

NATIONAL HUMAN IMMUNODEFICIENCY VIRUS PROGRAM

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive outlines standards for VHA's National Human Immunodeficiency Virus (HIV) Program.

2. SUMMARY OF MAJOR CHANGES: This VHA directive gives the VHA National HIV Program, within the Office of Specialty Care Services, the responsibility to provide primary guidance and advice to the Under Secretary for Health on VHA care and services related to HIV infection, and to lead coordination of activities intended to improve access to and quality of care, using population-based approaches for HIV prevention, diagnosis, and care across VHA. Significant changes include renaming the HIV, Hepatitis, and Public Health Pathogens Program (HHPHP) to the HIV, Hepatitis, and Related Conditions Programs (HHRC). This directive consolidates all HHRC policy and guidance related to HIV care and prevention in VHA, thereby rescinding all pre-existing directives and guidance statements issued by HHRC on HIV care and prevention. Specifically, this directive updates:

- a. Guidance on screening and laboratory diagnostic testing for HIV infection;
- b. Recommendations on prevention of infection with and transmission of HIV;
- c. Treatment and care of Veterans in VHA care who are living with HIV infection;
- d. Recommended staffing levels for HIV care within VA medical facilities;
- e. Removal of HIV Clinical Case Registry Coordinator responsibilities section;
- f. The HIV data source for national clinical outcomes and Veterans Equitable Resource Allocation (VERA) allocation;
- g. Removal of the requirement for documentation of specific oral consent for testing for sexually transmitted infections (STIs), including HIV; and
- h. Removal of the requirement that all VA medical facilities have local, facility-specific HIV testing policies. The HIV prevention, testing, and care policies and procedures described in this directive will apply to all VA medical facilities, thus obviating the need for redundant local policies.

3. RELATED ISSUES: VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015; VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 7, 2017; VHA Directive 1106, Pathology and Laboratory Medicine Service, dated July 27, 2018; VHA Directive 1406, Patient-Centered Management Module (PCMM), dated June 20, 2017; VHA Handbook 1101.10, Patient Aligned Care Team (PACT), dated February 5,

2014; VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009; and VHA Directive 1120, Responsibilities of the National Center for Health Promotion and Disease Prevention (NCP), dated July 30, 2015.

4. RESPONSIBLE OFFICE: The Director, HHRC is responsible for the content of this directive. Questions may be addressed to the Office of Specialty Care Services (10P11) in the Office of the Deputy Under Secretary for Health for Policy and Services (10P) by phone at 202-461-7120, or to HHRC by e-mail at VAHHRC@va.gov.

5. RESCISSIONS: VHA Directive 1304, National Human Immunodeficiency Virus (HIV) Program, dated November 24, 2014; VHA Directive 1113, Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities, dated May 5, 2015; and VHA Directive 1235, Use of Antiretroviral Agents and the Prevention and Treatment of Opportunistic Infections in Human Immunodeficiency Virus (HIV) Infected Veterans, dated May 19, 2017, are rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of August 31, 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health for
Policy and Services

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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NATIONAL HUMAN IMMUNODEFICIENCY VIRUS PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) directive defines VHA's National Human Immunodeficiency Virus (HIV) Program and provides requirements for:

- a. Screening and Laboratory Diagnostic Testing for HIV infection (Appendix A);
- b. Prevention of Infection with and Transmission of HIV (Appendix B);
- c. Treatment and Care of Veterans Infected with HIV (Appendix C); and
- d. Recommended Staffing Levels for HIV Clinical Care within VHA (Appendix D).

AUTHORITY: Title 38 United States Code (U.S.C.) 7301(b) and Title 38 Code of Federal Regulations (CFR) 17.38.

2. BACKGROUND

a. Despite many preventive and therapeutic advances, HIV infection remains a major public health concern. The U.S. Centers for Disease Control and Prevention (CDC) estimate that over 1,100,000 Americans are infected with HIV, that one in eight of these do not know they are infected, and that only half of those who have been diagnosed are virally suppressed.

b. The CDC HIV Care Continuum model consists of successive stages in HIV care: diagnosis of HIV infection, linkage to care, retention in care, prescription of antiretroviral drugs (ARVs), and complete viral suppression. The model quantitatively describes the state of care for a population of patients with HIV infection by indicating the proportion of patients at each stage in the continuum relative to the previous stage or to the whole population of individuals with HIV infection. Achieving virologic suppression is the primary goal of HIV care because it significantly decreases morbidity and mortality for people living with HIV, and dramatically reduces the risk of a person living with HIV transmitting the virus to others. More information about the CDC HIV Care Continuum model is available at: <https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>.

c. In July 2012, the U.S. Food and Drug Administration (FDA) approved the use of a fixed-dose combination of two ARVs as pre-exposure prophylaxis (PrEP) for the prevention of HIV-1 infection in high-risk adults. As medications and formulations are approved by the FDA for PrEP, they will be reviewed for addition to the VA national formulary.

d. Non-occupational post-exposure prophylaxis (nPEP) and occupational post-exposure prophylaxis (oPEP) involve the initiation of ARV therapy as soon as possible (preferably within 2 hours) but no later than 72 hours after exposure to prevent HIV.

nPEP and oPEP are important components of HIV prevention for both patients and health care workers (HCWs).

3. DEFINITIONS

a. **Acquired Immune Deficiency Syndrome.** Acquired Immune Deficiency Syndrome (AIDS) is the most severe stage of HIV infection and occurs when the immune system is extensively damaged making people more vulnerable to opportunistic infections and malignancies. AIDS is considered to have occurred when a person's CD4 cell count fall below 200 cells per cubic millimeter of blood (200 cells/mm³) or if someone has one or more opportunistic illnesses, regardless of CD4 count.

b. **Antiretroviral Therapy.** Antiviral Therapy (ART), also referred to as ARV or cART (combination ART) refers to medications used for the treatment of infection by retroviruses, primarily HIV.

c. **Fixed-Dose Combination.** A fixed-dose combination is two or more drugs contained in a single dosage form, such as a tablet or capsule. Fixed-dose combinations reduce the number of pills taken each day and help improve adherence to HIV treatment regimens.

d. **HIV Care Continuum.** The HIV Care Continuum is a care model that outlines a series of sequential steps or stages of HIV medical care that people living with HIV go through to achieve viral suppression (low level of HIV in the body). These series of steps are: HIV Diagnosis, Linkage to Care, Retention in Care, Prescribed Antiretroviral Therapy, and Viral Suppression.

e. **Human Immunodeficiency Virus.** HIV is a retrovirus that infects and destroys CD4+ lymphocytes, impairing cell-mediated immunity and increasing the risk of specific opportunistic infections and cancers.

f. **Infectious Disease-Patient Aligned Care Team.** Patients with infectious diseases requiring chronic management, particularly those living with HIV, benefit from integration of infectious disease and primary care in an appropriately staffed and organized setting such as can be achieved in an Infectious Disease - Patient Aligned Care Team (ID-PACT). ID-PACTs provide comprehensive primary and specialized HIV care to assigned Veterans.

g. **Integrated Care Delivery Systems.** Integrated care delivery systems are systems that coordinate and provide access to primary and behavioral healthcare services to achieve the best outcomes for patients with multiple health care needs.

h. **Known Risk Groups.** Known risk groups refer to populations with a particular characteristic associated with an increased risk for developing a particular disease, e.g., through genetic inheritance, environment, lifestyle, or habit. Persons who engage in unsafe or unprotected sex and those sharing needles or syringes for injection drug use (IDU) are known risk groups for contracting HIV.

i. **Non-formulary Drug Request (Special Drug Request)**. A non-formulary drug request (special drug request) refers to a request for a drug or product not listed or available on the VA National Formulary (VANF).

j. **Non-Occupational Post-Exposure Prophylaxis**. nPEP for HIV is a short-term treatment started as soon as possible, but no later than 72 hours after an exposure to HIV that occurs outside of the work place via sexual exposure, injection drug use, or another non-occupational route. The purpose of nPEP is to reduce the risk of HIV infection in the exposed individual.

k. **Occupational Post Exposure Prophylaxis**. oPEP for HIV is a short-term treatment started as soon as possible, but no later than 72 hours after an exposure to HIV resulting from a needlestick injury or other exposure to potentially infected fluids in a health care setting. The purpose of oPEP is to reduce the risk of infection in the exposed individual.

l. **Opportunistic Infections**. Opportunistic Infections (OIs) are infections such as pneumocystis carinii pneumonia, candidiasis (thrush), toxoplasmosis, and tuberculosis (TB) that occur more often and more severely in those with weakened immune systems.

m. **Pre-Exposure Prophylaxis**. PrEP for HIV is the administration of a medication to reduce the risk of HIV infection among individuals who are demonstrated to be HIV-negative and at high-risk for HIV acquisition, including individuals with sexual, or injection drug use risk factors.

n. **Viral Suppression**. Viral suppression refers to reducing or suppressing the function and replication of a virus, such as HIV.

4. POLICY

It is VHA policy that Veterans in VA care living with HIV receive patient-centered, state-of-the-art care and treatment, and that those without HIV infection, or who do not know if they have HIV, have access to HIV testing and state-of-the-art HIV prevention services. Further, it is VHA policy to immediately address occupational exposure to HIV.

5. RESPONSIBILITIES

a. **Under Secretary for Health**. The Under Secretary for Health is responsible for ensuring compliance with this directive.

b. **Deputy Under Secretary of Health for Operations and Management**. The Deputy Under Secretary of Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Directors of the VISNs.

(2) Ensuring that each VISN Director has the resources required to support the fulfillment of the terms of this directive in all VA medical facilities within that VISN.

(3) Ensuring that all VA medical facilities follow the most current CDC recommendations for HIV screening, HIV diagnostic laboratory testing, HIV pre-exposure prophylaxis (PrEP), sexually transmitted infection (STI) screening and treatment, and HIV nPEP (see paragraph 5.e.).

(4) Ensuring that all VA medical facilities follow the current versions of the U.S. Department of Health and Human Services (HHS) guidelines regarding the use of antiretroviral therapy, and prevention and treatment of opportunistic infections in people living with HIV (see paragraph 5.e.).

(5) Requesting and receiving updated identification and contact information for each VA medical facility's HIV Lead Clinician by disseminating an annual memorandum that is created by HHRC to VA medical facility Directors.

c. **Director, HIV, Hepatitis, and Related Conditions Programs.** The Director, HIV, Hepatitis, and Related Conditions Program (HHRC) is responsible for:

(1) Providing consultation and technical assistance regarding matters related to HIV by:

(a) Advising the Under Secretary for Health on matters of VHA services related to HIV prevention, testing, diagnosis, and care.

(b) Consulting at all levels of the organization on clinical care and care delivery for HIV prevention and care to support strategies to ensure high quality, evidence-based care.

(c) Working with VA medical facility HIV Lead Clinicians, local providers, and administrators to support field-based initiatives and system redesign to maximize access to and quality of HIV prevention, testing, diagnosis, and care in VHA.

(d) Providing technical assistance in developing integrated care delivery systems, using the PACT model for Veterans living with HIV infection outlined in VHA Handbook 1101.10, Patient Aligned Care Team (PACT) Handbook, dated February 5, 2014, that meet the primary care, general disease prevention, mental health, substance use, and socioeconomic needs of Veterans with HIV.

(2) Developing national policy and guidance on HIV, including:

(a) Appointing membership of the HIV Technical Advisory Group (HIV TAG) and ensuring the continued functioning of the HIV TAG, whose membership is appointed by HHRC.

(b) Obtaining input on national policy issues involving HIV testing, diagnosis, care and prevention from stakeholders, including VHA Central Office program offices, VISN

leaders, HIV TAG, HIV Lead Clinicians, Veteran stakeholders, and VA medical facility providers and administrative staff.

(c) Developing and communicating national VHA policy on HIV testing, diagnosis, care, and prevention to VA medical facilities and VISNs, as outlined in more detail in Appendices A-D. Guidance documents can be found at <http://www.hiv.va.gov>.

(3) Developing communications and education resources related to HIV, including:

(a) Developing educational and informational products to support VHA employees providing care for Veterans living with HIV and who may be at risk for HIV.

(b) Developing educational and informational products for Veterans living with HIV and who may be at risk for HIV.

(c) Ensuring the information on VA's HIV web site <http://www.hiv.va.gov> is accurate, complete, and current.

(d) Collaborating with HHS and other government agencies to support cross-agency initiatives related to HIV, and leading VA efforts related to the National HIV/AIDS Strategy (NHAS) and Federal HIV Care Continuum Initiatives.

(4) Developing VHA standards of quality of care and data monitoring, including:

(a) Ensuring collection and reporting of accurate data for monitoring quality of HIV care and prevention, for the purposes of reporting to the field, VHA, and VA leadership, HHS, the Office of the Inspector General (OIG), Congress, and other internal and external stakeholders.

1. As of October 1, 2018, the VHA Support Services Center (VSSC) HIV Clinical Cube became the data source for Veterans Equitable Resource Allocation (VERA) allocation, replacing the National HIV Clinical Case Registry (CCR).

2. HIV CCR Coordinators designated in VHA Directive 1635, Clinical Case Registry Software: Maintenance and Clinical Staff Support, dated November 28, 2017, are no longer required to confirm pending HIV patients into the CCR for VERA funding. The CCR software will continue to be supported, therefore any facility wishing to use their local HIV CCR will need to continue confirming HIV patients into the CCR for their local use.

(b) Establishing uniform quality criteria applicable to care provided to all Veterans in VA care with, or at risk for HIV infection with respect to HIV testing, treatment, care, and prevention through the HIV Clinical Cube and PrEP Facility Reports, available at: https://spsites.cdw.va.gov/sites/OPH_LDD/Pages/home.aspx. **NOTE:** *This is an internal VA Web site that is not available to the public.*

(c) Providing current electronic clinical and laboratory data on Veterans with HIV infection in VA care to the Allocation Resource Center for use in the VERA model.

(5) Drafting an annual memorandum for dissemination by the Office of the Deputy Under Secretary for Health for Operations and Management that requests updated HIV Lead Clinician information from each VA medical facility.

(6) Receiving responses to these annual memoranda regarding updated contact information for the designated HIV Lead Clinician for each VA medical facility and distributing these updates to all VA medical facilities. **NOTE:** *Updated HIV Lead Clinician information will be provided within 30 days if a new HIV Lead Clinician is designated more than 90 days before the next scheduled annual request.*

d. **HIV Technical Advisory Group.** The HIV TAG group is comprised of infectious disease specialists, clinical pharmacists, and other HIV clinical providers who are appointed by the Director, HHRC. HIV TAG is responsible for advising HHRC during quarterly meetings on issues related to national HIV policy, clinical education, patient care, testing, diagnosis, and prevention.

e. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring VA medical facility Directors comply with this directive.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Designating an HIV Lead Clinician at the VA medical facility to be the principal point of contact for all HIV and HIV prevention program information. **NOTE:** *This individual should be a clinical provider with expertise in HIV clinical care, or infectious diseases, as evidenced by appropriate certification or training (e.g., infectious diseases board or HIV Medicine Association certification for physicians, American Academy of HIV Medicine certification for non-MD providers, or appropriate training through VA Talent Management System (VA TMS) for other provider classes).* If the designated HIV Lead Clinician leaves the VA medical facility or is no longer available to serve in this role, the Director must designate a replacement within 90 days of the previous Lead Clinician's departure.

(2) Notifying the National HIV Program in HHRC of the identity of and contact information for the designated HIV Lead Clinician by responding to HHRC's annual request for updated contact information. This request is communicated through an annual memorandum from the Office of the Deputy Under Secretary for Health for Operations and Management. If a new HIV Lead Clinician is designated at a given VA medical facility more than 90 days before the next scheduled annual request from the Deputy Under Secretary for Health for Operations and Management, the VA medical facility Director is responsible for ensuring HHRC is notified within 30 days.

(3) If sufficient local expertise or resources are not available to designate an HIV Lead Clinician, VA medical facilities are encouraged to enter into an agreement with another VA medical facility in their VISN to share HIV Lead Clinicians. This arrangement must also be communicated to the Director of HHRC with all signatories in agreement (see letter template in Appendix E) in response to HHRC's request for

updated contact information. The HIV Lead Clinician's name must then be submitted on behalf of both VA medical facilities and updated annually.

(4) Ensuring that clinical providers who routinely treat patients for HIV hold appropriate clinical privileges that explicitly allow for HIV care. **NOTE:** See *VHA Handbook 1100.19, Credentialing and Privileging*, dated October 15, 2012.

(5) Ensuring that the VA medical facility follows the most current CDC recommendations regarding the following:

(a) HIV testing: HIV testing must be offered at least once as a part of routine health care to all Veterans enrolled in care. More frequent testing (at least annually) is recommended for those at higher risk of acquiring HIV (see Appendix A), consistent with CDC recommendations and VHA's Clinical Preventive Services Guidance Statement on HIV testing. If there is differing guidance, VA medical facilities should defer to CDC recommendations. The CDC guidance is available at: <https://www.cdc.gov/hiv/testing/index.html>. VA's guidance is available at: http://vaww.prevention.va.gov/Screening_for_HIV.asp. **NOTE:** *This is an internal VA Web site not available to the public. With the exception of HIV testing of source patients after an occupational exposure, documentation of specific oral consent for HIV testing is no longer required by VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009. Providers are still required to obtain oral informed consent for HIV testing, and to specifically document the oral informed consent for HIV testing of source patients after an occupational exposure.*

(b) HIV screening: HIV screening must be included in the routine panel of prenatal screening tests that are offered to all pregnant Veterans. This information is contained in the VA/DoD Clinical Guideline for Management of Pregnancy: <https://www.healthquality.va.gov/guidelines/WH/up/VADoDPregnancyCPG4102018.pdf>. **NOTE:** *This is an internal VA Web site not available to the public.*

(c) HIV pre-exposure prophylaxis: "Preexposure prophylaxis for the prevention of HIV infection in the United States--2017 update: a clinical practice guideline", or subsequent guidance (Appendix B). Available at: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>.

(d) Screening and treatment for Sexually Transmitted Infections (STIs): "Sexually Transmitted Diseases Treatment Guidelines, 2015", or subsequent guidance (Appendices B and C). Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm>.

(e) HIV non-occupational post-exposure prophylaxis (nPEP): "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Non-Occupational Exposure to HIV-United States, 2016", or subsequent guidance. Available at: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>.

(f) HIV occupational post-exposure prophylaxis (oPEP): “Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis,” or subsequent guidance. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm> and <https://stacks.cdc.gov/view/cdc/20711>. **NOTE:** *Procedures in VHA Handbook 1004.01 for consent for testing of a source patient after occupational exposure must be followed.* Given that not all VA pharmacies operate 24 hours a day, 7 days a week, it is the responsibility of the VA medical facility Director to ensure health care providers who have been exposed to HIV have access to PEP medications when the pharmacy is closed. Options to consider include:

1. Contracting with a non-VA pharmacy for ARV prescription fulfillment,
2. Stocking a supply of PEP medications in a secure area available to a prescriber who is also authorized to dispense medications (e.g. Emergency Departments, automated dispensing cabinets, emergency “lock-boxes”), or
3. Implementing “on-call” procedures for a pharmacist to quickly return to the VA medical facility after hours to dispense an ARV prescription.

(g) All HIV care delivered in VHA must follow the current versions of HHS guidelines regarding the use of combination antiretroviral treatment (cART) and prevention and treatment of opportunistic infections in patients living with HIV: “Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV” and “Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents.” These documents are available at: <https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/392/whats-new> and https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf.

(6) Ensuring that a clearly designated HIV screening test is included in the main lab order dialogue.

(7) Ensuring that confirmed positive HIV test results are communicated to appropriate providers in accordance with VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015.

(8) Ensuring that HIV test results are communicated to patients in accordance with VHA Directive 1088.

(9) Ensuring that Veterans with confirmed HIV-positive results are connected to HIV care as soon as possible, ideally within 14 days but no more than 30 days unless there are exceptional circumstances documented in the Veteran’s medical record.

(10) Ensuring adequate resources are available to the VA medical facility’s Pathology and Laboratory Medicine Service to conduct HIV testing required under this directive.

(11) Ensuring reporting of HIV to state and local public health departments in accordance with Appendix E of VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 7, 2017, or subsequent updates. According to VHA Directive 1131, VA medical facilities must report on the designated reportable diseases according to the laws, regulations, and policies of States and territories, and following VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016. HIV is a reportable disease and should be reported to State and territorial public health authorities, consistent with other reportable diseases. If there are questions about whether releasing protected health information is acceptable in these cases or accounting for disclosures, reporting providers should consult VHA Directive 1605.01 or their local privacy officer.

(12) Ensuring the availability of effective, evidence-based HIV prevention strategies for HIV-negative Veterans at risk of exposure (including PrEP, nPEP, oPEP, and condoms), as well as ensuring that Veterans in VA care living with HIV receive high quality care (see Appendix B).

(13) Ensuring that sufficient staffing and resources are available such that Veterans in VA care with HIV receive high quality care. If HIV clinical care is not available within the VA medical facility, the VA medical facility Director is responsible for ensuring high quality, accessible HIV care for VA patients at another VA medical facility, or through care in the community.

g. **Director or Chief, Pathology and Laboratory Medicine Service.** The Director or Chief, Pathology and Laboratory Medicine Service (PLMS) at each VA medical facility is responsible for:

(1) Ensuring that the facility's laboratory follows the most current CDC-recommended HIV testing algorithm, available at: <https://stacks.cdc.gov/view/cdc/23447> (see Appendix A).

(2) Ensuring that HIV screening tests that provide results within 1 hour, or as soon as possible thereafter, are available for testing of source and exposed individuals in the case of needlestick injuries or bloodborne pathogen exposure of either Veteran patients or employees, in order to initiate PEP as soon as possible if indicated.

h. **Privacy Officer.** The Privacy Officer at each VA medical facility is responsible for providing consultation to VA staff and providers on issues related to HIV disclosure, per VHA Directive 1605.01.

i. **Chief of Pharmacy.** The Chief of Pharmacy at each VA medical facility is responsible for:

(1) Ensuring that 3-month ARV medication supplies with additional refills are routinely available as the default fill to all Veterans in VA care living with HIV on a stable ARV regimen. **NOTE:** *A provider may opt for less than a 3-month supply in specific situations, such as:*

(a) Veterans whose HIV care is provided outside of VA when the VA provider does not have access to outside laboratory or clinical data to assess efficacy and safety of the prescribed regimen, or

(b) Veterans receiving a regimen change, with the provider needing to ensure the Veteran is stable on the new regimen before providing a 3-month supply.

(2) Ensuring that prescriptions for ARVs for PEP are available to a health care provider (HCP) exposed to HIV as soon as possible after exposure, with the following limitations:

(a) A prescription written by a VA provider with prescriptive privileges must be presented to pharmacy staff for fulfillment, and

(b) If the VA Pharmacy is not open, PEP medications will be made available to exposed HCPs as described in paragraph 5.f.(5)(f).

(3) Ensuring that condoms are listed as a supply item in the local drug file and as a VA National Formulary item in the local drug file with no restrictions.

j. **VA Medical Facility HIV Lead Clinician.** The VA medical facility HIV Lead Clinician is responsible for:

(1) Serving as the VA medical facility subject matter expert and point of contact on testing, diagnosis, and care of Veterans with HIV, and HIV prevention among those at risk of becoming HIV-infected.

(2) Utilizing the VHA VSSC HIV Clinical Cube to optimize the use of local population management tools and to report, as needed or requested, to the VA medical facility Chief of Staff and VA medical facility Director. Available at: <https://vssc.med.va.gov>. **NOTE:** *This is an internal VA Web site that is not available to the public. Please see paragraph 6, Training, for related training resources.*

(3) Serving as a point of contact for communications to and from VHA's National HIV Program in HHRC regarding policy and operational issues concerning HIV testing, diagnosis, care, and prevention.

(4) Notifying the Director or Deputy Director of the National HIV Program within HHRC if HIV care is routinely provided through the community or another VA medical facility.

k. **Health Care Providers.** VA medical facility health care providers are responsible for providing high quality HIV testing, treatment, care, and prevention consistent with CDC, DHHS, and NCP guidelines.

(1) Offering HIV testing as part of routine health care to all HIV-negative Veterans who have not already been tested and offering at least annually to those at higher risk of acquiring HIV.

(2) Assessing all Veterans for sexual risk as a part of routine care. **NOTE:** *VHA Directive 1340: Provision of Health Care for Veterans who Identify as Lesbian, Gay or Bisexual, dated July 6, 2017 requires providers to assess sexual health in addition to sexual risk. Assessing sexual risk is one part of a more comprehensive history of sexual health.*

(3) Ensuring that Veterans living with HIV, those at risk for HIV due to sexual transmission, and those on PrEP for HIV prevention, are tested for STIs as recommended by the CDC.

(4) Ensuring all Veterans receiving care in VHA who have risk factors for HIV but remain uninfected are considered for PrEP for HIV prevention. For any non-ID prescribing providers wanting to prescribe PrEP for their patients at risk for HIV, completion of the VA TMS PrEP trainings, or their successor trainings listed in Section 6 below, or equivalent trainings, may serve as qualifying training.

(5) A HCP exposed to HIV must have a prescription for PEP before PEP medications can be dispensed. This prescription can be written by any VA provider with prescriptive privileges. A HCP who receives a prescription for PEP is responsible for picking up PEP medications from the pharmacy where the prescription can be filled (see paragraph 5.f.(5)(f) above).

6. TRAINING

a. There are no formal training requirements associated with this directive. The following trainings are recommended.

b. Clinical providers routinely providing outpatient care to patients living with HIV should hold clinical privileges explicitly authorizing them to deliver such care. It is strongly recommended to be Board Certified/Board Eligible (BC/BE) in Infectious Diseases (preferred), Internal Medicine, or Family Medicine.

c. It is strongly recommended that physicians routinely providing care to patients with HIV have appropriate specialty training, as evidenced by certification in Infectious Diseases by the American Board of Internal Medicine or certification by the American Academy of HIV Medicine. Alternately, physicians may receive clinical privileges to routinely provide care to patients living with HIV if they have appropriate credentials, knowledge, and experience and inclusion of such privileges in their scope of practice is endorsed in writing by the appropriate Chief of Service.

d. It is recommended that HIV Advanced Practice Registered Nurses (APRN), and Physician Assistants (PA), HIV Clinical Pharmacists, HIV Registered Nurses (RN), and HIV Case Managers, have specialty training, or equivalent experience in HIV.

e. It is recommended that psychologists and psychiatrists working in HIV clinical settings have specialty training or equivalent experience in addiction and opioid treatment if possible.

f. It is preferred that psychiatrists, primary care providers, and HIV clinicians working in HIV clinical settings and with patients living with HIV have an X-waiver for prescribing buprenorphine products for treatment of opioid use disorder. Buprenorphine is a Schedule III controlled substance that requires a DEA X-license in order to prescribe. Trainings are available at: <https://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>.

g. For training on how to take a sexual history, the following CDC Guide to Taking a Sexual History is recommended, available at: <https://www.cdc.gov/std/treatment/SexualHistory.pdf>

h. For training on health care for Veterans who Identify as Lesbian, Gay or Bisexual, see VA TMS# 34628: Do Ask, Do Tell: 5 Awkward Minutes to Better Patient Care, available at: https://www.tms.va.gov/learning/user/deeplink_redirect.jsp?linkId=ITEM_DETAILS&componentID=34628&componentTypeID=VA&revisionDate=1510053720000. **NOTE:** *This is an internal VA Web site not available to the public.*

i. Training for the VSSC HIV Clinical Cube is available at: <https://vssc.med.va.gov/VSSCMainApp/> and is listed under Targeted Populations, Clinical Cohorts. **NOTE:** *This is an internal VA Web site not available to the public.*

j. These trainings, their successor trainings, or equivalent trainings are recommended for non-infectious disease providers who may wish to prescribe PrEP for HIV prevention: VA TMS #36785, #35751, or #35518 Pre-Exposure Prophylaxis (PrEP) for HIV Prevention, at <http://www.tms.va.gov>.

k. Training on screening for sexually transmitted infections, is available at: <https://www.std.uw.edu/>. **NOTE:** *This linked document is outside of VA control and may or may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. Public Law 115-182.
- b. 38 U.S.C. 7301(b), 7332, and 1703.
- c. 38 CFR 17.38, 1.487, and 17.4040.

d. VA Financial Policy, Volume XVI, Chapter 01, Government Purchase Card Program, dated July 29, 2016.

e. VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015.

f. VHA Directive 1106, Pathology and Laboratory Medicine Service, dated July 27, 2018.

g. VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 7, 2017.

h. VHA Directive 1340, Health Care for Veterans who Identify as Lesbian, Gay or Bisexual, dated July 6, 2017.

i. VHA Directive 1406, Patient Centered Management Module (PCMM), dated June 20, 2017.

j. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

k. VHA Directive 1635, Clinical Case Registry Software: Maintenance and Clinical Staff Support, dated November 28, 2017.

l. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.

m. VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012.

n. VHA Handbook 1101.10, Patient Aligned Care Team (PACT), dated February 5, 2014.

o. VHA Handbook 1330.03, Maternity Health Care and Coordination, dated October 5, 2012

p. VA/DoD Clinical Guideline for Management of Pregnancy:
http://vaww.oqsv.med.va.gov/functions/integrity/cpg/cpgOnline/mpg/COVER_mpg.htm.
NOTE: *This is an internal VA Web site not available to the public.*

q. VA HIV/AIDS Web site <http://www.hiv.va.gov>.

r. VHA Telehealth Services Web site at: <http://vaww.telehealth.va.gov/index.asp>.
NOTE: *This is an internal VA Web site that is not available to the public.*

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t. Centers for Disease Control and Prevention and Association of Public Health Laboratories: Laboratory Testing for the Diagnosis of HIV Infection: Updated

Recommendations. Published June 27, 2014. Available at <http://stacks.cdc.gov/view/cdc/23447>.

u. Centers for Disease Control and Prevention: Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. Available at: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>.

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w. National HIV/AIDS Strategy (NHAS) Available at: <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update>.

x. Federal HIV Care Continuum Initiatives. Available at: <https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>.

y. Barbee LA, Tat S, Dhanireddy S, Marrazzo JM. Implementation and Operational Research: Effectiveness and Patient Acceptability of a Sexually Transmitted Infection Self-Testing Program in an HIV Care Setting. *J Acquir Immune Defic Syndr*. 2016 Jun 1;72(2):e26-31.

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HUMAN IMMUNODEFICIENCY VIRUS (HIV) SCREENING AND TESTING

This appendix provides additional information to Department of Veterans Affairs (VA) providers on current VA recommendations and guidance on HIV screening, laboratory diagnosis of HIV, disclosure of HIV, and linkage to care.

1. VA HIV SCREENING RECOMMENDATIONS

a. VA follows the current CDC HIV screening recommendations, available at: <http://www.cdc.gov/hiv/testing/clinical/>. The Clinical Preventive Services Guidance Statement on HIV Screening published by VHA's National Center for Health Promotion and Disease Prevention Screening is also aligned with CDC recommendations.

b. All Veterans enrolled in VHA care must be offered HIV testing at least once as part of routine health care, with particular attention to the following known groups:

(1) All Veterans who do not have documentation of an HIV test.

(2) All Veterans documented to be HIV-negative and who have new or on-going risk factors; Veterans with ongoing risk factors should be offered HIV testing at least annually. Risk factors include:

(a) All Veterans initiating treatment for tuberculosis, or who are diagnosed with latent or active TB.

(b) All Veterans receiving treatment for sexually transmitted infections (STIs) should be screened for HIV at time of each new STI diagnosis.

(c) Veterans who request an HIV test.

(d) Sexually active men who have sex with men (MSM).

(e) Injection drug users and their sexual partners.

(f) Individuals who exchange sex for money or drugs, or who have sex partners who do.

(g) Individuals whose sex partners are HIV-positive.

(h) MSM or heterosexual individuals who have had, or whose sexual partners have had, more than one sexual partner since their most recent HIV test.

(3) HIV screening must be included in the routine panel of prenatal screening tests that are offered to all pregnant Veterans. This information is contained in the VA/DoD Clinical Guideline for Management of Pregnancy:

http://vaww.oqsv.med.va.gov/functions/integrity/cpg/cpgOnline/mpg/COVER_mpg.htm.

NOTE: This is an internal VA Web site not available to the public.

c. With the exception of HIV testing of source patients after an occupational exposure, documentation of specific oral consent for HIV screening is no longer required, however, VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009 continues to require that all Veterans must have an engaged conversation about informed consent for HIV testing and that oral informed consent is obtained prior to screening.

d. HIV-negative patients currently on opioids, tapering off opioids, or with an opioid use disorder, should be offered HIV testing at least once, and more frequently if risk factors (e.g. injection drug use (IDU), exchanging sex for drugs, screening positive for intimate partner violence IPV, etc.) are ongoing.

2. ORDERING OF HIV SCREENING TESTS

a. The process for ordering the most current CDC recommended HIV screening test must be the same as that for ordering any other common laboratory test. Information about CDC recommendations for screening is available at: <https://stacks.cdc.gov/view/cdc/23447> and <http://www.cdc.gov/hiv/pdf/testing/rapid-hiv-tests-non-clinical.pdf>. HIV viral load and HIV genotype tests must not be used for routine HIV screening, unless there are clinical circumstances that justify use of such tests for diagnosis of HIV infection.

b. A clearly demarcated HIV screening test must be included in every VA medical facility's generic laboratory order menu. VA medical facilities must not restrict ordering of HIV screening tests to quick order sets. However, use of quick order sets to order HIV screening tests is permitted as long as the HIV screening test can also be ordered through the main laboratory order menu.

3. COMMUNICATION OF HIV TEST RESULTS

a. All confirmed positive test results must be communicated to a patient by the health care provider as soon as possible, but in general, not more than 7 calendar days after the result is available unless extenuating circumstances described in writing preclude notification within this time frame. Although preferable, in-person notification of a Veteran of a positive HIV test result is not mandated by VHA policy, as stated in VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015; Directly informing the patient by telephone is also acceptable. While the VA medical facility must pursue any available options to directly contact the patient in person or by phone, using the United States Postal Service to communicate results is acceptable, but must be by certified letter. A positive result should never be conveyed through a voicemail message or an unauthorized third party. If an in-person notification of an HIV positive test results is deemed most prudent for a particular patient, in accordance with VHA Directive 1088, notification may be delayed beyond 7 days. However, it is strongly recommended that this notification be made as expeditiously as possible.

b. PrEP should be considered for individuals with a negative HIV screening result who remain at high risk for infection (see Appendix B).

4. LINKAGE TO CARE

a. Any Veteran with a new HIV diagnosis should be linked to care expeditiously, ideally within 14 days but no more than 30 days if possible, to allow timely assessment and initiation of treatment for HIV infection.

b. If there is no HIV service, or HIV provider at a VA medical facility, the ordering provider must ensure any patient living with HIV is referred to an HIV specialist at another VA medical facility, or to an HIV provider in the community, expeditiously, ideally within 14 days but no more than 30 days.

c. It is strongly recommended that an HIV specialist should have contact with a Veteran (either in-person encounter, phone encounter, or telehealth encounter) within 30 days of diagnosis, and sooner if clinically indicated. Only in exceptional circumstances (e.g. the Veteran declines HIV care in VA or is unable to be contacted or located) are delays beyond 30 days justifiable.

5. DISCLOSURE OF HIV STATUS

a. As with any protected health information (PHI), information regarding the HIV status of a Veteran enrolled in VHA care may only be disclosed as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA; P.L. 104-191, 42 CFR parts 160-164) and its implementing regulations.

b. In addition, disclosure of HIV-related information held by VA is also governed by 38 United States Code (U.S.C.) 7332, which requires written authorization by a Veteran for release of such information except for specific circumstances.

c. Such circumstances include the following:

(1) HIV-related information may be disclosed without written authorization from the Veteran to a non-VA entity for purposes of providing health care, including hospital care, medical services, and extended care services, to patients or performing other health care-related activities or functions (38 USC 7332(b)(2)(H)). The non-VA entity is not permitted to redisclose such information or use it for a purpose other than the one for which it was disclosed.

(2) Such information may also be disclosed without written authorization to a third party in order to recover or collect reasonable charges for care furnished to, or paid on behalf of, a patient in connection with a non-service connected disability (38 U.S.C. 7332(b)(2)(I)).

(3) Reporting to a Federal, state, or local public health authority charged under Federal or state law with protecting the public health, and to which disclosure of such information is required under Federal or state law (38 U.S.C. 7322(b)(2)(C)). Per VHA

Directive 1131 Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 7, 2017. VA medical facilities are required to report on designated reportable diseases, like HIV and some STIs, according to the laws, regulations, and policies of the States and Territories and may disclose protected health information for the public health or safety pursuant to a standing request as outlined in VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

(4) 38 U.S.C. 7332(f) allows disclosure of a Veteran's HIV status to a spouse or sexual partner without written authorization from the Veteran if, "after reasonable efforts to counsel and encourage the patient or subject to provide the information to the spouse or sexual partner," a physician or professional counselor reasonably believes that the Veteran will not disclose his or her HIV status to the spouse or sexual partner and such disclosure is necessary to protect the health of the spouse or sexual partner. Note that the Veteran must be given a chance to inform the spouse or sexual partner before VA is authorized to do so.

(5) More specific requirements and procedures for disclosure of a Veteran's HIV status to a spouse and sexual partner without written authorization from the Veteran are contained within the implementing regulations (38 CFR 1.487) and VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) PREVENTION

1. BACKGROUND

a. In 2017, there were over 38,000 new diagnoses of HIV infection in the U.S. (<https://www.cdc.gov/hiv/statistics/overview/ata glance.html>). Although the number of new HIV diagnoses nationally has fallen significantly in recent years prevention of new infections remains a critical step in ending the HIV pandemic.

b. For a given individual, the risk of exposure to HIV is driven by epidemiologic, behavioral, and virologic factors. Thus, decreasing this risk involves mitigating relevant risk factors in these domains. Mitigation strategies include the following:

(1) Pharmacologic interventions to decrease transmission to uninfected individuals (PrEP).

(2) Pharmacologic interventions to decrease transmission from infected individuals (Treatment as Prevention).

(3) Non-pharmacologic interventions to decrease sexual transmission.

(4) Non-pharmacologic interventions to decrease injection drug use transmission.

2. PRE-EXPOSURE PROPHYLAXIS (PrEP)

a. HIV pre-exposure prophylaxis (PrEP) is highly effective at reducing the risk of HIV acquisition, including in individuals with sexual and injection drug use risk factors. Daily PrEP has been found to be effective in reducing the risk of HIV from sex by more than 90% and by more than 70% among those who inject drugs. The VA follows the CDC's current recommendations for PrEP (see paragraph 5.f.(c) in the body of this directive).

b. All FDA approved medications for PrEP must be readily available at all VA medical facilities, and offered routinely as part of a comprehensive risk reduction program to those patients who belong to one or more the following groups at increased risk for HIV infection:

(1) Sexually active men who have sex with men (MSM) at substantial risk of HIV acquisition.

(2) Heterosexually active men and women at substantial risk of HIV acquisition.

(3) People who inject drugs (PWID) at substantial risk of HIV acquisition.

(4) Heterosexually active men and women whose partners are known to have HIV infection.

c. Every effort must be made to ensure that prescribing providers without expertise in PrEP who are interested in prescribing it in their clinics are supported institutionally.

The VA Talent Management System (VA TMS) PrEP trainings, successor trainings, or equivalent trainings listed in paragraph 6, Training of this directive should serve as sufficient training for PrEP prescribing.

d. Prescription of PrEP does not eliminate the risk of HIV infection or reduce the risk of other STIs. PrEP should be used as part of a comprehensive sexual risk reduction program incorporating components such as patient education, condom use, and other evidence-based interventions.

e. Providers should offer syphilis, gonorrhea, and chlamydia screening, as indicated based on risk assessment and as outlined by CDC STD guidelines in high-risk individuals, along with PrEP. Providers should strongly consider offering nucleic acid amplification tests self-swab options for screening for rectal and pharyngeal gonorrhea and chlamydia when clinically appropriate, for patients on PrEP for HIV prevention. The sensitivity and specificity of self-swabs has been found to be equivalent to those collected by provider and may reduce barriers to GC/CT screening for patients on PrEP (see paragraph 8.u. and 8.bb.).

f. VA resources for PrEP can be found here:

<https://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/CPHP/HIV/SitePages/PrEP.aspx>

NOTE: This is an internal VA Web site that is not available to the public.

3. TREATMENT AS PREVENTION (TasP)

Since an undetectable HIV viral load virtually eliminates the risk of sexual HIV transmission and dramatically reduces the likelihood of transmission via needle sharing, promptly starting newly diagnosed patients on antiretroviral (ARV) treatment is a priority HIV prevention strategy (treatment as prevention (TasP)). Additional information available at: <https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf>.

4. NON-PHARMACOLOGIC INTERVENTIONS TO DECREASE SEXUAL TRANSMISSION: CONDOM AVAILABILITY

(1) In accordance with VHA Directive 1120, Responsibilities of the National Center for Health Promotion and Disease Prevention, dated July 30, 2015, condoms must be readily accessible and available to reduce the incidence of HIV transmission with the aim of preventing future morbidity and mortality.

(2) Providers must continue to provide condoms via prescription.

(3) Providers may also use the Procurement and Logistic Office (P&LO) to purchase condoms for outreach campaigns such as HIV Testing Day, World AIDS Day, VA Stand Downs, and Zika outreach activities in endemic areas.

**5. NON-PHARMACOLOGIC INTERVENTIONS TO DECREASE INJECTION DRUG
USE TRANSMISSION: SYRINGE SERVICE PROGRAMS**

a. Under Public Law 114-113, Title V section 520, Federal agencies are permitted to use Federal funds to support comprehensive syringe service programs, however Federal agencies cannot use those funds to purchase sterile needles or syringes.
(<http://www.cdc.gov/hiv/risk/ssps.html>).

b. Where available and deemed appropriate for prevention of HIV and other bloodborne pathogens (e.g., hepatitis B and C viruses), VA medical facilities may collaborate with community partners to provide comprehensive syringe service programs.

TREATMENT AND CARE OF VETERANS INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV)

This appendix provides additional information to Veterans Health Administration (VHA) providers on current Department of Veterans Affairs (VA) recommendations and guidance on the use of antiretroviral agents to treat HIV infection and prevent opportunistic infections. These recommendations are not intended to be a substitute for the judgment of a provider who is an expert in the care of individuals living with HIV.

1. ANTIRETROVIRAL TREATMENT FOR HIV INFECTION

a. Every Veteran in care living with HIV should be offered combination antiretroviral treatment (cART) by their provider, regardless of their mental health and substance use history. All Veterans in care will be offered the opportunity to receive cART unless there is a compelling reason to delay cART, such as clinical contraindications in the setting of specific opportunistic infections or the Veteran declines cART. Every effort must be made by the team delivering care to a patient living with HIV to address barriers to treatment. When appropriate, consultation with the facility's Pharmacy Service, Social Work Service, and Mental Health Service may be particularly helpful in minimizing delays in cART initiation.

b. Patients not on cART should be re-evaluated for treatment readiness at least every 6 months and more frequently if clinically indicated and feasible. Accelerated cART initiation is highly recommended, including same day and rapid (within 14 days of HIV diagnosis) initiation, when clinically appropriate.

2. FACILITATING ADHERENCE TO HIV TREATMENT AND FOLLOW-UP CARE

Veterans living with HIV and receiving care in VA HIV clinical settings integrated with mental health and social services are 3.1 times more likely to achieve viral suppression than those receiving care in HIV primary care only. Treating depression in a collaborative care model in VA HIV clinical care settings has also been found to improve HIV clinical outcomes and resulted in greater cost savings than usual HIV care. VA medical facilities are strongly encouraged to allocate sufficient mental health and substance use resources to this patient population and are strongly encouraged to ensure ready access to mental health and substance use disorder expertise, ideally in an integrated care model (see Appendix D).

3. SCREENING AND TREATMENT FOR SEXUALLY TRANSMITTED INFECTIONS IN PEOPLE LIVING WITH HIV

For Veterans in VA care living with HIV, VA follows CDC guidelines for screening for sexually transmitted infections, which include specific guidance on screening among people living with HIV. These are available in the CDC STD Treatment Guidelines at: <https://www.cdc.gov/std>.

4. RETENTION IN CARE

a. Retention in HIV care, as measured by the frequency of face-to-face encounters, is an essential component in the HIV Care Continuum. There is no uniform standard indicating how often patients with HIV should be evaluated in person; the frequency of face-to-face visits depends, among other factors, on a patient's clinical and virological status, the need for assessment and management of comorbid medical and mental health conditions, the feasibility and utility of telephone encounters, and the relative burden on the patient in traveling to the VA facility. Thus, the recommendations below should be interpreted in the context of what will best meet an individual patient's needs.

b. Veterans on a stable cART regimen who are adherent to therapy, have achieved durable virological suppression for at least 2 years, and who are clinically stable should have a face-to-face, or telehealth video, HIV care encounter at least once annually.

NOTE: *Telehealth video encounters may be provided consistent with 38 CFR 17.417. Current guidance regarding Home Telehealth equipment is found on the VHA Telehealth Services website at <http://vaww.telehealth.va.gov/index.asp>, specific guidance regarding Home Telehealth technology is found at <http://vaww.telehealth.va.gov/pgm/ht/tech.asp>. These are internal VA Web sites that are not available to the public. Guidance regarding procurement of equipment can be found in VA Financial Policy, Volume XVI, Chapter 01, Government Purchase Card Program, dated July 29, 2016.*

c. Veterans who are not virologically suppressed should have a face-to-face HIV care encounter or telehealth video encounter at least once every 6 months. More frequent face-to-face or telehealth video encounters may be necessary, depending on a patient's clinical status.

(1) Outreach efforts necessary to ensure retention in care will vary according to the individual circumstances of the Veteran, such as coexisting mental health conditions, substance use disorders, homelessness, or incarceration.

(2) If standard outreach protocols do not result in retention in care, augmented retention strategies (e.g. increasing number of attempted patient contacts) should be developed and encouraged. Coordination with state and local public health authorities is strongly encouraged (see VHA Directive 1131).

5. DELIVERY OF PRIMARY CARE TO HIV PATIENTS

a. The dramatic decrease in HIV-related mortality and morbidity because of cART has led to the emergence among people living with HIV of chronic diseases typically found in older HIV-negative individuals, such as ischemic heart disease, hypertension, diabetes.

b. Although such conditions have often been managed in general medical or primary care clinics, integration of HIV care into primary care improves virologic outcomes. VA strongly encourages such integration, especially via co-location of HIV

and primary care services or, ideally, delivery of HIV and primary care by the same provider, using the Patient Aligned Care Team model (see VHA Handbook 1101.10, Patient Aligned Care Team (PACT) Handbook, dated February 5, 2014). At the same time, VA facilities may deliver HIV and primary care in different clinics (e.g., a subspecialty clinic for HIV care and a general medical clinic for primary care), depending on facility resources, provider schedules, and other considerations.

c. Regardless of the structure(s) used to deliver HIV and primary care to Veterans with HIV, the following principles should be observed in organizing such care:

(1) Coordination between HIV and medical teams to ensure continuity of care (particularly for patients who have been admitted to a facility's inpatient unit) and retention in care.

(2) Communication between HIV, primary care, and pharmacy to minimize medication-related issues (e.g., adverse drug-drug interactions, polypharmacy) and to promote medication adherence.

(3) Integration of therapeutic interventions, particularly those related to mental health, alcohol and substance use disorders, and tobacco use cessation.

6. PROVISION OF HIV CARE TO PREGNANT VETERANS

a. VHA Handbook 1330.03, Maternity Health Care and Coordination, dated October 5, 2012, describes maternity benefits in the VA medical benefits package, 38 CFR 17.38. Generally, these benefits begin with the confirmation of pregnancy, preferably in the first trimester, and continue through the postpartum visit, usually 6-8 weeks after delivery or when the Veteran is medically released from obstetric care. Maternity care is typically provided by non-VA providers in non-VA facilities, which are accredited to provide care to pregnant women and newborns. Veterans who are pregnant, however, continue to receive care through the VA health care system during their pregnancies, either for management of coexisting medical or mental health conditions or for acquiring laboratory tests or medications during their pregnancy. Coordination of care and information sharing between all providers, including non-VA and VA providers is critical to patient safety.

b. Regardless of whether a pregnant Veteran living with HIV receives prenatal care through an integrated ID-PACT, Primary Care, or Women's Clinic, the Veteran's VA HIV providers should continue to provide HIV care in collaboration with the community care obstetrician, and with an HIV community care provider when appropriate under the VA MISSION Act of 2018 (Pub. L. 115-182; 38 USC 1703) and its implementing regulations.

c. VA follows DHHS guidelines for the care of pregnant individuals living with HIV, including the frequency and timing of viral load testing during pregnancy, the importance of initiating ART as early as possible, and breastfeeding recommendations, available at:

<https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/24/70/hiv-medicines-during-pregnancy-and-childbirth>.

7. PROVISION OF DENTAL CARE

a. Individuals living with HIV are at higher risk of certain oral diseases such as periodontal infection, dento-alveolar abscess and tooth loss. Thus, access to dental evaluation and care may affect health status in these individuals.

b. The HIV/Acquired Immune Deficiency Syndrome (AIDS) Bureau Performance Measures in the Health Resources & Services Administration (HRSA) recommend that any patient with a diagnosis of HIV should receive an oral exam by a dentist at least annually, available at: <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/oralhealthmeasures.pdf>.

c. VHA recommends that all Veterans in VA care living with HIV receive at least one dental exam annually, either through a VA medical facility or Community Care whenever possible, given a Veterans benefit status, availability of care in the community, other dental insurance, or ability to pay for this service out of pocket.

d. Eligibility for outpatient dental care is not the same as for other VA medical benefits, 38 CFR 17.38. The eligibility criteria are prescribed by Federal law and regulations. Information Bulletin (IB) 10-442 contains an overview of these criteria; the IB is available at: https://www.va.gov/healthbenefits/resources/publications/IB10-442_dental_benefits_for_veterans_2_14.pdf. More detailed information is available in VHA Handbook 1130.01, Veterans Health Administration Dental Program, dated February 11, 2013, available at https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2867. Current information on referring Veterans for non-VA dental care is available at <https://vaww.infoshare.va.gov/sites/dental/HiddenContent/1130%20Non%20VA%20Care%20Section%20Original%20Amended.pdf>. **NOTE:** *This is an internal VA Web site not available to the public.*

e. Some Veterans who do not otherwise meet criteria for dental care benefits may be able to receive dental care through VHA. This limited care is provided if a dental condition is complicating a medical condition being treated by VHA. Veteran's medical providers must enter an electronic health record consultation request for the VA Dental Service. A VA Dental Provider may then evaluate the patient based on the clinical indication to provide any focused care as an adjunct to medical care. Veterans may qualify for some level of dental care benefits because of other factors such as homelessness. Because of the number and complexity of different categories of eligibility for dental care, HIV providers are encouraged to establish and maintain a strong working relationship with the Chief, Dental Service at their facility.

8. TREATMENT OF HIV-ASSOCIATED LIPOATROPHY

a. HIV facial lipoatrophy due to subcutaneous fat loss is common in people living with HIV receiving cART, and results in facial volume loss, also referred to as facial wasting. Lipoatrophy in these individuals may also involve subcutaneous fat loss in the limbs and buttocks.

b. Because HIV facial lipoatrophy is a recognized complication of treatment for HIV, treatment of this disorder is not considered a cosmetic procedure, and all eligible Veterans with HIV facial lipoatrophy may undergo treatment for this condition at VHA facilities or be referred to a non-VA provider for such treatment.

c. Once the clinical need for treatment of HIV facial lipoatrophy has been determined, no additional qualification criteria are required. FDA classifies injectable dermal fillers as devices rather than drugs; VA has accordingly classified these as prosthetic devices. The VA provider who is to inject such fillers may order them by placing a consult with the facility's Prosthetics Service.

RECOMMENDED STAFFING GUIDELINES FOR HIV CLINICAL CARE

1. This appendix provides additional information on recommended guidelines for sufficient staffing for Human Immunodeficiency Virus (HIV) clinical care, considering:

- a. The number of patients living with HIV in a Department of Veterans Affairs (VA) medical facility's catchment area; and
- b. The degree to which HIV clinics also serve as the primary care provider or team for Veterans living with HIV.

NOTE: *This staffing model is meant to complement current Veterans Health Administration (VHA) policy outlining staffing recommendations for Infectious Diseases and Infection Prevention and Control Functions outlined in VHA Directive 1131, Management of Infectious Disease and Infection Prevention and Control Programs, dated November 7, 2017, and Infectious Disease-Patient Aligned Care Teams (ID-PACT) outlined in VHA Handbook 1101.10(1), Patient Aligned Care Team (PACT) Handbook, dated February 5, 2014.*

2. HIV CLINICAL PROGRAM

a. An HIV Clinical Program would typically be located under an Infectious Diseases (ID) Section within a VA medical facility. If there is no ID Section, then the responsibility for tracking HIV care and medical facility level guidance must be assigned to an appropriate designee at the facility (HIV Lead Clinician designation, or to an ID-trained clinician).

b. The functions of an HIV Clinical Program include:

(1) Providing direct patient HIV care or consultation on clinical HIV care for all HIV patients receiving care at the facility and its affiliated units, such as Community-Based Outpatient Clinics and Community Living Centers.

(2) If the HIV Clinical Program does not itself deliver primary care to Veterans living with HIV receiving care at the facility, or if there are Veterans living with HIV who prefer to receive their primary care outside the HIV Clinical Program, collaborating with the facility's Primary Care Service (or other relevant primary care providers such as Women's Health) to effectively deliver integrated care to Veterans with HIV is warranted. In suitable circumstances, a written service agreement can be useful in such collaboration.

(3) In collaboration with the VA medical facility's Laboratory, Primary Care, and Emergency Medicine Services, and other services as required, collaborating to achieve effective, rapid linkage to care for Veterans newly diagnosed with HIV infection.

(4) Tracking and monitoring all HIV patients to ensure maximal rates of retention in care and minimal loss to follow-up.

(5) Providing patient care and consultation for HIV prevention across the facility, including post-exposure prophylaxis, both non-occupational and occupational post exposure prophylaxis (nPEP and oPEP), and pre-exposure prophylaxis (PrEP) against HIV.

(6) Collaborating with the VA medical facility's Privacy Officer and other stakeholders to timely report newly diagnosed cases of HIV infection to public health departments as required under the applicable laws of the state in which the VA medical facility is located.

3. MINIMUM RECOMMENDED STAFFING GUIDELINES FOR HIV CLINICAL CARE BY CLINICAL CENSUS

a. Clinic census may be determined locally by VHA Support Services Center's (VSSC) HIV Clinical Cube available at: <https://vssc.med.va.gov/VSSCMainApp/>.

NOTE: *This is an internal VA Web site not available to the public.*

b. Table 1 (below) provides recommended staffing levels for HIV clinical care, with the understanding that specific positions may be organized under different service lines (e.g., medical services, nursing, social work, mental health) as determined by the VA medical facility. However, staffing of all positions is recommended to support high quality HIV care and HIV prevention at each VA medical facility. The function of each position below should be filled and coordinated across service lines as needed. The full-time equivalent (FTE) staffing level recommended depends on the number of patients living with HIV at the VA medical facility, and whether the HIV clinical program also provides primary care; those that do not provide primary care are referred to in Table 1 as "without PACT".

c. While the services detailed in these staffing recommendations should be provided within a comprehensive HIV clinic, this guidance recognizes that factors such as organization of clinical services and the number of HIV patients enrolled in care at a given VA medical facility will impact how these recommended staffing levels are implemented. For example, some of the roles detailed below may overlap, such as case management duties performed by nursing staff and social workers assigned to support other roles in the HIV care program. In VA medical facilities with smaller numbers of HIV patients in care, or in which the HIV clinic offers only HIV care without primary care, programmatic and clinical responsibilities for the positions detailed below should be formally assigned to these individuals, with appropriate labor mapping, rather than as collateral duties. In addition, depending on the services offered in a VA HIV clinic, these staffing recommendations may require adjustment to avoid unintended decreases in provider productivity.

d. For VA medical facilities with limited or no on-site HIV care services, HIV patients should be well integrated into PACT clinics, with primary care coordinated with off-site HIV care.

e. VA medical facilities should consider telehealth and virtual care modalities based on the populations they serve.

f. These staffing guidelines were developed and agreed upon by the VHA's HIV Technical Advisory Group.

4. TABLE 1: MINIMUM RECOMMENDED STAFFING GUIDELINES FOR HIV CLINICAL CARE BY CLINICAL CENSUS AND INFECTIOUS DISEASE-PATIENT ALIGNED CARE TEAMS

Position title per PACT Model	<50	51-99	100-300	0.1 additional FTE for each additional N patients	Additional/50 PrEP patients*
HIV Physician (Attending)	0.2	0.5	0.7	50 patients	+ 0.1
Without PACT	--	--	1.0	50 patients	
HIV Physician (Resident/Fellow)	--	--	0.2	65 patients	
Without PACT	--	--	0.7	85 patients	
HIV Advanced Practice Registered Nurses (APRN)/Physician's Assistant (PA)	--	0.2	0.5-0.7	75 patients	
Without PACT	--	--	0.5	100 patients	
HIV Clinical Pharmacist	0.25	0.35	0.5	50 patients	+0.05
Without PACT	0.2	0.3	0.4	125 patients	
HIV Registered Nurse (RN)	0.2	0.75	1	50 patients	+0.05
Without PACT	0.25	0.5	0.75	100 patients	
Licensed Vocational Nurse (LVN)/Licensed Practical Nurse	0.1	0.3	0.5	50 patients	

(LPN)/Healthcare Technician (HT)					
Without PACT	0.1	0.5	0.75	100 patients	
HIV Case Manager	0.2	0.5	0.75	50 patients	+.05
Without PACT	0.2	0.5	0.75	100 patients	
Clerk	0.1	0.25	0.5	50 patients	+.05
Without PACT	0.1	0.25	0.5	50 patients	
HIV Nutritionist	0.1	0.1	0.1	50 patients	
Without PACT	0.1	0.1	0.1	50 patients	
Social Worker	0.2	0.25	0.5	50 patients	
Without PACT	0.2	0.25	0.5	50 patients	
Psychologist	0.1	0.25	0.5	50 patients	
Without PACT	0.1	0.25	0.5	50 patients	
Psychiatrist	0.1	0.1	0.1	85 patients	
Without PACT	0.1	0.1	0.1	85 patients	
HIV Lead Clinician	0.1	0.1	0.2	250 patients	
HIV Telehealth (Medical Doctor/NP/PA)	0.1	0.1	0.5	125 patients	

NOTE: For each of the positions detailed above, research activities are encouraged but staff needed for research activities are in addition to the FTE level defined by clinical need in Table 1.

5. ASSIGNMENT OF PATIENTS TO INFECTIOUS DISEASE-PATIENT ALIGNED CARE TEAM

a. In some VA medical facilities across the system, patients living with HIV who receive their primary care through an Infectious Disease Clinic and are thus assigned to an ID-PACT Clinic, may be erroneously dropped, or unassigned to a PACT clinic after 12-24 months. This is due to VHA Directive 1406, Patient Centered Management Module (PCMM), dated June 20, 2017, for primary care policy which does not currently

recognize any ID stop codes as “qualifying encounters” for primary care visits, even if patients have been seen routinely through ID-PACTs.

b. It is recommended that all VA medical facilities with ID-PACTs periodically review their patient lists to ensure no patients have been dropped and unassigned to a PACT clinic. VA medical facilities whose ID-PACT patients are dropped from PACT panels, should consider the addition of a primary care stop code (323) to the ID stop code (310) for all ID-PACT patients.

MEMORANDUM OF UNDERSTANDING

BETWEEN

[DONATING FACILITY]

AND

[RECEIVING FACILITY]

Effective Period: October 1, [YEAR] to September 30, [YEAR]

I. BACKGROUND

[FACILITY WITH HIV LEAD CLINICIAN (also referred to as the “Donating Facility”) has agreed to support [FACILITY WITHOUT HIV LEAD CLINICIAN (also referred to as the “Receiving Facility”)] by allowing [NAME OF HIV LEAD CLINICIAN] to serve as the HIV Lead Clinician for both facilities.

II. PURPOSE AND SCOPE OF WORK

Per VHA Directive XXXX, [NAME OF HIV LEAD CLINICIAN] will be responsible for the following for both facilities:

(1) Serving as the point of contact on testing, diagnosis, and care of Veterans with HIV, and HIV prevention among those at risk of becoming HIV-infected.

(2) Utilizing the VHA VSSC HIV Clinical Cube (available at: <https://vssc.med.va.gov>) to optimize the use of local population management tools and to report, as needed or requested, to the VA medical facility’s Director and/or Chief of Staff. **NOTE:** *This is an internal VA Web site not available to the public.*

(3) Serving as a point of contact for communications to and from VHA ’s National HIV Program in HHRC regarding policy and operational issues concerning HIV testing, diagnosis, care, and prevention.

(4) Notifying the Director or Deputy Director of the National HIV Program within HHRC if HIV care is routinely provided through the community or at another VA medical facility.

(5) Unless the HIV Lead Clinician at the Donating Facility will have responsibilities at the Receiving Facility that require credentialing and privileging under VHA Handbook 1100.19, *Credentialing and Privileging*, appointment of the Lead Clinician to the staff of the Receiving Facility should not ordinarily be necessary.

III. DURATION OF AGREEMENT

All parties are in agreement with this arrangement, which will be renewed each fiscal year, per 10N request, until staffing levels at the facility with no HIV Lead Clinician obviates the need for the agreement.

IV. EXECUTION

This Memorandum of Understanding (MOU) is executed [DATES]

Points of contact (POC) for this action will be:

_____	_____
Name, Degree	Date
HIV Lead Clinician	
Title	
_____	_____
Name, Supervisor	Date
Title	
_____	_____
Name,	Date
Medical Center Director [Donating Facility, with HIV Lead Clinician]	
_____	_____
Name,	Date
Medical Center Director [Receiving Facility, without HIV Lead Clinician]	