance, the Notice of Funding for the fiscal year 2020 includes a strategy to accelerate efforts to increase PrEP use, particularly amongst high-risk populations. This notice details that CDC funds "may be used for laboratory costs for screening or monitoring PrEP per CDC Guidelines for uninsured or underinsured people receiving PrEP in not-for-profit or governmental clinics" (Centers for Disease Control and Prevention., 2020). This stipulation is vague and requires further analysis into the intricacies of the CDC guidelines and the types of settings in which CDC funds can be used to cover laboratory costs. This alternative would focus on increasing federal funding streams rather than state funding streams, rendering it similar to a federal payer of last resort model. Specifically, this alternative draws on the successes of the PrEP "Jumpstart Sites" that were implemented in 2019 through the CDC implementation awards. The majority of CDC funding comes from congressional appropriations (~ $7 billion in Fiscal Year 2020), but two smaller funding streams for the CDC are direct gifts and the CDC Foundation (Centers for Disease Control and Prevention, 2020). Additionally, under the EHE initiative, $175 million was appropriated to the CDC for HIV infection reduction (Office of Infectious Disease and HIV/AIDS Policy, HHS, 2021). As such, the funding stream for this alternative would focus predominantly on the expansion of Congressional budget appropriations.

Reduction in cost-barriers of PrEP-associated costs

Similar to policy option #1 and #2, according to data from FAIR Health, the projected cost of PrEP care for the initiation of PrEP is $2,666.90 for uninsured patients, of which roughly $1,000 is encompassed in laboratory tests and medical visits (NASTAD, 2018). Under these assumptions, the annual cost amounts to a low-end estimate of roughly $3,000 for uninsured patients for just the PrEP-associated laboratory tests and medical visits, and approximately $24,000 including the cost of the drug. Given the success of these jump-start interventions with the CDC funding, this alternative would advocate for the expansion of CDC funding to cover PrEP, laboratory tests, and medical visits. If implemented, this would allow **uninsured PrEP-recipients in those states to save approximately $3,000** for PrEP-associated costs and $24,000 for total PrEP costs (including the drug) annually. As such, this alternative will receive a **score of 4** for effectiveness, as it covers the cost of PrEP-associated services for uninsured patients.

Policy Reach

In 2019, the CDC EHE implementation awards authorized the use of $4.5 million in federal funds to cover PrEP lab services in three "Jumpstart Sites" – East Baton Rouge Parish, LA, DeKalb County, GA, and Baltimore City, Maryland (Centers for Disease Control and Prevention, 2020). Through the expansion of CDC federal funding, The Open Health Care

Clinic in East Baton Rouge Parish acquired a new lab site and increased PrEP laboratory testing capacities. DeKalb County's STD clinic implemented a PrEP awareness campaign and expedited their testing capabilities (Centers for Disease Control and Prevention, 2020). Given the success of these jump interventions, this alternative would advocate for the expansion of CDC funding to cover PrEP, laboratory tests, and medical visits.

This policy reach of this alternative is difficult to estimate, as reach will be determined by the location of the jumpstart site and the city/state jurisdiction surrounding HIV prevention and healthcare coverage. Because these programs are community-centers and implemented in states with high need of PrEP-utilization, this report will assume that, upon expansion of CDC funds, more jumpstart sites will be set up in states such as Georgia and Louisiana. Focusing on Georgia, there were roughly 40,000 people at high-risk of contracting HIV in 2018, but only 15% of them were prescribed PrEP (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2018). Similarly, in Louisiana, 15,000 people were at high-risk in 2018, and only 23% received PrEP prescriptions (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2018). There is limited data on how many individuals are actually reached through the programs, but this policy option has the potential to increase access to PrEP for up to roughly 34,000 people in Georgia and 11,550 in Louisiana. Similar trends will scale to other localities. In sum, implementing programs in Georgia and Louisiana would allow the policy to **reach 45,500 (~13%) of the 330,000 uninsured individuals** in need of PrEP in the U.S. Given this, this alternative receives a **score of 2** for policy reach, because of the variability in reach across states and the ambiguity in the data.

Cost

Assuming this policy option prioritizes targeting states that have preexisting jumpstart sites, the total cost of the state level programs is approximately $140.8 million in the state of Georgia and $52.8 million in Louisiana, amounting to a **total across the two states of $193.6 million**. As such, this policy alternative will rank **medium** for cost and will receive a **score of 2.** This cost estimate assumes a steep policy reach of 40,000 individuals in Georgia annually and 15,000 individuals in Illinois as a proxy, and 10% administrative costs. This calculation is based on a projected cost of $3,000 annually per person for PrEP-associated costs (NASTAD, 2018) and an initial estimate of the cost of the drug, utilizing the proxy of the federal government spending of roughly $200 per bottle of Truvada (Rodriguez, 2019). A full description of this cost estimate is found in Appendix I.

Administrative Feasibility

This alternative would require a restructuring of a long-standing policy of the CDC that the federal funds cannot pay for most medications, laboratory tests, and medical visits associated with PrEP (Centers for Disease Control and Prevention, 2020). While the major funding sources do come from congressional appropriations, as well as direct gifts and funds from the CDC foundation, this long-standing bureaucratic policy will be a barrier to implementation.

Furthermore, while COVID-19 may pose an emerging window of opportunity in the future, the COVID-19 response and vaccine rollout is a significant priority for the CDC, which will hinder the immediate administrative feasibility of this option. As such, it will rank **low** for feasibility and receive a **score of 1.**

Equity

The jumpstart programs that were funded by the CDC EHE implementation award also utilized the HHS Minority HIV/AIDS funds to invest in the development of these sites and accelerate the HIV prevention mechanisms in these communities. There are positive implications for racial and geographic equity with this option, because it allows for implementation plans to be developed and executed on a community basis, with strategies tailored uniquely for each community – as such, it will earn 0.5 points for racial equity and 0.5 points for geographic equity. Additionally, this option addresses cost barriers for underinsured and uninsured individuals, so it earns 0.5 points for socioeconomic equity, amounting **1.5 points total.**

Option #4: Expansion of CDC EHE federal funds for PrEP-associated costs				
Effectiveness	***Policy Reach***	***Cost***	***Admin. Feasibility***	***Equity***
4 $3,000 annual reduction for uninsured patients	2 13% Up to 45,500 across GA/LA (varies by state)	2 $140.8 mil: GA $52.8 mil: LA $193.6 mil total	1 Low	1.5 0.5 – Racial Equity 0.5 – Geo. Equity 0.5 – Economic Equity **Total**: 1.5/3

OUTCOMES MATRIX

Criteria	Alternatives			
	A1: Federal Public Payer Model	**A2: State Public Payer Model**	**A3: Prohibiting Cost Sharing**	**A4: Expansion of CDC Federal Funding**
Effectiveness	4 **$3,000** reduction in annual cost for uninsured patients	4 **$3,000** reduction in annual cost for uninsured patients	3 **$4,800-9,000** reduction in cost for insured patients	4 **$3,000** reduction in annual cost for uninsured patients
Policy Reach	4 **60%** Up to 200,000 individuals annually	2 15% 49,780 patients across VA/IL (varies by state)	3 **52.6%** Up to 631,200 individuals with private insurance	2 13% Up to 45,500 across GA/LA (varies by state)
Cost	1 **$704 million** in annual program cost	2 $66 mil: VA $110 mil: IL **$176 mil total**	3 **$0 - cost for govt** $3-5 billion for insurance payers	2 $140.8 mil: GA $52.8 mil: LA **$193.6 mil total**
Admin. Feasibility	2 **Medium**	1 **Low**	1 **Low**	1 **Low**
Equity	2 0.5 – Racial Equity 0.5 – Geo. Equity 1 – Economic Equity **Total**: 2/3	1 0 – Racial Equity 0 – Geo. Equity 1 – Economic Equity **Total**: 1/3	1 1 – Racial Equity 0 – Geo. Equity 0 – Economic Equity **Total**: 1/3	1.5 0.5 – Racial Equity 0.5 – Geo. Equity 0.5 – Economic Equity **Total**: 1.5/3
Total	13	10	11	11.5

RECOMMENDATION

This report recommends that NASTAD pursue advocacy strategies to implement Policy Option #1:

Expand the federal "Ready, Set, PrEP" program as a federal public payer to cover both PrEP and PrEP-associated laboratory tests and medical visits.

From an effectiveness lens, options 1, 2, and 4 all target the intervention at uninsured PrEP-recipients – as a result, they all produce a net cost reduction of $3,000 for uninsured patients. Despite a large upfront cost, this option scores the highest for effectiveness, policy reach, feasibility, and equity relative to other options. It ranks highest in terms of feasibility because of its nature as an existing program, requiring the lowest relative program implementation and feasibility barriers. From NASTAD's perspective, it is also more administratively feasible to advocate at the federal level to expand this program, rather than advocate to select state health departments to implement public payer models or cost-sharing regulation enforcement.

IMPLEMENTATION

Funding for this program would come from Congress' federal budget appropriations for the EHE initiative to fund "Ready, Set, PrEP." In the fiscal year 2021, $386 million was appropriated for the EHE initiative, of which $102 million was allocated to provide "HIV testing, linkage to care, and prescription of PrEP" (Office of Infectious Disease and HIV/AIDS Policy, HHS, 2021). This proposal must first be presented to HHS or the EHE for the expansion of federal funds to cost PrEP-associated costs, who will then propose the budget expansion to either the President or Congress. The President will submit an annual budget request to Congress, and Congress will then create a congressional budget resolution on total discretionary spending. HRSA oversees the program "Ready, Set, PrEP" as well so this funding expansion must be approved by HRSA as well.

Funding Expansion Challenges

As this option necessitates additional federal funding allocated to the "Ready, Set, PrEP" program to cover the costs of medical visits and laboratory tests, the largest implementation challenge will be advocating Congress to appropriate more funds accordingly. The EHE initiative's policy goals are contingent on federal funding, however, past Congressional allocations for the EHE have not matched the requests from federal agencies and thus were not sufficient to meet the EHE's goals (Dawson & Kates, 2021). With the new administration, it is still unknown how the current EHE funding will expand, if at all – having said that, the Biden Presidential Campaign vowed to seek additional funding for HIV/AIDS research and prevention programs (Biden HIV Survey, 2020). He also claimed he would "ensure that federal health plans provide coverage for PrEP… including lab and clinical services" (Biden HIV Survey, 2020). As such, relevant stakeholders within funding expansion include the White House, the Department of Health & Human Services, Congress, and Gilead Sciences, who supplies PrEP to the "Ready, Set, PrEP" program. While Congress and the

White House may hesitate to expand EHE funding to cover these additional costs, the pandemic can be leveraged as a potential window of opportunity to emphasize the importance of access to preventive programs for infectious disease. In March 2020, the CARES Act allocated $90 million for the Ryan White HIV/AIDS Program (Long et al., 2020), having recognized the additional strain of the pandemic on HIV care and prevention. The CARES Act has set a precedent for issuers covering all coronavirus preventive services, including ancillary services, and this model could be scaled to a federal public payer model through "Ready, Set, PrEP." Further, NASTAD can point to the successes of state-level public payer programs to strengthen the case for an expansion of the existing federal program, as this expansion does not require a new program implementation.

COVID-19 and Local Level Implementation Challenges

EHE initiatives have continued to be rolled out throughout the COVID-19 pandemic, however, significant challenges and implementation delays have hindered the delivery of HIV prevention services (Dawson & Kates, 2021). A survey of demand for PrEP through Ryan White Part C and Part D providers indicated that roughly 25% of providers reported a decline in their ability to offer PrEP and 47% reported a decline in clients seeking out these services (Dawson & Kates, 2020). Grantees have also reported that, because of limited HIV testing capacity, the opportunity to educate patients about PrEP and programs like "Ready, Set, PrEP" have reduced as well (Dawson & Kates, 2020). The pandemic also poses resource allocation constraints, where many infectious disease specialists, health department staff, and frontline workers who previously focused on HIV had to redirect their attention to addressing and mitigating COVID-19. Additionally, despite its role as a federal program, it will be administered and implemented at state and local levels through providers – local-level limitations within jurisdictions, such as Medicaid Expansion disparities, socioeconomic factors, and service availability, can also facilitate or hinder EHE efforts (Kates et al., 2019). With these challenges, key stakeholders will be the state health departments and providers who offer PrEP under the "Ready, Set, PrEP" program, as well as HHS and Congressional funding structures. State health departments might be experiencing resource strain under COVID, however, NASTAD can leverage its advocacy strategy at both the federal and local levels. This also them to potentially exercise leadership to address implementation concerns on a case-by-case basis.

Increasing access to infectious disease prevention has never been more vital. Despite potential implementation challenges regarding funding expansions, COVID-19, and local jurisdiction, expanding "Ready, Set, PrEP" as a public payer to cover PrEP-associated costs requires the least amount of extensive program implementation for a significant gain in the financial accessibility of PrEP. With the EHE initiative and the current federal government's interest in health, this may be the right time to explore and advocate for increased financial accessibility for PrEP-associated costs and services, to help end the HIV epidemic in the U.S.

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APPENDIX

Appendix I: Cost Estimates

Alternative 1 Costs:

Total annual cost of PrEP-associated services
= cost of PrEP-associated services for uninsured recipients * projected reach of program
=$3,000 * 200,000
=$600 million

Total annual cost of PrEP paid by government to Gilead
= Cost per bottle paid by government to Gilead * projected reach of program
= $200 * 200,000
= $40 million

10% Administrative Cap
= (Total annual cost of PrEP + total annual cost of PrEP-associated services) * 0.10
= ($640,000,000) * 0.10
= $64 million

Total cost of alternative #1:
= Total annual cost of PrEP + total annual cost of PrEP-associated services + 10% admin.
= $600 million + $40 million + $64 million
= $704 million

Alternative 2 Costs:

Virginia
Total annual PrEP-associated costs through PrEP-AP program in VA
= cost of PrEP-associated services for uninsured recipients * projected reach of program
=$3,000 * 18,870
=$56.3 million

Total annual cost of PrEP through PrEP-AP program in VA
= Cost per bottle paid by government to Gilead * projected reach of program
= $200 * 18,780
= $3.75 million

10% Administrative Cap in VA
= (Total annual cost of PrEP + total annual cost of PrEP-associated services) * 0.10

= ($60 million) * 0.10
= $6 million

Total cost of VA PrEP-AP program:
= Total annual cost of PrEP + total annual cost of PrEP-associated services + 10% admin.
= $56.3 million + $3.75 million + $6 million
= $66 million

Illinois
Total annual PrEP-associated costs through PrEP-AP program in IL
= cost of PrEP-associated services for uninsured recipients * projected reach of program
=$3,000 * 31,235
=$93.7 million

Total annual cost of PrEP through PrEP-AP program in IL
= Cost per bottle paid by government to Gilead * projected reach of program
= $200 * 31,235
= $6.2 million

10% Administrative Cap in IL
= (Total annual cost of PrEP + total annual cost of PrEP-associated services) * 0.10
= ($100 million) * 0.10
= $10 million

Total cost of IL PrEP-AP program:
= Total annual cost of PrEP + total annual cost of PrEP-associated services + 10% admin.
= $93.7 million + $6.2 million + $10 million
= $110 million

Total cost of alternative #2: $176 million (across 2 states)

Alternative 3 Costs:

Annual low-end cost of co-payments for PrEP
= Low end monthly co-pay * 12
= $400 * 12
= $4,800

Annual high-end cost of co-payments for PrEP
= Low end monthly co-pay * 12
= $750 * 12

= $9,000

Total low-end cost of covering co-payments for all individuals with indications for PrEP and private insurance

= Total number of individuals with indications for PrEP * Percent of individuals with indications for PrEP with private insurance * low-end total cost of co-payments
= 1.2 million * 0.526 * $4,800
= $3 billion

Total high-end cost of covering co-payments for all individuals with indications for PrEP and private insurance

= Total number of individuals with indications for PrEP * Percent of individuals with indications for PrEP with private insurance * high-end total cost of co-payments
= 1.2 million * 0.526 * $9,000
= $5 billion

Total cost of alternative #3: $3-5 billion for insurance payers, $0 for government

Alternative 4 Costs:

Georgia

Total annual PrEP-associated costs through CDC jumpstart program in GA

= cost of PrEP-associated services for uninsured recipients * projected reach of program
=$3,000 * 40,000
=$120 million

Total annual cost of PrEP through CDC jumpstart program in GA

= Cost per bottle paid by government to Gilead * projected reach of program
= $200 * 40,000
= $8 million

10% Administrative Cap in GA

= (Total annual cost of PrEP + total annual cost of PrEP-associated services) * 0.10
= ($128 million) * 0.10
= $12.8 million

Total cost of CDC jumpstart program in GA

= Total annual cost of PrEP + total annual cost of PrEP-associated services + 10% admin.
= $120 million + $8 million + $12.8 million
= $140.8 million

Louisiana

Total annual PrEP-associated costs through CDC jumpstart program in LA

= cost of PrEP-associated services for uninsured recipients * projected reach of program

=$3,000 * 15,000

=$45 million

Total annual cost of PrEP through CDC jumpstart program in LA

= Cost per bottle paid by government to Gilead * projected reach of program

= $200 * 15,000

= $3 million

10% Administrative Cap in LA

= (Total annual cost of PrEP + total annual cost of PrEP-associated services) * 0.10

= ($48 million) * 0.10

= $4.8 million

Total cost of IL PrEP-AP program:

= Total annual cost of PrEP + total annual cost of PrEP-associated services + 10% admin.

= $45 million + $3 million + $4.8 million

= $52.8 million

Total cost of alternative #2: $193.6 million (across 2 states)