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FEDERAL REGISTER

Vol. 75, No. 070

Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

45 CFR Part 89

RIN 0991-AB60

Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act

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75 FR 18760

DATE: Tuesday, April 13, 2010

ACTION: Final rule.

SUMMARY: The Department is issuing a final rule establishing the organizational integrity requirements for Federal funding recipients under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Leadership Act). This rule requires that funding announcements and agreements with funding recipients include a clause that states that the recipient is opposed to prostitution and sex trafficking because of the psychological and physical risks they pose for women, men and children. This rule also modifies the requirements for recipient-affiliate separation and eliminates the requirement for an additional certification by funding recipients.

DATES: This rule is effective May 13, 2010.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Background

Congress enacted the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 ("Leadership Act") in May 2003. Public Law 108-25 [22 U.S.C. 7601-7682]. The Leadership Act contains limitations on the use of funds provided to carry out HIV/AIDS activities under the Act. Subsection 7631(f) prohibits the use of Leadership Act HIV/AIDS funds "to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking." Subsection 7631(f) was amended in 2004 to exempt certain public international organizations. Consolidated Appropriations Act of 2004, Public Law 108-199, Div. D, Title II (2004).

The United States government is opposed to prostitution and sex trafficking. In enacting the Leadership Act, Congress specifically found "Prostitution and other sexual victimization are degrading to women and children and it should be the policy of the United States to eradicate such practices. The sex industry, the trafficking of individuals into such industry, and sexual violence are additional causes of and factors in the spread of the HIV/AIDS epidemic." Leadership Act § 2(23) Public Law 108-25. Congressional hearings at the time of the Act showed a high incidence of HIV among prostitutes and that prostitution fueled the demand for sex trafficking. Accordingly, Congress unambiguously called for the elimination of prostitution and sex-trafficking as part of the United States' fight against HIV/AIDS.

Section 301(f) [22 U.S.C. 7631(f)] of the Leadership Act requires that funding recipients have a policy explicitly opposing prostitution and sex trafficking. Additionally, recipients of Leadership Act funds cannot engage in activities that are inconsistent with their opposition to prostitution and sex trafficking.

Congress did not dictate the means by which the Department would implement the policy and the Congressional intent of the Act was not to overburden applicants with unnecessary requirements. For example, during legislative debate on the Leadership Act, in response to a question from Senator Leahy on the Senate floor regarding section 301(f), Senator Frist stated that "a statement in the contract or grant agreement between the U.S. Government and such organization that the organization is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women * * * would satisfy the intent of the provision." 149 CONG. REC. S6,457 (daily ed. May 15, 2003) (statement of Sen. Frist).

B. Litigation and Regulatory Background

The Leadership Act was challenged on constitutional grounds in two separate lawsuits after its enactment. In a case filed in the U.S. District Court for the District of Columbia, plaintiffs claimed the anti-prostitution provision compelled speech when the organization had no policy either opposing or supporting prostitution. *DKT Int'l v. United States Agency for Int'l Dev. (USAID)*, 435 F. Supp. 2d 5 (D.D.C. 2006). Ultimately, the U.S. Court of Appeals for the District of Columbia Circuit upheld the anti-prostitution provision, holding that the government had a legitimate interest in ensuring that organizations chosen to communicate its particular viewpoint did so in an efficient and effective fashion. *DKT Int'l v. USAID*, 477 F.3d 758 (DC Cir. 2007). [*18761] In upholding this provision, the DC Circuit relied in part on the fact that nothing prevented the plaintiff from itself remaining neutral and setting up a subsidiary that had a policy opposing prostitution to receive government funds.

A second case was filed in the U.S. District Court for the Southern District of New York, which granted an injunction against the Government on the basis that the statute was unconstitutional because it did not leave open "adequate alternative channels for communication." *Alliance for Open Soc'y Int'l (AOSI) v. USAID*, 430 F. Supp. 2d 222 (S.D.N.Y. 2006). On appeal, the U.S. Court of Appeals for the Second Circuit remanded the case, in light of newly issued guidance by the Government providing for organizations to work with affiliates that would not be subject to the Leadership Act's requirements. *AOSI v. USAID*, 254 Fed. Appx. 843 (2d Cir. 2007). Upon remand, however, the

District Court maintained the injunction and allowed additional plaintiffs to join the suit. *AOSI v. USAID*, 570 F. Supp. 2d 533 (S.D.N.Y. 2008). The Government has appealed that decision.

Prior to and concurrent with the litigation, the Department took a number of steps to implement the prostitution policy requirement under the statute. By December 2003, HHS had begun including a requirement in all of its grant and cooperative agreement funding announcements that all recipients under the Leadership Act of HIV/AIDS funds have a policy explicitly opposing prostitution and sex trafficking. On July 23, 2007, HHS published "Organizational Integrity Guidance" in the **Federal Register** to clarify the scope of the policy requirement. The guidance allowed Leadership Act HIV/AIDS funding recipients to have relationships with organizations that engage in activities inconsistent with a policy against prostitution and sex trafficking. 72 FR 41,076 (7/26/2007). HHS followed the issuance of this guidance with a notice of proposed rulemaking (NPRM) on April 17, 2008, 73 FR 29,096, which initiated the notice-and-comment rulemaking process. The final rule was published on December 24, 2008, 73 FR 78,997, corrected on January 16, 2009, 74 FR 2,888 (codified at 45 CFR part 89), and took effect on January 20, 2009. The final rule established the legal, financial, and organizational standards for determining whether a funding recipient had objective integrity and independence from an affiliated organization that engaged in activities inconsistent with a policy opposing prostitution and sex trafficking. The final rule also required all Leadership Act HIV/AIDS funding recipients, including sub-recipients, to certify compliance with the rule.

On November 23, 2009, the Department again issued a notice of proposed rulemaking to modify the final rule of January 20, 2009. 74 FR 61096 (11/23/2009). The proposed amendment to the present rule modifies the criteria for evaluating the separation between recipients and affiliated organizations, while complying with the statutory requirement regarding opposition to prostitution and sex trafficking. It is essential to the Leadership Act that recipients of funds who implement HIV/AIDS programs and activities do not create confusion as to the U.S. Government's message opposing prostitution and sex trafficking by undertaking activities or advocating positions that conflict with this policy. However, as noted above, the Department has determined that the Congressional intent of the Leadership Act can be effectuated through the application of standards that allow more flexibility for funding recipients than the present guidelines.

II. Description of Final Rule and Response to Comments

The Department received twenty-seven comments in response to the proposed rule, including one comment filed after the close of the comment period which was also considered. Comments came from individuals and organizations both opposed to and in favor of changes to the previous rule. Several comments were not responsive to the proposed rule and therefore are not addressed. Several commenters stated the policy requirement was inconsistent with the Leadership Act or improperly conflated prostitution with sex trafficking. However, the final rule is consistent with section 301(f) of the Act which requires organizations receiving funds to have a policy opposing "prostitution and sex trafficking." Other comments are discussed under applicable headings.

Section 89.1 Applicability

This section provides that the policy requirement applies to all funding recipients not exempted by the Leadership Act. Currently, those organizations exempted are the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the World Health Organization, the International AIDS Vaccine Initiative and any other United Nations agency.

This section also states what is required of HIV/AIDS funding recipients under the Leadership Act. The Department shall include in any HIV/AIDS public funding announcement under the Leadership Act the requirement that recipients agree that they are opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men and children. This statement will also be included in any Leadership Act HIV/AIDS funding instrument entered into with the recipient. As explained, the Department believes this statement is consistent with the anti-prostitution provision and the Congressional intent behind it, as well as other goals of the Act.

The Department will work with the Department of State and with other agencies implementing the Leadership Act to ensure consistent application of its requirements.

Section 89.2 Definitions

This section defines terms used in this rule. It retains several terms from the previous iteration of the rule such as "commercial sex act" and "prostitution." However, given the regulation now requires the anti-prostitution statement only in the announcement and the awarding instrument to the "recipient," it deletes the terms "prime recipient" and "subrecipient." A definition of "recipient" that mirrors the former "prime recipient," directly funded entity, is included. While the section deletes the definition of subrecipient, any organization receiving Leadership Act HIV/AIDS funds must comply with the statutory requirements.

Several commenters objected to the lack of definition for a number of terms such as "affiliate," "restricted activities," and "to the extent practicable." As explained below, the Department's commitment to a case-by-case approach in this area will allow flexibility based on the circumstances presented. Some organizations may be better able to separate themselves from an affiliate "in the circumstances." Conditions in some countries may make it difficult for organizations to meet certain factors relevant to determining whether sufficient separation exists. Therefore, any attempt to strictly prescribe the degree of separation would undermine the purpose of the regulation.

Similarly, the Department does not define the term "affiliated organizations." In common usage, "affiliate" means "to bring into close connection as a member or branch." *Merriam-Webster's Collegiate Dictionary* at 21 (11th ed. 2007). Legal affiliation is only one aspect of this relationship. The use of separate personnel, accounting, [*18762] timekeeping, space and identifying signage are also factors, among others. In determining whether there is sufficient separation, the Department will not base its decision solely on whether an entity is a legally separate "affiliate," but instead will consider the likelihood that the degree of separation between a recipient of Leadership Act HIV/AIDS funds and other connected organizations that are not required to have a policy opposing prostitution and sex trafficking will not undermine or confuse the Government's position in opposition to prostitution and sex trafficking.

As noted by multiple comments, the proposed rule did not define "restricted activities." Several comments expressed concerns that organizations that work with the victims of prostitution and sex trafficking would stop providing services that could prevent HIV/AIDS because of their fear that the Government would determine the activities were "restricted activities," and revoke Federal funding. Several comments also sought approval of particular hypotheticals. The Department does not believe it should provide opinions on hypothetical scenarios because information may be incomplete. While the Department does not define restricted activities in the rule, working with other agencies implementing the Leadership Act, the U.S. Government intends to provide broad information on types of activities that illustrate what would be covered.

Section 89.3 Organizational Integrity of the Recipients

This section sets forth the separation requirements for funding recipients who wish to affiliate with organizations that do not have a policy opposing prostitution and sex trafficking. Specifically, the final rule no longer requires that an affiliate be a legally separate entity. As stated in the November 23, 2009, NPRM, separate legal incorporation in each of the host countries where a recipient might work could prove complicated. Additionally, the inherent difficulty of the Department analyzing multiple foreign legal requirements makes this factor unworkable as a determinative criterion.

The rule also allows greater flexibility for funding recipients to demonstrate organizational separation from entities which do not have a policy opposing sex trafficking and prostitution. As noted in the NPRM, these changes include changing separate personnel requirements to allocation of personnel requirements, and the deletion of separate management and governance requirements.

Many commenters believe that the proposed rule, even with modification, unlawfully compels speech in violation

of the First Amendment, and therefore cannot be enforced against domestic entities. The Department disagrees. As explained above, the DC Circuit Court of Appeals upheld the Leadership Act against constitutional claims even prior to the promulgation of implementing regulations. The court in that case specifically relied on the fact that entities were free to set up affiliates which "would qualify for government funds as long as the two organizations' activities were kept sufficiently separate." *DKT Int'l v. USAID*, 477 F.3d at 763. Likewise, the Supreme Court and the Second Circuit Court of Appeals have upheld more burdensome regulations where funding recipients had "adequate alternative channels for protected expression." *Brooklyn Legal Servs. Corp. v. Legal Serv's Corp.*, 462 F.3d 219, 231 (2d Cir. 2006); *Rust v. Sullivan*, 500 U.S. 173 (1991).

The goal in implementing the revised rule on the prostitution policy provision is to ensure that the Government's position opposing prostitution and sex trafficking is not undermined while allowing Leadership Act funding recipients greater flexibility in finding alternative channels for protected expression in diverse areas for diverse populations. Given the numerous factual situations that may arise, the Department has deliberately adopted a case-by-case approach in this area, recognizing that circumstances in some countries may make it difficult for organizations to satisfy some of the factors demonstrating objective integrity and independence. The Department also plans to work with recipients to address individual questions regarding the separation criteria, and to help remedy violations before taking enforcement action. We believe these steps will ensure recipients have adequate channels for engaging in protected speech while still adhering to the requirement of the Leadership Act that recipient organizations be opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men and children.

Several commenters also objected to the Department's listing of only five factors relevant to the integrity analysis when the regulation allows that other unlisted factors may be taken into account. Again, the relevant inquiry will not be the presence or absence of any particular factor, but the "totality of circumstances," under which the recipient organization is shown to be sufficiently separate from an affiliate organization that does not have a policy opposing prostitution. The court decisions previously discussed all upheld similar regulations where the Government specifically stated the factors were "not limited to" those set forth in regulation.

Several commenters expressed concern that the extent of restricted activities by the affiliated organization would be a factor considered by the Department. Given that the purpose of affiliate separation requirements is to determine when an affiliated organization is so closely tied to the funding recipient that a reasonable observer would attribute its activities to the funding recipient, the Department agrees that the extent of restricted activities by a separate entity should not be considered, and therefore has deleted that part of Subsection 89.3(b)(4).

Several commenters believed the proposed rule should mirror the Department's non-discrimination regulations for faith based organizations. Under these regulations, the commenters insist, "religious activities" require only time or space separation. However, the faith based regulations rely on different statutory and constitutional foundations. The faith based regulations allow religious and non-religious organizations to compete equally in applying for Federal funds as long as time, place and other restrictions on religious activities are met consistent with the Establishment Clause of the U.S. Constitution. By contrast, the Leadership Act requires all funding recipients, regardless of the character of their organization, to have a policy against prostitution and sex trafficking. The Leadership Act requires that HIV/AIDS funding recipients act consistently with their opposition to prostitution and sex trafficking. This requirement necessitates greater separation between funding recipients and organizations that engage in activities inconsistent with an opposition to prostitution and sex trafficking, than the faith based regulations require between governmental programs operated by a faith based organization and its religious activities. The Department believes this rule best meets the goals of the Leadership Act's anti-prostitution provision without infringing upon the constitutional rights of recipients.

Deleted Section 89.3 Certification

As proposed, former section 89.3 requiring annual certification of compliance with the anti-prostitution provision by both recipients and sub-recipients has been deleted. The Department does not believe such procedures are necessary

for compliance [*18763] under the Leadership Act. Recipients are still required to follow the dictates of the Leadership Act and maintain the required separation from affiliates that engage in activities inconsistent with an opposition to prostitution and sex trafficking. The required notice in the public announcement and awarding instrument will provide notice to funding recipients of the Leadership Act's anti-prostitution requirements and allow an opportunity to engage the Department in further dialogue on the issue if an applicant desires.

Those commenting on this deletion suggested the lack of certification would make the Leadership Act unenforceable, adding that the negligible cost of certification is far outweighed by its benefits. The Department disagrees. The Department is not hampered in its monitoring or enforcement by the lack of certification, and may still conduct audits of discretionary grant programs whenever they are warranted to ensure compliance with program requirements. Nothing in the Leadership Act requires certification by recipients or prevents enforcement when those requirements are not met. Given the cost to the public of administering the certification and the negligible benefit to the Department, deleting the requirement comports with the goals of the Paperwork Reduction Act to "minimize the paperwork burden * * * from the collection of information by and for the Federal Government." 35 U.S.C. 3501.

III. Impact Analysis

Executive Order 12866 and Paperwork Reduction Act

As explained in the NPRM to this final rule, this rule is a "significant regulatory action" under Executive Order 12866, section 3(f)(4), because it raises novel legal or policy issues that arise out of legal mandates and the President's priorities, and accordingly, the Office of Management and Budget has reviewed it.

This rule modifies a previously issued final rule on the same subject, published on December 24, 2008, in the **Federal Register**. The modification reduces the burden on applicants and funding recipients in complying with the policy. The December 24, 2008, final rule required statements and formal documentation from recipients before they could receive Leadership Act HIV/AIDS funds. The Impact Analysis and the Paperwork Reduction Act in the December 24, 2008, final rule estimated the burden and cost of writing the additional documentation. This rule no longer requires this additional documentation. As a result, applicants for Leadership Act HIV/AIDS funds will no longer have to incur the costs outlined in the December 24, 2008, impact analysis and paperwork burden analysis.

Therefore, the rule should relieve regulated entities by the amounts specified in the December 24, 2008, final rule. We are republishing the impact table from the December 24, 2008, final rule. The burden estimate was \$ 7,337 calculated by assuming an additional half hour of clerical work to prepare documentation on behalf of 555 grantees at an hourly rate of \$ 26.44.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Average cost per hour	Total burden hours	Total burden cost
Certifications	555	1	0.5	\$ 26.44	277.5	\$ 7,337

List of Subjects in 45 CFR Part 89

Administrative practice and procedure, Federal aid programs, Grants programs, Grants administration.

Dated: January 22, 2010.

John Monahan,

Interim Director, Office of Global Health Affairs.

Dated: January 22, 2010.

Kathleen Sebelius,

Secretary.

Therefore, under the authority of section 301(f) of the Leadership Act, as amended, and for the reasons stated in the preamble, the Department revises 45 CFR part 89 to read as follows:

PART 89--ORGANIZATIONAL INTEGRITY OF ENTITIES IMPLEMENTING PROGRAMS AND ACTIVITIES UNDER THE LEADERSHIP ACT

Sec.

89.1 Applicability and requirements.

89.2 Definitions.

89.3 Organizational integrity of recipients.

Authority: Section 301(f) of the Leadership Act, Pub. L. 108-25, as amended (22 U.S.C. 7631(f)) and 5 U.S.C. 301.

§ 89.1 Applicability and requirements.

(a) This regulation applies to all recipients unless they are exempted from the policy requirement by the Leadership Act or other statute.

(b) The Department of Health and Human Services (HHS) components shall include in the public announcement of the availability of the grant, cooperative agreement, contract, or other funding instrument involving Leadership Act HIV/AIDS funds the requirement that recipients agree that they are opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children. This requirement shall also be included in the award documents for any grant, cooperative agreement or other funding instrument involving Leadership Act HIV/AIDS funds entered into with the recipient.

§ 89.2 Definitions.

For the purposes of this part:

Commercial sex act means any sex act on account of which anything of value is given to or received by any person.

Leadership Act means the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Public Law 108-25, as amended (22 U.S.C. 7601-7682).

Prostitution means procuring or providing any commercial sex act.

Recipients are contractors, grantees, applicants or awardees who receive Leadership Act funds for HIV/AIDS programs directly or indirectly from HHS.

Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

§ 89.3 Organizational integrity of recipients.

A recipient must have objective integrity and independence from any affiliated organization that engages in activities inconsistent with the recipient's opposition to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men and children ("restricted activities"). A recipient will be found to have objective integrity and independence from such an organization if:

(a) The affiliated organization receives no transfer of Leadership Act HIV/AIDS funds, and Leadership Act HIV/AIDS [*18764] funds do not subsidize restricted activities; and

(b) The recipient is, to the extent practicable in the circumstances, separate from the affiliated organization. Mere bookkeeping separation of Leadership Act HIV/AIDS funds from other funds is not sufficient. HHS will determine, on a case-by-case basis and based on the totality of the facts, whether sufficient separation exists. The presence or absence of any one or more factors relating to legal, physical, and financial separation will not be determinative. Factors relevant to this determination shall include, but not be limited to, the following:

(1) Whether the organization is a legally separate entity;

(2) The existence of separate personnel or other allocation of personnel that maintains adequate separation of the activities of the affiliated organization from the recipient;

(3) The existence of separate accounting and timekeeping records;

(4) The degree of separation of the recipient's facilities from facilities in which restricted activities occur; and

(5) The extent to which signs and other forms of identification that distinguish the recipient from the affiliated organization are present.

[FR Doc. 2010-8378 Filed 4-12-10; 8:45 am]

BILLING CODE 4150-38-P