CHANGE
COMMUNITY HEALTH & HIV ADVOCATES NAVIGATING GLOBAL EMERGENCIES

Global Health Security and Diplomacy issues additional clarification of activities approved under the PEPFAR 90-Day Limited Waiver

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Updated February 6 State Department Guidance on PEPFAR Waiver

On February 6, 2025, the U.S. Department of State issued a further and more specific update on its humanitarian, life-saving waiver to its previous stop work/funding freeze on US foreign assistance as applied to PEPFAR, **HIV Care & Treatment and Prevention of Mother to Child Transmission Activities Approved Under PEPFAR Limited Waiver.** Although the February 6 PEPFAR waiver guidance does not change the previous, more abbreviated Info Memo for PEPFAR Implementing Agencies and PEPFAR Country Coordinators, it does clarify coverage of certain critical testing, treatment-and-care, and PMTCT activities and also provides a foundation for ensuring the ability of implementing partners (IPs) to provide such services to key populations, including young women in Africa, through differentiated service models.

The Feb. 6 PEPFAR waiver guidance, which has been delivered to all PEPFAR IPs, covers multiple services described below. Key language that should be interpreted to permit full and differentiated service delivery to key populations and others is highlighted in summarized permitted commodities and service activities described below.

Note, at the time of publication, U.S. Courts have directed the administration not to suspend, pause, or otherwise prevent the obligation or disbursement of appropriated foreign-assistance funds in connection with any contracts, grants, cooperative agreements, loans, or other federal foreign assistance award that was in existence as of January 19, 2025.

By reversing the blanket freeze on foreign aid funding, accurately enforcing the terms of the waiver should, ideally, become less important, because the temporary restraining order holds supremacy over the waiver obtained by PEPFAR.

However, it is important for advocates to understand waiver details, particularly if this temporary order is halted, or if the parameters of the waiver are raised again in new contexts by the administration.

HIV TESTING SERVICES FOR ALL POPULATIONS [FOR HIV CASE FINDING, RE-ENTRY IN CARE, AND PMTCT]

Approved testing in community and facility setting includes referral and navigation for confirmatory testing (including those who screen positive with a self-test) to allow HIV+ people to initiate antiretroviral treatment (ART) and received appropriate PMTCT services. It allows screening and testing for people diagnosed or symptomatic for tuberculosis (TB) and all PMTC and HIV exposed infant (HEI)-related testing and retesting (during pregnancy and breastfeeding), for Pre-Exposure Prophylaxis (PrEP) initiation and continuation for pregnant and breastfeeding women, partner testing, and early infant diagnosis (EID). Procurement and supply of HIV test kits, including self-test are included as is supply chain support for HIV testing commodities and related lab commodities.

HIV CARE AND TREATMENT SERVICES FOR ALL PLHIV

Approved HIV Care and Treatment Services includes provision of HIV medicines and support to prevent treatment interruptions, care for advanced HIV disease, including CD4 testing, prevention and treatment of opportunistic infections, HIV treatment adherence support, and viral load testing. Care and treatment can be provided in stand-alone programs, and HIV testing and treatment in community settings, including 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 are covered as are "differentiated service delivery models," including community ART and multi-month dispensing. ART optimization and nutrition support for malnourished PLHIV are included as are services to trace and return people to care, adherence counseling, "peer support," and treatment follow-up to promote continuation of treatment, including via facility or community-based "peer support groups." Testing, counseling and post-exposure prophylaxis are covered as are STI screening and treatment and presumptive treatment and referrals for survivors of sexual violence.

LABORATORY SUPPORT AND SUPPLY CHAIN MANAGEMENT

There is broad support for quality and quantity controls and monitoring; sample collection, handling and reporting; laboratory and point-of-care testing equipment service and repair; and laboratory information systems. Likewise, HIV-related commodity procurement, transport, storage, distribution and management of supply chains is fully supported.

PEDIATRIC AND ADOLESCENT SPECIFIC CONSIDERATIONS

The February 6 guidance allows pediatric and adolescent specific case finding and care and treatment activities and family-based differentiated service delivery models. There is support for optimizing CLHIV to DTG-based regimens and other treatment transitions and counseling and adherence support to children and their caregivers. Care & Treatment services for PLHIV and CLHIV delivered through the orphans and vulnerable children program are fully covered including referral to testing, linkage of HIV+ caregivers and children to ART, adherence counseling and VL testing, routine home visits and follow-up after treatment interruption, nutrition support, and EID for HIV-exposed infants. Supportive delivery models for HIV+ adolescents may include mobile units, hybrid models, and adolescent-friendly provider treatment services.

PMTCT AND HIV-EXPOSED INFANTS (HEI) SPECIFIC CONSIDERATIONS

Coverage of Prevention of Mother-to-Child Transmission of HIV, 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" and support for procurement and supply of medicines and commodities for PMTCT. More specifically, PMTCT services should address early identification, treatment linkage/continuity, and viral load suppression of pregnant and breastfeeding women. Community health workers and PMTCT cadre/mentors can be used for risk-assessment and peer support for ART adherence and longitudinal tracking. Community and facility-based adherence support is also to be supported. HIV negative pregnant and breastfeeding women can receive oral or long-acting PrEP. In another exception to the exclusion of waiver coverage for prevention, not only does the waiver support partner testing, it also supports distribution of condoms to pregnant and breastfeeding women and their partners. For infants exposed to HIV from an HIV+ mother, such infants can initiate appropriate postnatal prophylaxis regimens.

ADVANCED HIV DISEASE – [PREVENTION AND TREATMENT OF OPPORTUNISTIC INFECTIONS]

Advanced HIV Disease Diagnostics and Treatment are covered inclusive of prevention, testing, and treatment of opportunistic infections, including TB, cryptococcal meningitis, histoplasmosis, and talaromycosis.

LIFE-THREATENING OPPORTUNISTIC INFECTION: TB ACTIVITIES

Screening, preventing, and treating TB, inclusive of TB screening and TB diagnosis of People Living with HIV (PLHIV) is covered using available methods, which may include molecular diagnostic tests, chest X-ray, stool-based testing, LF-LAM assay and symptom screening per normative guidance. Also covered is Referral for Tuberculosis Treatment of any person living with HIV who has active TB as well as TB Preventive Therapy for all people living with HIV who do not have active TB disease. Laboratory Support for TB activities which are covered include sample collection, transport for testing using PCR equipment (including GeneXpert and other platforms) in hub locations, processing, transport, and result return. Also covered is quality control/quality assurance/proficiency testing and quality indicator monitoring required to ensure accurate and valid test results, laboratory and point of care testing site equipment service/repair and preventative maintenance/calibration required for biosafety/biosecurity and provision of accurate test results, and use of laboratory information systems.

LIFE-THREATENING CERVICAL CANCER AMONG WOMEN LIVING WITH HIV (WLHIV)

Likewise, there is full coverage of "screen and treat" or "screen, triage, and treat" coverage for HIV+ women for cervical cancer in 12 Go Further Countries. (Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Mozambique, Malawi, Namibia, Tanzania, Uganda, Zambia, Zimbabwe). Precancerous lesions can be immediately treated and invasive cervical cancer cases can be referred to established treatment referral sites.

HIV PRE-EXPOSURE PROPHYLAXIS (PREP)

PrEP is **only** available to pregnant and breastfeeding women and is not available to any other person at high risk of HIV infection including people who have previously been receiving PEPFAR-supported PrEP.

ADMINISTRATIVE COSTS

Administrative expenses and staff supports, including salaries, are included, as are expenses for required oversight and management of the PEPFAR program.

DATA AND SYSTEMS ACTIVITIES APPROVED UNDER PEPFAR WAIVER TO SUPPORT HIV CARE & TREATMENT AND PMTCT ACTIVITIES

There is a separate detailed overview of data and systems support activities. It continues support for country-level health information systems support and headquarters-level information systems as well. Certain indicators are included.

EXCLUSIONS

In addition to specifying permitted activities, the February 6 PEPFAR waiver guidance also identifies specific activities not covered under the waiver, including most prominently various surveys and surveillance activities, community-led monitoring information systems, implementation science projects, and planning and targeting for FY2026:

***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 costs associated with activities not covered under the waiver are excluded and certain indicators are also excluded. Key population indicators are removed, including KP disaggregates from indicators that are covered.

ANALYSIS: EXCLUSION OF VIRTUALLY ALL PREVENTION ACTIVITY AND SUPPORT FOR COMMUNITY-LED MONITORING REMAINS DEEPLY PROBLEMATIC, BUT THERE IS WAIVER SUPPORT FOR SERVICE DELIVERY TO KEY POPULATIONS

The near total exclusion of structural and comprehensive prevention commodities and services, other than in the context of PMTCT, remains deeply problematic. There is paradoxically no prevention support for HIV-negative women who may become pregnant, but only for HIV-negative women who are pregnant or breastfeeding. There is also no support to counteract violence against women, which is highly correlated with increased risk of infection. Prevention services are also central to the needs of high-risk populations, including young women in Africa, MSMs, transgender people, sex workers, people who inject drugs, prisoners, migrant and displaced populations, people with disabilities, and others, but these populations are neglected, marginalized, stigmatized, and more vulnerable as a result of the myopic and incomplete waiver and its guidance. Similarly, community led monitoring is central to effective testing, care and treatment, and PMTCT programs but is excluded. Removing community input in priority-setting and assessments of service delivery is shortsighted and counterproductive.

It would have been better if the February 6 PEPFAR waiver guidance had more directly indicated allowance of testing, treatment, and care programming to key populations. There has been understandable consternation and uncertainty within KPs and their allies about the waiver's coverage of KPs, given the Trump Administration's stated antipathy to DEI and gender ideology. But multiple elements in the new communication signal permission for IPs to fully meet the needs of KPs with respect to allowed activities. In several places, as highlighted previously, the new waiver guidance communication directs that authorized services should be delivered to all populations. In addition, the care and treatment guidance specifically mandates support for the "provisions of services to persons at high risk for or living with HIV." The guidance further supports differentiated service delivery models and discusses several examples of such, including for pediatric and adolescent services and PMTCT and HIV-Exposed Infant services.

Referenced care and treatment delivery models include locations in community settings and outside of hospitals and clinics, including drop-in centers and stand-alone programs that have been central features of KP service delivery. Likewise, at several points the guidance references allowance for peer-support services, another common component of KP programming. Even the provisions removing KP indicators and KP disaggregates supports an interpretation that KP programming should continue, since such data deletions would not be necessary if KP services were discontinued.

It is fundamental to health care provision, that health services and products must be delivered equitably to all people who need them and that specialized and targeted service delivery models are central to effective and egalitarian health care. We have pediatric health services that are not deemed discriminatory just because they focus on young people; likewise geriatric health services are not questioned because they exclude younger people. We have breast-cancer screening that focuses on women even though men also get breast cancer. Health services should go to where there is health need, and in the context of HIV, KPs include those who are at highest risk of HIV infection and who are most likely to be underserved in health service delivery unless specialized and sometimes separate health services are offered.

CONCLUSION

Although deficient in its coverage, the February 6 PEPFAR waiver guidance authorizes resumption of a broad spectrum of testing, treatment and care, PMTCT, and key population programming. Prime implementing partners should interpret and operationalize this guidance in the broadest possible terms and direct and support their sub-contracts/grantees to do so as well. Similarly, governments should recognize the broad authority they have been given to restart most PEPFAR-supported activities. However, advocates cannot be satisfied with this guidance. Continued campaigning is needed for the waiver be expanded further to cover prevention, community-led monitoring, and other excluded activities.

At the same time that IPs and countries can and should rely on the February 6 PEPFAR waiver guidance, they should also take advantage of the existing temporary restraining orders (TROs) discussed in CHANGE Info Sheet 2 to resume all PEPFAR programming, even that which is beyond the existing waiver guidance. In signing any required documents relating to resumption of waiver supported work, IPs should reserve rights arising from the TROs and related judicial orders stopping enforcement of the initial stop work/funding freeze orders for foreign financial assistance. Such language may take the following form:

> ***"while we submit this workplan/budget under the waiver process, we reserve our rights with regard to our full grant activities and in accordance with any notified TRO or injunction."***

It is also important that anyone who gets a notice that they have to "certify" that they are not engaging in "DEI/DEIA" programming reserve their rights in relation to this:

> *"[Org] hereby certifies that as of the date of this communication, [Org] does not knowingly operate any illegal "diversity, equity, and inclusion" (DEI) or "diversity, equity, inclusion, and accessibility" (DEIA) mandates, policies, programs, preferences, or activities in connection with the above referenced award. In the absence of implementing regulations or guidance from the U.S. Government regarding the definition of terms in Executive Order [X], this certification is based on [Org's] current understanding of what constitutes illegal DEI and DEIA, and is subject to revision should such implementing regulations or guidance be issued."*