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INFORMATION MEMO FOR AMBASSADOR SCOTT, MALAWI

FROM: Mamadi Yilla (Chair) and Jackson Booth (PPM)

THROUGH: S/GAC – Ambassador Deborah L. Birx, MD

SUBJECT: Fiscal Year (FY) 2021 PEPFAR Planned Allocation and Strategic Direction

Dear Ambassador Scott,

I sincerely hope that this note finds you and your team well, safe, and healthy. We are grateful for your leadership protecting staff through this difficult time.

This year has brought unprecedented challenges with the COVID-19 pandemic impacting the entire global community. Despite obstacles faced, what has remained unwavering is the tireless commitment and incredible resiliency of our PEPFAR program, partners, and team across the over 50 countries in which we work. This includes rapid program adaptations, emerging innovations, and client-centered solutions to ensure continuity of HIV services. As the threat of COVID-19 has impacted PEPFAR countries, PEPFAR country teams and programs have proven to be focused and resilient in the face of dual pandemics of HIV and COVID-19.

PEPFAR implementation over the past year has shown tremendous effort to maintain clients on treatment, initiating and accelerating client centered service delivery adaptations, while doing what was possible in HIV prevention programs deeply affected by COVID-19 shutdowns. The following themes have emerged across all of PEPFAR-supported countries; as the economic impact of COVID continues to be seen at both national and community levels, it is more important than ever to use granular data and expand what is working in specific SNUs for viral load coverage and suppression. We saw differential progress in this area independent of the impact of COVID19. Focus groups and deep analytics of client returning to care to ensure we are addressing the critical persistent and new structural barriers. Focus on areas of recent treatment interruption to understand how COVID may have created or exacerbated barriers to access and treatment continuity. Across all countries we see persistent gaps in pediatric diagnosis, treatment and viral suppression. Particular attention should be paid to the pediatric cascade and identifying challenges by district and country for clear and actionable plans. In addition, leverage OVC, DREAMS and other resources for clear accountability to work with mothers and improve early infant diagnosis by two months of age and strengthen resiliency among at-risk women and girls. Community-led monitoring must raise visibility and appropriate response to the needs of populations already vulnerable before COVID. The assessment of needs, and strategies to reinforce OVC caregivers and HIV-affected families in crisis should contribute to budget and activity planning for care and treatment, DREAMS, OVC and wraparound resources. Furthermore, analyzing expenditures at mechanism and program areas level, along with the work teams have done, to build relationships and co-planning with your partner government, the Global Fund, UN organizations and other donors. These relationships and planning efforts are critical to supply chain stability for key commodities as well as understanding COVID relief and other potential funding available in country to ensure most effective and efficient use of PEPFAR's contributions to the national HIV response in COP21.

We understand that specific programs will have carryover and others may not and these funds will be critical to ensure stabilization and expansion of critical prevention programming.

The COVID pandemic also laid bare the depth and breadth of inequities still across the globe and clear evidence that when constrained, Ministries of Health and governments make choices that differentially impact specific programming areas and specific populations. The pandemic revealed vulnerabilities in our non-public sector community efforts that we knew were present, and are now fully exposed, as these specific activities were the first to be dropped. Communities of women and children, and key populations including men who have sex with men, transgender individuals, sex workers, people who inject drugs, and people in prisons and other closed settings are not being adequately and sustainably supported by public-sector mechanisms. We have lost ground in all of our prevention services for all populations and for our most vulnerable and marginalized populations and must make every effort to recover.

Despite the disruptions caused by the COVID-19 pandemic, a number of countries have shown a level of resiliency and were achieving epidemic control of HIV, and others are on the brink of epidemic control. With continued implementation, most PEPFAR countries are on a path to achieving program coverage goals. With that in mind, PEPFAR programs should focus on four key themes as we approach Country Operational Plan 2021 planning and implementation: advancing client-centered services; engaging with communities; implementing resilient and adaptive approaches; and supporting capacities for sustainable epidemic control.

We commend you and your team for your attention to the adoption and implementation of the public health policies that have the greatest impact on HIV, particularly as these very policies are critical to ensuring sustained HIV services during COVID-19. Also, we appreciate your role in supporting PEPFAR teams through this challenging period and continuing to hold implementing partners accountable for their performance.

We are grateful to your incredible PEPFAR team in country, working together across agencies to ensure the most effective and efficient use of U.S. taxpayer dollars. We know there are strengths and weaknesses across the board and across the implementing agencies; and we look forward to working together to support those strengths and address those challenges.

We are very excited about your progress in:

- Establishing a public health response system using Recency testing as a surveillance tool of future outbreaks, and enhancing patient care and case management via the EMR system
- Demonstrating the effectiveness and resilience of peer-led KP programming efforts through the KPIF community program that leveraged CSO-led online platforms, navigators and educators and showed an effective approach that should be scaled up
- Transitioning over 90% of adult patients to TLD as well as the implementation of 6MMD which is critical to assist clients better manage their care, in partnership with the Global Fund.

Together with the Government of Malawi and civil society leadership we have made tremendous progress together. Malawi should be proud of the progress made over the past 18 years of PEPFAR implementation and we are deeply grateful for the ongoing deep coordination with the Global Fund and UNAIDS.

As you will see in COP guidance this year, there are no substantial changes in program direction. While assessing possible deficits in programming arising from COVID-19 our fundamental challenges continue and we again highlight 5 overarching issues we see across PEPFAR.

1. Continued new HIV infections in adolescents and young women
2. Supporting key populations with prevention and treatment services
3. Ensuring men are diagnosed and treated early (testing positive and new on treatment (linkage surrogate))
4. Ensuring 15-35-year-old asymptomatic clients are maintained on treatment and virally suppressed [net new on treatment and treatment current growth, (retention surrogate)]
5. Ensuring all children are diagnosed and are on the best treatment regimens and virally suppressed

Moreover, we note the following specific key challenges in PEPFAR Malawi:

- Treatment gaps remain in pediatrics and adolescents requiring a refocused strategy
- Poor retention of men and low viral load suppression rates in our pediatric population
- A significant delay in PrEP rollout for populations at high risk

A fuller set of details, including funding earmarks and specific program direction are included in the accompanying COP 21 PEPFAR Planned Allocation and Strategic Direction Summary

Consistent with the approach from last year, PEPFAR teams will once again be responsible for setting their targets in consultation with stakeholders. Teams should bear in mind that PEPFAR targets are not PEPFAR's but flow directly from the partner country government's commitment to the UNAIDS and SDG 3 goals. Since 2016 PEPFAR and the Global Fund resources have been focused on achieving these global goals that have been translated to each country by UNAIDS and subsequently supported financially and technically by the PEPFAR family. Since 2016, PEPFAR has utilized these global commitment targets as PEPFAR targets with the commensurate increased funding to countries to achieve the goals set out by the Heads of State. Many countries have made tremendous progress towards these targets and others need to accelerate. Although Malawi did not fully achieve all the 2020 goals, we remain confident that Malawi is on track to achieve 2030 goals early which means sustaining the amazing gains will need to be our constant focus.

S/GAC will not assign targets to countries, but only provide notional budget levels sufficient to achieve the full SDG goal and sustain gains made. **Teams will develop their own targets across PEPFAR program areas, with the treatment current target no less than the result that was to be achieved in COP 2020.** After the PEPFAR country team submits their COP21 targets, the notional budget will then be adjusted to the presented level of ambition.

The PEPFAR Country Operational Plan (COP 2021) notional budget for Malawi is **$175,785,000 i**nclusive of all new funding accounts and applied pipeline. All earmarks and program direction provided below must be met. Targets and the subsequent approved budget should reflect the level of ambition the PEPFAR team, in collaboration with the Government of Malawi and civil society of Malawi, believes is critical for the country's progress towards controlling the pandemic and maintaining control.

We are hoping this approach to target-setting and budget will establish an open dialogue on target-setting and empower teams to work with all stakeholders to plan a strategic and impactful COP. The expectation is for country teams and agencies to propose to S/GAC the targets they believe are achievable and feasible and hold their partners accountable to that achievement.

PEPFAR, with partner governments, multilateral partners, and communities, continues to move rapidly toward control of the HIV pandemic and plan for sustainability of programs. Achieving epidemic control for HIV will be a remarkable accomplishment, saving millions of lives, significantly lowering the burden of HIV/AIDS in countries and communities, reducing the future costs required to sustain the HIV response, and building sustainable public health systems capacity in host countries.

Please note that within the next few days our PEPFAR Chairs and PEPFAR Program Managers (PPMs), working closely with our CAST teams, will plan to review this planning letter and details contained, herein, with your wider PEPFAR country team. Where PEPFAR successfully navigated disruption due to COVID-19 during 2020, it was a result of strong teams, local partners, communities, dedicated health and community workers, leveraging longstanding capacities and platforms established by PEPFAR. Our teams, partners, and communities worked together to adapt and further innovate program implementation and models of service delivery so that the adverse impacts of a dual pandemic threat on essential HIV services were mitigated. Stakeholder engagement is essential for a productive and impactful planning process. Included in this planning letter is an outline of the expectations for engaging key stakeholders and civil society, as we continue to finalize our approach to hosting a virtual 2021 COP planning and approval process.

I am so grateful to you and your entire team for your leadership and engagement in the planning, review and implementation of the President's Emergency Plan for AIDS Relief (PEPFAR) program, along with the community and Government to enhance PEPFAR's program impact.

Sincerely,

Deborah Birx

Attachment: **Fiscal Year (FY) 2021 PEPFAR Planned Allocation and Strategic Direction Summary.**

CC: **S/GAC – Mamadi Yilla (Chair), Jackson Booth (PPM), Funmi Adesanya (PEPFAR Coordinator)**

Overview: Fiscal Year (FY) 2021 PEPFAR Planned Allocation and Strategic Direction

With input from the field teams through the quarterly POARTs, the agency self-assessments and from Headquarters Country Accountability and Support Teams (CAST), a thorough program review of your country over time has been conducted. This includes the end of year results of the Country Operational Plan (COP) 2019 and current COP 2020 implementation as we plan for COP 2021. We have noted the following key successes and challenges:

Successes:

1. **Public health response system for Epidemic Control**: Prior to the COVID-19 lockdown impact, Malawi showed great progress in FY20 to set up strong systems for public health surveillance and response to sustain epidemic control. Recency testing, as a surveillance tool of future outbreaks, was being well established. Quality client-centered patient care was also possible for greater numbers of people by expanding the availability of an electronic medical record (EMR) system to health providers across the 28 districts.

2. **CSO-led community programming success:** Malawi demonstrated the effectiveness and resilience of peer-led KP programming efforts through the KPIF community program that leveraged CSO-led online platforms, navigators and educators showing an effective approach to achieve improved KP cascades. Exponential growth in self-testing must also be applauded.

3. **Achievement in VLS rates as a result of transitioning over 90 percent of adult patients to Dolutegravir-based regimens, implementing 6 MMD:** In partnership with the Global Fund, PEPFAR Malawi began FY20 Q1 with 72% of clients receiving standard first line adult regimens on TLD regimens and ended the year in FY20 Q4 with 98% on TLD regimens among those clients. Additionally, Malawi implemented 6MMD despite the ongoing COVID-19 pandemic.

Challenges:

1. **Treatment for Pediatric and Adolescent Clients**: The pediatric treatment cohort steadily declined; viral load coverage declined; the rate of positive TB screening in children was very low.

2. **Poor Retention challenges:** During FY20, almost all scale-up districts in Malawi did not achieve their TX_CURR or TX_New targets. There is a need to regain the losses in treatment, especially among children and men.

3. **PrEP Provision**: Delay in PrEP rollout, especially among 15-24-year-old AGYW; PrEP guidelines are still undergoing approval by the MOH. While there were more clients initiated on PrEP in FY20 Q4 compared to FY20 Q2, PrEP targets were not achieved.

Given Malawi's status of achieved or are near achieving epidemic control, the following priority strategic and integrated changes are recommended:

1. This COP letter provides U.S. government support to the Malawi national response via our bilateral PEPFAR program and through the Global Fund as one comprehensive strategy, not as separate pieces and until programing is done in a holistic manner, we will continue to perceive shortfalls that are not data-derived. So for example, the KP program success is only possible if the needed KP size estimates IBBS survey is funded. This is also true for needed PrEP, TPT and

viral load commodities. We look forward to discussing "one plan" during the COP21 consultations.

2. Rapid completion of the MPHIA is expected as the results will inform how close we are to saturation and steady state and provide a lens into outstanding programmatic gaps and/or systemic challenges to be addressed.
3. Scale up the rollout of the evidence-based prevention intervention PrEP, including in DREAMS districts, and create efficiencies in the VMMC program.
4. Implement a new and refocused strategy to increase case finding, treatment retention and viral load suppression among pediatrics, adolescents and men, specifically ensuring the expected shift from PITC to quality index testing of is fulfilled, and interrupting transmission in these priority groups.
5. Retention efforts must succeed in COP20 to ready the national response supported by PEPFAR to focus on surveying epidemic control in COP21.
6. Expand the concept of family-centered and family care models used in COP19 and 20 to deliver patient-centered care, leveraging our OVC, VMMC, DREAMS programs as access points into the family for improved outcomes.

SECTION 1: COP/ROP 2021 PLANNING LEVEL

Based upon current analysis of spend levels, information submitted for the End-of-Fiscal Year 2020 (EOFY) tool, and performance data, the total COP 2021 planning level is comprised as follows: Note – all pipeline numbers were provided and confirmed by your agency. Due to increased costs in FY 2020, including those due to COVID, and correspondingly lower applied pipeline going into COP21, COP envelopes have been decreased in some OUs so that S/GAC has funds reserved to address program gaps identified by PHIAs that have yet to be completed and to address other potential future requirements as the impacts of COVID on the program are better known. These funds will be allocated to OUs at a later date as appropriate.

TABLE 1: All COP 2021 Funding by Appropriation Year

	Bilateral				Central				Total
	FY21	FY20	FY19	Unspecified	FY21	FY20	FY19	Unspecified	TOTAL
Total New Funding	$ 166,597,085	$ -	$ -	$ -	$ 785,000	$ -	$ -	$ -	$ 167,382,085
GHP-State	$ 165,084,585	$ -	$ -		$ -	$ -	$ -		$ 165,084,585
GHP-USAID	$ -				$ 785,000				$ 785,000
GAP	$ 1,512,500				$ -				$ 1,512,500
Total Applied Pipeline	$ -	$ -	$ -	$ 8,402,915	$ -	$ -	$ -	$ -	$ 8,402,915
DOD				$ 408,022				$ -	$ 408,022
HHS/CDC				$ 696,819				$ -	$ 696,819
HHS/HRSA				$ -				$ -	$ -
PC				$ 1,967,177				$ -	$ 1,967,177
USAID				$ 3,759,857				$ -	$ 3,759,857
USAID/WCF				$ 71,040				$ -	$ 71,040
State				$ -				$ -	$ -
State/AF				$ 1,500,000				$ -	$ 1,500,000
State/EAP				$ -				$ -	$ -
State/EUR				$ -				$ -	$ -
State/PRM				$ -				$ -	$ -
State/SCA				$ -				$ -	$ -
State/SGAC				$ -				$ -	$ -
State/WHA				$ -				$ -	$ -
TOTAL FUNDING	$ 166,597,085	$ -	$ -	$ 8,402,915	$ 785,000	$ -	$ -	$ -	$ 175,785,000

SECTION 2: COP 2021 BUDGETARY REQUIREMENTS AND OTHER CONSIDERATIONS

Malawi should plan for the full Care and Treatment (C&T) level of **$94,000,000** and the full Orphans and Vulnerable Children (OVC) level of **$20,000,000** of the PLL across all funding sources. These earmark levels on new funding are subsets of those amounts that must be programmed with specific types of

funding due to Congressional requirements. The full amount programmed across all sources will be visible in the FAST.

TABLE 2: COP 2021 Earmarks by Appropriation Year

	Appropriation Year			
	FY21	FY20	FY19	TOTAL
C&T	$ 94,000,000	$ -	$ -	$ 94,000,000
OVC	$ 20,000,000	$ -	$ -	$ 20,000,000
GBV	$ 1,400,000	$ -	$ -	$ 1,400,000
Water	$ 200,000	$ -	$ -	$ 200,000

**Only GHP-State and GHP-USAID will count towards the Care and Treatment and OVC earmarks. **Only GHP-State will count towards the GBV and Water earmarks.'*

TABLE 3: COP 2021 Initiative Controls

	Bilateral	Central	TOTAL
Total Funding	**$ 175,000,000**	**$ 785,000**	**$ 175,785,000**
Core Program	$ 142,080,000	$ -	$ 142,080,000
Cervical Cancer	$ 3,500,000	$ -	$ 3,500,000
Community-Led Monitoring	$ -	$ -	$ -
Condoms (GHP-USAID Central Funding)	$ -	$ 785,000	$ 785,000
DREAMS	$ 20,000,000	$ -	$ 20,000,000
HBCU Tx	$ -	$ -	$ -
Malawi Education	$ -	$ -	$ -
One-time Conditional Funding	$ -	$ -	$ -
Surveillance and Public Health Response	$ -	$ -	$ -
VMMC	$ 9,420,000	$ -	$ 9,420,000

TABLE 4: State ICASS Funding

	Appropriation Year			
	FY21	FY20	FY19	Unspecified
ICASS	$ 59,013	$ -	$ -	

SECTION 3: PAST PERFORMANCE – COP/ROP 2019 Review

Table 5. COP/ROP OU Level FY20 Program Results (COP19) against FY21 Targets (COP20)

Indicator	FY20 Result (COP19)	FY21 Target (COP20)
TX Current <15	43,839	50,182
TX Current >15	776,712	943,693
VMMC >15	55,964	157,425
DREAMS (AGYW_PREV)	86,819	
Cervical Cancer Screening	81,343	103,671
TB Prevenative Therapy	23,874	415,568

Table 6. COP/ROP 2019 | FY 2020 Agency-level Outlays versus Approved Budget

Agency	Sum of Approved COP/ROP 2019 Planning Level	Sum of Total FY 2020 Outlays	Sum of Over/Under Outlays
DOD	**2,818,061**	**1,968,232**	**849,829**
HHS/CDC	**80,669,130**	**69,069,848**	**11,599,282**
PC	**2,007,572**	**1,147,683**	**859,889**
USAID	**73,070,275**	**61,821,378**	**11,248,897**
Grand Total	**158,565,038**	**134,007,141**	**24,557,897**

These figures include only bilateral figures at present

Table 7. COP/ROP 2019 | FY 2020 Implementing Partner-level Significant Over-Outlays versus Approved Budget

The following IMs outlayed at least 110 percent in excess of their COP/ROP19 approved level.

Mechanism ID	Partner Name	Funding Agency	Total Planning Level	Total Outlays	Outlay Delta Check
17097	Project Concern International	DOD	$394,382	$1,680,986	($1,286,604)
17590	Population Council, Inc., The	USAID	$100,000	$327,323	($227,323)
80043	Remote Medicine Inc.	USAID	$157,500	$181,100	($23,600)

Table 8. COP/ROP 2019 | FY 2020 Results & Expenditures

Agency	Indicator	FY20 Target	FY20 Result	% Achievement	Program Classification	FY20 Expenditure	% Service Delivery
HHS/CDC	HTS_TST	1,458,493	**1,756,246**	120%	HTS Program Area		
	HTS_TST_POS	72,338	**62,867**	87%	HTS Program Area	**$7,035,462**	**85%**
	TX_NEW	73,465	**55,791**	76%	C&T Program Area		
	TX_CURR	575,666	**485,791**	84%	C&T Program Area	**$21,820,817**	**64%**
	VMMC_CIRC	88,113	**34,239**	39%	VMMC Sub-Program Area	**$3,555,909**	**100%**
	OVC_SERV	N/A	**N/A**	N/A	N/A		
DOD	HTS_TST	34,064	**12,831**	38%	HTS Program Area		
	HTS_TST_POS	2,679	**640**	24%	HTS Program Area	**$110,766**	**15%**
	TX_NEW	2,247	**594**	26%	C&T Program Area		
	TX_CURR	11,331	**7,130**	63%	C&T Program Area	**$435,148**	**0%**
	VMMC_CIRC	6,102	**542**	9%	VMMC Sub-Program Area	**$231,431**	**100%**
	OVC_SERV	N/A	**N/A**	N/A	N/A		
USAID	HTS_TST	1,248,582	**1,493,504**	120%	HTS Program Area		
	HTS_TST_POS	58,867	**41,867**	71%	HTS Program Area	**$5,774,919**	**72%**
	TX_NEW	53,457	**38,989**	73%	C&T Program Area		
	TX_CURR	410,541	**336,554**	82%	C&T Program Area	**$19,200,532**	**57%**
	VMMC_CIRC	112,181	**33,162**	30%	VMMC Sub-Program Area	**$7,985,809**	**98%**
	OVC_SERV	125,899	**121,004**	96%	OVC Beneficiary	**$4,642,913**	**85%**
					Above Site Programs	**$11,720,176**	**0%**
					Program Management	**$25,808,880**	**0%**

COP 2019 | FY 2020 Analysis of Performance

Overall – Test positive and new on treatment are the "gateway" metric on clinical partner performance so those indicators provide a proxy view of the quality of services the partner offers. We acknowledge that the specific DHO plays a critical role in the outcomes district by district.

- The impact of COVID-19 attributed to a decrease in program performance and lower than normal budget execution in COP19/FY20.
- Nearly all partners failed to meet targets on TX_CURR, TX_NEW or both.
- The largest partners EGPAF and Baylor had low C&T budget execution paired with higher than average TX target achievement in Malawi. Baylor spent 83% of their HTS budget and Local Capacity KP and GHSC-RT spent 115% and 107% of their HTS budgets respectively.
- The team must present a cost benefit analysis of HHS/CDC, USAID and DOD funding to JHPIEGO to do VMMC programming, and a decision made for one agency to fund the activity on behalf of USG.

DOD:

DOD needs to find and retain 4,201 clients in addition to its COP 2021 targets.

- *JHPIEGO:* DOD's VMMC partner, JHPIEGO had a non-satisfactory performance in COP19, reaching only 9% of its VMMC_CIRC target while spending 53% of its VMMC budget.
- *Manerla+:* is a new partner and performance will need to be monitored as they support above-site activities to improve retention and uptake of services for at-risk men as well as youth.

HHS/CDC:

CDC partners performed well. No IMs met their retention targets. CDC needs to find and retain 91,767 clients in addition to its COP 2021 targets.

- *EGPAF*:
  - The mechanism is commended for reaching 88% of its target for new positives, while only expending 66% of its HTS budget. Performance on self-testing improved overall from 23% in COP18 to 45% in COP19. The mechanism only achieved 75% of its TX_NEW targets. The mechanism is at risk of being over extended and this must be carefully reviewed in COP 21.
- *Lighthouse:*
  - The mechanism in Lilongwe achieved 74% of its TX_NEW and 81% of its TX_CURR targets and spent 113% of its C&T budget. Achievement on case finding was 73%, TB performance was good, but achievements on PMTCT were low.
- *JHPIEGO:*
  - IM 18244 achieved 55% of its new positives target and did not fully expend its HTS budget.
  - IM 18247, focused on VMMC, and only achieved 38% of its VMMC_CIRC targets.

- *University Research Co.:*
  - The mechanism achieved 166% of HTS_POS and 83% of its TX_NEW. However, its achievement on PVLS was low.

USAID:

USAID partners performed well on finding new positives except for a few mechanisms. Pakachere Institute of Health and Development Communication achieved 190% of its TX_CURR target and only spent 43% of its C&T budget. The mechanism was the only mechanism to achieve its retention targets. USAID needs to find and retain 72,104 clients in addition to its COP 2021 targets.

- *Baylor:* Baylor's overall performance was good, with especially strong achievements on PMTCT and TB. Baylor reached 67% of its target for new positives while spending 83% of its HTS budget.
- *Johns Hopkins University*: JHU did not perform well with its HTS and HTS_INDEX targets; however, it reached 93% of OVCs and priority populations. While JHU did not over test, the IM did spend 102% of its HTS budget while only achieving 21% of its new positives target.
- *FHI360:* LINKAGES performed well on several program areas. While exceeding its target for case finding (111%), it only expended 88% of its HTS budget. It reached 103% of its target for self-testing and showed very strong results on prevention interventions for KPs.
- *Partners in Hope:* PIH performed very well, exceeding targets on self-testing, PMTCT and TB. It achieved 72% of its case finding target, with a 62% expenditure of its HTS budget.

Peace Corps:
Despite Volunteers being evacuated, Peace Corps is commended for pivoting and repurposing staff to ensure it continues to support epidemic control through innovative efforts. Staff in country remain engaged with the PEPFAR interagency teams support efforts including:

- Communication and coordination with interagency teams
- TA and training for counterparts assist with activities previously started with volunteers in the communities that includes Grassroot Soccer (GRS), HIV prevention, SRHR, and Life Skills Training
- Providing PPE to Counterparts for community level interventions to observe COVID prevention measures

SECTION 4: COP/ROP 2021 DIRECTIVES

The following section has specific directives for COP 2021 based on this year's guidance. Please review each section carefully including the minimum program requirements and specific country directives.

Minimum Program Requirements (MPR)

All PEPFAR programs – bilateral and regional– were expected to have the following minimum program requirements in place by the beginning of COP20 implementation (FY2021). Adherence to these policies and practices is essential to the success of all PEPFAR programs at the national, subnational, and service delivery levels (e.g. facility, school, community). Evidence demonstrates that lack of any one of these policies/practices significantly undermines progress to reaching epidemic control and results in inefficient and ineffective programs.

All PEPFAR programs are expected to meet all of the requirements below, and the COP21 Planning Meeting will include a review of the status of each requirement, including assessment of implementation (including barriers) at the point of client services. To the extent that any requirement(s) have not been met by the time of the COP21 Planning Meeting, the PEPFAR OU team will need to present a detailed description of existing barriers and the remediation plans proposed that will allow them to meet the requirement(s) prior to the beginning of FY2021. The list will be included in the Strategic Direction Summary (SDS), as well.

Failure to meet any of these requirements by the beginning of FY2022 may affect the OU budget. The minimum requirements for continued PEPFAR support include the table on the following page.

Table 9. COP/ROP 2021 (FY 2022) Minimum Program Requirements

	Policy	Status and issues hindering Implementation
Care and Treatment	1. Adoption and implementation of Test and Start with demonstrable access across all age, sex, and risk groups, with direct and immediate (>95%) linkage of clients from testing to treatment across age, sex, and risk groups.[1]	Test and Start services are available in all 750 ART sites.
	2. Rapid optimization of ART by offering TLD to all PLHIV weighing ≥30 kg (including adolescents and women of childbearing potential), transition to other DTG-based regimens for children weighing ≥20kg, and removal of all nevirapine-based regimens.[2]	Successful DTG transition by the end of FY 20. 98% of Adults >15 currently receiving DTG based regimens. Pediatrics ARV optimization: Transition to DTG based regimen for children weighing at least 20kgs is underway at all ART sites. pDTG regimens expected FY21 (Q2)
	3. Adoption and implementation of differentiated service delivery models, including six-month multi-month dispensing (MMD) and delivery models to improve identification and ARV coverage of men and adolescents.[3]	All PEPFAR supported sites are implementing MMD6. Through various MOH/G2G cooperative agreements, MOH will begin providing DSD models in sites previously categorized as TA in COP19, in FY21.
	4. All eligible PLHIV, including children, should complete TB preventive treatment (TPT) by end of COP20, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.[4]	Five TB/HIV high burden districts are already implementing 6H and 3HP. By end of FY21, all 28 districts are expected to have TPT rolled out.
	5. Completion of Diagnostic Network Optimization activities for VL/EID, TB, and other coinfections, and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including 100% access to EID and annual viral load testing and results delivered to caregiver within 4 weeks.	As of Q4 FY20, OU has achieved 61% VL coverage, 92.3% viral load suppression. Expand coverage through patient education/literacy efforts. Reduce TAT from 13.6 days to 10 days. Continue conventional lab optimization through current and additional Hologic and increased utilization of existing multiplex GeneXpert POC. Sample transportation optimization scaled and transition from URC to University of Maryland in progress.

[1] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization, September 2015
[2] Update of recommendations on first- and second-line antiretroviral regimens. Geneva: World Health Organization, July 2019
[3] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization, 2016
[4] Latent Tuberculosis infection: Updated and consolidated guidelines for programmatic management. Geneva: World Health Organization, 2018

		By the end of COP20, 85% viral load coverage expected with 95% viral suppression. Additional Hologic devices will also be procured to increase lab capacity.
Case Finding	6. Scale up of index testing and self-testing, ensuring consent procedures and confidentiality are protected and assessment of intimate partner violence (IPV) is established. All children under age 19 with an HIV positive biological parent must be tested for HIV.[5]	Policy adopted: implementation in progress in PEPFAR-supported community and facility sites. IPV screening and testing of children integrated into index testing procedures.
Prevention and OVC	7. Direct and immediate assessment for and offer of prevention services, including pre-exposure prophylaxis (PrEP), to HIV-negative clients found through testing in populations at elevated risk of HIV acquisition (PBFW and AGYW in high HIV-burden areas, high-risk HIV-negative partners of index cases, key populations and adult men engaged in high-risk sex practices)[6]	National expansion of PrEP beyond the demonstration projects expected by end of FY21 and must occur. FY21 targets for PrEP ~18,080 including AGYW, PBFW, high-risk HIV negative partners and key populations.
	8. Alignment of OVC packages of services and enrollment to provide comprehensive prevention and treatment services to OVC ages 0-17, with particular focus on 1) actively facilitating testing for all children at risk of HIV infection, 2) facilitating linkage to treatment and providing support and case management for vulnerable children and adolescents living with HIV, 3) reducing risk for adolescent girls in high HIV-burden areas and for 9-14 year-old girls and boys in regard to primary prevention of sexual violence and HIV.	In COP 20, the PEPFAR funded USAID OVC program will expand to 44 new sites resulting in a total of 114 sites in 9 districts (49 with CDC treatment partner and 65 USAID treatment partner). The selection of sites was influenced by the number of TX_CURR < 15 with high volume sites being prioritized over low volume sites. The OVC program has enrolled an additional 11, 715 young PLHIV (<18) into the program as of the beginning of COP 20. This brings the coverage total to 75% (19,354 Reported CLHIV in program/ 25,624 TX_CURR <20) of TX_CURR under 20 in the 114 OVC sites.
Policy & Public Health Systems Support	9. Elimination of all formal and informal user fees in the public sector for access to all direct HIV services and medications, and related services, such as ANC, TB, cervical cancer, PrEP and routine clinical services, affecting	Malawi's policy does not allow user fees to be charged for HIV services. GOM to expand SLA to include new elements of HIV services including TB treatment, cervical cancer screening and treatment, and GBV services at CHAM facilities where user

[5] Guidelines on HIV self-testing and partner notification. Supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization, 2016 https://www.who.int/hiv/pub/self-testing/hiv-self-testing-guidelines/en/

[6] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization; 2015 (http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en).

	access to HIV testing and treatment and prevention.[7]	fees for these services exist.
	10. OUs assure program and site standards are met by integrating effective quality assurance and Continuous Quality Improvement (CQI) practices into site and program management. CQI is supported by IP work plans, Agency agreements, and national policy.[8]	CQI will remain an integral approach to identifying and addressing bottlenecks that hamper Malawi's progress towards achieving and sustaining epidemic control.
	11. Evidence of treatment and viral load literacy activities supported by Ministries of Health, National AIDS Councils and other host country leadership offices with the general population and health care providers regarding U = U and other updated HIV messaging to reduce stigma and encourage HIV treatment and prevention.	U=U messaging is integrated into the Faith and Community Initiative component of Finding Men messaging. PEPFAR Malawi is supporting national treatment literacy campaigns including funding for CSO demand creation and coordination via NAC. Rewriting the treatment narrative can improve viral load coverage and suppression, and bring patients back to care to increase TX_CURR.
	12. Clear evidence of agency progress toward local, indigenous partner direct funding.	COP20 includes three new government-to-government agreements with NAC, MOH, and MOF to increase government capacity to implement and deliver HIV services. Over $1M is being allocated to civil society organizations to support community led monitoring and implementation.
	13. Evidence of host government assuming greater responsibility of the HIV response including demonstrable evidence of year after year increased resources expended.	Through willingness to pay agreements as part of the Global Fund application process and investments in human resources for health via CHAM, the GOM continues to demonstrate an increasing commitment to investing in the HIV response. Malawi is expected to meet its Global Fund 2020-2022 co-financing requirement of $76,940,862.
	14. Monitoring and reporting of morbidity and mortality outcomes including infectious and non-infectious morbidity.	PEPFAR Malawi is using EMRS and active tracing systems for PLHIV who missed their appointments or defaulted from care to monitor morbidity and mortality outcomes. Mortality surveillance is being expanded through the national civil registration and vital statistics (CRVS) program. 12 out of the 28 districts will be covered by mortality surveillance as part of CRVS by end of FY20.

[7] The practice of charging user fees at the point of service delivery for HIV/AIDS treatment and care. Geneva: World Health Organization, December 2005

	15. Scale-up of case-based surveillance and unique identifiers for patients across all sites.	National policy on using the national ID in health is being tested as part of the EMR rollout.

In addition to meeting the minimum requirements outlined above, it is expected that Malawi will consider all the following technical directives and priorities:

Table 10. COP/ROP 2021 (FY 2022) Technical Directives

OU –Specific Directives
1. In collaboration with the Global Fund, complete the needed KP size estimates IBBS survey and prioritize needed PrEP, TPT and viral load commodities.
2. Complete the MPHIA.
3. Aggressively scale up access to and use of PrEP for KPs, AGYW (including DREAMS beneficiaries – see below), SDCs, and PBFW by implementing demand creation activities and employing differentiated service delivery models at both the facility and community levels.
4. Create efficiencies in the VMMC program; three agencies cannot each fund the same VMMC partner in COP21.
5. Implement a new and refocused strategy to increase case finding, treatment retention and viral load suppression among pediatrics, adolescents and men, specifically ensuring the expected shift from PITC to quality index testing is fulfilled, and interrupting transmission in these priority groups.
6. Continue focusing on retention efforts to ready the national response supported by PEPFAR to focus on surveying epidemic control in COP21. In COP20 and into COP21, the pivot to site-level work in COP20 must continue to ensure we retain clients in care, and that viral load suppression monitoring becomes a routine expectation of clients.
7. Expand the concept of family-centered and family care models used in COP 19 and 20 to deliver patient-centered care, leveraging our OVC, VMMC, DREAMS programs as access points into the family for improved outcomes – see bullet below
8. Resume Recency testing and promote HIVST in all HIV prevention programs, including secondary distribution to contacts of index clients and primary distribution targeting men at hot spots.
9. As appropriate, redirect funding to support effective peer-led community monitoring and service delivery where it is proving more effective than facility-based services to reach high-risk groups. This strategy should be amplified in all our KP programming.
Other Government Policy or Programming Changes Needed
• Work to create a long-term plan for government financing and sustainability. By the end of the first quarter of COP21, in conjunction with the Government of Malawi, civil society, the Global Fund CCM and other collaborating partners, the PEPFAR team will develop a review of functional and financial barriers to local responsibility for HIV epidemic control with the goal of producing an actionable plan to increase the sustainability of the HIV response. • As Malawi reaches epidemic control, it is appropriate that the team leverage accessibility to the "family" through programs offered via our OVC program, and use the VMMC and DREAMS platforms to meet client needs as laid out in the COM letter. These additional entry points to the family present a pathway to provide an integrated multi-sector support for the wellbeing of our clients.

COP/ROP 2021 Technical Priorities

Client Centered Treatment Services

COP21 planning must ensure treatment continuity for all current and new clients. To do this, programs must specifically and thoroughly address the challenge of interrupted antiretroviral treatment, especially after initiating ARVs and through young adulthood. Maintaining epidemic control, as measured by the proportion of PLHIV with viral suppression, will require long-term, continuous adherence to ART for an adult population that is asymptomatic— and for whom HIV treatment is easily interrupted by drug side effects, inconvenience, lack of time, poor customer service, stigma and discrimination, or life circumstances. Maintaining long-term viral suppression necessitates planning and implementing services that are free, fit the lives of the clients, and empower clients to on ART to stay the course. PEPFAR requires development and full implementation of key client-centered policies and practices at the site-level, including client education on the benefits of lifelong treatment, optimized treatment (dolutegravir-based therapy) and multi-month dispensing, convenient and safe ARV access arrangements, and community and client participation in design and evaluation of services.

Pediatric- and Adolescent-Centered Services

In COP21, PEPFAR programs are required to demonstrate improvement in pediatric case finding, including safe and ethical index testing, to close HIV treatment gaps across age and sex bands. Programs must move forward with the introduction and broad use of pediatric DTG formulations in FY21 (COP20), with full implementation expected to occur during the first quarters of FY22 (COP21). Programs need to further advance pediatric- and adolescent-specific continuity of treatment programming, including age-appropriate differentiated models of care and leveraging bidirectional synergies with clinical and OVC implementing partners. OUs must develop a comprehensive plan to achieve ≥ 90% viral load coverage and viral load suppression across all age and sex bands. To further reduce morbidity and mortality, clinical programs should include an evidence-based advanced HIV disease package of care for children and adolescents.

Community-led Monitoring

In COP 21, all PEPFAR programs are required to develop and support and fund a community-led monitoring activity through State Department Ambassador's small grants in close collaboration with independent, local civil society organizations and host country governments. Collaboration with community groups, civil society organizations and patients/beneficiaries can help PEPFAR programs and health institutions diagnose and pinpoint persistent problems, challenges, and barriers to effective service and client outcomes at the site level.

Pre-Exposure Prophylaxis (PrEP)

In COP 2021, PrEP should continue to be made widely available with a focus on getting PrEP, (including possible new PrEP options) to the people that need it. Groups to be prioritized for PrEP include HIV negative partners of index cases key populations including sex workers, men who have sex with men, transgender persons, people in prisons and other closed settings, people who inject drugs, adolescent girls and young women and, pregnant and breastfeeding women, in areas with high HIV incidence or with higher risk partners, and other identified serodifferent couples. Groups should be tailored to the OU's epidemic context.

TB/HIV

TB/HIV services must be integrated, including DSD and MMD models for both TB and TB preventive treatment (TPT). All PLHIV must be routinely screened for TB and have access to molecular diagnostic testing and/or point of care tests such as LF-LAM. TPT is considered routine HIV care, and all country programs must have offered TPT to all PLHIV on treatment by the end of COP21; targets have been set

accordingly. Countries should budget for full coverage, and plan to use optimal regimens (3-HP) as supply allows.

Advanced HIV disease

The advanced disease package of care should be fully integrated into clinical care and includes diagnostics and therapeutics for tuberculosis and cryptoccal meningitis as well as cotrimoxazole. Countries should budget adequately for commodities including urinary LAM, CrAg, amphotericin B and flucytosine. Please see section 6.5.2 of the COP guidance.

DREAMS

DREAMS funding is allocated within your COP 2021 planning level and must be used exclusively for the goal of HIV Prevention among adolescent girls and young women (AGYW) in DREAMS SNUs in accordance with all DREAMS and COP 2021 Guidance. In addition to ensuring that all DREAMS beneficiaries complete the core package of relevant services, priorities for COP21 DREAMS implementation include systematically identifying and engaging AGYW that are most vulnerable to HIV acquisition; particularly pregnant AGYW and those who are mothers; improving the package of economic strengthening services offered to AGYW (including exploring potential job opportunities through PEPFAR); ensuring evidence-based curricula are implemented with quality and fidelity; enhancing mentoring selection, training, compensation and supportive supervision processes; and accelerating PrEP uptake for AGYW in DREAMS SNUs.

Additionally, PEPFAR Malawi should:

- Scale-up PrEP in DREAMS districts.
    - PrEP uptake among AGYW remains low and needs to be scaled-up.
    - Per the DREAMS narrative, Ministry of Health is yet to approve the PrEP implementation guidelines, which this has delayed PrEP implementation.
    - Of the three DREAMS districts, only Blantyre reported on PrEP_NEW due to the PrEP demonstration project. In FY20, 26 AGYW aged 15-19 years and 89 20-24-year-old AGYW were initiated on PrEP.
- Focus on improving layering and program completion rates among AGYW enrolled in the DREAMS program and continue to prioritize offering comprehensive economic strengthening models to bridge AGYW aged 15-24 years to wage-employment or entrepreneurship opportunities.
- Continue to expand gender norms change intervention in DREAMS, improve the quality of post-violence care and adolescent friendly health services, and scale-up interventions and best practices from the Justice for Children component of the Faith and Community Initiative. With a focus on identifying/reaching sexual violence survivors with timely services, including PEP; and also, specific efforts to identify and reach 10-14-year-old survivors of violence.

OVC

To support the Minimum Program Requirement described above, in COP21 clinical sites and OVC implementing partners should jointly develop formal relationships, such as a memoranda of understanding (MOU), outlining the roles and responsibilities of each member of the multi-disciplinary care team and addressing key issues such as bi-directional referral protocols, pediatric case finding, case conferencing, shared confidentiality, joint case identification, and data sharing. In high volume clinics within high burden SNUs, at least 90% of children (<age 19) in PEPFAR-supported treatment sites should be offered enrollment in OVC programs. OVC staff placed in clinics (e.g., as linkage coordinators, case managers, etc.) should have the capacity to assess child and family needs (including food and economic security) and to offer appropriate referrals. PEPFAR-supported treatment clinicians should play a key role in training OVC community case workers to build their knowledge in areas such as adherence,

retention, and disclosure. PEPFAR Malawi should build upon its psychosocial support model to ensure that this directive is achieved.

VMMC

Funds have been provided to conduct VMMC for males 15 years or older. The team is reminded of the revised guidance which allows surgical VMMC for those 15 or older. While Shang ring may be considered for those below age 15 with headquarters approval, it should be limited to those age 13 or above who are able to understand the procedure and provide informed consent, along with parental consent as dictated by local laws. All VMMC providers must adhere to the requirements for reporting of Notifiable Adverse Events.

Cervical Cancer Screening and Treatment:

Funding for cervical cancer screening and treatment of pre-invasive lesions. The target for screening must be equal to half of the TX_CURR for women age 25-49. All teams performing cervical cancer screening must adhere to the PEPFAR screening guidance and report into the cervical cancer MER indicators. Basic treatment should be available for pre-cancerous lesions at the site of screening except under exceptional circumstances. All sites performing screening should establish clear referral mechanisms for patients needing treatment not available on site such as LEEP or evaluation for potential invasive cancer. Patient referral between sites should be facilitated and outcomes of the referral tracked to assure appropriate treatment and to allow reporting of results.

Condoms and Lubricants

Condoms are key to a successful combination HIV prevention approach and are a cost-effective tool for preventing other sexually transmitted infections and unintended pregnancies. PEPFAR's goal is to ensure high levels of use, equitable access to, and sustained demand for condoms and lubricants among key and priority populations and low-income groups. In COP21, through the Condom Fund, GHP-USAID will provide $20.3 million in assistance to PEPFAR-supported countries to procure and deliver condoms and lubricants to address key condom supply and demand issues This funding is in addition to funds allocated for condom programming and additional condom/lubricant procurement in each country from COP21 country funding as determined during the COP planning process.

Malawi will have access to **$785,000** from the Condom Fund in COP21/FY22, contingent upon adequate justification of need. Coordination with other donors that provide commodities, including the Global Fund, is also critical and expected. The process for estimating your country's total condom and lubricant need is outlined in the COP21 guidance. Among other items, this justification should include an outline of how Malawi will support condom programming in FY22 with funds from your base COP21, the Condom Fund, the GF and/or other donors, and the host-country government. Please note that in FY22 there will also be limited funding available to cover unexpected or emergency condom and/or lubricant requests from PEPFAR-supported countries. Access to these funds will be provided on a first come, first served basis, and OUs will be required to provide a justification for why their special request is being made.

PLHIV Stigma Index 2.0

PEPFAR teams are required to either fund host country PLHIV network-led implementation of the revised PLHIV Stigma Index 2.0 utilizing the standard methodology, or complement Global Fund or other donors financing implementation of the PLHIV Stigma Index 2.0, if it has not already been implemented in the OU. If the revised PLHIV Stigma Index 2.0 has not been previously conducted in the OU, then PEPFAR teams must work with UNAIDS, Global Fund or other donors to ensure its implementation during COP 21, whether supported by PEPFAR or other resources. Completion of the PLHIV Stigma Index 2.0 should be accompanied by a response and action plan discussed and agreed upon by all stakeholders that will address findings. Where the PLHIV Stigma Index 2.0 has already been conducted, COP/ROP 21 focus should be on concerted action to address findings.

Human Resources for Health (HRH) and Sustainability
Using data from the HRH Inventory completed in COP20 Q4, OUs are expected to complete a comprehensive HRH analysis to optimize staffing at the site- and above-site-levels. PEPFAR programs in countries that will be near to or reach 95/95/95 in the COP20 implementation cycle are required to develop and implement plans to sustain their progress and effectively retain clients in quality HIV treatment programs. Results from the Sustainability Index and Dashboard (SID) 2019 should inform the OUs on their progress and gaps related to the policies and technical areas for inclusion in the sustainability plans. Resource alignment data should be used to understand the HIV funding landscape--especially with a more granular understanding of PEPFAR and GFATM investments-- who is paying for what services in order to enhance strategic collaboration and coordination and avoid duplication during the program planning cycle.

Cross-HIS Data interoperability - Use and Analysis
Improved data visibility, and analysis are essential for better understanding the HIV epidemic and reaching epidemic control.

PEPFAR Malawi should 1) consistently and continuously use and analyze data at the individual patient level with aim of program improvement (e.g. use patient level data to understand retention differences across patient cohorts and create more tailored risk models and intervention). 2) utilize available data interoperability solutions to harmonize and triangulate data across EMRs, commodities, pharmacy dispensation, laboratory data, HRH and other data.

Systems Investments
PEPFAR teams are expected to align systems investments with key systems barriers to achieving epidemic control. System investments should also be aligned to achieving and maintaining minimum program requirements for COP including adoption and use of unique identifiers, building country capacity in disease surveillance and other core competencies to achieve and maintain epidemic control including country ability to perform continuous quality improvement. Systems investments that have achieved their goals should be candidates for countries to assume responsibility to achieve the minimum program requirement for increased responsibility and increased government expenditures.

Faith and Community Initiative (FCI)
Building upon PEPFAR's standing principle to ensure "every dollar is optimally focused for impact", OUs with continuing FCI investments should continue implementing best practices in accordance with FCI and COP21 Guidance. Priorities for COP21 FCI implementation for addressing gaps in reaching men and children include: coordination through an Inter-Faith Steering Committee to advance treatment literacy; and decentralized, continuing care through faith-engaged community posts, faith-engaged highly targeted HIV self-testing, and/or community adolescent treatment programs for youth living with HIV.

Menstar:
Despite a significant number of adult men being returned to treatment in FY20, Malawi also experienced interruptions in treatment among men, particularly among the 35-39 years old, in Q3 and Q4, and in particular, in Q4, at greater than 3 months after initiation for all adult men as opposed to women, who experienced interruptions in treatment at less than 3 months. Overall returns to treatment were fairly similar when comparing males to females in Q4, although given a greater risk of interruptions among men, we suggest implementing interventions that specifically target men for return to treatment. As such, we recommend leveraging Menstar approaches, especially focused on men 35-39 years old. In particular, Malawi should utilize Menstar to focus on interventions for men already on treatment, including those that have already disengaged from treatment. Using Menstar, your program should implement a core basic package of services that meet men where they are with what they need. Please see Menstar

resources on SharePoint (https://pepfar.sharepoint.com/sites/MenStar), including the Menstar Strategy, Operational Guidance, and Compendium, for recommended strategies, interventions, and examples.

Innovative solutions and adaptive practices
There are extraordinary examples of innovation by our field teams and partners during COVID. These include adaptations and lessons learned that span across many of our technical and program areas as well as all countries we work in. Teams should look at ways to strengthen and improve our capacity to innovate, design, and create within the communities we serve. This includes systematically looking at the evidence base and how to learn from these examples as well as strengthen our methods to help scale proven strategies and interventions.

Supply Chain
PEPFAR Malawi should increase data visibility and decrease risk of supply chain through proactive monitoring and mitigation: PEPFAR will improve effectiveness of supply chains and proactively monitor and mitigate supply chain risks through audits and security assessments; based on expanding OpenLMIS that will allow for improved data use and triangulation and introducing GS1 serialization for tracking and tracing of HIV commodities. In COP 21, PEPFAR will support expansion of direct data entry sites from the expected 260 to close to half of the 740 ART sites. PEPFAR will also support implementation of GS1 standards following completion of Product Master list and National Product Catalogue (NPC) which are catalytic for tracking and tracing. PEPFAR Malawi should also advance and promote sustainable supply chain strategies for procurement, warehousing, and distribution of HIV commodities: In COP 21, PEPFAR will continue supporting the reintegration of parallel supply chains together with other donors and ensure the Government of Malawi takes an overseeing role for supply chain services and leverage private sector competencies.

COP/ROP 2021 Active Engagement with Community and Civil Society (see section 2.5.3 of COP Guidance)

The full participation of community stakeholders and civil society in every stage of PEPFAR programming, planning, and monitoring as appropriate and consistent with applicable law, regulations and policy, from advocacy to service delivery, is critical to the success and sustainability of PEPFAR and the global effort to combat HIV. Sustained control of the HIV/AIDS epidemic necessitates that PEPFAR teams actively and routinely coordinate and communicate with all partners, including local, regional and international civil society and community stakeholders, multilateral partners and the host country government.

As in years past, civil society organizations are considered essential and invited to participate both in the virtual COP21 strategic planning meetings, as well as virtual approval meetings. .

This engagement, of both civil society, and of faith-based organizations/faith communities, specifically includes the sharing of FY 2020 Q4 and FY 2020 APR results and analyses and the convening of an in-country planning retreat with local stakeholders during the last two weeks of January 2021 in order to introduce and discuss all COP 2021 tools, guidance, results and targets as well as the proposed trajectory and strategy for COP 2021. The PEPFAR investments to support the national response must be planned intentionally with the Global Fund with teams demonstrating how complementarity was achieved to ensure maximal impact on the HIV/AIDS epidemic is achieved.

In February and March 2021, PEPFAR will convene virtual meetings where outstanding decisions will be discussed and finalized. In addition to host-country representatives, the meetings will also include representatives from local and international civil society and community organizations, faith-based

organizations/faith communities, and multilateral partners. Specific guidance for the 2021 virtual meeting delegations will be provided separately.

Engagement with all stakeholders is required beyond the meetings and throughout COP 2021 development, finalization, and implementation. As in COP 2020, the draft Strategic Direction Summary (SDS) and Data Pack are required to be shared with both CSO and FBO stakeholders for their input and comments at least 48 hours prior to submission of these materials to the Embassy Front Office. Please refer to the COP 2021 Guidance for a full list of requirements and engagement timelines.

APPENDIX 1: Detailed Budgetary Requirements

Care and Treatment (C&T): OU's COP 2021 minimum requirement for the C&T earmark is reflected in Table 2. If there is no adjustment to the CO 2021 new funding level due to an adjustment in applied pipeline, countries must program to the full Care and Treatment earmark amount across new FY 2021 GHP-State and GHP-USAID funding. The Care and Treatment earmark will be calculated as the sum of the following:

- 100% Care and Treatment (C&T) Program Areas
- 50% Testing (HTS) Program Areas
- 100% Above Site Program: Laboratory System Strengthening
- 70% Pregnant and Breastfeeding Women Beneficiary Group
- Proportional % Program Management (Proportional Program Management will vary by mechanism and will be determined by the amount of other interventions at the mechanism that count towards the C&T earmark)

Orphans and Vulnerable Children (OVC): OU's COP 2021 minimum requirement for the OVC earmark is reflected in Table 2. Countries must program to the full OVC earmark amount across new FY 2021 GHP-State and GHP-USAID funding. The OVC earmark will be calculated as the sum of the following:

- 85% (DREAMS initiative funding — commodities planned under DREAMS initiative — Any HTS interventions planned under DREAMS initiative — Any C&T intervention planned under DREAMS initiative)
- 100% (OVC Beneficiary group funding — commodities planned under any intervention with OVC beneficiaries — Any HTS planned under interventions with OVC beneficiaries
- Proportional Program Management (Proportional Program Management will vary by mechanism and will be determined by the amount of other interventions at the mechanism that count towards the OVC earmark)

Abstinence, Be Faithful/Youth (AB/Y) Reporting Requirement: If AB/Y-programmed activities do not reach a 50 percent threshold of all sexual prevention funding, as calculated by the formula below, in any country with a generalized epidemic, S/GAC is required to report to the appropriate Congressional committees on the justification for the decision. In such cases, teams should provide brief justifications and explain the rationale for prevention programming decisions given the epidemiologic context, contributions of other donors, and other relevant factors. The written justifications should be uploaded as 'Budgetary Requirements Justification' to the document library of FACTS Info.

Abstinence, Be Faithful/Youth (AB/Y) programming, formerly captured in the HVAB budget code, will now be captured by using a combination of prevention program areas and beneficiaries, which are identified in the formula below. The numerator captures those interventions that are Abstinence, Be Faithful/Youth (AB/Y) programming, and the denominator approximates all sexual prevention activities. The proportion of Abstinence, Be Faithful/Youth (AB/Y) programming as a proportion of all sexual prevention activities is calculated by dividing the numerator by the denominator:

Numerator

Prevention: primary prevention of HIV and sexual violence

(For OVC, OVC caregivers, young people and adolescents, children, young women and adolescent females, girls, young men and adolescent boys, and boys)

+

Prevention: community mobilization, behavior, and norms change

(For OVC, OVC caregivers, young people and adolescents, children, young women and adolescent females, girls, young men and adolescent boys, boys, adults, not disaggregated)

Denominator

Prevention: primary prevention of HIV and sexual violence (all populations)

+

Prevention: community mobilization, behavior, and norms change (all populations)

+

50 % Prevention: Not disaggregated (all populations)

Gender Based Violence (GBV): OU's COP 2021 minimum requirement for the GBV earmark is reflected in Table 2. Your GBV earmark requirement is calculated as the total **new FY 2021** funding programmed to the GBV cross-cutting code. Your COP/ROP 2021 earmark is derived by using the final COP 2020 GBV earmark allocation as a baseline. The COP 2021 planned level of new FY 2021 funds for GBV can be above this amount; however, it cannot fall below it.

Water: OU's COP 2021 minimum requirement for the water earmark is reflected in Table 2. Your water earmark requirement is calculated as the total **new FY 2021 funding** programmed to the water cross-cutting code. Your COP 2021 earmark is derived by using the final COP 2019 water earmark allocation as a baseline. The COP 2021 planned level of new FY 2021 funds for water can be above this amount; however, it cannot fall below it.

Transitioning HIV Services to Local Partners: To sustain epidemic control, it is critical that the full range of HIV prevention and treatment services are owned and operated by local institutions, governments, and organizations – regardless of current ARV coverage levels. The intent of the transitioning to local partners is to increase the delivery of direct HIV services, along with non-direct services provided at the site, and establish sufficient capacity, capability, and durability of these local partners to ensure successful, long-term local partner engagement and impact. This action is a priority for all OUs, Regional Programs and Country Pairs. PEPFAR has set a 70% goal **by agency** by the end of FY21 and must meet 40% by FY20. Each country has to contribute to this goal based on the context of the local partner mix and types of public and private partners available to provide essential services. Therefore, each OU agency should work with their respective agency HQ in determining their contribution in meeting the agency level local partner requirement for FY21 as appropriate through their COP 2020 submission.

State ICASS: Table 3 shows the amount that the OU must program under State for ICASS Costs.

COP/ROP 2021 Applied Pipeline (See Section 9.1.2 Applied Pipeline of COP Guidance)

All agencies in Malawi should hold a **3-month pipeline** at the end of COP 2021 implementation whenever possible to ensure sufficient funds and prevent disruptions in service delivery in the event of funding delays. If an agency/OU combination has a history of over-outlays, or in cases where an agency/OU COP envelope has increased in recent years, there may not be sufficient funding to maintain a 3-month buffer. Any agency that anticipates ending COP 2020 implementation (end of FY 2021) with a pipeline in excess of 3 months is required to apply this excessive pipeline to COP 2021, decreasing the new funding amount to stay within the planning level.