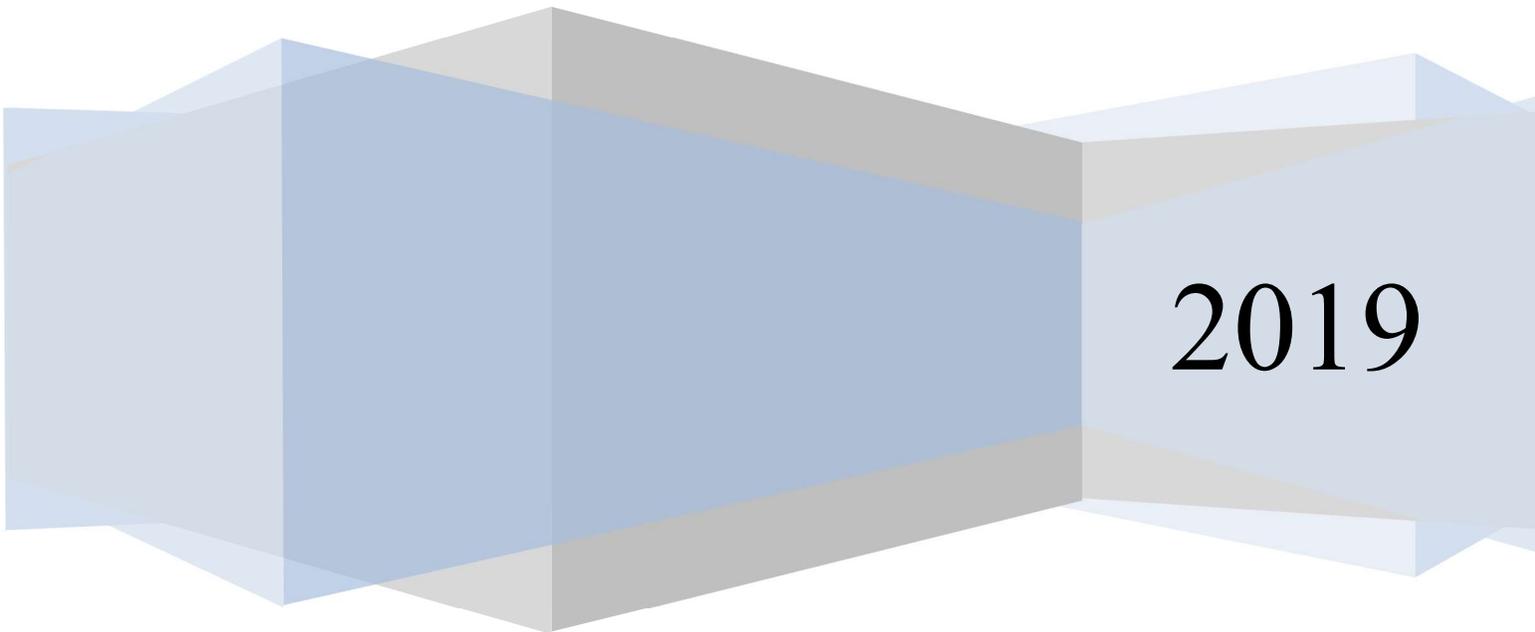


Pre-Exposure Prophylaxis (PrEP)

Clinic Resource Manual



VDH VIRGINIA
DEPARTMENT
OF HEALTH

Promoting & Protecting the Health of All Virginians
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This document is a product of the Virginia Department of Health (VDH) and should only be used by entities affiliated with the Division of Disease Prevention (DDP) HIV and Hepatitis Prevention and its PrEP programs. This manual is a resource for internal use only. Should questions about content or process arise, please contact:

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For information about the VDH **nPEP** program (non-occupational post-exposure prophylaxis), please contact Eric Mayes or visit the website for the **nPEP Protocols for Local Health Departments** and additional resources.

**PrEP Clinic Reference Manual
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I. Virginia Department of Health –Division of Disease Prevention: HIV PrEP Protocols for Local Health Departments

A. Summary: Purpose of PrEP

In 2017, the Centers for Disease Control and Prevention (CDC) released its updated guidelines for the use of daily pre-exposure prophylaxis (PrEP) for the prevention of HIV infection. The following PrEP reference documents are available:

- CDC: PrEP information index: <https://www.cdc.gov/hiv/risk/prep/index.html>
- CDC: Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update: (<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>)
- CDC: Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update Clinical Providers' Supplement: (<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>)
- Gilead: Truvada Package Insert (http://www.gilead.com/~media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf)

Truvada is FDA-approved for use “in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.” (Source: <https://www.truvada.com/hcp/home>). Ongoing research data suggests that it can be useful in preventing acquisition of HIV by injection drug users as well.

PrEP is indicated for individuals who have a documented negative HIV test result and are at substantial risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.

PrEP is not meant to be used as a lifelong intervention, but rather as an additional prevention tool during periods when people are at greatest risk of acquiring HIV. The length of use will depend on the individual’s behaviors, which may change over time. PrEP is intended to be a part of an individual’s overall “prevention package” and not an individual’s only prevention method. Condoms, sterile injection equipment and other prevention and harm reduction measures should still be used correctly and consistently while the patient is on PrEP; however, **the inability to practice these behaviors correctly and consistently does not exclude a person from being prescribed PrEP.**

These protocols serve as a guide for project personnel and providers administering PrEP under the VDH-Division of Disease Prevention (DDP) PrEP Program. These protocols are based on the CDC Guidance (see above).

B. Program Eligibility

- Patient must be a Virginia resident if state funding is necessary for prescription and/or lab work funding assistance. Proof of residency must be documented at least yearly.
- Patient must be willing to participate in adherence/follow-up interventions and evaluation processes.
- Minors require parental consent.

AND

- Determination of the prescribing medical provider based on best-evidence for use of PrEP as an HIV prevention tool for an HIV negative person practicing potentially high-risk behaviors (defined below).

C. Behavioral Screening

Please use a screening tool to obtain behavioral information.

- Local health departments (LHDs) should use the STI History Forms. These can be found in the following location:

<http://vdhweb.vdh.virginia.gov/community-health-services/sti-clinical-efficiency-effectiveness-projects-list/> under STI Charting/Quality Assurance - Project Documents

- Other entities should use a behavioral health screening for PrEP (See Appendix A, PrEP and nPEP Questionnaire)

Providers should obtain a thorough sexual and drug use history, and regularly discuss risk-taking behaviors with their patients to assess indications for PrEP, encourage safer-sex practices and safer injection techniques (if applicable), as well as assist in the decision of when to use PrEP and when to discontinue use. *Please contact DDP if you need training or technical assistance on behavioral screening, including taking a thorough sexual health history.*

Applicable High-Risk Behaviors Include:

- Unprotected vaginal or anal intercourse with individual(s) living with HIV or individual(s) of unknown HIV status.
- Needle Sharing.
- Sex while under the influence of drugs or alcohol with multiple partners.
- Engaging in commercial or transactional sex work (the exchange of sex for money, drugs, housing or other items of worth).
- Sex with partners who have these risk factors.

Clinicians should discuss PrEP with the following non-HIV infected individuals who have substantial ongoing behavioral risks:

- Men who have sex with men who engage in unprotected anal intercourse.
- Individuals who are in a serodiscordant sexual relationship with a known HIV-infected partner.
- Male to female and female to male transgender persons engaging in high-risk sexual behaviors and/or share injection equipment (e.g. share needles for silicon injections).
- Individuals engaging in transactional sex, such as sex for money, drugs or housing, or those working in the commercial sex industry, such as pornographic film actors/actresses.
- Injection drug users who report any of the following behaviors: sharing injection equipment and/or works, injecting one or more times daily, injecting methamphetamines.
- Individuals diagnosed with at least one anogenital sexually transmitted infection in the last 6 months or any sexually transmitted infection (STI) within the last year.
- Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who continue to demonstrate high-risk behavior or have been prescribed multiple courses of nPEP.

Please see the CDC Guidelines for more guidance.

Identification of Participants:

Entities that can identify eligible participants include, but are not limited to:

- HIV testing and prevention contractors, during HIV counseling and testing.
- HIV Care contractors, case managers, patient navigators primarily as identifiers of partners of HIV positive individuals.
- Health Department STI and Family Planning Clinic staff.
- Disease Intervention Specialists (DIS) during the patient and partner notification process.
- Behavioral health providers.
- Other medical providers.

D. Patient Education and Informed Decision Making

Patient education is critical to shared decision-making and the success of PrEP as part of the prevention plan. The Patient Education Checklist, Appendix B, provides the basis from which shared decision-making about initiation of PrEP can occur, providing the clinician with the opportunity to educate the patient about risks, benefits, and options, while providing the patient with the opportunity to discuss preferences, needs, and individual circumstances. Medication adherence may be improved when patients participate in treatment decisions.

Patients need to understand how PrEP works, including risks and benefits, the need for strict adherence to maintain protective drug levels, and what it will and will not do for them. Explanations should be given in the patient’s native language and should be easy to understand.

For example: *The pill, Truvada, can block HIV from infecting the body in somebody who is HIV negative. The pill needs to be taken every day in order for the body to build up enough of the drug to block HIV. It cannot be expected to work if somebody only takes it before or just after having sex. PrEP reduces, but does not eliminate, somebody’s risk for getting HIV. You should use condoms even if you are taking PrEP because PrEP does not protect against other sexually transmitted diseases.*

Patient should be informed of:

- How PrEP works
- Efficacy of PrEP
- Limitations of PrEP
- Importance of daily adherence
- Potential side effects associated with Truvada
- Long term safety of PrEP
- Symptoms of sero-conversion
- PrEP procedures and administration
- What to do in case of missed doses
- Importance of other risk reduction strategies
- PrEP and pregnancy

For more details, see Patient Education Checklist, Appendix B.

Below are a few additional resources that may help with PrEP Patient Education:

1. Virginia Greater Than AIDS <https://www.greaterthan.org/virginia/>
2. “Demystifying HIV Pre-Exposure Prophylaxis” by YourekaScience.
 - a. **Link/Location:** <https://www.youtube.com/watch?v=-Xx92whZS0o&t=28s>
 - b. **Licensing information:** This has a Creative Commons Attribution license. Click to learn more about this license type: <https://creativecommons.org/licenses/by/4.0/>
3. “What is PrEP” by “Pre-Exposure Prophylaxis”
 - a. **Location:** <https://vimeo.com/79717700> and <http://www.whatisprep.org>.
 - b. **Source:** PrEP REP project, led by K Rivet Amico, University of Michigan, and Sybil Hosek, Stroger Hospital of Cook County Chicago, in collaboration with Chris Balthazar, Stroger Hospital.
 - c. **Licensing information:** This has an Attribution Non-Commercial license. Click to learn more about this license type: <https://creativecommons.org/licenses/by-nc/4.0/>.

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E. Clinical Screening

Medical History considerations for project exclusions:

- PrEP is not for use for patients with HIV infection.
- PrEP is not for use for patients with a history of renal or liver disease, osteoporosis..
However, these are not definitively exclusionary.
- Patient use of other medications that reduce kidney renal function or compete for active renal tubular secretion should be considered before prescribing PrEP. Monitor these patients for dose-related renal toxicities.
- ***See Truvada package insert referenced above for full medical recommendations.***

Diagnostic Baseline Screening test required:

Also refer to the PrEP Lab Test Table, Appendix C.

Baseline Tests:	Comments and Rationale
HIV Test: 4 th Generation or RNA PCR testing	Test for HIV infection in ALL patients initiating PrEP with a 4 th Generation combination HIV Ag/AB assay. Screen for HIV infection symptoms. If patient has chronic HIV infection, Truvada alone is not sufficient treatment and the risk of developing resistance to this classification of drugs (nucleoside analog reverse transcriptase inhibitor) is high with extended exposure.
Creatinine	Calculated CrCl should remain ≥ 60 ml/min (Cockcroft Gault) to safely use tenofovir.
HepB, HBcAb, HBsAb+Ag	Truvada is active against hepatitis B virus (HBV). Patients with chronic HBV can use Truvada for PrEP, but should have regular liver function tests every 3-6 months as well as hepatitis B viral loads every 6 months while using PrEP. Also, caution the patient rebound viremia may occur after discontinuing PrEP and PrEP discontinuation should be coordinated with hepatitis B provider. Patients who are HBsAg negative should be offered HBV vaccination if test indicates non-immunity. HBV RT PCR Quant (Graph) should be performed with the first positive HBsAG, then repeated at 6- and 12-month visits.
HepC, HCV antibody with reflex to NAA	Patients with active hepatitis C should be referred for treatment and consideration for PrEP therapy coordinated with hepatitis treatment provider only. The hepatitis C treatment provider may recommend that PrEP be postponed until hepatitis C treatment is completed.
STIs (based on patient's self- reported sexual history)	Male and female participants should be tested for syphilis and genital, rectal and pharyngeal GC and CT as indicated by risk profile.
Pregnancy test (if applicable) for women of reproductive potential	If positive, PrEP should be coordinated with OB/GYN care provider.

Other important considerations when prescribing PrEP:

- **Is the patient pregnant or attempting to conceive?** PrEP may be one of several options to help protect the HIV seronegative partner from acquiring HIV infection in serodiscordant couples during attempts to conceive.

Truvada is FDA pregnancy category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, TRUVADA should be used during pregnancy only if clearly needed. (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21752s002lbl.pdf)

- If a patient is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking TDF/FTC during pregnancy.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry.
- Patients should be referred to their OB/GYN provider.
- **Is the patient an adolescent?**
 - If PrEP is indicated for/or requested by an adolescent, contact DDP for guidance on a case by case basis. Participation in the VDH program requires parental consent. See Appendix E for PrEP Adolescent Consent Form.
 - On May 15, 2018, the Food and Drug Administration approved an indication for Truvada for pre-exposure prophylaxis (PrEP) in adults and adolescents who weigh at least 35 kg (77 lb). The indications for PrEP, initial and follow-up prescribing and laboratory testing recommendations are the same for adolescents and adults.
- **Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC?**
 - Obtain a thorough medication history and consult the medication package insert for additional information on drug interactions.
 - Encourage or consider consultation and collaboration with the prescribing providers or primary care provider.
- **Does the patient have osteopenia/osteomalacia/osteoporosis?** There may be a risk of bone loss associated with tenofovir.
 - Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia.
 - Bone density testing is not covered by VDH; patient will need referral if indicated by history.
 - Encourage or consider consultation and collaboration with the primary care provider.

F. PrEP Management and Documentation Chart
(Also see PrEP Lab Test Table, Appendix C)

Step	Actions	Documentation and Additional information
Initial (Pre-Prescription) Visit:	<ul style="list-style-type: none"> • Identify patients with indications for PrEP therapy utilizing comprehensive sexual and drug use history. • Discuss PrEP use with patient; clarify misconceptions and provide current information. • Perform following laboratory tests: <ul style="list-style-type: none"> ○ HIV test-4th generation ○ Serum creatinine (for calculated creatinine clearance) ○ Hepatitis B and C serology ○ STI screening: syphilis, genital and extragenital CT/GC ○ Pregnancy test (if applicable) • Assess for nPEP indication – If prescribed, plan transition to PrEP at conclusion of nPEP treatment. (See Appendix D nPEP Lab Test Table) • Patient education/counseling with documentation in the medical record: <ul style="list-style-type: none"> ○ PrEP efficacy ○ Procedures ○ Medication dosing ○ Side effects ○ Managing missed doses ○ Strategies for strict daily adherence ○ Reinforce HIV risk reduction plan ○ Signs of acute HIV infection ○ Reproductive counseling ○ Clinic contact information ○ Referrals as indicated • Revisit appointment(s) should be given to patient before leaving clinic and documented in the medical record. 	<p>VDH sites: Utilize Patient Medical Record for documenting all PrEP-related services, including navigator and/or case management notes. Interdisciplinary notes should be integrated (i.e. clinical and nonclinical) and recorded in chronological order. Documentation in the medical record should adhere to all current VDH policies and procedures.</p> <p>VDH sites: For Initial Visit, complete full STI Visit utilizing STI clinic forms; for additional and/or narrative documentation needs, use Exception Notes.</p> <p>All sites: Ensure indication for PrEP is clearly documented in the record as well as on the PrEP Application.</p> <p>Patients with positive HIV results must be promptly linked to care.</p>
After confirmation of negative HIV test and no other contraindication to PrEP therapy:	<ul style="list-style-type: none"> • Forward PrEP application to DDP. • <i>Prescribe 30-day supply.</i> • <i>Follow up in 2 weeks to assess side effects (in person or by phone).</i> 	<p>Medication order should be entered into the medical record by the prescribing provider.</p> <p>Medication Order Forms are filed in the medical record in reverse chronological order. <i>(Continued, next page)</i></p>

		<p>Document the calculated creatinine clearance in the medical record.</p> <p>Any abnormal lab values must be addressed by provider in the medical record.</p> <p>Patients with positive HIV results must be promptly linked to care.</p>
<p>30-day visit (counting from medication start)</p>	<ul style="list-style-type: none"> • Update medical history and medication list. • Evaluate adherence at every visit (subjective and objective). <ul style="list-style-type: none"> ○ If significant lapse in treatment with potential for exposure, evaluate for nPEP treatment. • Assess for side effects. • Labs - IF there is any concern that an early infection/pregnancy might have been undetected at the initial visit <u>or</u> with clinical indication: <ul style="list-style-type: none"> ○ HIV test-4th generation ○ STI screening: syphilis, genital and extragenital CT/GC ○ Pregnancy test ○ Serum creatinine for calculated creatinine clearance should be performed in patients at increased risk of nephrotoxicity (e.g., >65 years of age, black race, hypertension, or diabetes, hx of renal disease, concurrent use of nephrotoxic meds) • Patient education/counseling (as indicated) with documentation in the medical record: <ul style="list-style-type: none"> ○ Medication dosing ○ Side effects ○ Managing missed doses ○ Strategies for strict daily adherence ○ Reinforce HIV risk reduction plan ○ Signs of acute HIV infection ○ Reproductive counseling ○ Clinic contact information ○ Referrals • VDH-affiliated sites: Medication pick-up. • Revisit appointment(s) should be given to patient before leaving clinic and documented in the medical record. • <i>Prescribe 60-day refill; patient must return for 3-month visit for HIV test and follow-up</i> 	<p>VDH sites utilize PrEP/nPEP Flow Sheet. For additional and/or narrative documentation needs, use Exception Notes.</p> <p>Document the calculated creatinine clearance in the medical record.</p> <p>Any abnormal lab values must be addressed by provider in the medical record.</p> <p>Patients with positive HIV results must be promptly linked to care. Complete and fax withdrawal form.</p> <p><i>(Continued, next page)</i></p>

	<p><i>assessments, then 90-day schedule can begin. For patients accessing medication through Virginia's PrEP DAP program, PrEP is dispensed for 30 days at a time.</i></p>	
<p>3-month visit (90 day visit) (counting from medication start)</p>	<ul style="list-style-type: none"> • Update medical history and medication list. • Evaluate adherence at every visit (subjective and objective). <ul style="list-style-type: none"> • If significant lapse in treatment with potential for exposure, evaluate for nPEP treatment. • Assess for side effects. • Labs: <ul style="list-style-type: none"> • HIV test-4th generation • Serum creatinine for calculated creatinine clearance if indicated by history • STI screening: syphilis, genital and extragenital CT/GC • Pregnancy test • Patient education/counseling (as indicated) with documentation in the medical record: <ul style="list-style-type: none"> • Medication dosing • Side effects • Managing missed doses • Strategies for strict daily adherence • Reinforce HIV risk reduction plan • Signs of acute HIV infection • Reproductive counseling • Clinic contact information • Referrals as indicated • VDH-affiliated sites: Medication pick-up • Revisit appointment(s) should be given to patient before leaving clinic and documented in the medical record. • <i>Prescribe 90-day refill; patient must return for 3-month visit for HIV test and follow-up assessments every 90 days. For patients accessing medication through Virginia's PrEP DAP program, PrEP is dispensed for 30 days at a time.</i> 	<p>VDH sites utilize PrEP/nPEP flow sheet. For additional and/or narrative documentation needs, use Exception Notes.</p> <p>Document the calculated creatinine clearance in the medical record.</p> <p>Any abnormal lab values must be addressed by provider in the medical record.</p> <p>Patients with positive HIV results must be promptly linked to care. Complete and fax withdrawal form.</p>
<p>6-month visit (180 day visit) (counting from medication start)</p>	<ul style="list-style-type: none"> • Update medical history and medication list. • Evaluate adherence at every visit (subjective and objective). <ul style="list-style-type: none"> • If significant lapse in treatment with potential for exposure, evaluate for nPEP treatment. • Assess for side effects. • Labs: <ul style="list-style-type: none"> • HIV test-4th generation <p><i>(Continued, next page)</i></p>	<p>VDH sites utilize PrEP/nPEP flow sheet. For additional and/or narrative documentation needs, use Exception Notes.</p> <p>Document the calculated creatinine clearance in the medical record.</p> <p><i>(Continued, next page)</i></p>

	<ul style="list-style-type: none"> • Serum creatinine for calculated creatinine clearance • STI screening: syphilis, genital and extragenital CT/GC • Pregnancy test, if indicated • HepB viral load if active disease present • Patient education/counseling (as indicated) with documentation in the medical record: <ul style="list-style-type: none"> • Medication dosing • Side effects • Managing missed doses • Strategies for strict daily adherence • Reinforce HIV risk reduction plan • Signs of acute HIV infection • Reproductive counseling • Clinic contact information • Referrals as indicated • VDH-affiliated sites: Medication pick-up. • Revisit appointment(s) should be given to patient before leaving clinic and documented in the medical record. • <i>Prescribe 90-day refill; patient must return for 3-month visit for HIV test and follow-up assessments every 90 days. For patients accessing medication through Virginia's PrEP DAP program, PrEP is dispensed for 30 days at a time.</i> 	<p>Any abnormal lab values must be addressed by provider in the medical record.</p> <p>Patients with positive HIV results must be promptly linked to care. Complete and fax withdrawal form.</p>
<p>9-month visit (270 day visit) (counting from medication start)</p>	<ul style="list-style-type: none"> • Update medical history and medication list. • Evaluate adherence at every visit (subjective and objective). <ul style="list-style-type: none"> • If significant lapse in treatment with potential for exposure, evaluate for nPEP treatment. • Labs: <ul style="list-style-type: none"> • HIV test-4th generation • Serum creatinine for calculated creatinine clearance if indicated by history • STI screening: syphilis, genital and extragenital CT/GC • Pregnancy test • Patient education/counseling with documentation in the medical record (as indicated): <ul style="list-style-type: none"> • Medication dosing • Side effects • Managing missed doses • Strategies for strict daily adherence • Reinforce HIV risk reduction plan • Signs of acute HIV infection • Reproductive counseling 	<p>VDH sites utilize PrEP/nPEP flow sheet. For additional and/or narrative documentation needs, use Exception Notes.</p> <p>Document the calculated creatinine clearance in the medical record.</p> <p>Any abnormal lab values must be addressed by provider in the medical record.</p> <p>Patients with positive HIV results must be promptly linked to care. Complete and fax withdrawal form.</p> <p><i>(Continued, next page)</i></p>

	<ul style="list-style-type: none"> • Clinic contact information • Referrals as indicated • VDH-affiliated sites: Medication pick-up. • Revisit appointment(s) should be given to patient before leaving clinic and documented in the medical record. • <i>Prescribe 90-day refill; patient must return for 3-month visit for HIV test and follow-up assessments every 90 days. For patients accessing medication through Virginia’s PrEP DAP program, PrEP is dispensed for 30 days at a time.</i> 	
<p>12-month visit (1 year visit) (counting from medication start)</p>	<ul style="list-style-type: none"> • Update medical history and medication list. • Evaluate adherence at every visit (subjective and objective). <ul style="list-style-type: none"> • If significant lapse in treatment with potential for exposure, evaluate for nPEP treatment. • Labs: <ul style="list-style-type: none"> • HIV test-4th generation • Serum creatinine for calculated creatinine clearance • STI screening: syphilis, genital and extragenital CT/GC • Pregnancy test, if indicated • Hep B viral load, if active disease present • Hep B and C screening, if nonimmune • Patient education/counseling with documentation in the medical record (as indicated): <ul style="list-style-type: none"> • Medication dosing • Side effects • Managing missed doses • Strategies for strict daily adherence • Reinforce HIV risk reduction plan • Signs of acute HIV infection • Reproductive counseling • Clinic contact information • Referrals as indicated • VDH-affiliated sites: Medication pick-up • Revisit appointment(s) should be given to patient before leaving clinic and documented in the medical record. • <i>Prescribe 90-day refill; patient must return for 3-month visit for HIV test and follow-up assessments, every 90 days. For patients accessing medication through Virginia’s PrEP DAP program, PrEP is dispensed for 30 days at a time.</i> 	<p>VDH sites: For 12-month (24, 36, 48-month, etc.) visits, complete full STI Visit utilizing STI clinic forms; for additional and/or narrative documentation needs, use Exception Notes.</p> <p>Document the calculated creatinine clearance in the medical record.</p> <p>Any abnormal lab values must be addressed by provider in the medical record.</p> <p>Patients with positive HIV results must be promptly linked to care. Complete and fax withdrawal form.</p> <p><i>(Continued, next page)</i></p>

Interim Visits	<p>As needed for problems, complaints, issues with drug adherence, etc.</p> <p>VDH-affiliated sites: Medication pick-up at any visit whenever feasible.</p>	<p>VDH sites utilize PrEP/nPEP flow sheet, STI Clinic Visit Record, and/or Exception Notes for interim visits as indicated by reason for visit.</p> <p>Patients with positive HIV results must be promptly linked to care. Complete and fax withdrawal form.</p>
Medication Pickups (MPUs)	<p>Medication pickups ordered at VDH-affiliated sites are picked up at the prescribing site unless prior arrangements are made to provide MPU at alternate health department site. Patients who have signed releases for designated proxies to pick up their medication (e.g., CBO representative) may obtain their medication at that alternate site. Such organizations must have CSR registration (and meet the requisite requirements) if meds are held for patients overnight.</p> <p>PrEP site staff must verify with the alternate site that the patient picked up the medication. Any medication not delivered at/by the alternate site within 30 days must be immediately returned to the PrEP clinic site for return to the Central Pharmacy.</p> <p>Medications should be provided during each <u>follow-up</u> visit, pending lab results notwithstanding. Meds may be quickly discontinued if lab results indicate need to do so.</p> <p>Mail delivery – please see Section J.</p>	<p>MPUs must be documented in the patient’s chart, ensuring adherence to VDH policies and procedures. MPU’s provide a useful tool in assessing med adherence; review of MPU’s should be noted at each visit.</p> <p>MPUs at alternate sites must be documented in the PrEP Medical Record, consistent with VDH policies and procedures.</p>
Medication Order Forms	<p>Ensure medications are ordered so they are in the clinic for patient pick-ups when due. After the Initial Visit, provide MPUs during clinic visits.</p>	<p>See Appendix J for updated Medication Order Form. Please discard old forms.</p> <p>Medication Order Forms are filed in the medical record in reverse chronological order.</p>

G. Adherence Counseling

PrEP is only useful as a prevention tool if the patient takes the medication daily as prescribed.

Since PrEP is a long-term commitment for some, helping the patient form strategies that ensure adherence may be useful. Strategies may include formulation of a patient-centered adherence plan, which accounts for time of day to take the drug, storage of the drug, what to do if the patient misses a dose, and what to do if side effects occur, etc.

Adherence is often compromised by other factors such as mental illness, alcohol or substance use, lack of stable housing and interpersonal violence. Forgetfulness and stigma are also common causes of non-adherence. In addition, adherence has been shown to vary widely according to age. It is important to take these factors into consideration when providing adherence counseling.

Clinical staff and the patient should discuss barriers to adherence and possible means of overcoming barriers before the patient is prescribed PrEP and throughout the course of therapy.

Examples of subjective assessment of adherence:

- How often do you take your Truvada?
- What time of day do you take your Truvada?
- How often do you [miss, skip] doses or take doses late?
- How many doses do you [estimate, guess] you have missed in the last [week, month]?
- What situations make it difficult to take your Truvada on time every day?
- What helps you remember to take your Truvada on time?
- How often do you have Truvada tablets left in the bottle when your next med pick up is due?
- How many Truvada tablets are usually in the bottle when your next med pick up is due?
- What can we do to help you take your Truvada on time every day?

Examples of objective assessment of adherence:

- Pill bottle counts (in clinic or on home visits)
- Tracking medication pick up dates
- Urine screening for Truvada

If there has been a significant lapse in treatment with potential for exposure, the patient should be evaluated for nPEP treatment.

Some community-based organizations (CBOs) provide interventions that may help increase adherence. If the clinical staff feels these would be useful to the patient, they can make a referral. To obtain information about local CBOs, please contact DDP's HIV/STD/Hepatitis Hotline (1-800-533-4148).

H. The Role of the PrEP Navigator

PrEP navigators are key members of the clinical team for PrEP patients. PrEP navigators may also be known as PrEP caseworkers, community health workers or case managers.

Core Skills

- Knowledge of HIV, STIs, risk reduction, prevention and care issues
- Ability to manage multiple clients' needs
- Ability to stay organized and manage and track a large amount of information
- Ability to fill out screening tools, data forms and maintain good documentation practices
- Ability to support clients in accessing a wide range of services
- Ability to use a client-centered counseling approach and motivational interviewing (MI)
- Ability to adhere to a strict code of client confidentiality
- Ability to demonstrate cultural and linguistic sensitivity, comfort and ability to work with diverse populations

Activities

PrEP navigators are expected to help clients obtain clinical services related to PrEP, access medication (through any one of the following: Virginia's PrEP Drug Assistance Program, Gilead's patient assistance program, their insurance company), ensure that patients are able to maintain the ongoing regimen of testing and care related to PrEP, and help patients with adherence to daily therapy.

For PrEP specific medical management, tasks include:

- Reading and understanding the most updated version of this manual.
- Ensuring clients have completed a behavioral screening for PrEP. This can be done either with the STI history form (at the local health department) or the PrEP and nPEP Questionnaire (See Appendix A).
- Providing PrEP education - specific education regarding Truvada^R as a medication. Please see Appendix B – Patient Education Checklist.
- Introducing patients to Virginia's program and educating potential clients on the programmatic aspects of the DDP program.
- Helping clients make and keep appointments based on the cyclical timeline outlined in Virginia's PrEP protocols (See Section F, PrEP Management and Documentation), which should include appointment reminders and any follow-up needed. For example, if an STI is found during routine lab testing, ensure treatment is administered.

- Helping patients with medication pick-up, where applicable, through reminders to the patient and submission of appropriate forms to the PrEP team at Central Office and Central Pharmacy.
- Providing appropriate adherence counseling. This entails ensuring patients are taking their medication as prescribed. For patients who have difficulty with adherence this also involves using motivational interviewing to help patients understand their barriers to adherence, and helping patients develop adherence plans.
- Follow-up on patient withdrawal. The navigator is responsible for notifying central office staff of the patient's withdrawal (See PrEP Withdrawal Form, Appendix J) and helping ensure the medication is returned to pharmacy within 30 days.
- Follow documentation guidelines outlined in Section F, PrEP Management and Documentation.

Service Navigation for PrEP patients may also include:

- Knowing where regional PrEP clinics are located.
- Obtaining specific contact information for PrEP navigators at each PrEP clinic and have it readily available to give to clients.
- Working out the referral process with these PrEP clinics so they can help clients more efficiently. Even if navigators work in a PrEP clinic, it is still important to make connections with other sites in case clients prefer a clinic elsewhere.
- Assessing clients for service needs in addition to PrEP.
- Making referrals to service and PrEP providers based on need.
- Following upon referrals to see if clients were linked with a provider.
- Documenting client encounters, referrals, and linkages appropriately.

For additional information on Service Navigation, please contact DDP or refer to the VDH Service Navigation Manual.

I. Prescription Schedule and Medication Management

Prescriptions should be written for a 30-day supply with two refills; however, each medication supply will be for 30 days only. After the initial 30 days of medication, patients will need to follow-up in person and complete a medical evaluation. After the 30-day evaluation, a medical evaluation will not be needed for another 60 days, although medication pick-ups will occur every 30 days. At the end of 60 days (which will mark 3 months after the initial prescription, calculated from the medication start date), another medical evaluation will occur.

Clinic visits are then required every 90 days, utilizing the PrEP/nPEP Flow Sheets for documentation of visits. A full STI visit utilizing the STI Clinic Visit Forms is required at the Initial and every-12-month visits. Interim visits may be provided as needed for problems, complaints, issues with drug adherence, etc. Medication will continue to be dispensed and delivered for 30 days at a time. Follow-up appointment planning is necessary to ensure that patient does not run out of medication waiting for medical evaluation. PrEP site staff are encouraged to schedule upcoming medication pick-up and clinic visit appointments at each clinic visit and provide written appointment reminders to patients before they leave clinic.

The patient has 10 business days to pick up medication. For the first fill, the window period begins from the day the medication arrives to the partner site. For subsequent fills, medication may be delivered to patients between 25-35 days from previous medication pick-up. If a patient does not pick up medication within 10 days of the medication arriving at the partner site, the patient may need to undergo medical evaluation in order to receive medication. After 30 days, undelivered medication must be promptly returned to Central Pharmacy.

If a patient cannot be reached to arrange an evaluation, or is no longer interested in the program, return the medication to Central Pharmacy and notify the PrEP Eligibility Specialist (see Contact List, Section Q) of the withdrawal. Complete the Withdrawal Form (Appendix J) and fax to Central Office. File the Withdrawal Form and fax confirmation in the patient's chart. Unclaimed medication must be returned to Central Pharmacy within 30 days.

Medication pick-ups may be arranged at alternate health department sites within the state if patient is traveling or temporarily out of his/her area of enrollment, e.g. college student, vacation.

Emergency Supply: A request for an additional 30 day fill can be made. This request can only be made once within a 12-month period, and the decision to provide additional fill is made on a case-by-case basis by VDH-DDP, Central Pharmacy, clinician and PrEP navigator.

For information about financial eligibility, please see Appendix L.

Medications provided by through Gilead's Patient Assistance Program will be mailed directly to the local health department for distribution to patient. However, partner sites should submit an application for a patient if they want access to DDP's laboratory services.

J. PrEP Mail Delivery Program and Protocol

If a patient proves adherent, the patient may be eligible to have medication sent to their home after consultation with the PrEP navigator.

The decision to allow home delivery is made collaboratively by the site PrEP navigator, clinician, VDH-DDP and Central Pharmacy, and is based on patient's prior adherence, accessibility, and possible barriers. A patient must provide a physical address for shipment by Central Pharmacy. For patients without a physical shipping address, DDP will work with the patient and Central Pharmacy to determine a solution.

Patients who are eligible to have their medications delivered must confirm the successful delivery with the PrEP navigator who will in turn complete the PrEP Medication Order Form. If a patient does not confirm delivery within 5 days of shipping, the PrEP coordinator will attempt to contact the patient. If the patient does not respond to call within 24 hours, the patient will no longer be eligible for home delivery.

If a patient does not receive the medication within 7 days of delivery, the patient should notify Central Pharmacy immediately. An appointment for the patient to have a medical evaluation will be necessary for the client, and home delivery will be suspended unless a resolution is reached which satisfies VDH-DDP, Central Pharmacy and partner site to ensure safe and timely deliveries.

PrEP Mail Delivery Protocol

Clients are eligible for mail delivery upon completion of their first 90-day prescription (one 30-day fill with two refills). Mail delivery may be initiated when the client returns for the 90-day follow-up visit. At this visit, the clinician or navigator should discuss mail delivery with the patient, and review several factors which will help determine if mail delivery is an option.

In order to participate in the mail delivery program, the client must have a physical mailing address where they are able to safely receive mail; PO boxes will not be accepted for mail delivery. Additionally, UPS must be able to deliver the medication to the provided physical address.

When deciding if a client is a good candidate for mail delivery, consider past adherence and barriers to picking up medication. It is also important to discuss with the client if the address that has been provided is a shared address with others, who may receive the package, and if the package may be delivered to an address where it may be taken or misplaced easily. Clients may opt to require a signature for delivery. Emphasize that with this option, someone must be present when the package is delivered and able to pick up the medication from a UPS store if delivery is missed.

Mail delivery does not completely eliminate visits to the health department. Clients will continue to come in for 90-day tests, results, and subsequent prescription for a 30-day fill with two refills. In order for the mail delivery program to be successful and operate smoothly, **it is imperative that all prescriptions be written for a thirty day fill with two refills** and that the 90-day cycle is maintained.

Eligibility for mail delivery should be determined at a clinical visit to ensure the prescription fills and delivery cycle are synchronized. Once it is determined that mail delivery may be a good option for the client, the PrEP navigator should mail the client a **sample** Delivery Enrollment (DE) form to the physical mailing address where the client intends to receive packages within 24 hours (See Sample Delivery Enrollment Form, Appendix F1). **The sample Delivery Enrollment (DE) form should be printed on green paper with a ‘SAMPLE’ watermark across the sheet** (Appendix F1). Note that the letter will be mailed via US Postal Service, whereas the package will be delivered via UPS. This will be particularly important for those who have the package delivered to a multi-unit location where US Postal Service may have access to a shared mailbox with individual units, but UPS will likely deliver the package to the door.

The client must return the **green sample Delivery Enrollment (DE) form** at the follow-up appointment to receive lab results and the first of three 30 day fills. When the client returns the **green sample Delivery Enrollment (DE) form**, the navigator should review the contents of the letter, ensure that each section is completed and legible, including the prescription number and check the preferred delivery method for the following fill. Also, the navigator should give the patient his/her contact information in case the medication is not received, is damaged or if the letter is misplaced. Clients must notify the navigator or PrEP program support within five days of receiving medication in order to continue receiving medication through the mail. Failure to notify staff of receipt of medication will result in the client no longer being eligible to receive the medication through the mail, but he or she will still be able to receive medication in-person at their clinic location.

Figure 1. PrEP Mail Delivery Program: 90 Day Cycle



Upon return and review of the **green sample Delivery Enrollment (DE) form**, pending lab results, the client will be written a prescription for a 30-day fill with two refills. The client will receive the first of these fills at the local health department or other sub-recipient clinic.

Upon review and receipt of the first of three 30-day fills, provide the client the **Delivery Enrollment (DE) Form** (See Appendix F2) and envelope addressed to Virginia Department of Health. Instruct the patient to mail the letter at least 14 days before his/her next fill is needed to allow time for internal VDH processes of mail delivery and prescription order. If the **DE Form** is misplaced, the client decides to no longer receive mail delivery, or wishes to withdraw from PrEP-DAP entirely, the client should be encouraged to call the PrEP navigator or PrEP support specialist.

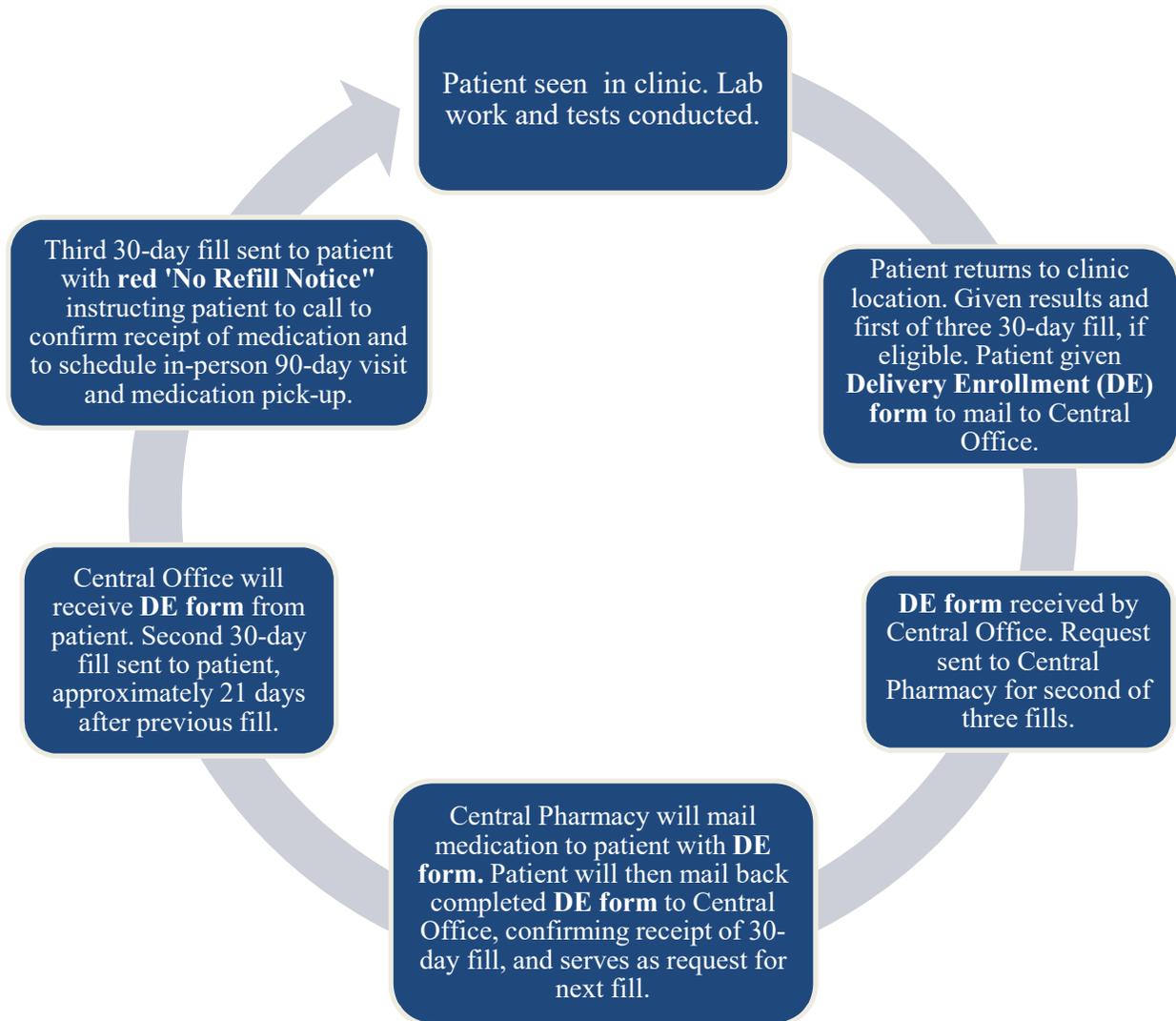
Upon receipt of the signed and completed **DE Form** to VDH, the PrEP program support specialist will request the client's next fill, the second of three 30-day fills, from Central Pharmacy. The prescription will then be sent to the physical mailing address from Central Pharmacy, and will typically arrive to the requested location within 48 hours. In addition to a 30-day fill of medication, the package will contain another **DE Form** and return envelope. The form must be filled out appropriately and clearly, and then mailed back within five days of receiving the package. In the event that a form is misplaced, damaged, or otherwise unable to be submitted, the client is responsible for contacting the PrEP navigator or program support specialist to verbally confirm receipt and information in the form. Failure to return the form or make contact with LDH or VDH staff with five days of receiving the package will result in the client no longer being able to receive medication through mail delivery.

The **DE letter** serves both as confirmation of the second of three 30-day fills, as well as provides instructions to LHD and VDH PrEP staff on how, and if, the client would like to receive the third of three 30-day fills. The client may choose to have the medication sent to the same address, sent to a new address (which they will need to provide), or to no longer receive medication via mail. In the event the third option is selected, LHD staff should be notified to coordinate future medication pick-up.

If the patient chooses to continue mail delivery, VDH staff will request the fill via the Medication Order Spreadsheet approximately 20 days after the second fill. Central Pharmacy will then mail out the medication to the patient with a No Refill Notice (See Appendix F3). **This No Refill Notice is printed on pink paper and informs the client that there are no more fills remaining on the prescription, to schedule an appointment for renewal labs, and instructs the client to call their local navigator or VDH staff to confirm receipt of medication.** As with the second fill, failure to confirm receipt of medication with the LHD or VDH staff within 5 days will result in the client no longer being able to receive medication via mail delivery.

When the client returns for the 90-day follow-up, the navigator should discuss challenges and successes of receiving medication via mail delivery. If mail delivery continues to be the best choice for the patient, continue with the cycle of receiving the first of three 30-day fills at the pick-up site, provide the client with the initial **DE letter** to be sent to VDH no less than 15 days before next fill, and follow the 90-day cycle.

Figure 2. PrEP Mail Delivery Cycle



K. Quality Assurance and Evaluation

DDP will evaluate the PrEP program in order to determine program effectiveness and to assist in similar future projects. Evaluation will include activities such as assessing progress towards goals and objectives, tracking PrEP program enrollment, and using data to understand and improve adherence rates. DDP will also conduct chart reviews on a regular basis for quality assurance purposes. Please see Appendix K for the PrEP Chart Review Tool.

PrEP clinic staff are encouraged to conduct their own internal PrEP quality assurance activities and chart reviews on a regular basis. A recommended schedule is to review at least 5 charts quarterly. Charts should be evaluated as to the degree to which they follow the guidelines in this manual. The Chart Review Tool, Appendix K, may be used locally.

Patients receiving DDP funded medications must consent to be involved in the evaluation process. This process involves:

1. Permission for the local health department to share information on behavioral risks, HIV/STD/Hepatitis status, and drug adherence with VDH-DDP PrEP project staff.
2. Completion of periodic short patient satisfaction surveys. Permission to contact patient if they withdraw without notification to ascertain their reason for stopping PrEP.

L. Patient Withdrawal from Program

Patients may withdraw from the program at any time, for any reason or no reason. DDP requests that clinicians ask patients to contact the clinic or DDP if they choose to withdraw from the program.

The local health department or provider site may also choose to stop providing PrEP services for a patient if the patient fails to return for the 30 day follow-up appointment or any subsequent appointment required for PrEP maintenance. Before discontinuing services, the agency should try to contact the patient by telephone with three total attempts, one of which must be outside of regular business hours. These attempts should be documented in the patient's records. A new set of calls is made if new telephone contact information is obtained.

Once withdrawal has been determined, the provider site will complete a PrEP Withdrawal form (See Appendix J), and fax this form to both the PrEP Eligibility Specialist (See Contact List, Section Q) and Central Pharmacy. DDP uses this form to monitor patient withdrawal, and also to monitor the reasons clients withdraw for program planning purposes.

The patient should return any unused medication, and repeat HIV testing if they have been off PrEP for 30 or more days.

M. How to Order PrEP Educational Materials

VDH makes PrEP educational materials, such as patient brochures and posters, available at no cost through the HIV/STD/Hepatitis Hotline. Please call 800-533-4148 to order materials.

N. Additional Resources

1. AIDSvu.org <http://www.aidsvu.org> AIDSvu is an interactive online mapping tool that visualizes the impact of the HIV epidemic on communities across the United States.
2. CDC's PrEP information index: <https://www.cdc.gov/hiv/risk/prep/index.html>
3. CDC's Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>
4. CDC's Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update Clinical Providers' Supplement:
 - a. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>
5. Gilead's Truvada Package Insert
http://www.gilead.com/~media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf
6. PrEP Locator:
 - a. <https://www.greaterthan.org/get-prep/>
 - b. <https://prelocator.org/>
7. VDH DDP HIV STD HEPATITIS Hotline: 800-533-4148
8. VDH PrEP and nPEP Information Page
 - a. <http://www.vdh.virginia.gov/disease-prevention/disease-prevention/prep-and-npep/>
9. Virginia Greater Than AIDS <https://www.greaterthan.org/virginia/>

Access a complete list of resources through the Virginia Department of Health website at:

<http://www4.irissoft.com/IFTWSQL4/vdhh/public.aspx>

O. Provider Training and Consultation Resources

VDH Division of Disease Prevention can provide training, consultation and technical assistance on a variety of topics. Please reach out to DDP staff to discuss how DDP can meet your needs. Listed below are other training and consultation resources related to HIV prevention.

Virginia and Nearby Resources	National Resources
Mid-Atlantic AIDS Education Training Center https://www.maaetc.org/ The MAAETC provides HIV/AIDS education, consultation and resources throughout Pennsylvania, Maryland, Virginia, West Virginia, DC.	HealthHIV http://healthhiv.org/ 2000 S Street NW Washington, DC 20009 202.232.6750
Virginia HIV/AIDS Resource and Consultation Center- Virginia Commonwealth University Johanna McKee 804-828-2430 jmckee2@mcvh-vcu.edu	His Health Build capacity to deliver high quality care for black LGBT patients https://www.hishealth.org/
Virginia HIV/AIDS Resource and Consultation Center – Eastern Virginia Medical School Tanya Kearney 757-446-6170 kearneTK@evms.edu	National LGBT Health Education Institute A Program of the Fenway Institute https://www.lgbthealtheducation.org/
Virginia HIV/AIDS Resource and Consultation Center – Inova Jupiter Call 703-321-2600 for more information or learn more.	University of California, San Francisco Clinician Consultation Warmline Call for a Phone Consultation (855) 448-7737 or (855) HIV-PrEP Monday – Friday, 9 a.m. – 8 p.m. ET

P. PrEP Data Collection and Submission

Organizations that have a contract with VDH to provided PrEP services are required to collect and submit data to VDH on a monthly basis. Please contact the Program Coordinator or Data Manager for instructions.

Q. VDH Division of Disease Prevention Contact Information

<p>Program Coordinator Project Support and Financial Qualification</p> <p>Eric Mayes 804-864-7335 Eric.Mayes@vdh.virginia.gov</p>	<p>Data Support Technician</p> <p>Debbie Woodson 804-864-7995 Debbie.Woodson@vdh.virginia.gov</p>
<p>PrEP Eligibility Specialist</p> <p>Maurice May 804-864-7938 Fax: 804-864-8053 Maurice.May@vdh.virginia.gov</p>	<p>Social Media Coordinator</p> <p>Chris Barnett 804-864-8110 Chris.Barnett@vdh.virginia.gov</p>
<p>Central Pharmacy Support</p> <p>Stephanie Wheawill (804) 786-4326 Stephanie.Wheawill@vdh.virginia.gov</p>	<p>Quality Improvement Specialist</p> <p>Mary Beth Cox 804-864-7285 Marybeth.cox@vdh.virginia.gov</p>
<p>HIV Prevention Director</p> <p>Elaine Martin 804-864-7962 Elaine.Martin@vdh.virginia.gov</p>	<p>HIV Prevention Data Manager</p> <p>Fatima Elamin (804) 864-7903 Fax: (804) 864-8053 Fatima.Elamin@vdh.virginia.gov</p>
<p>Comprehensive Harm Reduction Coordinator</p> <p>Bruce Taylor 804-864-8015 Bruce.Taylor@vdh.virginia.gov</p>	<p>Nurse Practitioner Consultant:</p> <p>804-864-7328</p>

II. Application for the VDH PrEP Drug Assistance Program (DAP)

A. Contact Information

Central Pharmacy Phone Number: 804-786-4326

Central Pharmacy Fax Number: 804-371-0236

B. Procedures

- Fill out the VDH PrEP DAP application form (See Appendix G)
 - If necessary, please use the No Income Verification Letter (See Appendix H)
- Fax the application form to the PrEP Eligibility Specialist at Central Office Richmond 804-864-8053
- After the application form is received at Central Office, the PrEP Eligibility Specialist will review the application and ensure that all needed documentation is present and sufficient to approve application. Once the application is approved, the PrEP Eligibility Specialist will inform the PrEP navigator, at which point the PrEP Eligibility Specialist will fax the approved application. Upon approval, the provider will fax the prescription, along with the corresponding completed PrEP Medication Order Form (See Appendix I) to Central Pharmacy: 804-371-0236.
- Orders faxed to Central Pharmacy before 1 p.m. will ship the same day. Orders received after that will ship the following day. **NEVER e-mail patient information to Central Pharmacy.**
- Central Pharmacy will fill and ship the medication, along with the PrEP Medication Order Form to the pick-up site designated for the client. The medication will be in a brown paper bag with a “P” on it so that it is easily distinguishable from other medications stored at the pick-up site.
- When the client picks up the medication, the site must obtain the client signature and date on the PrEP Medication Order Form that accompanied the medication. If the pickup site is different than the program site, the PrEP Medication Order Form will need to be faxed back to the program site fax number, found at the top of the form, so that the program site knows when to reorder medication from Central Pharmacy. Completed PrEP Medication Order Forms are to be sent to be faxed to Eric Mayes, PrEP Coordinator at 804-864-7335, no later than the end of each month.
- All refills need to be tracked and submitted by the program site PrEP navigator. If the prescription sent to Central Rx contains multiple refills, after the initial fill, only the completed PrEP Medication Order Form is required to be faxed to Central Pharmacy. If there are no remaining fills, a prescription will need to accompany the PrEP Medication Order Form. Medication will not be filled earlier than 14 days from the date that it is due. Central Pharmacy will only fill a 30 day supply at a time.
- *If a patient withdraws, or is otherwise deemed ineligible, after a prescription has been filled by Central Pharmacy, please fax a completed withdrawal form to both the PrEP Eligibility Specialist and Central Pharmacy.*

Appendix A.
Behavioral Screening Tool – PrEP and nPEP Questionnaire

PrEP and nPEP Questionnaire

Name: _____

Today's Date: _____

Please think about your answers to Questions 1-6; you can choose to write your answers if you wish. Then answer questions A, B and C in the box below.

<p>1. Do you...have sex, without using condoms, with people of unknown HIV status? a. IF YES, When is the last time you had sex without a condom? Date: ____/____/____*</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>2. Do you...have a sex partner who has HIV? a. IF YES, When is the last time you had sex with this partner? Date: ____/____/____*</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>3. Have you... been diagnosed with syphilis or <u>rectal</u> gonorrhoea/chlamydia in the past 6 months? Or any sexually transmitted infection (STI) in the past year?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>4. Do you... share needles or “works” with other people for medical or non-medical purposes - for example, injecting drugs, hormones, silicone or steroids? a. IF YES, When is the last time you shared needles? Date: ____/____/____*</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>5. Do you... ever agree to have sex with someone because you need something from the other person, like money, housing or drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>6. [FOR FEMALES] Are you... trying to become pregnant with a male who is HIV positive?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

If somebody says “Yes” to any of these statements, they have a higher chance of getting HIV.

<p>A. Did you say “Yes” to any of these statements?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>B. Are you interested in PrEP, the pill that can help prevent HIV?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>C. *If you said “Yes” to #1, #2 or #4, was the last time within the past 72 hours (3 days)?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No ➔ IF YES: Talk about nPEP

Appendix B. Patient Education Checklist

PrEP Patient Education Checklist

1. How PrEP works	<ul style="list-style-type: none"> • PrEP is two drugs in one pill and has the brand name Truvada. • When taken once a day, PrEP may prevent HIV infection.
2. Importance of other risk reduction strategies	<ul style="list-style-type: none"> • PrEP works as part of a comprehensive prevention plan. • PrEP does not prevent other sexually transmitted infections (STI's) and it is recommended that you still use condoms, take other actions to reduce your risk for HIV, and/or get regular STI screenings.
3. Efficacy and limitations of PrEP	<ul style="list-style-type: none"> • Efficacy is dependent on adherence. PrEP works ONLY when taken consistently – daily, preferably at the same time each day – to maintain levels of the drug in your blood. • When taken correctly and consistently, PrEP has been shown to be 90 percent effective in preventing HIV infection. PrEP reduces, but does not eliminate, HIV transmission risk. • PrEP is still being studied and, though a number of studies have shown that it prevents infection, long term risks remain unknown.
4. Dosing and daily adherence	<ul style="list-style-type: none"> • Being on PrEP means a regimen of taking one pill every day. • It must be taken consistently to be effective. Taking PrEP incorrectly could lead to resistance, which means that PrEP will no longer prevent HIV infection, so it's important that you take the pills as prescribed.
5. Number of doses to achieve protective effect	<ul style="list-style-type: none"> • PrEP is not effective immediately. Research suggests that it's not fully effective for 30 days, though it may reach an acceptable level of effectiveness in rectal tissue after seven days and in vaginal tissue after 20 days.
6. Missed doses	<ul style="list-style-type: none"> • If doses are accidentally missed, there is no need to double up doses the following day. Just take one pill the following day at the usual time and maintain your pill schedule after that.
7. Common side effects	<ul style="list-style-type: none"> • PrEP does come with some side effects but they are typically tolerable and diminish or disappear after a few weeks. • Common side effects are: headache, abdominal pain, and weight loss. • Side effects usually resolve or improve after first month. Talk to your prescribing provider about interventions/treatments which may reduce your discomfort during this time.
8. Baseline tests and schedule for monitoring	<ul style="list-style-type: none"> • Prior to being prescribed PrEP, your provider will run a series of medical tests including an HIV test and renal function tests. Truvada can impact kidney function and your eligibility depends on those test results. A positive HIV test is an automatic disqualifier for PrEP but you will be referred for care promptly.

<p>9. Elements of, and schedule for, follow-up monitoring, including HIV testing at least every 3 months</p>	<ul style="list-style-type: none"> • Though an individual prescription may be written for an initial fill and subsequent refills, if you are prescribed PrEP, Central Pharmacy will only provide medication for 30 days at a time. • At the end of the first 30 days, you will be required to come in so we can make sure you're taking your meds and everything is going ok. • After that, and at the end of 60 days, you'll come in so we can do a follow-up HIV test and other assessments. Then you'll only have come to in every three months for medical evaluation.
<p>10. Symptoms of new HIV infection</p>	<ul style="list-style-type: none"> • Symptoms of a new HIV infection, also called "seroconversion," may include: Fever, headache, muscle aches and joint pain, rash, sore throat and/or painful mouth sores, swollen lymph glands, night sweats, loss of appetite, fatigue, and diarrhea.
<p>11. Criteria for discontinuing PrEP</p>	<ul style="list-style-type: none"> • Positive HIV test result: If at any time while you're on PrEP you have a positive HIV test result, PrEP will be discontinued immediately and you will be referred for care. • Development of renal disease: PrEP may also be stopped if you develop kidney disease or your kidneys show signs of distress. • Non-adherence to medication or appointments: Taking PrEP incorrectly or not attending follow-up appointments could result in PrEP being stopped. • Change in risk behaviors (i.e., PrEP is no longer needed): If anything in your life changes – for example: you break up with an HIV positive partner, you start a monogamous relationship with an HIV negative partner or your patterns of sexual behavior change, or you begin drug treatment / rehabilitation services – let us know and we'll discuss whether PrEP is still right for you. • Please notify us if you plan to discontinue PrEP yourself.
<p>12. PrEP and Pregnancy</p>	<ul style="list-style-type: none"> • Truvada is FDA pregnancy category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, TRUVADA should be used during pregnancy only if clearly needed.

Appendix C. PrEP Lab Test Table

Page 2	Initial	30 days	3 months	6 months	9 months	12 months	Comments
Chlamydia/ Gonorrhea NAAT: Pharyngeal	X	X As indicated by history	X As Indicated by history	X	X As indicated by history	X	
Serum Creatinine (for calculated creatinine clearance)	X	X With increased risk of nephro- toxicity	X As indicated by history	X	X As indicated by history	X	Consider age >65, African- American, DM, HTN, hx of renal disease, concurrent nephrotoxic medications
Pregnancy	X	X As indicated by history	X	X	X	X	Females at risk for pregnancy
Urinalysis for protein							As indicated for evaluation of renal safety threat
Liver function tests (AST/ALT)							As indicated for eval of clinical symptoms or in the presence of concurrent hepatitis B or C

Appendix D. nPEP Lab Test Table

Lab Tests – nPEP Guidelines (CDC, 2017; VDH, 2018)

	Baseline	4-6 weeks after exposure	3 months post exposure	6 months post exposure	Comments
HIV 4 th generation	X	X	X	X	If positive at any point, perform confirmatory testing and referral for linkage to care
Hepatitis B (HBcAb+HBsAb+Ag)	X			X if neg at baseline	Refer positive for evaluation and treatment
Hepatitis C (HCV Ab w/reflex to NAA)	X			X If neg at baseline	Refer positive for evaluation and treatment
Syphilis – Reverse Algorithm Cascade	X	X		X	Serial post-treatment RPR titers for positive results per CDC 2015 STD Treatment Guidelines
Chlamydia/Gonorrhea NAAT: Genital	X	X If not treated as baseline or symptomatic			
Chlamydia/Gonorrhea NAAT: Rectal	X	X If not treated as baseline or symptomatic			
Chlamydia/Gonorrhea NAAT: Pharyngeal	X	X If not treated as baseline or symptomatic			
Pregnancy	X	X			For females at risk for pregnancy (Tivicay contraindicated if positive or at risk or pregnancy)
Serum Creatinine (for calculated creatinine clearance)	X	X			If prescribed Truvada/Isentress or Truvada/Tivicay
Liver function tests (AST/ALT)	X	X			If prescribed Truvada/Isentress or Truvada/Tivicay

Appendix E. PrEP Adolescent Consent Form

VIRGINIA DEPARTMENT OF HEALTH
Patient Application and Consent for Health Care – CHS-1A

Patient Name:

Date of Birth:

ID#

PATIENT CONSENT FOR GENERAL PRIMARY CARE

I hereby authorize the Physicians, Nurses, Nurses Practitioners, and other medical care providers of the Virginia Department of Health (VDH) to examine and/or treat me and/or my dependent, as name above.

NOTICE OF DEEMED CONSENT FOR HIV, HEPATITIS B OR C TESTING

VDH is required by § 32.1-45.1 of the Code of Virginia (1950), as amended, to give you the following notice.

1. If any VDH health care professional, worker or employee should be directly exposed to your blood or body fluids in a way that may transmit disease, your blood will be tested for infection with human immunodeficiency virus (the "AIDS" VIRUS), AS WELL AS FOR Hepatitis B and C. A physician or other health care provider will tell you the result of the test. Under Va. Code § 32.1-45.1(A), you are deemed to have consented to the release of the test results to the person exposed.
2. If you should be directly exposed to blood or body fluids of a VDH health care professional, worker or employee in a way that may transmit disease, that person's blood will be tested for infection with human immunodeficiency virus (the "AIDS" VIRUS), as well for Hepatitis B and C. A physician or other health care provider will tell you and that person the result of the test.

HIV TESTING

If HIV testing is performed, you will be told ahead of time, be given information about the test, and allowed to decline testing. All results will remain confidential except as allowed by law.

Signature of Patient

Date Signed

Signature of Parent/Guardian - Relationship

Signature of Person Obtaining Consent

PAYMENT FOR SERVICES

Some services are free, but we charge for many of them. You will be responsible for paying for those services. We have a sliding fee scale, bases on your family income and family size that may lower the charges. You will be liable for any charges not paid by third party payers according to this sliding scale. The percentage you pay will remain the same until your income or family size changes. Some services are charged on a flat fee basis, regardless of income or family size (everyone pays the same price). It is possible that our charges may change. We will try to discuss those changes with you. Your information is being entered into a statewide database that can be accessed from any local health department in the state. Based on the information you have provided, you are responsible for paying 100% of the charges. If there is a charge for services and you do not pay at the time of visit, we will establish a payment plan for the amount due.

If my health care provider orders lab test, I understand that I may receive a separate bill from an outside lab. My insurance company will determine the amount, if any, that I may owe to that lab provider, and I will be responsible for payment. I understand that any sliding fee scale that may apply to other services provided by VDH will not apply to the lab bill from the outside lab provider. _____ (Client's initials)

VIRGINIA DEPARTMENT OF HEALTH
Patient Application and Consent for Health Care – CHS-1A

Patient Name:

Date of Birth:

ID#

I give my permission for me and/or my dependent (as named above) to be interviewed about family income and family size. I understand that I am responsible for paying the bill.

RECEIPT OF THE NOTICE OF PRIVACY PRACTICES

I acknowledge that I have received the Notice of Privacy Practices from the Virginia Department of Health.

RECORD KEEPING

I understand that medical records will be retained for ten years after the date of the last visit, then destroyed in a manner that assures confidentiality throughout the process and in its results. In the case of a minor, the record will be retained for twenty-eight years after birth, then destroyed in a manner that assures confidentiality throughout the process and in its results. I authorize VHD to release records necessary to support the application for payment by Medicare, Medicaid, and other health care benefits. I request the third party payer to pay any authorized benefits to VDH on my behalf.

I understand that this consent will remain in effect as long as my dependent or I receive care from VDH or until I withdraw it.

I certify that the information I have provided is a true and complete statement according to my best knowledge and belief, and that a full explanation of services and charges has been given to me. I understand that if I give false information, withhold information, or fail to report changes promptly, I will be breaking the law and can be prosecuted and/or have services discontinued.

Signature of Patient

Date Signed

Signature of Parent/Guardian - Relationship

Signature of Person Obtaining Consent

Appendix F. Home Delivery Forms

- a. Sample Medication Enrollment Form
- b. Delivery Enrollment (DE) Form
- c. No Refill Notice

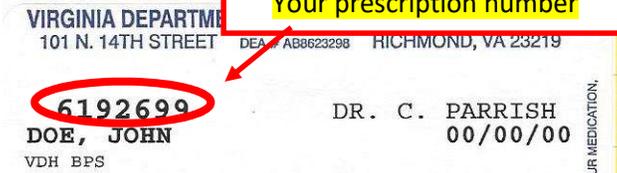
Delivery Enrollment Form

Please PRINT Legibly

Name: _____

Date of Birth: _____

Prescription Number: _____



TAKE 1 TABLET BY MOUTH DAILY

In order to continue receiving mail delivery, **you must complete this form and return it within 5 days** of receiving your most recent delivery. Failure to do so will result automatic disenrollment from the delivery program.

1.) Send next month's delivery to (check one):

- The address on the front of this envelope.
- I would like a signature to be required so that medication is not left at the door if I'm not home. Signature required means I **must** be home at the time when UPS delivers the medication.
- I would like to change my address. Please make my next delivery to:

Please print legibly

Street Address _____ Apt/Unit _____

City: _____, VA Zip: _____

- I no longer want to receive deliveries

2.) My phone number (check one):

- Has not changed
- I have a new phone number, it is: (_____) _____ - _____
- I currently do not have a personal phone, but if something comes up, you can leave a message for me at: (_____) _____ - _____

My signature indicates that the Virginia Department of Health (VDH) should send my medication to the address provided and that VDH is not responsible if the medication is lost or stolen.

SIGNATURE: _____ DATE: _____

Mail this form to: The Virginia Department of Health
ATTN: PrEP Specialist
Room 341-B1
109 Governor St.
Richmond, Va. 23218

If you have any questions, please contact your local navigator or call 804-864-7938

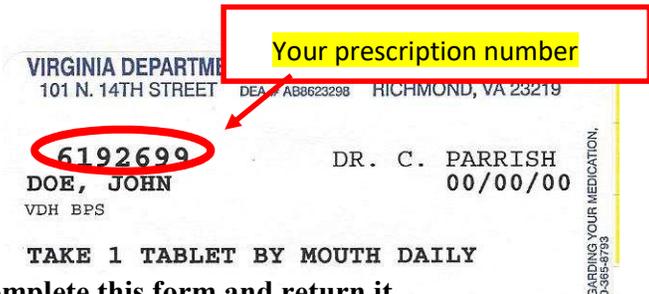
Delivery Enrollment Form

Please PRINT Legibly

Name: _____

Date of Birth: _____

Prescription Number: _____



In order to continue receiving mail delivery, **you must complete this form and return it within 5 days** of receiving your most recent delivery. Failure to do so will result automatic disenrollment from the delivery program.

3.) Send next month's delivery to (check one):

- The address on the front of this envelope.
- I would like a signature to be required so that medication is not left at the door if I'm not home. Signature required means I **must** be home at the time when UPS delivers the medication.
- I would like to change my address. Please make my next delivery to:

Please print legibly

Street Address _____ Apt/Unit _____

City: _____, VA Zip: _____

- I no longer want to receive deliveries

4.) My phone number (check one):

- Has not changed
- I have a new phone number, it is: (_____) _____ - _____
- I currently do not have a personal phone, but if something comes up, you can leave a message for me at: (_____) _____ - _____

My signature indicates that the Virginia Department of Health (VDH) should send my medication to the address provided and that VDH is not responsible if the medication is lost or stolen.

SIGNATURE: _____ DATE: _____

Mail this form to: The Virginia Department of Health
ATTN: PrEP Specialist
Room 341-B1
109 Governor St.
Richmond, Va. 23218

If you have any questions, please contact your local navigator or call 804-864-7938

You have no more fills left.

Please call your navigator within the next 5 days to confirm that you received this delivery and to schedule an appointment.

Failure to confirm delivery may result in no longer being eligible to receive home deliveries.

If you have any questions, please contact your local navigator or call 804-864-7938.

You have no more fills left.

Please call your navigator within the next 5 days to confirm that you received this delivery and to schedule an appointment.

Failure to confirm delivery may result in no longer being eligible to receive home deliveries.

If you have any questions, please contact your local navigator or call 804-864-7938.

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Please call your navigator within the next 5 days to confirm that you received this delivery and to schedule an appointment.

Failure to confirm delivery result in no longer being eligible to receive home deliveries.

If you have any questions, please contact your local navigator or call 804-864-7938.

You have no more fills left.

Please call your navigator within the next 5 days to confirm that you received this delivery and to schedule an appointment.

Failure to confirm delivery may result in no longer being eligible to receive home deliveries.

If you have any questions, please contact your local navigator or call 804-864-7938.

Appendix G. VDH PrEP Drug Assistance Program (DAP)
Application

Virginia Pre-Exposure Prophylaxis Drug Assistance Program
(VA PrEP DAP) C O N F I D E N T I A L A P P L I C A T I O N

Health Insurance and Medical History

Do you currently have any type of health insurance? Yes No

If yes, does your insurance provide prescription drug coverage? Yes No

Prior to today, have you ever been diagnosed with (check all that apply):

- Syphilis Gonorrhea Chlamydia

If you checked any of the boxes above, were you diagnosed with these in the last year? Yes No

Have you ever used any of the following substances (check all that apply):

- Alcohol (ex. beer, wine, liquor)
- Amphetamines (ex. meth, speed, non-prescription use of Adderall)
- Cocaine or crack-cocaine
- MDMA (ex. molly, ecstasy)
- Hallucinogens (ex. LSD, acid, mushrooms)
- GHB
- Marijuana (ex. joints, blunts, edibles)
- Opiates (ex. heroin, Fentanyl, OxyContin or Morphine)

Have you ever injected any of the following substances (check all that apply):

- Amphetamines (ex. meth, speed, non-prescription use of Adderall)
- Cocaine or crack-cocaine
- Opiates (ex. heroin, Fentanyl, OxyContin or Morphine)
- Injected other substance, specify: _____

Please check ALL risk categories that apply to you: in the last year

- Man who has sex with men and engages in unprotected anal intercourse
- Diagnosed with a Sexually Transmitted Infection (example: syphilis, gonorrhea, chlamydia)
- Exposure to an STI through a sexual network
- Ten or more sexual partners
- Injection drug user who has shared injection drug equipment and/ or injected one or more times a day and/or injected methamphetamines and/or engaged in high risk sexual behavior
- Have had unprotected anal intercourse with a partner of unknown HIV-1 status with any of the factors listed above
- Engaged in transactional sex (sex for money, drugs, gifts, etc)

What is your annual income from all sources? \$ _____

Authorized Representative

Please provide the following information for any family/friends you would like us to be able to talk to about your PrEP DAP

First and Last Name: _____

Primary Phone Number: _____ **Email:** _____

Date of Birth: ____/____/____
MM DD YYYY

ClientName: _____ PrEP DAP ID: _____

Virginia Pre-Exposure Prophylaxis Drug Assistance Program
(VA PrEP DAP) C O N F I D E N T I A L A P P L I C A T I O N

Eligibility, Agreement, Release of Information, & Assignment of Benefits

CONSENT and Signature

I understand that continuation of this program depends on the availability of funds. I understand it is my responsibility to provide medical status and proof of income every 12 months. I further understand it is my responsibility to notify VDH of any changes in my contact information, income or insurance status (if applicable). Failure to provide the necessary documentation could jeopardize my approved assistance through the Virginia Department of Health.

My information is being entered into a statewide database by the Virginia Department of Health. VDH agrees to treat all information as confidential. I hereby give my consent to VDH to obtain, verify, and/or release my demographic, medical, prescription, and/or insurance coverage information, with other entities as necessary to effectively determine financial eligibility and manage my medication access. Information may be shared with but is not limited to the following: physician, health department personnel, other Division of Disease Prevention programs (including Surveillance, Care and Prevention), treatment center personnel, pharmacy services provider, referral source, clinic, insurance broker and/or insurance carrier. VDH agrees to treat any and all such information as confidential.

I understand that this consent will remain in effect as long as my dependent or I remain on PrEP DAP or until I withdraw it.

I have read, understand and agree to the above Client Responsibilities and Release of Consent. I verify that the information provided in this application is complete and accurate to the best of my knowledge.

Signature of Client, Parent/Legal Guardian or Person acting in Loco Parentis

Date Signed

Relationship (If signature is not of Client)

Signature of Person Obtaining Consent

Date Signed

Please provide the information below if a friend, family member or advocate helped to complete this application:

First Name

MI

Last Name

Address

City

State

Zip

Phone Number

In order to process your application in a timely manner it is important that the application is complete. If your application is not complete, we will not be able to process your application and there may be a delay in obtaining your medication.

ClientName: _____ PrEP DAP ID: _____

Virginia Pre-Exposure Prophylaxis Drug Assistance Program
(VA PrEP DAP) C O N F I D E N T I A L A P P L I C A T I O N

Checklist for Submitting a Complete PrEP DAP Application:

Proof of Legal Name (New PrEP DAP Applicants Only)

Please provide us a copy of one of the following to verify your full legal name:

- Any state driver's license or identification card
- Passport

Proof of VA Residency

Please provide us a copy of one of the following to verify your VA residency:

- Current Virginia State driver's license or identification card
- Virginia voter registration card
- Utility bill (cell phone bills are not accepted)
- Lease/rental/mortgage agreement

Proof of Income

Please provide us a copy of one of the following to verify your proof of income:

- Copies of three most recent, consecutive pay stubs that show group income and payroll deductions
complete copy of most recent Federal Income tax return
- Veteran's or other retirement benefits (a copy of award letter or any other official documentation showing the amount received on a regular basis)
- Government benefits and/or award (such as Social Security and unemployment benefits)

Proof of No Income

Please provide us a copy of one of the following to verify no income proof:

- Termination or layoff notice from most recent employer on company letterhead
- A "proof of no income" letter that identifies the source of the applicant's food and shelter (letter signed by agency, shelter, relative, friend, or some other non-agency source of support)

Insurance Card

If you have insurance, please provide us a copy of your insurance card.

Application completed in pen

Application filled out completely (both Section 1 & Section 2) with all required documentation, dates and signatures

ClientName: _____ PrEP DAP ID: _____

Appendix H. No Income Verification Letter

Sample Individual Statement

SELF DECLARATION OF "NO INCOME"

I, _____, certify that I have no income.
name of applicant

I understand that "income" includes:

- pay, wages, or salaries
- Tips
- unemployment benefits
- social security benefits
- welfare benefits
- disability, worker's compensation or other payments for an injury or illness
- retirement or pension benefits
- alimony or child support payments
- insurance or annuity payments to me
- interest or dividends from savings accounts or investments
- rental income or other income from a business
- income from royalties, patents, gambling, or lottery winnings

I understand that if I have any of these types of income, I must tell the eligibility worker about them.

I have 30 days to give the health department a letter from a church, shelter, relative, or some other person who is providing my housing and meals. If I do not do this, I will be charged the full amount for any care the health department provides to me.

(Signature of applicant or guardian)

(Printed name of applicant or guardian)

(Date)

Sample Agency Support Statement

STATEMENT MUST BE ON AGENCY LETTERHEAD STATIONERY*

We understand that _____ (name of applicant) is receiving medical care from the Virginia Department of Health. Because the applicant has no income, our agency is providing food and shelter for the applicant.

(Signature of agency representative)

(Printed name of agency representative)

(Position at the agency)

(Telephone number if not given above)

(Date)

Sample Relative or Friend Support Statement

I understand that _____ (name of applicant) is receiving medical care from the Virginia Department of Health. Because the applicant has no income, I am either providing the applicant with food and shelter or providing the applicant with financial support.

(Relationship to applicant - for example, friend, cousin)

I am providing _____ food and shelter, _____ financial support.

(Approximate amount of financial support per month)

(Signature of person providing support)

(Printed name of person providing support)

(Address)

(Telephone number)

(Date)

Source: Virginia Department of Health Guidance Document for Virginia Administrative Code Chapter 200. "Regulations governing eligibility standards and charges for medical care services to individuals." January 1, 2010

Appendix I. PrEP Medication Order Form

PrEP Medication Order Form

Program/Provider Site: _____
Program Site PrEP Navigator/Contact Name: _____
Program Site Contact Fax Number: _____
Pick-up Site: _____
Medication Ordered By: _____ Date: _____

PrEP Client Name and Date of Birth Name: _____ Date of Birth: _____	Pharmacy Use
--	--------------

Client Signature: _____
Pick-up Date: _____

Instructions for Program Site: Please fill out the Provider/Program site, PrEP Navigator/Contact person and fax number at the top. Fill in the client name and date of birth in the middle left box. Fax to VDH Pharmacy Services at 804-371-0236.

Instructions for Pickup Site: Keep this form so that it is readily available with the medication upon pick-up. Upon pick up, have client sign and date the bottom of the form. Following pick up, if the provider is different from the pick up site, this form will need to be faxed back to the provider fax number at the top of this form so that they know when to reorder the medication from VDH Pharmacy Services. At the end of the month, you will need to fax all the PrEP Medication Order Forms to Eric Mayes, VDH PrEP Drug Assistance Program Coordinator at 804-864-8053.

Appendix J. PrEP Withdrawal Form

PrEP Program Withdrawal Form

A team member at the provider site (e.g. navigator, nurse, case manager) will complete this form and fax this form to both the PrEP Eligibility Specialist and Central Pharmacy.

Name: _____

Date of Enrollment: _____

Date of Withdrawal: _____

HIV Status:

Reactive

Non-reactive

Date of Last Test: _____

<input type="checkbox"/> A. Withdrawal by Clinician Select reason below:	<input type="checkbox"/> B. Self-Withdrawal Select reason below:
<input type="checkbox"/> Reactive HIV test result <input type="checkbox"/> Development of Renal Disease <input type="checkbox"/> Use of Medication for unintended purposes <input type="checkbox"/> Non-adherence to medication or appointments <input type="checkbox"/> Lost to follow-up <input type="checkbox"/> Other, please explain: _____ _____	<input type="checkbox"/> Change in risk behaviors <input type="checkbox"/> Side effects - Please explain: _____ _____ <input type="checkbox"/> Unable to keep up daily regimen <input type="checkbox"/> Other, please explain: _____ _____

By signing below, I _____, acknowledge that I will no longer be a participant of the Commonwealth of Virginia's PrEP Program. I understand that I will no longer receive prescriptions for Truvada through the program.

Signature: _____ Date: _____

Appendix K. PrEP Chart Review Tool

COVER PAGE

Site: _____

Review Date: _____

Reviewer: _____

Key: *(Scoring, unless otherwise indicated in explanation of individual elements.)*

- **Complete** = Action was indicated and documentation indicated item WAS completed
- **Incomplete** = Action was indicated and documentation indicated item was PARTIALLY completed
- **Not done** = Action was indicated and documentation indicated it was NOT completed
- **N/A** = Action was not indicated

Chart ID:	Explanation	Initial date	30-day Date	90-day date / 15 months	180 days / 18 months	270 days / 21 months	One-year / 2 years	Comments
➤ Pharyngeal*	N/A – patient denies oral sex history; 30-day Visit only as indicated	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 30 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	
➤ Rectal*	N/A – patient denies anal sex history; 30-day Visit only as indicated	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 30 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	
Hepatitis B	HBcAb+HBsAb+Ag; viral loads at 6 & 12 months if positive; N/A = positive serology history	Complete 1 Incomplete 2 None 3 N/A 99	Complete 1 Incomplete 2 None 3 N/A 99		Complete 1 Incomplete 2 None 3 N/A 99		Complete 1 Incomplete 2 None 3 N/A 99	
	<i>Hep B Alternate Test Dates</i>	_____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date)						
Hepatitis C	HCV Ab w/reflex to NAA; viral load and refer for tx if positive; N/A = positive serology history	Complete 1 Incomplete 2 None 3 N/A 99	Complete 1 Incomplete 2 None 3 N/A 99				Complete 1 Incomplete 2 None 3 N/A 99	
	<i>Hep C Alternate Test Dates</i>	_____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date)						
Syphilis	Reverse algorithm; 30-day Visit only as indicated	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 30 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	Complete 1 Incomplete 2 None 3 <input type="checkbox"/> Done within past 90 days	
Serum creatinine	30-day Visit only as indicated	Complete 1 Incomplete 2 None 3	Complete 1 Incomplete 2 None 3	Complete 1 Incomplete 2 None 3	Complete 1 Incomplete 2 None 3	Complete 1 Incomplete 2 None 3	Complete 1 Incomplete 2 None 3	
	<i>Serum creatinine Alternate Test Dates</i>	_____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date) _____ (Date)						

Chart ID:	Explanation	Initial date	30-day Date	90-day date / 15 months	180 days / 18 months	270 days / 21 months	One-year / 2 years	Comments
Additional Documents								
➤ Med Order Forms	Completed & faxed – copy on chart – 1 signed by the patient per month; N/A – pt. disenrolled	Complete 1 Incomplete 2 None 3 N/A 99						
	<i>Medication order form dates of completion</i>	_____ (Date)						
		_____ (Date)						
		_____ (Date)						
➤ Med Pickup	N/A=Med pick-up not due		Complete 1 Incomplete 2 None 3 N/A 99					
	<i>Medication pickup dates</i>	_____ (Date)						
		_____ (Date)						
		_____ (Date)						
Referral(s)*	Include ACA/Medicaid application; N/A – no referral need identified	Complete 1 Incomplete 2 None 3 N/A 99						
Services & Referral Form* and/or Screening and Referral Tracker	Minimum of Brief Screener at Initial Visit; Follow-up Visits as indicated; if not indicated, chart so noted	Complete 1 Incomplete 2 None 3						
Documents that need to be present in the chart (not visit specific)								
➤ Eligibility	Including insurance info; N/A – patient not enrolled							Complete 1 Incomplete 2 None 3 N/A 99
➤ Consent for Tx	Minor requires parent/guardian consent; N/A – patient not enrolled							Complete 1 Incomplete 2 None 3 N/A 99
➤ PrEP Application	Completed & faxed – copy on chart; N/A – patient not enrolled							Complete 1 Incomplete 2 None 3 N/A 99

Chart ID:	Explanation	Initial date	30-day Date	90-day date / 15 months	180 days / 18 months	270 days / 21 months	One-year / 2 years	Comments
➤ When discontinuing PrEP services, three (3) telephone attempts*	At least one after regular business hours; N/A=patient discontinued treatment <u>or</u> patient currently active							Complete 1 Incomplete 2 None 3 N/A 99
➤ PrEP Withdrawal Form*	Completed & faxed whenever PrEP is discontinued; copy on chart; documentation that med returned to pharmacy							Complete 1 Incomplete 2 None 3 N/A 99

*As indicated

NOTES:

Signature/Title _____ Date _____

Appendix L. PrEP Financial Eligibility Guidelines
(coming soon)
