Tab 1—Determination and Findings (D&F)—Authorization for Use of Other than Full-and-Open Competition in the Award or Modification of Contracts Funded under the President's Emergency Plan for AIDS Relief

1. <u>U.S. Agency for International Development (USAID).</u>

Pursuant to the authority set forth in Section 706.302-70(b)(3)(ii) of USAID's Acquisition Regulation (AIDAR), I have determined that it is necessary to provide for the following exceptions to competition in the award and modification of contracts in support of activities and programs USAID manages under the President's Emergency Plan for AIDS Relief (PEPFAR) to avoid the impairment of U.S. foreign-assistance and foreign-policy objectives. I make this determination in consideration of the supporting findings set forth below, and it will remain in force and effect from this date through December 31, 2024.

2. <u>The nature and/or description of the action being approved.</u>

As a matter of law and policy, USAID's normal practice is to follow full-and-open competition in the award of contracts and in instances in which a proposed modification to an existing contract triggers competition requirements. However, in exceptional circumstances, these interests must give way to the overriding objective of providing life-saving interventions on a timely basis. Renewal of this authorization for exceptions to full-and-open competition is necessary to provide the flexibility that is essential to USAID's ability to implement activities under PEPFAR in a timely and vigilant manner in the context of new and ambitious targets and shifting mandates and priorities.

This authorization covers activities under PEPFAR financed from all sources, including funds accepted by USAID under gift authority and prior-year funding and appropriations from the current and future Fiscal Years, whether appropriated directly to USAID or transferred from another Federal Department or Agency, unless Congress enacts special rules for these appropriations. This action authorizes the award of new contracts by using other than full-and-open competition procedures. It also authorizes non-competitive modifications to existing contracts for additional work similar to that performed under the initial contract. Authorization of the use of other than full-and-open competition is necessary, given the urgent and overwhelming needs that come from the ambitious targets set for the treatment and prevention of HIV/AIDS under PEPFAR, the vast quantity of resources dedicated to these interventions, and the shifting strategies and priorities of the U.S. Government and the governments of the countries in which we fund HIV/AIDS programs. Expeditiously providing assistance in the most-responsive manner possible takes priority over other options that would delay such assistance, especially where delay or inflexibility could compromise USAID's ability to provide life-saving medicines and treatment to those affected by HIV/AIDS to meet PEPFAR's targets.

3. <u>Citation of the appropriate statute and/or regulation upon which the D&F is based.</u>

Under Section 113(e)(2) of Title 40 of the United States Code (USC), competition requirements shall not impair or affect the authorities of an Executive Branch Department or Agency with respect to "any program conducted for purposes of ... transfer to foreign governments, or foreign aid, relief or rehabilitation." USAID has implemented this provision through Section 706.302-70(b)(3)(ii) of Title 48 of the Code of Federal Regulations (CFR), which provides an exception to competition for "awards for countries, regions, projects, or programs for which the Administrator of USAID makes a formal written determination with supported findings that compliance with full-and-open competition procedures would impair foreign assistance objectives, and would be inconsistent with the fulfillment of the foreign assistance program."

Under Section 706.302-70(c)(2) of Title 48 of the CFR, determinations under the authority used herein will not be subject to the requirement for certification by a Contracting Officer or approvals in accordance with Subpart 6.304 of the Federal Acquisition Regulation (FAR).

4. <u>Findings that detail the particular circumstances, facts, or reasoning</u> <u>essential to support the determination</u>. Necessary supporting documentation <u>shall be obtained from appropriate requirements and technical personnel</u>.

While it is impossible to list all of the circumstances that justify the use of this authorization, the following are some of the most-common situations in which it continues to be necessary, and examples of how the Expedited Procedures Package (EPP) of which this authorization in a part, has supported U.S. foreign-assistance objectives:

First, bilateral PEPFAR portfolios at times experience the need to extend existing contracts beyond their present scope to bridge gaps between existing activities and programs and the establishment of new ones. Indeed, the continuation of treatment regimens such as anti-retroviral (ARV) medication is of utmost importance during programmatic changeovers and transitions. Expedited procedures that authorize the extension of programs beyond their present scopes of work will enable USAID to maintain treatment regimes, patient relations, information systems, and other programmatic components while advancing the goals of PEPFAR. In one example, the USAID Mission in the Republic of Zambia used the EPP to increase and extend a contract to continue providing critical prevention and treatment for HIV in six of Zambia's ten Provinces after the openly competed follow-on award was protested, which caused an unanticipated delay of more than six months. The EPP allowed the Mission to extend the prior contract rapidly to ensure continued coverage of essential care and prevent serious disruption in Zambia's progress toward epidemic control. In the absence of this authority, the Mission would have been unable to extend the contract, or would have faced severe delays in extending it, which would have resulted in a gap in care that could have cost lives as well as wasted financial and managerial resources.

In addition, as funding levels for newly emerging priority areas change and programs expand under PEPFAR, USAID often uses existing contracts to meet the demand, which sometimes exhausts the available approved Total Estimated Cost of an award years before its original completion date. When this happens, stopping programs prematurely or re-competing an award is not necessarily in the best interest of USAID, PEPFAR, or U.S. foreign policy, and USAID needs the tools to respond flexibly and conduct expedited procurements. When such rapid changes are necessary, existing contractors might not be able to absorb all of the allocated funding or demand, and a Mission or the Bureau for Global Health might need to add new activities and contractors in an urgent manner.

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Moreover, as priorities under PEPFAR continue to evolve, significant and unanticipated changes can occur in the supplies and services needed to carry out activities and initiatives. Several programs under PEPFAR countries are transitioning the delivery of care and other programmatic components to local institutions, When the schedules for such transitions experience delays and modifications, USAID's programs need the flexibility to fill gaps and provide technical assistance to ensure the sustainability of investments under PEPFAR. For example, the USAID Mission in the Socialist Republic of Vietnam used the EPP to allow one contractor to continue its work in shifting the financing of HIV programs, including ARVs, to the host government. A two-year, sole-source contract allowed the Mission to engage the most-qualified contractor efficiently, by building on previous investments to ensure no disruption took place during this pivotal stage in the Journey to Self-Reliance.

As PEPFAR programs rapidly scale up and their technical priorities shift, USAID's Mission often require commensurate shifts in their staffing to ensure adequate oversight of U.S. foreign-assistance investments. In many instances, the rapid expansion and re-organization of staffing is required to meet demands set forth by the Office of the U.S. Global AIDS Coordinator (OGAC). While following standard contracting procedures for Personal Services Contracts (PSCs) could take up to one year, the use of restricted competition to issue PSCs allows Missions to obtain the services of new qualified staff and/or adjust existing staff in an expeditious manner to support programming under PEPFAR. By facilitating the alignment of staff technical skills with evolving technical priorities, the EPP allows USAID to ensure our programs remain at the forefront of global efforts to reach epidemic control.

Other urgent or critical situations could arise in which it might be necessary to rely on this authority. The EPP provides the flexibility necessary for Missions to respond most appropriately to these situations, without undue procedural constraints that would negatively affect program results. For example, OGAC provided additional funding to the PEPFAR programs in South Africa to implement an "HIV Treatment Surge Plan" to reach epidemic control by 2020. OGAC subsequently declared that country's epidemic to be in a heightened "state of emergency," and demanded an urgent and transformative response, including the more-efficient use of contracts, and the expansion of high-performing awards. The EPP permitted rapid reallocations of hundreds of millions of dollars, the prompt

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implementation of unexpected surge funding, and efficient revisions to major awards for the care and treatment of HIV to respond to OGAC's requirements.

Finally, this authorization furthers the Journey to Self-Reliance by allowing USAID to limit solicitations to a specific type of entity (*e.g.*, local partners) and to diversify the contractors that implement programs in a geographic area.

5. <u>A determination, based on the findings, that the proposed action is</u> justified under the applicable statute or regulation.

I have determined that it continues to be critical to the objectives of PEPFAR that USAID be able to maintain flexibility to respond rapidly and effectively to the HIV/AIDS pandemic and to save lives. Since President George W. Bush launched PEPFAR in 2003 as an emergency response to HIV, substantial progress has taken place controlling the epidemic; however, the urgency in the U.S. Government's response to the pandemic remains. Understanding that we can best control HIV by pivoting to a data-driven approach that targets geographic areas and populations strategically to achieve the most impact for our investments, PEPFAR 3.0 is increasingly data-driven, from the national level down to the most-granular site level, to guide programmatic decision-making and solidify sustainability and quality. To be responsive, it is imperative that assistance can flow rapidly to the area where it is needed most, with the most-effective interventions. The timeframe required by fully competitive award procedures, if followed, will not enable USAID to act in a manner consistent with U.S. foreign policy. The magnitude of the HIV/AIDS pandemic and the need for urgent assistance, coupled with the anticipated continuing high levels in authorized funding and the continued need to reach targets set by the Administration and Congress, necessitate the availability and use of expedited procedures. In light of such needs, the use of the cited authorities to expedite acquisition on a case-by-case basis will provide the flexibility to implement PEPFAR programs effectively. Failure to do so will result in an impairment of the U.S. Government's foreign-assistance objectives.

6. Expiration date of the D&F, if required.

This D&F is effective through December 31, 2024.

7. <u>The signature of the official authorized to sign the D&F and the date</u> signed.

In accordance with Section 706.302-70(b)(3)(ii) of the AIDAR , as Administrator of USAID I am the appropriate official to sign this class D&F.

Administrator Mark A Green

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Tab 2—Blanket Determination for Restricting Eligibility in the Award or Amendment of Assistance Instruments

Consistent with the Federal Grant and Cooperative Agreement Act of 1977, the U.S. Agency for International Development (USAID) encourages unrestricted competition in the award of discretionary grants and cooperative agreements. USAID's policy regarding these assistance awards requires unrestricted competition unless one of the justifications to restrict eligibility set forth in Chapter 303 of the Agency's Automated Directives System (ADS), Grants and Cooperative Agreements to Non-Governmental Organizations, applies and is documented in accordance with that Chapter.

However, in exceptional circumstances, these interests must give way to the overriding objective of providing life-saving interventions on a timely basis. The previous Expedited Procedures Package (EPP) for HIV/AIDS included a blanket authorization to restrict eligibility in the award or amendment of grants and cooperative agreements based on the critical objectives of the foreign-assistance program, as set forth in ADS Chapter 303, typically for specific blanket justifications for a class of awards, and for a particular purpose or period of time.

On December XX, 2019, USAID published revisions to the restricted eligibility guidance in ADS Chapter 303. The authority to restrict eligibility now depends on either programmatic purposes or certain pre-approved conditions, including an award made under an Administrator-approved blanket determination or justification to restrict eligibility for an approved class of awards. Accordingly, a determination to restrict eligibility when critical to the objectives of a foreign-assistance program is a valid basis for such a blanket justification.

Pursuant to ADS Chapter 303, I have determined that it is necessary, to support critical foreign-policy objectives, to allow for restricted eligibility in the award or amendment of grants and cooperative agreements in support of USAID's management of activities and programs under the President's Emergency Plan for AIDS Relief (PEPFAR), and that no other exception in ADS 303 Chapter applies. I base this authorization on the justifications set forth below, and it applies to all forms of restricted eligibility, including: (1) a funding opportunity limited to a specific type of entity or that otherwise narrows the pool of applicants that may compete for a grant or cooperative agreement; and, (2) an award or other assistance action that is limited to one or a limited number of recipients.

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This authorization covers activities under PEPFAR financed from all sources, including funds accepted by USAID under gift authority and prior-year funding and appropriations from the current and future Fiscal Years, whether appropriated directly to USAID or transferred from another Federal Department or Agency, unless Congress enacts special rules for these appropriations.

Justification

I have determined that it continues to be critical to the objectives of PEPFARthat USAID be able to maintain flexibility to respond rapidly and effectively to the HIV/AIDS pandemic and to save lives. Since President George W. Bush launched PEPFAR in 2003 as an emergency response to the HIV epidemic, substantial progress has taken place in controlling the epidemic; however, the urgency in the U.S. Government's response to the pandemic remains. Understanding that we can best control HIV by pivoting to a data-driven approach that targets geographic areas and populations strategically to achieve the most impact for our investments. PEPFAR 3.0 is increasingly data-driven, from the national level down to the mostgranular site level, to guide programmatic decision-making and solidify sustainability and quality. To be responsive, it is imperative that assistance can flow rapidly to the area where it is needed most, with the most-effective interventions. The timeframe required by fully competitive award procedures, if followed, will not enable USAID to act in a manner consistent with U.S. foreign policy. The magnitude of the HIV/AIDS pandemic and the need for urgent assistance, coupled with the anticipated continuing high levels in authorized funding and the continued need to reach targets set by the Administration and Congress, necessitate the availability and use of expedited procedures. In light of such needs, the use of this authorization to expedite the issuance of grants, cooperative agreements, and other assistance instruments on a case-by-case basis will provide the flexibility to implement PEPFAR programs effectively. Failure to do so will result in an impairment of the U.S. Government's foreign-assistance objectives.

While it is impossible to list all of the circumstances that justify the use of this authorization to restrict eligibility in the award and amendment of grants, cooperative agreements, and other assistance instruments under PEPFAR, the following are some of the most-common situations in which it continues to be necessary, and examples of how the Expedited Procedures Package (EPP) of which this authorization in a part, has supported U.S. foreign-assistance objectives:

- Bilateral PEPFAR portfolios at times experience the need to extend existing assistance awards beyond their present scope to bridge gaps between existing activities and programs and the establishment of new ones. Indeed, the continuation of treatment regimens such as anti-retroviral (ARV) medication is of utmost importance during programmatic changeovers and transitions. Expedited procedures that authorize the extension of programs beyond their present scopes of work will enable USAID to maintain treatment regimes, patient relations, information systems, and other programmatic components while advancing the goals of PEPFAR. Several programs under PEPFAR are transitioning the service delivery of care and other programmatic components to local institutions. When the schedules for such transitions experience delays and modifications, USAID's programs need the flexibility to fill gaps and provide technical assistance to ensure the continuity of care for patients and the sustainability of investments under PEPFAR.
- In addition, as funding levels for newly emerging priority areas change and programs expand under PEPFAR, USAID often uses existing implementers of assistance to meet the demand, which sometimes exhausts the available approved Total Estimated Amount of an award years before its original completion date. When this happens, stopping programs prematurely or re-competing an award is not necessarily in the best interest of USAID, PEPFAR, or U.S. foreign policy, and USAID needs the tools to respond flexibly and conduct expedited procurements. When such rapid changes are necessary, existing implementers might not be able to absorb all of the allocated funding or demand, and a Mission or the Bureau for Global Health might need to add new activities and recipients of funding in an urgent manner. For example, when research indicated that Zambian men and adolescents were reluctant to engage with public-sector health hospitals and clinics, the Mission needed to support a local organization to roll out new approaches rapidly through the private sector.
- As PEPFAR's priorities continue to evolve, significant and unanticipated changes in programs are needed to carry out activities and initiatives. For example, in one country, two new PEPFAR initiatives announced by the Office of the U.S. Global AIDS Coordinator (OGAC) —one focused on accelerating treatment for HIV/AIDS in children, and one focused on reducing HIV infections among Sub-Saharan African adolescent

girls—required rapid changes in PEPFAR activities. USAID's Missions used the EPP to increase and expand an activity to improve the care and resilience of vulnerable populations, which allowed the recipients to expand their areas of intervention quickly in response to these two new PEPFAR priorities.

• Mandates from OGAC related to the transition to local recipients or to diversify the recipients that implement programs in a specific geographic area also could require limited competition.

Beyond these examples, other urgent or critical situations could arise in which it will be necessary to restrict eligibility in the award or amendment of grants or cooperative agreements for activities under PEPFAR. Renewal of this authorization for exceptions to full-and-open competition is necessary to provide the flexibility that is essential to USAID's ability to implement activities under PEPFAR in a timely and vigilant manner in the context of new and ambitious targets and shifting mandates and priorities.

This authorization will provide the flexibility necessary for USAID's Missions to respond most appropriately to these situations, without undue procedural constraints that would negatively affect program results.

Tab 3—Source-and-Nationality Waiver for Activities and Programs under the President's Emergency Plan for AIDS Relief

In the three previous Expedited Procedure Packages (EPP) for HIV/AIDS, the Administrator approved a source-and-nationality waiver to establish Geographic Code 935 (which includes any source except those prohibited by U.S. law or regulation or otherwise determined to be ineligible for Federal funding) for the procurement of goods and services for activities and programs under the President's Emergency Plan for AIDS Relief (PEPFAR) and previous initiatives against the disease. Those waivers were critical to the ability of the U.S. Agency for International Development (USAID) to ensure the ready availability of services and commodities in the implementation of PEPFAR. Absent this waiver, USAID would experience significant barriers in providing services under PEPFAR in a timely manner and would have to expend significant time and resources to address source-and-nationality issues. For these reasons, we recommend maintaining Code 935as the applicable code for source and nationality code for activities and programs under PEPFAR.

Background

According to Section 228.11 of Title 22 of the Code of Federal Regulations (CFR) and Chapter 301 of USAID's Automated Directives System (ADS), the Principal Geographic Code for procurement of goods and commodities by USAID is Code 937 (the United States, the recipient country, and developing countries other than advanced developing countries, but excluding any country that is a prohibited source). An Executive Branch Department or Agency may authorize source-and-nationality waivers to Code 935 under 228.30(a)(3) of Title 22 of the CFR §based on a determination that such a waiver will "promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives." Departments and Agencies may approve such waivers on a regional, country, or program basis.

The original EPP from 2000 included a source-and-nationality waiver for the procurement of any goods and services procured under the HIV/AIDS and Infectious Disease Strategy, including motor vehicles, but excluding pharmaceuticals (handled by a separate waiver process). The EPP from 2008 also included a source-and-nationality waiver for goods and services procured by USAID in support of USAID's activities and programs under PEPFAR, specifically including motor vehicles, anti-retroviral (ARV) medications, and other

pharmaceuticals. Finally, the EPP from 2014 tailored a source-and-nationality waiver for all goods and services procured in support of USAID's activities and programs under PEPFAR, including restricted and unrestricted commodities.

Recommendation

We recommend that you approve this source-and-nationality waiver for goods and services USAID will procure in support of activities and programs under PEPFAR to allow our Missions and the Bureau for Global Health to implement them in a timely, flexible, and cost-effective manner. Permitting USAID and our PEPFAR implementing partners to use sources under Code 935 would ensure we can procure a sufficient quantity of high-quality goods and services at competitive pricing, which will speed the rapid flow of assistance to the areas where it is needed most. This waiver also would increase the effectiveness of our programs to reach PEPFAR's targets for prevention, care, and treatment and respond to rapidly shifting mandates and priorities from OGAC.

Although other source-and-nationality waivers might cover *some* goods procured for programs funded under PEPFAR, this waiver would apply to *any* goods and services procured in support of activities under PEPFAR, and is thus necessary to meet overall the initiative's overall objectives. Further, although Code 937 includes the recipient country and other developing countries, capacity, quality, and other considerations require that programs under PEPFAR maintain the option to source commodities and services beyond Code 937, on a worldwide basis.

This waiver would make Code 935 fully applicable for procurement at both the prime contract and sub-contract level (including procurements under grants and cooperative agreements). This waiver would cover unrestricted and restricted commodities, including motor vehicles and pharmaceuticals. However, the following rules would apply:

- For pharmaceuticals, this waiver would not obviate the additional approvals for "restricted commodities" required in ADS Chapter 312, including for quality; and
- The purchase of motor vehicles would require additional considerations, as set forth below.

For awards and purchases that rely on this source-and-nationality waiver, the CO or AO should document the applicability of this waiver in each award file in the Agency Security Image and Storage Tracking System (ASIST). This source-and-nationality waiver applies to awards made on or before December 31, 2024, or when the waiver does not apply to an entire instrument, to purchases made on or before December 31, 2024.

Motor Vehicles

The source-and-nationality waiver to Code 935 above covers the purchase of motor vehicles. In addition to the restrictions on source and nationality in Section 228 of Title 22 of the Code of Federal Regulations, Section 636(i) of the Foreign Assistance Act (FAA) of 1961, as amended, requires that USAID-financed motor vehicles be manufactured in the United States, but states that the Agency may waive this requirement based on the existence of "special circumstances." ADS Chapter 312.3.3.2.b.3 further provides that the Administrator may issue blanket waivers for procurement of non-U.S.-manufactured motor vehicles on a regional, country, or program basis if the waiver documents the special circumstances and provides adequate supporting justification. ADS Chapter 312 provides that the "special circumstances" that merit waiving the requirement include, but are not limited to, the following:

- (a) The inability of U.S. manufacturers to provide a particular type of needed motor vehicle;
- (b) The present or projected lack of adequate service facilities and supply of spare parts for U.S.-manufactured motor vehicles in the country or region within a country where the vehicle will be used; or
- (c) An emergency requirement for motor vehicle(s) that can be met in time only by "the purchase of non-U.S.-manufactured motor vehicle(s) and for which no non-USAID funds are available.

The emergency nature of the HIV/AIDS epidemic continues to meet the "special circumstances" requirement in Section 636(i). The approval process for the purchase of non-U.S.-procured motor vehicles adds additional time and costs, which diverts attention and resources from managing critical interventions in prevention, treatment, and care. In most of the areas where USAID is conducting activities under PEPFAR, service and maintenance facilities for U.S.-procured

vehicles are not readily available, and it is difficult or impossible to obtain spare parts for them.

The Agency would keep the overall procurement of non-U.S.-produced motor vehicles w to a minimum. USAID's Missions and implementing partners would have to document a special circumstance for each purchase in the same way they have in the past, according to the procedures set forth in ADS Chapter 312. Specifically, implementing partners must provide, within 90 days after each such purchase, an informational copy of such documentation to the USAID Contracting Officer's Representative/Agreement Officer's Representative to include in the file for the contract or award in ASIST. Your approval of this source-and-nationality waiver constitutes the required finding of a "special circumstance" required for non-U.S.-manufactured motor vehicles under ADS Chapter 312 and Section 636(i) of the Foreign Assistance Act of 1961, as amended.