Pharmacist-operated Pre-Exposure Prophylaxis (PrEP) Clinic

Collaborative Practice Agreement

Signatories Include:

* Clinic Director
* Pharmacy Director
* Medication Management Therapy Coordinator

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# **Statement of Need**

Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) is a complex and growing problem in the United States, affecting an estimated 1,189,700 people with approximately 36,801 people receiving an HIV diagnosis in 2019, according to the Centers for Disease Control and Prevention (CDC). Although American Indians and Alaskan Natives comprise only about one percent of the National HIV/AIDS infections, there was a 22% increase in new HIV diagnoses between 2015-2019, the only group to see an increase. Pre-exposure prophylaxis (PrEP) has been shown to reduce the risk of transmission of HIV in those at highest risk by more than 90% in adherent patients.

Successful reduction in transmission using PrEP requires continuous follow up with laboratory monitoring and counseling on side effects and adherence. IHS facilities serve patients at risk for transmission of HIV. Utilization of pharmacist-run PrEP clinic will improve access to treatment, improve patient outcomes and reduce provider workload for routine follow up management.

# **Purpose and Goals**

PrEP has the potential to decrease not only the burden of HIV at IHS facilities and in the community, but also to decrease the prevalence of sexually transmitted infections through frequent screenings and treating new infections promptly. By screening persons who are at a high risk of contracting HIV and other sexually transmitted infections frequently, we will be able to respond with treatment to prevent further spread within the community and complications in the patient. Use of emtricitabine 200mg/tenofovir 300mg has shown to be effective in preventing infection with HIV in persons who engage in high-risk behaviors such as sharing injection equipment, and inconsistent condom use with sexual partners of unknown HIV status. PrEP clinic visits will also allow the opportunity to provide primary care services, such as immunizations and harm reduction counseling. It also improves access to treatment and reduces provider workload due to required, quarterly follow up. Allowing pharmacists to manage PrEP treatment by ordering labs, collecting subjective and objective data, and providing counseling and refills will accomplish this.

# **Program Director**

The chief of pharmacy and/or the clinical director will select the PrEP Pharmacy-Run Clinic director. Responsibilities will include:

  Management of patients referred to clinic

  Reporting of outcomes and performance improvement measures

# Referrals

Medical provider or primary care provider who will have initial visit along with one visit annually will refer patients. If eligible for treatment, provider will initiate medications and submit electronic health record (EHR) consult for PrEP Pharmacy-Run Clinic, documenting any precautions for treatment.

Selection Criteria:

Must be HIV negative with a documented negative HIV Ag/Ab test result within 1 week before initially starting PrEP, has an estimated creatinine clearance >30 ml/min, not on any contraindicated medications, willing to adhere to PrEP and keep clinic visits and not showing signs of acute HIV infection in the past 4 weeks in addition to one of the following:

* Men who have sex with men (MSM) who engage in condomless anal intercourse or have had a sexually transmitted infection diagnosed in the past 6 months
* Heterosexual men and women engaging in high-risk sexual behavior defined as infrequent use of condoms during sex with one or more partner of unknown HIV status or diagnosed with a sexually transmitted infection within the last 6 months
* Transgender women (male to female transgender individuals) who have sex with men and engage in condomless anal intercourse or have had a sexually transmitted infection diagnosed in the past 6 months
* HIV negative persons in an ongoing sexual relationship with an HIV positive person, particularly for those not virally suppressed.
* IV drug users who have shared injection or drug preparation equipment

Considerations:

* Contraindicated
	+ HIV positive
	+ Creatinine clearance less than 60ml/min
	+ Lack of readiness to adherence
* Considerations
	+ Chronic active Hepatitis B infection
	+ Pregnancy, attempting to conceive or breast/chest feeding
	+ Age younger than 18
	+ Presence of osteopenia/osteomalacia/osteoporosis
	+ At risk of chronic kidney disease

Criteria for staying in clinic:

* Minimum of one visit with a provider or PCP annually
* Minimal missed appointments without calling to reschedule
* Must have visit with benefits coordinator to check eligibility for insurance and cooperate with pharmacy in regard to enrollment in patient assistance plans or insurance enrollment

# Pharmacists' Responsibilities

* Review most recent CDC Pre-Exposure Prophylaxis guidelines
	+ For the MSM population, there is scientific evidence that taking PrEP on-demand (2-1-1 schedule: take 2 pills 2-24 hours before sex, 1 pill 24 hours after the first dose, 1 pill 24 hours after the second dose) provides effective protection when having anal sex without a condom. Note, on-demand PrEP is not currently approved by the FDA, and not fully endorsed by CDC.
	+ Consider offering DoxyPEP once guidelines are published by CDC for STI prevention among MSM and transwomen.
* Review patient chart and referral for clinic
* Provide/document counseling on adherence
* Provide refill authorization of daily PrEP medication for no more than 90 days (1 prescription with 2 refills) until the next HIV test in 3 months
	+ Pharmacists will ensure that patients get HIV testing every 3 months before refilling/dispensing PrEP medication
* Immunizations: pharmacists who are immunization certified may administer immunizations per ACIP recommendations to eligible patients
	+ These include but not limited to the annual influenza vaccine, Tdap, HBV, HAV, and PPV23
* Harm reduction principles pertaining to patient specific risk factors will be discussed at every visit
	+ Pharmacist will provide condoms/lube and refer patients to the local Department of Health for harm reduction services if necessary, if these services are not yet available at the local service unit.
	+ Alcohol, tobacco and other drug use will be discussed at each visit using motivational interviewing to help patients to decrease substance abuse
	+ Pharmacist may also refer patients to behavioral health if needed
* Follow up with laboratory monitoring base on the Appendix A
* STI management (chlamydia, syphilis, and gonorrhea)
	+ Discuss and refer to PrEP referring provider for evaluation and treatment

**Discontinuation of PrEP:**

After consultation with PrEP referring provider, patients will be discharged from the PrEP clinic and PrEP therapy discontinued for the following reasons:

* If patient receives a positive HIV test result
* Non-adherent to medication and appointments after several attempts to engage patient
* No longer want to continue PrEP
* Renal insufficiency
* Reduce risk behaviors to the extent that PrEP is no longer needed

It is important to provide education on how to safely discontinue PrEP. Patients must continue to take PrEP for 28 days since their last exposure before discontinuing.

# **Quality Assurance and Outcomes**

PrEP re-evaluation of baseline measures (6 months after implementation):

* Number of patients on PrEP treatment
* Cost outcome for third party reimbursements
* Adherence rate based on refill history
* Frequency of labs and follow up monitoring

PrEP Annual Outcomes:

* Number of incident cases of HIV in the PrEP clinic
* Number of STIs diagnosed and treated
* Cost outcome

# **Pharmacy-Run Clinic Credentialing**

* Review most current CDC Pre-Exposure Prophylaxis guidelines and discuss with PrEP Pharmacy Clinic Director.

  Complete patient case for initial competency and review with PrEP Pharmacy Clinic Director.

* Complete annual competency as assigned by PrEP Pharmacy Clinic Director.
* Participate and receive chart review as assigned by PrEP Pharmacy Clinic Director.
* Complete 5 visits with PrEP Pharmacy Clinic Director or previously trained pharmacist.
* Attain 2 hours of continuing education relevant to disease state.

# **Business Plan**

The PrEP Pharmacy Run Clinic will continue to work toward becoming a reimbursable service. The clinic, as its primary billing objective, will continue to seek "provider-deemed" status for IHS pharmacist providers from CMS and third-party payers. In addition, the clinic will attempt to collect reimbursement through the recent Current Procedural Terminology (CPT) billing codes to bill third-party payers when providing Medication Therapy Management (MTM) services.

**References**

* CDC website. http://www.cdc.gov/hiv/. Accessed 7/12/20
* Centers for Disease Control and Prevention. Preexposure Prophylaxis for HIV Prevention in the United States — 2017. A Clinical Practice Guideline. Available at: http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.
* FJ Walker, E Llata, M Doshani, MM Taylor, J Bertolli, HS Weinstock, et al. HIV, chlamydia, gonorrhea, and primary and secondary syphilis among American Indians and Alaska Natives within Indian Health Service areas in the United States, 2007-2010. Journal of Community Health, 2015. 40:484-492.

# Appendix

Flow chart of clinic visits:

Referral/First visit:

* Negative HIV viral load and antibody test at baseline
* CMP
* CBC
* RPR
* Chlamydia/gonorrhea
* Hepatitis serology
* Pregnancy test as appropriate

One month visit:

* Assess adherence and commitment to PrEP regimen
* Discuss risk reduction and motivate the use of condoms
* Assess side effects
* Patient will now visit clinic every 3 months
* Pregnancy testing & pregnancy intent

Three-month visit:

* Renal function at first three month visit then every 6 months thereafter
* Assess adherence and commitment to PrEP regimen
* Discuss risk reduction and motivate the use of condoms
* Assess side effects and HIV risk acquisition behaviors
* HIV testing
* STI testing
* pregnancy testing & pregnancy intent
* Evaluate need to continue PrEP

Six-month visit:

In addition to all labs listed under three-month visit, also collect,

* Renal function (serum creatinine and creatinine clearance)

Twelve-month visit:

* Must be seen by a PCP or referring provider
* In addition to all three month visit requirements,
* Renal function (serum creatinine and creatinine clearance)
* Hepatic panel