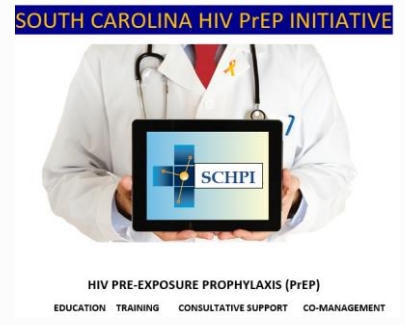


# PrEP: Pre-Exposure Prophylaxis

RSFH Ryan White Wellness Center  
Charleston, SC

Aaron O'Brien, MPH





**RYAN WHITE  
WELLNESS CENTER**  
ROPER ST. FRANCIS

**PrEP:**

Pre-Exposure Prophylaxis

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# Ryan White Wellness Center



- 7 counties of coastal SC
- Serve 980 patients
- HIV Care
- Medical Case Management
- Housing
- Peer Navigation
- Mental Health
- PrEP
- Telemedicine
- Pharmacy
- Contracted specialty care

# Highlights & Hurdles

## High Quality, High Engagement

- 94% Optimally Retained
- 92% Virally Suppressed
- 99% newly diagnosed patients are virally suppressed in 3 visits
- 140 Active PrEP patients

## Barriers & Social Stressors

- Disparities in viral load suppression remain
- 41% of newly diagnosed patients have AIDS
- Limited HIV/STI prevention funding
- Hospital Infrastructure + Federal Requirements

# What is PrEP?

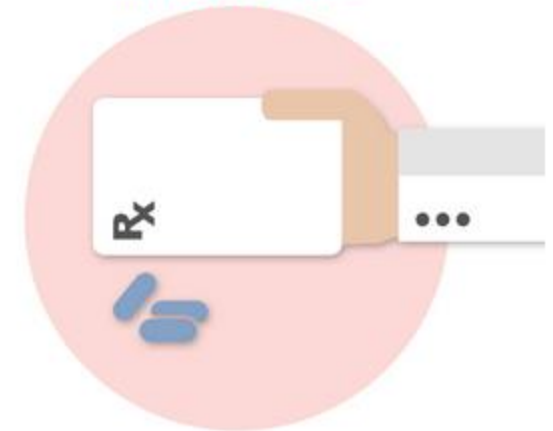


PrEP is a new prevention method in which **people who do not have HIV** infection **take a pill daily to reduce their risk** of becoming infected.



People who use PrEP must **commit to taking the drug every day** and seeing their health care provider **every 3 months for follow-up**.

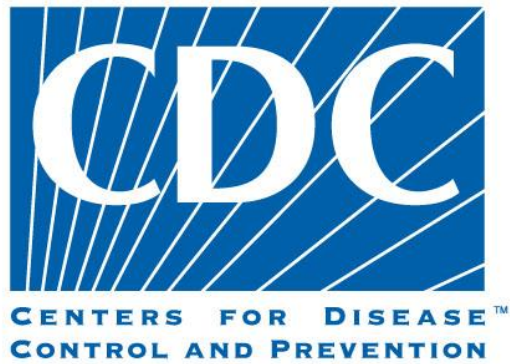
PrEP can only be prescribed by a health care provider and **must be taken as directed to work**.



[www.aids.gov](http://www.aids.gov)

# Why PrEP?

- Why not?
- We needed it in our community
- 90%, 90%, 90%
- Access to great candidates for PrEP
- HRSA told us to
- Mad skills
- Everyone else is doing it...



National Institutes  
of Health



World Health  
Organization



**HRSA**  
Health Resources & Services Administration



EMORY  
UNIVERSITY

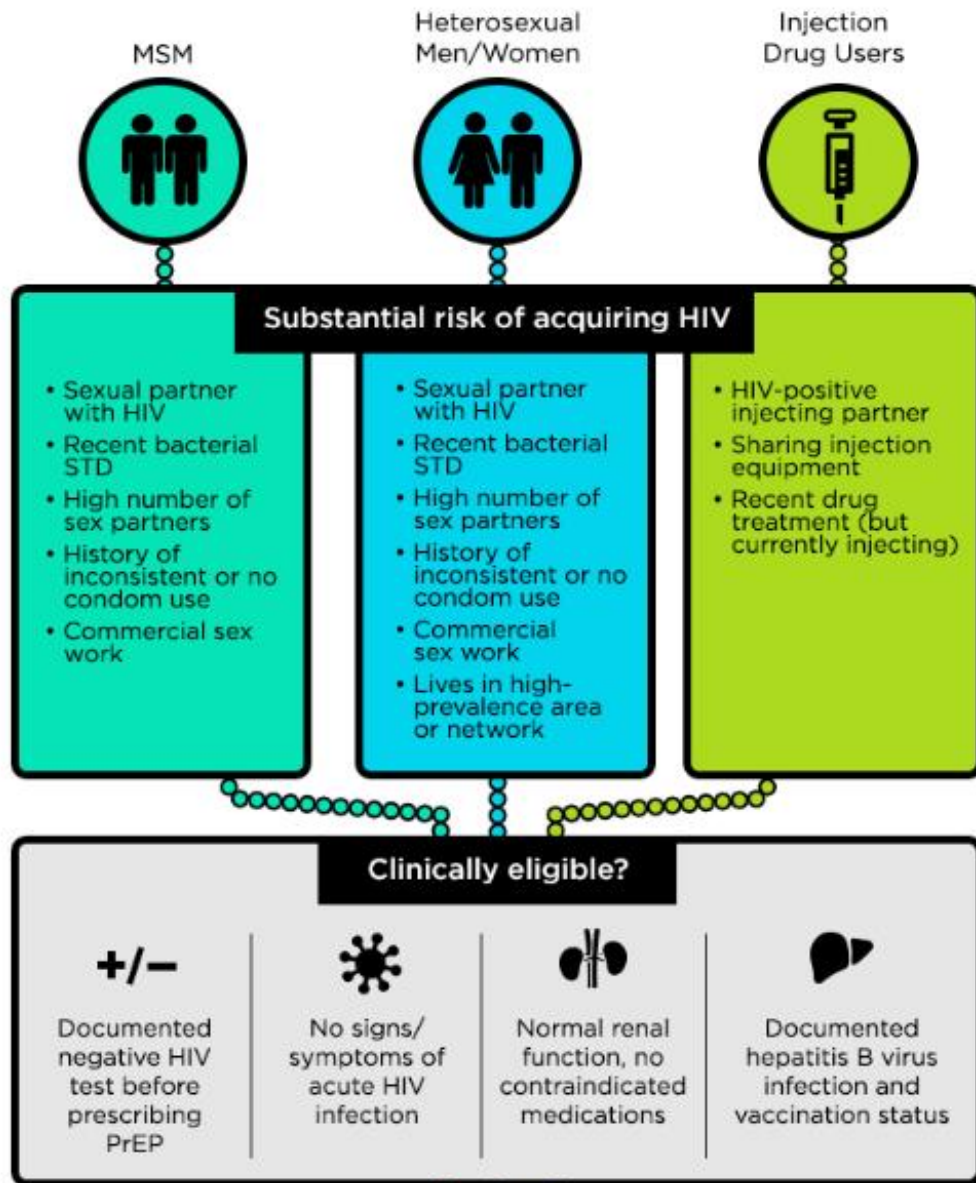


KAISER  
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APHA

AMERICAN PUBLIC HEALTH ASSOCIATION  
*For science. For action. For health.*





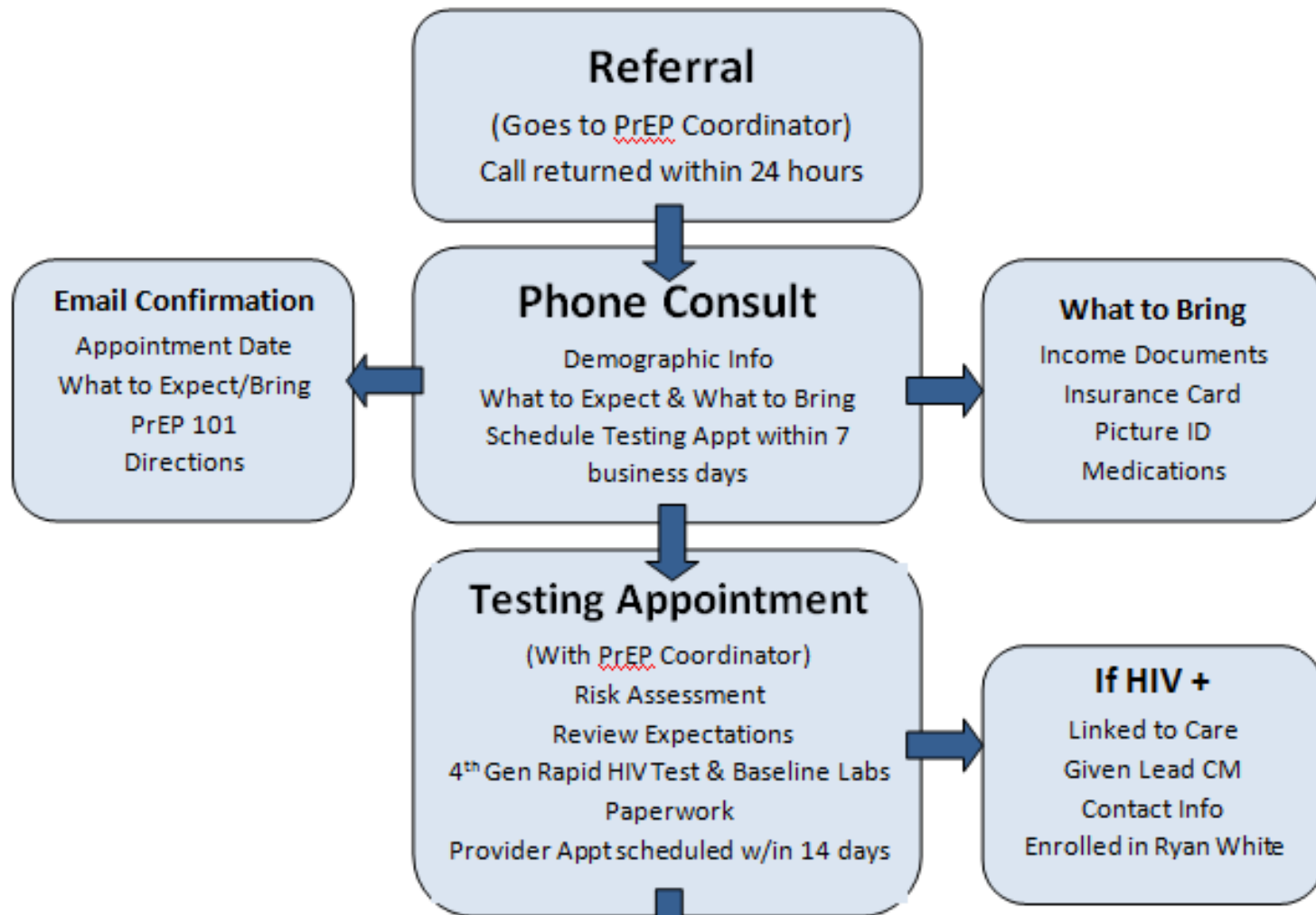
# PrEP Efficacy Trial Results

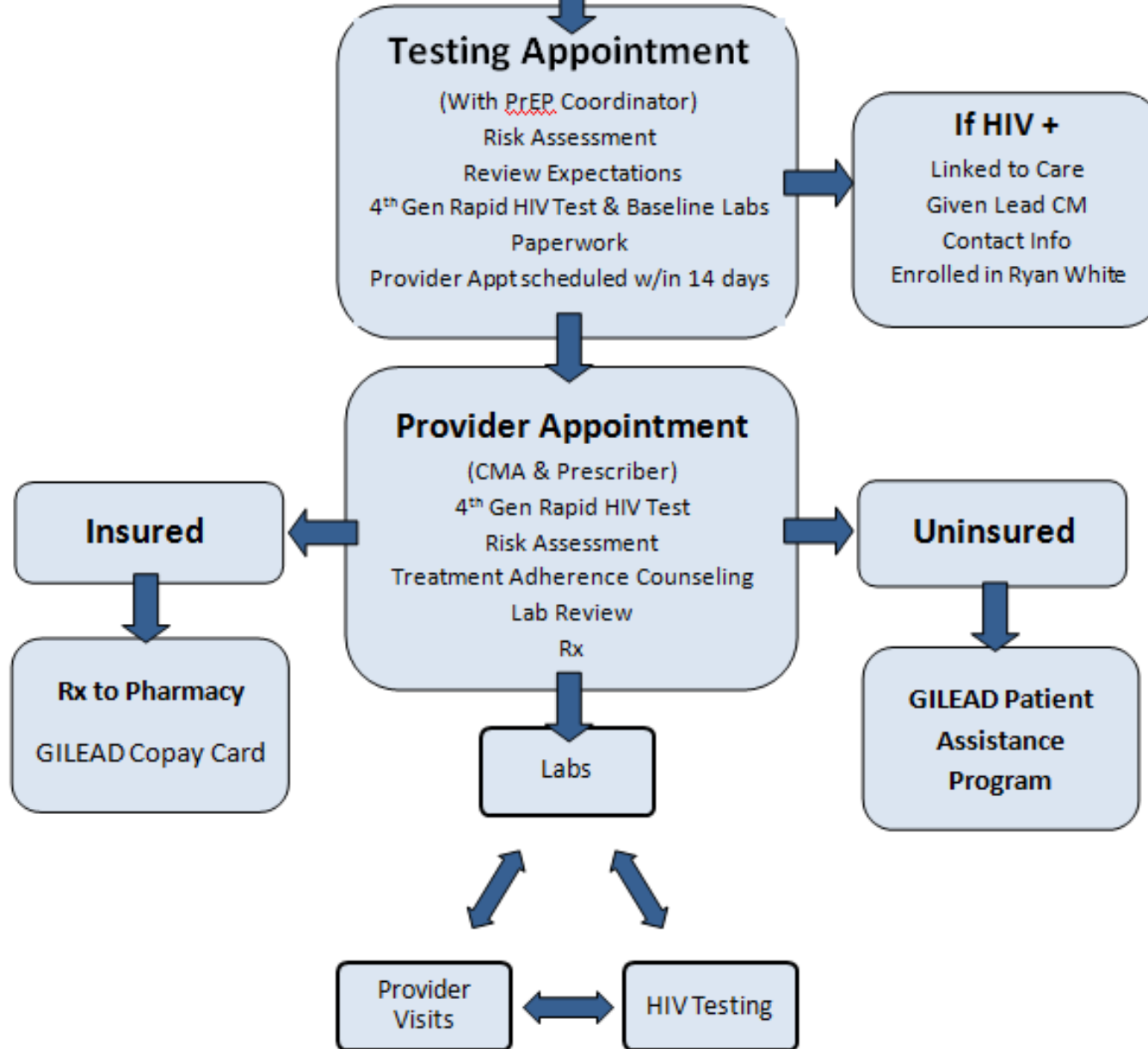
| Study   | Population                                  | Locations   | Regimen / Results  |
|---|---|---|--|
| <p><b>iPrEx</b></p> <p>Phase III trial that evaluated the safety and efficacy of once-daily oral Truvada to prevent HIV infection in gay men, other men who have sex with men (MSM) and transgender women.</p> <p>For more information: <a href="http://www.avac.org/trial/iprex">www.avac.org/trial/iprex</a></p>  | 2,499 gay men, other MSM, transgender women | <ul style="list-style-type: none"> <li>• Brazil</li> <li>• Ecuador</li> <li>• Peru</li> <li>• South Africa</li> <li>• Thailand</li> <li>• US</li> </ul> | <ul style="list-style-type: none"> <li>• Daily oral Truvada showed 44% efficacy</li> </ul>   |
| <p><b>TDF2 Study</b></p> <p>Phase II/III trial that evaluated the safety of once-daily oral Truvada in heterosexual men and women.</p> <p>For more information: <a href="http://www.avac.org/trial/tdf2">www.avac.org/trial/tdf2</a></p>  | 1,200 men and women                         | <ul style="list-style-type: none"> <li>• Botswana</li> </ul>  | <ul style="list-style-type: none"> <li>• Daily oral Truvada showed 62% efficacy</li> </ul>   |
| <p><b>Partners PrEP Study</b></p> <p>Phase III trial that evaluated the safety and efficacy of two different strategies to prevent HIV transmission in HIV-serodiscordant couples: once-daily oral tenofovir and once-daily oral Truvada.</p> <p>For more information: <a href="http://www.avac.org/trial/partners-prep">www.avac.org/trial/partners-prep</a></p> | 4,758 serodiscordant heterosexual couples   | <ul style="list-style-type: none"> <li>• Kenya</li> <li>• Uganda</li> </ul>   | <ul style="list-style-type: none"> <li>• Daily oral Truvada showed 75% efficacy</li> <li>• Daily oral tenofovir showed 67% efficacy</li> </ul>   |
| <p><b>Bangkok Tenofovir Study (CDC 4370)</b></p> <p>Phase II/III trial that evaluated the safety and efficacy of once-daily oral tenofovir to prevent HIV infection in people who inject drugs.</p> <p>For more information: <a href="http://www.avac.org/trial/cdc-4370-bangkok-tenofovir-study">www.avac.org/trial/cdc-4370-bangkok-tenofovir-study</a></p>     | 2,400 people who inject drugs               | <ul style="list-style-type: none"> <li>• Thailand</li> </ul>  | <ul style="list-style-type: none"> <li>• Daily oral tenofovir showed 49% efficacy</li> </ul>   |
| <p><b>FEM-PrEP</b></p> <p>Phase III trial that evaluated the safety and effectiveness of once-daily oral Truvada for HIV prevention in women.</p> <p>For more information: <a href="http://www.avac.org/trial/fem-prep">www.avac.org/trial/fem-prep</a></p>   | 1,950 women                                 | <ul style="list-style-type: none"> <li>• Kenya</li> <li>• South Africa</li> <li>• Tanzania</li> </ul>   | <ul style="list-style-type: none"> <li>• Daily oral Truvada showed no effect</li> </ul>  |
| <p><b>VOICE (MTN 003)</b></p> <p>Phase IIb trial that evaluated the safety and effectiveness of three different strategies to prevent HIV in women: once-daily oral tenofovir, oral Truvada, and vaginal tenofovir gel.</p> <p>For more information: <a href="http://www.avac.org/trial/mtn-003-voice">www.avac.org/trial/mtn-003-voice</a></p>                   | 5,029 women                                 | <ul style="list-style-type: none"> <li>• South Africa</li> <li>• Uganda</li> <li>• Zimbabwe</li> </ul>  | <ul style="list-style-type: none"> <li>• Daily oral tenofovir showed no effect</li> <li>• Daily oral Truvada showed no effect</li> <li>• Daily vaginal tenofovir gel showed no effect</li> </ul> |

# Program Development

- Procedures were developed in a collaborative process including medical staff, testing personnel, peers, and management.
  - Access
  - Integrate into HIV Clinic
  - Consistent with Guidelines
  - Cost Effective
  - Patient Centered







# Drug Assistance Program



1

### **Gilead Advancing Access Co-pay Card**

[gileadcopay.com](http://gileadcopay.com)  
877-505-6986

- \$3,600 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

If pharmacy is unable to process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card.

Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at [gileadcopay.com](http://gileadcopay.com).

#### **FSA (flexible spending account)**

If employer offers an FSA, it can help cover up to \$2,550 of out-of-pocket costs.

2

### **Patient Access Network Foundation**

[panfoundation.org/hiv-treatment-and-prevention](http://panfoundation.org/hiv-treatment-and-prevention)  
866-316-7263

- \$8,000 max/year, re-apply
- Income <500% FPL (\$60,300)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

3

### **Patient Advocate Foundation (PAF)**

<https://www.copays.org/diseases/hiv-aids-and-prevention>

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,240)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

*These programs may be subject to funding shortfalls, which may limit enrollment.*

#### **On Medicaid?**

Medicaid should cover medical costs related to PrEP. If you encounter barriers to coverage, consult a legal advocate.

## U.S. RESIDENT?

## NON-RESIDENT/ UNDOCUMENTED?

What's the date?



NOV 1 – JAN 31

FEB 1 – OCT 31

### Enroll in an insurance marketplace

[obamacarefacts.com/state-health-insurance-exchange/](http://obamacarefacts.com/state-health-insurance-exchange/)

Avoid Bronze plans if you can: they generally have higher costs. Silver plans will offer lower costs for people earning up to 250% FPL (\$30,150). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

#### Special enrollment

You can get insurance during the rest of the year for "qualifying life events" such as: pregnancy, loss or change of job, change in household size, change in income, recent move, change in citizenship.

below 138% FPL / yr  
( $< \$16,643$ )

Check if you're eligible for your state Medicaid plan.

above 138% FPL / yr  
( $> \$16,643$ )

To get care, find a public clinic (FQHC) that serves undocumented patients. ([findahealthcenter.hrsa.gov](http://findahealthcenter.hrsa.gov))

Check if you can get an insurance plan through marketplace/employer.

IF NO

What's your income?

below

60,300

above

Enroll in the Gilead MAP.  
[www.truvada.com/truvada-patient-assistance](http://www.truvada.com/truvada-patient-assistance)

500% FPL  
(2017 FPL: \$12,060 taxable income + \$4,180 per dependent, higher FPL in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)

Retail cost of Truvada

~ only drug costs ~

<https://tinyurl.com/FPLincomes>

# Common Problems

- I am unemployed
  - Letter of support from the person providing assistance
- I get paid under the table
  - Have the employer write a letter
- I don't want to bill my insurance
  - Only works for uninsured



# Common Issues

- I am undocumented
  - Put all “0” in the SSN section
- Pharmacy Selection
  - The patient can pick it up at ANY local pharmacy or work with Gilead Pharmacy, Theracom
- My insurance doesn't cover Truvada
  - Submit documentation to Gilead

# Average Costs

- Approx \$1700/ year for an uninsured patient
  - Medical visits & lab costs

|                        | <b>Amount Billed</b> | <b>Adjusted</b> | <b>Insurance Paid</b> | <b>Program Paid</b> |
|------------------------|----------------------|-----------------|-----------------------|---------------------|
| Insured Office Visit   | \$545.20             | \$367.97        | \$105.02              | \$153.01            |
| Uninsured Office Visit | \$334.88             | \$51.65         | \$0.00                | \$279.48            |
| Combined Lab Costs     | \$203.81             | \$153.73        | \$7.25                | \$43.21             |

# Using our Resources

| RWHAP Eligible                                   | Other Funding Resources      |
|--|------------------------------|
| Case Management/Navigator Staff                  | Provider/ Office Visit Costs |
| HIV Tests  | Labwork                      |
| Testing Materials                                | Prescriptions                |
| Prevention Information                           | Vaccines                     |
| Office Resources (Pens, Copy Machines, building) |                              |



**ELTON JOHN  
AIDS FOUNDATION**

# Challenges

- Ryan White Funding
- New focus for our program
- PrEP patients face same barriers
- Reaching the right people

# Opportunities

- Telemedicine
- Universal Opt-out HIV Testing
- Broader STD/sexual health services
- Injection Drug Users

U=U

# Questions?

**Aaron O'Brien, MPH**

**Quality & Development Manager**

Ryan White Wellness Center

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