Protecting Life in Global Health Assistance Six-Month Review February 6, 2018

The information below summarizes the implementation of the Protecting Life in Global Health Assistance (PLGHA) policy through the end of fiscal year 2017, and identifies implementation challenges that have arisen, along with actions to address them.

I. Background on Protecting Life in Global Health Assistance

On January 23, 2017, President Trump issued a Presidential memorandum reinstating the January 22, 2001, Presidential memorandum on the "Mexico City Policy" for family-planning assistance awarded by USAID, and directing the Secretary of State, in coordination with the Secretary of Health and Human Services, to implement a plan to extend the Mexico City Policy to "global health assistance furnished by all departments or agencies" to the extent allowable by law. The expanded policy is referred to as "Protecting Life in Global Health Assistance (PLGHA)."

On May 9, 2017, the Secretary of State, in coordination with Secretary of Health and Human Services, approved the implementation plan for the PLGHA policy. State, working with USAID, HHS, and DoD, committed to conduct a comprehensive review of progress in extending the policy to global health assistance, identify any implementation challenges, and recommend solutions to them. State has worked closely with USAID, HHS, and DoD to implement the policy consistently, examine progress in carrying it out, and monitor its effects.

With less than six months of policy implementation, it is too early to assess the full range of benefits and challenges of the PLGHA policy for global health assistance. State, HHS, DoD, and USAID have been adding a standard provision implementing the policy in new grants and cooperative agreements for global health assistance, and in existing global health assistance grants and cooperative agreements when they receive new funding. Departments and agencies obligated much of the global health assistance funding subject to the policy toward the end of the fiscal year, and not all existing agreements have received new funding, so the picture on progress and challenges is still developing.

The content of this report reflects both internal and external feedback. Each implementing department and agency conducted focus groups or structured conversations with selected internal operating units. USAID spoke with seven management teams at headquarters, as well as four field Missions. HHS spoke with four of its operating divisions that conduct programs to which the policy applies (the Centers for Disease Control and Prevention, the National Institutes of Health, the Health Resources and Services Administration, and the Substance Abuse and Mental Health Services Administration), and conducted focus groups with field staff in two countries. DoD focused its discussions at headquarters, where it awards and manages the majority of its agreements. In addition, in the course of implementing the policy, the Department of State and relevant departments and agencies conducted numerous calls and meetings with operating units, implementing partners, and other stakeholders that contributed to our analysis.

The Department of State requested stakeholder comments on the implementation of the policy to date. Thirty-one stakeholder groups, including three foreign governments as well as non-governmental entities, provided written comments. Of those stakeholder groups, several submitted comments in support of the policy. For example, the United States Conference of Catholic Bishops lauded PLGHA as "one of the most significant policy initiatives on abortion ever taken by the United States in an area of foreign assistance." Others expressed the need for guidance on aspects of the policy, concerns about the continuity of healthcare services, and a potential chilling effect of the policy on global health services in situations in which the application of the policy is unclear.

II. Implementation by U.S. Government Departments and Agencies

As of September 30, 2017, the Department of State (including the Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC)), USAID, HHS, and DoD have taken multiple steps to implement the PLGHA policy. The interagency developed a common PLGHA standard provision for relevant agreements with minor department- or agency-specific variations. Departments and agencies are including the standard provision in grants and cooperative agreements for global health assistance, and are conducting numerous trainings to ensure the U.S. government workforce is appropriately applying the policy. In addition, the interagency is taking steps to develop a standard PLGHA clause in contracts for global health assistance at multiple departments and agencies.

Department of State

S/GAC directed the U.S. government departments and agencies that implement the President's Emergency Plan for AIDS Relief (PEPFAR) to include the PLGHA standard provision in all PEPFAR grant agreements for global health assistance. S/GAC included the standard provision in all centrally funded PEPFAR global health assistance awards completed by September 30; many awards had not been made as of that date. S/GAC facilitated web-based training across U.S. government implementing departments and agencies in over 60 countries to ensure the maximum number of staff could receive training on the policy. S/GAC has also conducted training of trainers, to allow the information to cascade to increasing numbers of U.S. government personnel around the world. For those activities managed through Department of State mechanisms, the standard provision will continue to be a part of all future global health assistance awards, and existing awards modified with new funding. The new standard provision is available on the Department of State website (https://www.state.gov/m/a/ope/index.htm).

U.S. Agency for International Development

USAID began implementing the policy on May 15, 2017. USAID has included the new PLGHA standard provision in all new grants and cooperative agreements that provide global health assistance, and in all existing grants and cooperative agreements that provide global health assistance when it amends such agreements to add incremental funding. USAID also is including the provision in all existing agreements that previously received the "Mexico City Policy (March 2017)" standard provision when such agreements are next modified, or as soon as reasonably practicable. The new standard provision, "Protecting Life in Global Health Assistance (May 2017)," is publicly available on the USAID website in the Agency's Automated Directives System (ADS) Chapter 303 (https://www.usaid.gov/ads/policy/300/303).

After the announcement of the PLGHA policy, USAID/Washington conducted extensive outreach to, and training for, its staff in the field and at headquarters. In addition, USAID established a team in Washington with representatives from across the Agency to oversee the proper implementation of the policy. USAID/Washington's outreach also included meetings with implementing partners to discuss the standard provision and its application.

USAID/Washington continually works with USAID's field missions to review programs, monitor compliance with the PLGHA policy and other requirements, and develop stronger, more-systematic procedures for monitoring and reporting. USAID has developed training materials and compliance tools to assist its staff and implementing partners in understanding and applying the policy, including a publicly available e-learning course that has been very well received. USAID/Washington continues to design additional tools to facilitate the policy's implementation, including a matrix to help staff review their programs to assess compliance risk related to the policy. This tool supports staff to identify potential vulnerabilities and develop effective monitoring strategies to ensure compliance with the policy. USAID shared the risk assessment matrix with all its missions that are implementing global health programs.

Department of Health and Human Services

Early in March 2017, HHS began to establish parameters for the implementation of the PLGHA policy across HHS. The HHS-specific standard provision was finalized and distributed for inclusion in all applicable grant awards as of May 31, 2017. The standard provision with explanatory language is published on grants management internet sites HHS-wide, and standard language appears in all Notices of Funding Opportunities (NOFOs) that expect to award global health assistance funds appropriated to State, USAID, and/or DoD and transferred to HHS.

HHS has integrated its compliance activities into grant award processes prior to the notice of award (NOA) via several methods of communication with the awardees, including through site visits, conference calls, emails, in-person conversations, official letters of notification, and postings on the websites of its operating divisions. At the time of issuance of an NOA, the relevant grants management and program staff review with the awardee the details of the policies and regulations that govern the acceptance of the PLGHA conditions. Official acceptance by the awardee of the provision occurs once the awardee draws down funds. Because the majority of these awards are cooperative agreements (which denote close working coordination and collaboration between HHS and an awardee), site visits, project oversight, monitoring calls, grant management meetings and other communications with the awardees occur on a frequent basis.

HHS has developed monitoring tools that implementing partners can use to monitor their programs for compliance with the PLGHA standard provision. Technical assistance from HHS is available to assist partners to use these standardized tools. To assist HHS staff, frequently asked questions (FAQs) specific to HHS grants management and partners are published on the HHS grants management Intranet site, accompanied by relevant background material, and updated as needed.

Department of Defense

All active DoD grants for global health assistance will include the provision by the end of FY 2018. DoD informed implementing partners regarding the provision prior to making an award. For all future awards, DoD will notify the implementing partner prior to its submission of a full proposal.

Contract Provision

Consistent with the PLGHA implementation plan, the Department of State and USAID initiated the process of developing, through rule-making, a PLGHA contract clause. It is expected that the requirements of the contract clause would be similar to those included in the standard provision for grants and cooperative agreements. The clause would be included in contracts for supplies or services for global health assistance except for the procurement of commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight-forwarding. It would apply to foreign NGOs that receive global health assistance funding, either as prime contractors or as subcontractors of U.S. or foreign NGOs. The PLGHA policy will not apply to contracts for global health assistance until the rule-making process is completed.

Grants and Cooperative Agreements

The table below provides information about the number of affected agreements with prime implementing partners, i.e., those organizations that have a direct agreement with a U.S. department or agency. Information on sub-awards under these prime agreements is limited because U.S. departments and agencies only have a legal relationship with prime recipients.

Agency	Agency Implementation Date	Number of Grants and Cooperative Agreements with Global Health Assistance Funding	Number of Grants and Cooperative Agreements with Global Health Assistance Funding That Received New Funding from the Implementation Date through 9/30/2017 and are subject to the PLGHA policy
State ¹	15-May-17	142	108
USAID	15-May-17	580	419
HHS	31-May-17	499	160
DoD	15-May-17	77	42

[1 This reflects PEPFAR funding implemented through the Department of State. (Other departments and agencies implement the majority of PEPFAR funding.)]

The table above demonstrates that a majority of global health assistance agreements have already received new funding, and therefore are subject to the PLGHA policy. Nearly all prime partners that have had the opportunity to accept the policy have done so; prime partners declined to sign in only four instances out of 733 awards. All four affected departments and agencies have existing assistance agreements that had not yet received their additional funding by September 30, 2017, which means implementers of those agreements had not yet received the PLGHA standard provision. The difference between the number of total agreements and the

agreements that have received funding since the effective date of the PLGHA policy reflects this; this number will decrease over the coming year as departments and agencies provide more funding to implementing partners.

As of September 30, 2017, USAID is aware of three centrally funded prime partners, and 12 sub-awardee implementing partners, that refused to agree to the PLGHA terms in their awards. USAID is working to transition the activities of those organizations that have not agreed to the PLGHA standard provision to other partners, while minimizing disruption of services. One DoD partner, a U.S. NGO, declined to agree in one country but accepted the PLGHA standard provision in other countries. No HHS partners declined as of September 30. It is too early to analyze systematically what effect, if any, this will have on programming. When a partner declines to agree to the policy and the department or agency reprograms funds to other organizations, the amount of funding directed to respective recipient countries will remain the same.

Training

Implementing departments and agencies have conducted numerous trainings on the PLGHA policy, and used standardized joint training materials developed by an interagency working group. In addition, USAID developed a free public e-learning course that, as of September 30, 2017, 4,572 people had taken, including staff, partners, and the general public. As of September 30, 2017, USAID/Washington has conducted nine in-person trainings at headquarters, two webinars, and two mission-level trainings. In total, USAID provided live training to approximately 453 staff at headquarters and in the field. S/GAC, with support from USAID, conducted an interagency train-the-trainer, and then a subsequent interagency webinar for over 60 countries that included 78 office connections. HHS conducted four webinar trainings across its operating divisions, with 254 staff participating. For CDC within HHS, training on the PLGHA policy is mandatory for regional associate directors, country directors, deputy directors, project officers, cooperative agreement officers, and extramural staff. DoD conducted one headquarters training, which all relevant staff were required to attend. In addition, all relevant DoD field staff participated in the S/GAC web-based training. In total, U.S. government training reached approximately 5,357 U.S. government employees, implementing partners, and other stakeholders through September 30, 2017.

USAID E-Learning Trainings (through 9/30/17)

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Trainee Organization	International NGO	National/Local NGO	Non-U.S Based University	Multilateral	National Gov't	U.S. Agency (CDC)	U.S. Agency (Other)	U.S. Agency (State)	U.S. Agency (USAID)	Other	No Response
Number Trained	2374	934	10	6	27	86	24	5	633	418	55
										TOTAL	4572

III. Findings and Actions

While partners presented with the standard provision have largely accepted the policy, stakeholder feedback and discussions with U.S. government staff indicate areas where further guidance is needed. Keeping in mind that the primary goal of the policy is to stop U.S. taxpayer funding from flowing to entities that promote or provide abortions as a method of family planning, several issues emerged as areas that could be clarified or improved. These include providing guidance around implementation, clarifying terms of the standard provision, strengthening monitoring, and continuing to review the policy.

Steps to Improve Understanding and Implementation of the PLGHA Policy

The information gathered to date demonstrates the need for further guidance regarding the PLGHA policy to improve a common understanding of its intent, implementation, compliance, and oversight. For example, organizations shared questions about what work falls within the provisions of the policy, including activities beyond direct services (such as referrals). Stakeholder input also indicates that some organizations are seeking additional guidance regarding what relationships are allowed with organizations that choose not to comply. Additional guidance would help increase clarity and address these concerns.

Action: Upon completion of additional review of policy guidance, U.S. government departments and agencies should provide harmonized, updated central and field-based training, tools for compliance and oversight, and publicly available frequently asked questions (FAQs) for the PLGHA policy that are translated into appropriate languages.

Application to U.S. State and Local Governmental Entities

As described in the PLGHA fact sheet, "[g]lobal health assistance to national or local governments, public international organizations, and other similar multilateral entities is *not* subject to [the PLGHA] policy." There was a question whether the standard provision on the PLGHA policy should be part of global health assistance awards to public universities, hospitals, or other state/local government entities in the United States.

Action: Clarify, including through the development of appropriate FAQs, that U.S. government departments and agencies must include the PLGHA standard provision in awards to U.S. state or local governmental entities, including state universities, in the same manner as they include it in awards to U.S. NGOs.

<u>Guidance on the Terms of the Standard Provision for the Protecting Life in Global Health</u> Assistance Policy

Based on the input received, stakeholders seek further guidance on three aspects of the standard provision: (1) the meaning of "provide financial support to any other foreign organization that conducts such activities"; (2) the termination provision; and (3) the application of the policy to in-kind assistance, such as training and technical assistance (TA).

1. "Financial Support" Provision

The standard provision states that foreign NGOs (FNGOs) that receive U.S. global health assistance will not "perform or actively promote abortion as a method of family planning in foreign countries or *provide financial support to any other foreign non-governmental organization that conducts such activities*" (italics added). The policy prohibits FNGOs from providing a sub-award to another FNGO that performs or actively promotes abortion as a method of family planning under a global health assistance award from the U.S. government. The standard provision clearly articulates what it means to perform or actively promote abortion as a method of family planning. The standard provision does not, however, specifically define the "financial support" requirement.

Large NGOs with multiple activities across health and development express the need for guidance regarding the application of the language on "financial support." Organizations do not share a common understanding of this language, and several interpretations have emerged. Some NGOs interpret the requirement to mean that an FNGO subject to the PLGHA policy may not, with any source of funds, provide funding to any other FNGO for the purpose of performing or actively promoting abortion as a method of family planning. Others interpret the requirement to mean that an FNGO subject to the PLGHA policy would be prohibited from providing funding, with any source of funds, to another FNGO that performs or actively promotes abortion as a method of family planning. This latter interpretation would mean that the FNGO awardee would need to ensure that each of what could be a very large number of sub-recipients to which it provides its own funding does not perform or actively promote abortion as a method of family planning. This would require that awardees conduct extensive due diligence on their own partners' finances, even when those organizations receive from them no U.S. government funds. Awardees would also assume significant risk under their U.S. government award, including termination, for the sub-recipients' activities that the awardees do not themselves fund.

Therefore, the "financial support" provision needs clarification. An approach that places the appropriate level of due diligence on implementing partners for their U.S. global health assistance funds will ensure that the U.S. government is able to work with capable organizations while preventing U.S. taxpayer dollars from funding the promotion or performance of abortion as a method of family planning abroad. (The clarification would not change the standard

provision requirement that an FNGO subject to the policy cannot provide U.S. global health assistance to any other FNGO unless such sub-recipient agrees to the PLGHA policy.)

Action: Revise the PLGHA standard provision to clarify that FNGOs subject to the policy may not provide any financial support, no matter the source of funds, to any other FNGO for the purpose of performing or actively promoting abortion as a method of family planning.

2. Termination Provision

The PLGHA standard provision states that "health assistance furnished to the recipient under this award *must* be terminated if the recipient violates any undertaking required by this [provision]..." (italics added). This is more prescriptive than other U.S. government awards, which generally make termination an option as opposed to a mandatory action following a violation of a condition of the funding. In the event of a violation, the standard provision offers no discretion to U.S. government departments and agencies to continue assistance to FNGOs that might, in good faith, have attempted to abide by the policy's terms. Given the number of FNGOs now subject to the expanded policy that might not have historical experience with implementation of the Mexico City Policy, inadvertent or unintended violations are a possibility. Some discretion in the application of the termination provision would be prudent.

An analogue is USAID's approach to implementation of the Tiahrt Amendment, which requires that family-planning programs financed by USAID are entirely voluntary, and do not, among other things, assign targets or quotas to service-providers, or offer incentives for women to accept family planning. To implement the Amendment, USAID investigates alleged violations, and imposes corrective action in the event it can prove a violation has occurred; this process permits USAID the discretion to direct implementers to remediate the violation and put in place mitigation plans to prevent future missteps instead of automatically proceeding to termination.

With respect to enforcement of the PLGHA standard provision, discretion regarding remediation or termination on the part of the U.S. government could provide opportunities to train and monitor FNGOs that are providing critical services in some parts of the world if they make an honest mistake under the new policy, while still assuring ultimate compliance with the requirements of the PLGHA. In practice, immediate termination would remain the presumptive sanction for egregious or recurrent violation of the PLGHA.

Action: Maintain immediate termination as the presumptive sanction for egregious or recurrent violations of the PLGHA policy, but revise the PLGHA standard provision to clarify that if an FNGO fails to comply with the PLGHA policy, the U.S. government has discretion to require the implementer to remediate and institute corrective action, instead of terminating the award immediately.

3. Application to Training and Technical Assistance

The PLGHA standard provision applies to U.S. global health assistance, whether delivered in the form of funds or in-kind assistance. Specifically, the provision states that "[f]urnishing health assistance to a[n FNGO] includes the transfer of funds made available under this award or goods or services financed with such funds, but does not include the purchase of goods or services from an organization or the participation of an individual in the general training programs of the recipient or sub-recipient" (italics added). Some organizations are not clear when the provision of a service, such as training or technical assistance (TA), funded under a global health assistance award would require application of PLGHA to an FNGO. For example, the question has been raised whether, in the case of an implementer that receives U.S. government funds and provides limited training to service providers at private-sector clinics, such clinics need to comply with the PLGHA policy, and, if so, for how long, given that they receive no support beyond initial training and additional follow-up? Similar examples are numerous across USAID's health portfolio. There is also uncertainty about when partners must apply the policy to FNGOs that receive no funding but receive TA, often with no formal sub-agreement. Frequently, USAID implementers provide training and TA to beneficiaries, such as privatesector nurses or doctors, without a written agreement, which further complicates application of the PLGHA requirements to such recipients.

In a similar vein, USAID has identified challenges in applying the policy to programming that hinges on continued partnership with private-sector entities in some settings. It is a major aim of the U.S. government's global health assistance to improve stewardship by foreign governments of their healthcare marketplace, increase private-sector delivery of healthcare, and ensure higher quality in both public and private healthcare provision.

USAID often engages a range of types of private-sector providers through the provision of TA or training only. These include small private health facilities, local pharmacies, insurance companies, international consulting firms, private universities and hospitals, and local entrepreneurs and innovators. Particularly with providers who are at a lower, or community, level in the health system (for example, pharmacists or village doctors), the engagement models used by USAID and its partners often consist of offering light-touch guidance on certain technical areas or tasks, without concluding an agreement to provide financing to an organization. In this context, some private providers have been uncomfortable in signing on to the policy with its due diligence requirements when they only receive TA or training from USAID on a specific health intervention, not financing.

Clarifying that the PLGHA policy does not apply to beneficiaries of training and TA that are not FNGO awardees or sub-awardees would allow U.S. government departments and agencies to better focus their compliance resources, and provide clarity that could further our ability to reach the front lines of healthcare, including through private-sector providers.

Action: Revise the standard provision and create corresponding publicly available materials to clarify that the PLGHA requirements apply to recipients/beneficiaries of training and technical assistance only if they are FNGOs that receive an award or subaward of U.S. government global health assistance funds.

Monitoring through the President's Emergency Plan For AIDS Relief

The interagency has taken important steps to monitor the implementation of the policy, as noted above. To assess the impact of the PLGHA policy on HIV/AIDS services, PEPFAR will continue its routine capture, monitoring, and use of age- and sex- disaggregated data, by partner and by site, to track precisely whether and to what extent the PLGHA policy has affected life-saving activities related to HIV/AIDS. In addition, S/GAC will develop guidance for U.S. government departments and agencies on how to use PEPFAR's routine Site Improvement and Monitoring Systems (SIMS) visits as an ongoing opportunity to track site-level impacts of the policy and monitor compliance with it. S/GAC will also include instructions on the PLGHA provisions in its Country Operational Plan guidance for 2018 to help ensure partners are clear about the policy.

Action: Task S/GAC, working with the interagency, to develop guidance for PEPFAR implementing agencies on how to better use SIMS visits to track, monitor, and ensure compliance with the PLGHA policy in PEPFAR programs.

Additional Review

This six-month review takes place early in the policy's implementation, when affected U.S. government departments and agencies have added a significant portion of the funding affected by the policy to grants and cooperative agreements only recently. A follow-on analysis would allow an opportunity to address one of the primary concerns presented in feedback from third-party stakeholder organizations, namely that six months is insufficient time to gauge the impacts of the PLGHA policy.

Action: Conduct a further review of implementation of the policy by December 15, 2018, when more extensive experience will enable a more thorough examination of the benefits and challenges.