



Global Health Security and Diplomacy

U.S. DEPARTMENT of STATE

HIV Care & Treatment and Prevention of Mother to Child Transmission Activities Approved Under PEPFAR Limited Waiver

February 6, 2025

PEPFAR-supported life-saving HIV Care & Treatment and Prevention of Mother to Child Transmission (PMTCT) services should be resumed as soon as possible. PEPFAR implementing agencies should take necessary actions to expedite resumption of these services.

This document is intended to provide additional clarification of activities approved under the PEPFAR 90-Day Limited Waiver. Activities not specifically listed should not be resumed. If further clarification is needed, send an email to ghsd_pq@state.gov. Resumption of activities approved under the PEPFAR 90-day waiver is limited to activities within previously approved PEPFAR Country and Regional Operational Plans.

“For purposes of this limited waiver, life-saving humanitarian assistance applies only to: Delivery of life-saving HIV care and treatment services through support for health workers (doctors, nurses, and other clinical and community health workers, etc.) delivering or monitoring HIV care and treatment to ensure continuity of service provision. These workers deliver care at hospitals, primary healthcare clinics, faith-based clinics, and community settings.”

Salaries for health workers, laboratory, and supply chain staff necessary to carry out the specific activities described in this document are included in this waiver.

HIV Testing Services for All Populations [For HIV Case Finding, Re-entry in Care, and PMTCT]

- *“Provision of HIV testing in community and facility settings”* – To identify people living with HIV
 - Referral and navigation to confirmatory HIV testing (including for those who screen positive with an HIV self-test)
 - Referral and navigation to antiretroviral treatment (ART) for those with a positive HIV test
 - Referral and navigation as appropriate to PMTCT services
- HIV screening for people diagnosed with TB: All individuals who are either diagnosed with or presenting with pulmonary or extrapulmonary symptoms of tuberculosis should be tested for HIV
- All PMTCT and HIV exposed infant (HEI)-related testing, inclusive of:

- ANC1 testing
- Retesting during pregnancy and breastfeeding (Post ANC1 testing)
- Testing at all maternal and child health (MNCH)/PMTCT points of entry
- Testing for PrEP initiation and continuation for pregnant and breastfeeding women
- Partner Testing
- Early Infant Diagnosis (EID)
- EID (before 2 months and 12 months) at postnatal, well-child/immunization, and other pediatric entry points
- Broader EID coverage at <8 weeks of age, including HIV birth testing and linkage to treatment <4 weeks
- Procurement and distribution of HIV test kits, including HIV self-test kits, and referral/follow-up for confirmatory testing and ART for those who test positive
- Supply chain support for HIV testing commodities and lab commodities needed to support HIV testing

HIV Care and Treatment Services for All PLHIV

- *“Provision of HIV drugs and support to prevent treatment interruptions for adults and children in community and facility settings.”*
- *“Provision of care for advanced HIV disease, including CD4 testing (immune function test), prevention and treatment of opportunistic infections, and HIV treatment adherence support.”*
- *“Provision of HIV viral load testing, which allows patient monitoring to ensure that HIV drug treatments are effective.”*
- Specific components of HIV care and treatment that should be supported:
 - Care and treatment services provided in stand-alone programs; HIV testing and treatment in community settings – including locations where individuals can access HIV care and treatment services outside of a hospital or clinic, such as mobile clinics and drop-in centers for provision of services to persons at high risk for or living with HIV.
 - Linkage to ART, including counseling and treatment literacy
 - Differentiated service delivery models, including community ART and multi-month dispensing (MMD)
 - ART optimization for PLHIV
 - Nutrition support for malnourished PLHIV
 - Tracing and returning to care individuals who have missed appointments or had treatment interruption
 - Adherence counseling, peer support, and follow-up to promote continuity of treatment, including facility- or community-based peer support groups
 - Rapid HIV testing, counseling and provision of HIV post-exposure prophylaxis for individuals with HIV exposure, STI screening and presumptive treatment, and referrals for survivors of sexual violence as necessary
 - Viral Load: Facility and community-based viral load sample collection

Laboratory support

- Quality control/quality assurance/proficiency testing and quality indicator monitoring required to ensure accurate and valid test results
- Sample collection, processing, transport, and result return
- Laboratory and point of care testing site equipment service/repair and preventive maintenance/calibration required for biosafety/biosecurity and provision of accurate test results
- Use of laboratory information systems

Supply Chain Management

- *“Procurement of HIV medicines and other commodities required for provision of HIV care and treatment services to prevent stockouts in national HIV programs (e.g., HIV drugs, HIV test kits, early infant HIV tests, viral load tests and lab equipment for clinical monitoring, TB prevention and treatment drugs, opportunistic infection medicines for advanced HIV disease).”*
- *“Support for transport, storage, distribution, and management of HIV care and treatment commodity supply chain to ensure timely provision of medications and tests to patients”*

Pediatric and Adolescent Specific Considerations

- Pediatric or adolescent specific case finding and care and treatment activities
- Family-based differentiated service delivery models that deliver HIV treatment, continuity of treatment, and adherence support such as MMD for children, family-centered models of care, Mentor Mothers, and peer support programs
- Optimizing CLHIV to DTG-based regimens and transition to pALD from pDTG-based ART when pALD is available in country. Provision of appropriate counseling and adherence support to children and their caregivers to support this transition.
- Care & Treatment services for PLHIV and CLHIV delivered through the orphans and vulnerable children (OVC) program that directly impact clinical outcomes as listed above. These include:
 - Referring children with an unknown HIV Status for HIV testing
 - Linkage of the caregiver living with HIV or CLHIV to ART, adherence counseling and VL testing
 - Routine home visits and follow ups for CLHIV who have had an interruption in treatment
 - Nutritional assistance for malnourished CLHIV
 - Support for early infant diagnostic testing of HIV-exposed infants
- Supportive models for adolescents living with HIV may include mobile units, hybrid models and adolescent-friendly provider treatment services

PMTCT and HIV-Exposed Infants (HEI) Specific Considerations

“Prevention of Mother-to-Child Transmission of HIV, which consists of testing and re-testing pregnant and breastfeeding women, providing HIV prevention services for [pregnant and breastfeeding] women who are HIV negative including Pre-exposure Prophylaxis (PrEP) and HIV treatment drugs for pregnant and breastfeeding women who are positive, HIV testing for partners, early infant diagnosis tests, and comprehensive care for infants.”

“Support for procurement, transportation, storage, distribution and management of HIV commodity supply chain to ensure timely provision of medicines and medical commodities for PMTCT.”

- Services to address early identification, treatment linkage/continuity, and viral load suppression for pregnant and breastfeeding women:
 - Community case workers to perform household risk-assessments to identify support services needed for exposed mother-baby pairs
 - Joint OVC partner and PMTCT cadre/mentor mothers visits to provide peer support for ART adherence
 - Community and facility adherence support groups
 - Longitudinal tracking for mother-baby pairs by facility and community health workers until final outcome
- Services to prevent HIV incident infections among pregnant and breastfeeding women and their infants:
 - Pre-exposure prophylaxis (PrEP) should be offered only to pregnant and breastfeeding women (PBFW). PBFW may receive either oral or long-acting PrEP.
 - Partner testing and distribution of condoms to PBFW and their partners as part of PMTCT services.
- Services for infants exposed to HIV:
 - Registration of HIV-exposed infants (HEI) in birth cohort
 - Timely initiation of appropriate infant postnatal prophylaxis (PNP) regimens for high-risk infants born to mothers living with HIV and comprehensive HEI services

Advanced HIV Disease – [Prevention and Treatment of Opportunistic Infections]

“Life-saving HIV care and treatment services, inclusive of HIV testing and counseling, prevention and treatment of opportunistic infections including TB, laboratory services, and procurement and supply chain for commodities/medicines.”

Included in waiver:

- Advanced HIV Disease (AHD) Diagnostics and Treatment
 - LF-LAM
 - Molecular diagnostic tests for TB
 - Cryptococcal antigen testing (CrAg)
 - Lumbar puncture and testing of spinal fluid
 - CD4 testing

- o Diagnosis of Histoplasmosis and talaromycosis where applicable
- Prevention of OIs: per normative guidance
 - o Cotrimoxazole
 - o Fluconazole
 - o TB preventive treatment
- Treatment of OIs
 - o Fluconazole
 - o Flucytosine
 - o Liposomal amphotericin B
- Testing for OIs (laboratory services)
 - o Laboratory services as necessary
 - o Imaging services as necessary
- Laboratory support for AHD activities including:
 - o Sample collection, processing, transport, and result return
 - o Quality control/quality assurance/proficiency testing and quality indicator monitoring required to ensure accurate and valid test results.
 - o Laboratory and point of care testing site equipment service/repair and preventative maintenance/calibration required for biosafety/biosecurity and provision of accurate test results
 - o Use of laboratory information systems

Life-threatening opportunistic Infection: TB Activities

- TB screening and TB diagnosis of People Living with HIV (PLHIV)
 - o Facilities that provide care to people living with HIV should screen all PLHIV for TB using available methods, which may include molecular diagnostic tests, chest X-ray, stool-based testing, LF-LAM assay and symptom screening per normative guidance
- Referral for Tuberculosis Treatment
 - o Any person living with HIV who has active TB disease should be referred for treatment using anti-TB medications per routine protocols and following normative guidance
- TB Preventive Therapy
 - o All people living with HIV who do not have active TB disease should be provided a full course of TB Preventive Therapy for TB prevention
- Laboratory Support for TB activities, including:
 - o Sample collection, processing, transport, and result return
 - o Quality control/quality assurance/proficiency testing and quality indicator monitoring required to ensure accurate and valid test results.
 - o Laboratory and point of care testing site equipment service/repair and preventative maintenance/calibration required for biosafety/biosecurity and provision of accurate test results
 - o Use of laboratory information systems

Life-threatening Cervical Cancer among Women living with HIV (WLHIV)

- Given that Cervical Cancer is an opportunistic cancer, all Women living with HIV (WLHIV) should be screened for cervical cancer in the 12 Go Further Countries (Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Mozambique, Malawi, Namibia, Tanzania, Uganda, Zambia, Zimbabwe).
- Use of “screen and treat” or “screen, triage, and treat” approach followed by immediate treatment of precancerous lesions for WLHIV
 - Cervical pre-cancer can be treated with cryotherapy, thermo-coagulation, LEEP or cold knife conization (for eligible lesions).
 - Sites providing cervical cancer screening that do not provide precancerous lesion treatment should establish a referral system for WLHIV needing treatment or a more definitive diagnosis.
- Additional evaluation and treatment at the same facility or referral to established treatment referral sites for WLHIV with suspected invasive cervical cancer.

HIV Pre-exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) should be offered only to pregnant and breastfeeding women (PBFW; see section above) during this pause of U.S. Foreign Assistance. PBFW may receive either oral or long-acting PrEP.

- Note: People other than PBFW who may be at high risk of HIV infection or were previously initiated on a PrEP option can not be offered PEPFAR-funded PrEP during this pause of U.S. Foreign Assistance or until further notice.

Administrative Costs:

The waiver in State ALDAC 25 STATE 6828 “for salaries and related administrative expenses, including travel, for U.S. direct hire employees, personal services contractors, and locally employed staff,” continues to allow for expenses required to operate U.S. Government offices responsible for oversight and management of the PEPFAR program including but not limited to: staff communications devices, IT support and services, software licenses, rent, ICASS, office supplies as well as indirect costs that are operating expenses including payroll systems, accounting and financial management utilities, security, facility lease, and building maintenance.

The PEPFAR limited waiver also allows for administrative expenses to include other contract and grant related administrative expenses at headquarters and in country, including third party contract support, reasonably necessary to provide the care and treatment and PMTCT activities listed above. Agencies and implementing partners should be judicious in ensuring that any administrative costs are necessary for the performance and oversight/management of the care and treatment and PMTCT activities listed above.

Data and Systems Activities Approved Under PEPFAR Waiver to Support HIV Care & Treatment and PMTCT Activities

Overview: This document clarifies elements of monitoring, data, and systems related activities covered under the PEPFAR limited waiver.

Timeline for Reporting: We do not currently expect FY25Q1 reporting to proceed as scheduled given reporting period occurred during the pause, disrupting operation of country and central data systems and their support teams. We anticipate a resumption of reporting according to **new guidelines** in time for FY25Q2 reporting with specific guidance forthcoming.

Covered under the Waiver

“Reasonable implementing agency and implementing partner administrative costs strictly necessary to deliver and provide oversight of this assistance, including related country-based data activities and portions of PEPFAR’s central data platform used for clinical monitoring and program management”

Country-Level Health Information Systems Support that is allowed:

- Support for the operations, maintenance, and use of current facility and community, and national data systems (including paper and electronic record systems) necessary for patient management and program monitoring in the provision of the services covered in the waiver. This includes:
 - Clinical systems, Electronic medical records, community-based information systems for testing and treatment delivery (not community led monitoring), DHIS2 systems, central data repositories, warehouse management systems, case-based surveillance systems, laboratory information systems, logistics management information systems, commodity systems, procurement systems, stock out systems, pharmacy information systems supply chain systems, contact tracing systems essential for index testing, and all other systems required to support the activities covered in the waiver and provide necessary oversight and compliance.
- Support to other country-data systems necessary to provide the services covered in the waiver to ensure program oversight and compliance, including routine program monitoring and reporting. This includes:
 - Data & IT workforce necessary to operate, maintain and secure the systems and data for PEPFAR program monitoring, oversight, reporting, and compliance.

Headquarters-Level Information Systems (Including PEPFAR Centrally Supported Systems) that is allowed:

- To support the activities covered in the waiver and provide necessary oversight and compliance; systems support, and activities covered include:
 - Support for data collection and ingestion systems; including system operations, cybersecurity compliance, and end user support
 - Support for data management and infrastructure system updates to facilitate streamlined data submission processes.
 - Support for enterprise analytics systems including data engineering and management activities as well as help desk and systems administration.
 - Support for knowledge management and collaboration systems; including restoring PEPFAR SharePoint platform in the in short term and simultaneously investigating alternative platforms that can provide cost savings and better integration
 - Activities including webinars and/or support calls to provide instructions and support for developing data submissions and import files.

Staff:

- All data and systems related staff required to enter, operate, manage, secure, analyze, and otherwise make function the data and systems to support the provision of activities covered by the waiver in country and at HQ.

Indicators:

These include quarterly, semi-annual, and annual indicators. Data for the following indicators should be collected, as best as possible given constraints on feasibility both in country and centrally, even though the indicators reported annually are not expected to be reported during the waiver period.

1. HTS_TST
2. HTS_INDEX
3. HTS_SELF
4. CXCA_SCRN
5. CXCA_TX
6. PMTCT_EID
7. PMTCT_FO (reported at Q4)
8. PMTCT_HEI
9. PMTCT_STAT
10. PrEP_CT for Pregnant and Breastfeeding women only
11. PrEP_NEW for Pregnant and Breastfeeding women only
12. TB_STAT
13. PMTCT_ART
14. TB_ART
15. TB_PREV

16. TX_CURR
17. TX_ML
18. TX_NEW
19. TX_TB
20. TX_RTT
21. TX_PVLS
22. LAB_PTCQI (reported at Q4)

Not Covered under the Waiver:

Systems support that is not allowed:

- Support for the operations, maintenance, and use of data systems designed exclusively for services not covered in the waiver
- Expanding current data systems or developing new data systems
- DREAMS information systems
- OVC information systems that focus exclusively on elements not focused on care and treatment

Activities that are not allowed:

- Population-based HIV surveys (PHIA and BBS)
- Violence against children (VACs) surveys
- Program-based HIV surveillance (e.g., case surveillance, recent infection surveillance, HIV drug resistance surveillance, ANC surveillance, mortality surveillance, etc.)
- Community-led monitoring information systems
- Implementation science projects
- Planning and targeting for FY2026

Staff:


- Staff associated with activities not covered under the waiver

Indicators:

1. AGYW_PREV
2. GEND_GBV
3. KP_PREV
4. OVC_SERV
5. OVC_HIVSTAT
6. PrEP_CT (for all populations except Pregnant and Breastfeeding Women)
7. PrEP_NEW (for all populations except Pregnant and Breastfeeding Women)
8. VMMC_CIRC
9. SC_ARVDISP (optional under MER 2.8)


Disaggregates:

The KP disaggregates are removed from the indicators covered under the indicator. They are also removed from the MER guidance, data entry screens, and from the data model.




UNDER WAIVER: PEPFAR MONITORING, EVALUATION AND REPORTING (MER) INDICATORS

TESTING




- HTS_INDEX
- HTS_TST
- HTS_SELF
- PMTCT_EID
- PMTCT_FO
- PMTCT_HEI
- PMTCT_STAT
- TB_STAT

TREATMENT




- CXCA_TX
- CXCA_SCRN
- PMTCT_ART
- TB_ART
- TB_PREV
- For Preg, BF Women Only
 - PREP_NEW & PREP_CURR
- TX_TB
- TX_CURR
- TX_ML
- TX_NEW
- TX_RTT

VIRAL SUPPRESSION



- TX_PVLS

HEALTH SYSTEMS



- LAB_PTCQI