

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 88

RIN 0991-AB46

Office of Global Health Affairs; Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act

Wednesday, December 24, 2008

AGENCY: Office of Global Health Affairs, U.S. Department of Health and Human Services.

***78997 ACTION:** Final rule.

SUMMARY: The Office of Global Health Affairs within the U.S. Department of Health and Human Services ("HHS") is issuing this final rule to clarify that recipients of HHS funds to implement HIV/AIDS programs and activities under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (the "Leadership Act"), [Public Law 108-25](#) (May 27, 2003), that are required to have a policy opposing prostitution and sex trafficking, and must submit certification of this policy with the grant or contract application, may, consistent with this policy requirement, maintain an affiliation with organizations that do not have such a policy, provided such affiliations do not threaten the integrity of the government's programs and its message opposing prostitution and sex trafficking. The rule describes the separation that must exist between a recipient of HHS HIV/AIDS funds that has a policy opposing prostitution and sex trafficking, as required under section 301(f) of the Leadership Act, [22 U.S.C. 7631\(f\)](#), and another organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking.

DATES: This rule is effective January 20, 2009.

FOR FURTHER INFORMATION CONTACT: Jeanne Monahan, Office of Global Health Affairs, Hubert H. Humphrey Building, Room 639H, 200 Independence Avenue, SW., Washington, DC 20201, Tel: 202.690.6174, E-mail: Jeanne.monahan@hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The U.S. Government is opposed to prostitution and related activities, which are

inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. It is critical to the effectiveness of the Leadership Act, and to the U.S. Government's foreign policy that underlies this effort, that organizations that receive Leadership Act funds maintain the integrity of the Leadership Act programs and activities they implement, and not confuse the U.S. Government's message opposing prostitution and sex trafficking by holding positions that conflict with this policy.

On April 17, 2008, HHS published in the Federal Register ([73 FR 20900](#)), a Notice of Proposed Rulemaking ("NPRM") regarding the requirement expressed in [22 U.S.C. 7631\(f\)](#), which provides that organizations that are receiving Leadership Act funds must have a policy explicitly opposing prostitution and sex trafficking. Specifically, the NPRM described the legal, financial, and organizational separation that must exist between entities that receive grants, contracts, or cooperative agreements from HHS under the Leadership Act and another organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking.

A Notice of Correction of Proposed Rule to correct a technical error in the NPRM was published in the Federal Register ([73 FR 29096](#)). Although the public comment period initially closed on May 19, 2008, a Notice of Reopening of the Comment Period was published in the Federal Register ([73 FR 36293](#)), and the final date to submit comments on the NPRM was July 28, 2008.

This final rule is designed to provide additional clarity for contracting and grant officers, contracting officers' technical representatives, program officials and implementing partners (e.g., grantees, contractors) of HHS regarding the application of language in Notices of Availability, Requests for Proposals, and other documents pertaining to the policy requirement expressed in [22 U.S.C. 7631\(f\)](#). This final rule clarifies that the Government's organizational partners that have a policy opposing prostitution and sex trafficking may, consistent with this policy requirement, maintain an affiliation with organizations that do not have such a policy, provided such affiliations do not threaten the integrity of the Government's programs and its message opposing prostitution and sex trafficking, as specified in this final rule. To maintain program integrity, adequate separation, as outlined in this final rule, is required between an organization that expresses views on prostitution and sex trafficking contrary to the Government's message and any federally funded partner organization. Examples of activities inconsistent with a policy ***78998** opposing prostitution and sex trafficking include, but are not limited, to advocating for the legalization of the institution of prostitution or organizing or unionizing prostituted people for the purpose of advocating for the legalization of prostitution.

This final rule applies to funds used by HHS to implement HIV/AIDS programs and activities under the Leadership Act. The rule includes certification language that organizations must provide to receive grants, cooperative agreements, contracts, and other funding instruments made available by HHS.

All recipients that receive funds directly from HHS ("prime recipients") must certify compliance with the final rule prior to actual receipt of such funds, in a written statement addressed to the HHS agency's grants or contract officer. The

certifications by prime recipients are prerequisites to payment by HHS of any U.S. Government funds in connection with an award under the Leadership Act.

All recipients must insert provisions to implement the applicable parts of this final rule in all sub-agreements under their awards. These provisions must be express terms and conditions of the sub-agreement, must acknowledge that compliance with this final rule is a prerequisite to the receipt and expenditure of U.S. Government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement, prior to the end of its term.

Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient that relate to the organization's compliance with this final rule.

Nothing in this rule is intended to affect relevant prohibitions on Federal Government funding under other applicable Federal laws.

II. Discussion of the Final Rule

These sections discuss the final rule by defining the terms relevant to this final rule and discussing the requirements that must be satisfied by organizations that receive Leadership Act funds.

Section 88.1 Definitions

This section defines the terms that are pertinent to this rule. Specifically, we include the following definitions:

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

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

"Prostitution" means procuring or providing any commercial sex act.

"Recipients" are contractors, grantees, applicants or awardees that receive Leadership Act funds for HIV/AIDS programs directly or indirectly from HHS. Recipients include both prime recipients and sub-recipients.

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

"Sub-Recipients" are contractors, grantees, applicants or awardees that receive Leadership Act funds for HIV/AIDS programs from other recipients rather than directly from HHS.

Section 88.2 Objective Integrity of Recipients

This section of the final rule describes the separation that must exist between a recipient of funds from HHS to implement HIV/AIDS programs under the Leadership Act and another organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking, as required under section 301(f) of the Leadership Act.

Paragraph (a) sets forth criteria for establishing the objective integrity and independence that a recipient must have from another organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.

The criteria for organizational integrity and independence in this final rule is modeled on criteria upheld as facially constitutional by the U.S. Court of Appeals for the Second Circuit in Velazquez v. Legal Services Corp., 164 F.3d 757, 767 (2d Cir. 1999), and Brooklyn Legal Services Corp. v. Legal Services Corp., 462 F.3d 219, 229-33 (2d Cir. 2006), cases involving similar organization-wide limitations applied to recipients of Federal funding.

This final rule clarifies that an organization affiliated with a recipient of Leadership Act funds need not have a policy explicitly opposing prostitution and sex trafficking for the recipient to maintain compliance with the policy requirement. The affiliated organization's position on these issues will have no effect on the recipient's eligibility for Leadership Act funds, so long as the recipient satisfies the criteria for objective integrity and independence detailed in this final rule. By ensuring adequate separation between the recipient and affiliate, these criteria guard against a public perception that the affiliate's views on prostitution and sex trafficking may be attributed to the recipient, and thus to the Government, thereby avoiding the risk of confusing the Government's message opposing prostitution and sex trafficking. In addition, the separation also guards against a public perception that resources between affiliate and recipient are fungible, and thus Government funds could inadvertently subsidize other activities inconsistent with a policy opposing prostitution and sex trafficking.

Under Paragraph (b) of this section, an organization is eligible to receive from HHS Federal funds made available under the Leadership Act only if it has provided the certifications required by section 88.3.

Section 88.3 Certifications

This section of the rule describes the certifications required to receive Leadership Act funding from HHS.

The certifications section contains an Organizational Integrity Certification, located at section 88.3(d)(1), in which a recipient of Leadership Act funds administered by an HHS agency certifies it has objective integrity and independence from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.

The certification section also contains Acknowledgement and Sub-Recipient Compliance Certifications at section 88.3(d)(2) and (3). These require each recipient to acknowledge that its provision of the certifications is a prerequisite to receiving

Federal funds, that the Federal Government can stop or withdraw those funds if HHS finds a certification to have been inaccurate or to have become inaccurate, and that the prime recipient will ensure all its sub-recipients provide the required certifications. A sub-recipient must provide the same certifications as those provided by the prime recipient. Paragraph (e) contains information regarding requirements for the renewal of the certifications. HHS requires each recipient to provide renewed certifications each Federal Fiscal Year, in alignment with the award cycle. Additionally, current recipients, as of the effective date of the regulation, must file a certification upon any extension, amendment, or modification of the funding instrument that extends the term of such instrument or adds additional funds to it.

III. Response to Public Comments

In response to the proposed rule, the Office of Global Health Affairs received five written comments from Members of ***78999** Congress, a university law school, non-governmental organizations involved in public health and advocacy, and other organizations. The following is a summary of the comments and the responses from the HHS Office of Global Health Affairs:

Comment: Several commenters argue that the proposed rule did not address the merits of the underlying policy requirement expressed in the Leadership Act, which provides that organizations that are receiving Leadership Act funds must have a policy explicitly opposing prostitution and sex trafficking. They state that the policy requirement in the Leadership Act runs contrary to best practices in public health efforts to stem the spread of HIV/AIDS and human trafficking, and the regulation appears to prohibit organizations receiving Leadership Act funds from participating in prevention programs that use strategies that involve those engaged in prostitution and sex trafficking.

Response: The objective of the rule is to clarify that recipients of HHS HIV/AIDS funds that have adopted a policy opposing prostitution and sex trafficking may, consistent with this policy requirement, maintain an affiliation with other organizations that do not have such a policy, provided such affiliations do not threaten the integrity of the Government's programs and its message opposing prostitution and sex trafficking. In doing so, the rule describes the legal, financial, and organizational separation that must exist between these recipients of HHS funds and other organizations that engage in activities that are not consistent with a policy opposing prostitution and sex trafficking. The rule is not designed to address the merits of the policy requirement in the Leadership Act. Moreover, the rule does not prevent an organization from providing prevention, care and treatment to marginalized populations. In fact, most Leadership Act funds are going expressly for those purposes. Organizations around the world that receive Leadership Act funds, including those with extensive experience working directly with prostituted people, have stated they are in compliance with the requirement that they must have a policy opposing prostitution and sex trafficking.

Comment: Several commenters note that the regulation does not define "activities inconsistent with a policy opposing prostitution and sex trafficking." They state that the language of the regulation is vague and that there is confusion in the field about permissible activities. The commenters note that the broadness of the language of the rule increases the possibility that organizations will curtail ef-

fective programs for fear of being seen as supporting or promoting prostitution.

Response: As stated above, the purpose of the rule is to describe the degree of separation that must exist between recipients of HHS HIV/AIDS funds, who must have a policy opposing prostitution and sex trafficking, and other organizations who do not have such a policy, in order to preserve the integrity of the Government's message opposing prostitution and sex trafficking. The purpose of the rule is not to define activities that are inconsistent with a policy opposing prostitution and sex trafficking. As stated above, the rule does not prevent recipients of Leadership Act funds from providing prevention, care and treatment programs to marginalized populations, and organizations around the world that receive Leadership Act funds, including those with extensive experience working directly with prostituted people, have stated that they have a policy opposing prostitution and sex trafficking.

Comment: One commenter notes that the regulation does not define "affiliate." The commenter writes that there are no limitations on organizations that might be considered affiliates. The commenter notes that the speech and activities of affiliate organizations will be scrutinized to a high degree, and that cooperation between non-governmental organizations ("NGOs") will be discouraged.

Response: The Office of Global Health Affairs has determined that the term "affiliate" is not necessary to the rule, as the objective of the rule is to describe the degree of separation that must exist between recipients of Leadership Act funds and any other organizations that do not have a policy opposing prostitution and sex trafficking, regardless of whether these other organizations are technically defined as "affiliates" of the recipient. Consequently, the HHS Office of Global Health Affairs has deleted the term "affiliate" from the rule. Further, the separation requirements are designed to ensure the U.S. Government's message opposing prostitution and sex trafficking is not confused or diluted. Organizations may still cooperate with each other, provided that, if they receive Leadership Act funds for HIV/AIDS programs, they also have a policy opposing sex trafficking and prostitution, and remain sufficiently separate from organizations that do not have such a policy.

Comment: Several commenters note that the level of separation required by the rule is unnecessary. The commenters state that the level of separation currently applied to faith-based organizations would be sufficient for recipients of HIV/AIDS funding. The commenters also claim that the rule is inconsistent with HHS's previous conclusion that, in the context of faith-based organizations, separation requirements of this sort are excessive.

Response: The policy requirement in the Leadership Act is not analogous to the Federal Government's partnership with faith-based organizations. The Constitution of the United States requires the Government to be neutral on matters of faith and religion. However, the Constitution does not require the Government to be neutral on prostitution and sex trafficking. The United States is free to adopt policies that favor or disfavor activities related to prostitution and sex trafficking. In the Leadership Act, Congress chose to establish a policy that requires funding recipients to have a policy against prostitution and sex trafficking, which is inherently different from the neutrality the U.S. Government must exhibit towards faith-based organizations. The U.S. Government has found prostitution and sex trafficking

to be degrading and harmful to those involved, and therefore a stronger separation standard is required than is established for faith-based organizations.

This clearer form of separation is necessary to ensure that the U.S. Government policy against prostitution and sex trafficking is clear and not confused with a contrary policy held by a grantee or contractor.

Comment: Several commenters argue that the regulation requires recipients to achieve a level of separation from affiliates that will be an undue burden on NGOs, and defies Congress' intent to promote efficiency in foreign aid. The commenters note that the level of separation required for recipients of HIV/AIDS funding is so stringent that recipients will not be able to set up affiliates. They note that having separate personnel and management factors will create lengthy delays in working in developing countries. They also claim that the separation requirements will harm the recipients' ability to raise money.

Response: The burden and cost of the rule is unlikely to be significant for organizations that are receiving Leadership Act funds because the policy requirement has been in place for a number of years. Since 2004, over 18 billion dollars have supported HIV/AIDS prevention, care, and treatment programs, and these groups have stated *79000 their compliance with section 301(f) of the Leadership Act. The rule does not alter the policy requirement. Rather, it clarifies that a recipient of Leadership Act funds may maintain an affiliation with an organization that does not have a policy opposing prostitution and sex trafficking if the two organizations are sufficiently separate.

Comment: One commenter states that the policy undermines Congress' desire to promote public/private partnerships in the delivery of HIV/AIDS services. The commenter claims that recipients will find it dangerous, and in some cases illegal, to work with other NGOs. The commenter notes that the separation requirements will force recipients to increase administrative costs, and will undercut organizations' ability to raise funds both from the Government and from the private sector.

Response: The intent of the rule is not to prevent public/private partnerships, but to more clearly define the organizations that can enter into those partnerships and receive funding under the Leadership Act. The cost of the rule is unlikely to be significant for organizations receiving Leadership Act funds. Since 2004, HHS has required recipients of Leadership Act funds to certify their compliance with section 301(f) of the Leadership Act, and on July 23, 2007, the Office of Global Health Affairs issued a "Guidance on Organizational Integrity," similar to this final regulation. The Office of Global Health Affairs instructed HHS agencies to disseminate the guidance to their contractors and grantees that receive funding under the Leadership Act, and provided means for the public to comment on the guidance, including whether the guidance is economically significant under definitions provided by the Office of Management and Budget ("OMB"). The Office of Global Health Affairs has received no comments on the guidance.

Regulatory Flexibility Act

The Secretary certifies under [5 U.S.C. 605\(b\)](#), as enacted by the Regulatory Flexibility Act ([Pub. L. 96-354](#)), that this rule will not result in a significant impact

on a substantial number of small entities. Since enactment of the policy requirement in the Leadership Act, HHS has required its contract solicitations and grant announcements for Leadership Act funding to include a section regarding "Prostitution and Related Activities."

[Executive Order 12866--Regulatory Planning and Review](#)

HHS has drafted and reviewed this regulation in accordance with [Executive Order 12866](#), section 1(b), Principles of Regulation. HHS has determined this rule is a "significant regulatory action" under [Executive Order 12866](#), section 3(f)(4), Regulatory Planning and Review, 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.

The benefits of this rule are that the limitations on promoting or advocating the legalization or the practice of prostitution and sex trafficking will (1) help further the U.S. Government's strategy to reduce sexual exploitation that fuels the spread of HIV/AIDS and opportunistic infections, such as tuberculosis and malaria, and (2) demonstrate the U.S. Government's opposition to prostitution and sex trafficking.

The cost of this rule is unlikely to be significant, according to cost estimations, approximately \$7337.10 in total. Since 2004, HHS has required recipients of Leadership Act funds to certify their compliance with section 301(f) of the Leadership Act. Further, the Office of Global Health Affairs issued a guidance, similar to this final rule, on July 23, 2007. The Office of Global Health Affairs instructed HHS agencies to disseminate the guidance to their contractors and grantees that receive funding under the Leadership Act, and provided means for the public to comment on the guidance, including whether the guidance is economically significant under definitions provided by OMB. The Office of Global Health Affairs has received no comments on the guidance.

[Executive Order 13132--Federalism](#)

[Executive Order 13132](#) on Federalism requires Federal Departments and agencies to consult with State and local Government officials in the development of regulatory policies with implications for Federalism. This rule does not have Federalism implications for State or local Governments, as defined in the Executive Order.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that a covered Federal Department or agency prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that could result in the expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. HHS has determined that this rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$100 million in any one year.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal Departments and agencies to determine whether a final policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. This rule will not have an impact on family well-being, as defined in this legislation.

Paperwork Reduction Act

To obtain or retain Leadership Act funding, HHS will require recipients to submit certifications. The title of the information collection is "Certification Regarding the Organizational Integrity of Entities Implementing Leadership Act Programs and Activities." The documents are necessary to ensure that recipients of Leadership Act funding have objective integrity and independence from any organizations that engage in activities inconsistent with a policy opposing prostitution and sex trafficking.

HHS estimates that 555 respondents will prepare documents to validate that recipients have objective integrity and independence from organizations that engage in activities inconsistent with policies opposing prostitution and sex trafficking. HHS also estimates that the average cost per hour will be \$26.44, with 1/2 hour estimated time burden per response. In total, the estimated burden cost is approximately \$7337.10.

HHS therefore estimates annual aggregate burden to collect the information as follows:

[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a meaningful review of its contents. The table has been divided into multiple pieces with each piece containing information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

***** This is piece 1. -- It begins at character 1 of table line 1. *****

Annual Burden Estimates

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Average cost per hour |
|--|--------------------------|--|--|-----------------------------|
| Certifications | 555 | 1 | .5 | \$26.44 .. |
| 1....+....10....+....20....+....30....+....40....+....50....+....60....+....70....+... | | | | |

***** This is piece 2. -- It begins at character 78 of table line 1. *****

Total Total burden
burden cost
hours

... 277.5 .. \$7,337.10

78.....+....90.....+....0

During the Notice of Revised Rulemaking (NPRM) process, HHS accepted comments from the public, in accordance with the Paperwork Reduction Act of 1995. HHS will submit this information collection to the Office of Management and Budget (OMB) for regular approval.

Affected parties do not have to comply with the information collection requirements in the final rule until the Department of Health and Human Services publishes in the Federal Register the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 45 CFR Part 88

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

Dated: September 26, 2008.

William R. Steiger,

Director, Office of Global Health Affairs.

Approved: October 22, 2008.

Michael O. Leavitt,

Secretary of Health and Human Services.

Editorial Note: This document was received in the Office of the Federal Register on Friday, December 19, 2008.

For the reasons stated in the preamble, the Office of Global Health Affairs amends 45 CFR subtitle A to add Part 88 as follows:

PART 88-ORGANIZATIONAL INTEGRITY OF ENTITIES IMPLEMENTING PROGRAMS AND ACTIVITIES UNDER THE LEADERSHIP ACT

Sec.

88.1 Definitions.

88.2 Organizational integrity of recipients.

88.3 Certifications.

Authority: 22 U.S.C. 7631(f) and 5 U.S.C. 301.

45 CFR § 88.1

§ 88.1 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.

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

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. Recipients include both prime recipients and sub-recipients.

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

Sub-Recipients are contractors, grantees, applicants or awardees, other than prime recipients, who receive Leadership Act funds for HIV/AIDS programs from other recipients rather than directly from HHS.

45 CFR § 88.2

§ 88.2 Organizational integrity of recipients.

(a) A recipient must have objective integrity and independence from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking. A recipient will be found to have objective integrity and independence from such an organization if:

(1) The organization is a legally separate entity;

(2) The organization receives no transfer of Leadership Act funds, and Leadership Act funds do not subsidize activities inconsistent with a policy opposing prostitution and sex trafficking; and

(3) The recipient is physically and financially separate from the organization. Mere bookkeeping separation of Leadership Act 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 physical and financial separation exists. The presence or absence of any one or more factors will not be determinative. Factors relevant to this determination shall include, but will not be limited to, the following:

- (i) The existence of separate personnel, management, and governance;
 - (ii) The existence of separate accounts, accounting records, and timekeeping records;
 - (iii) The degree of separation from facilities, equipment and supplies used by the organization to conduct activities inconsistent with a policy opposing prostitution and sex trafficking, and the extent of such activities by the organization;
 - (iv) The extent to which signs and other forms of identification that distinguish the recipient from the organization are present, and signs and materials that could be associated with the organization or activities inconsistent with a policy opposing prostitution and sex trafficking are absent; and
 - (v) The extent to which HHS, the U.S. Government and the project name are protected from public association with the organization and its activities inconsistent with a policy opposing prostitution and sex trafficking in materials such as publications, conferences and press or public statements.
- (b) An organization is ineligible to receive any Leadership Act funds unless it has provided the certifications required by § 88.3.

45 CFR § 88.3

§ 88.3 Certifications.

(a) HHS agencies shall include the certification requirements for any grant, cooperative agreement, contract, or other funding instrument in the public announcement of the availability of the grant, cooperative agreement, contract, or other funding instrument.

(b) Unless the recipient is otherwise excepted, a person authorized to bind the recipient shall execute the certifications for the grant, cooperative agreement, contract, or other funding instrument.

(c) A prime recipient must submit its certifications to the grant or contract officer of the HHS agency that will award funds. A sub-recipient must provide its certifications to the prime recipient. The prime recipient will submit certifications from its sub-recipients when requested to do so by the HHS grant or contract officer.

(d) The certifications shall state as follows:

***79002** (1) Organizational Integrity Certification: "I hereby certify that [name of recipient], a recipient of the funds made available through this [grant, cooperative agreement, contract, or other funding instrument], has objective integrity

and independence from any organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking."

(2) Acknowledgement Certification: "I further certify that the recipient acknowledges that these certifications are a prerequisite to receipt of U.S. Government funds in connection with this [grant, cooperative agreement, contract, or other funding instrument], and that any violation of these certifications shall be grounds for termination by HHS in accordance with the Federal Acquisition Regulations, Part 49 for contracts, 45 CFR Parts 74 or 92 for grants and cooperative agreements, as well as any other remedies as provided by law."

(3) Sub-Recipient Compliance Certification: "I further certify that the recipient will include these identical certification requirements in any [grant, cooperative agreement, contract, or other funding instrument] to a sub-recipient of funds made available under this [grant, cooperative agreement, contract, or other funding instrument], and will require such sub-recipient to provide the same certifications that the recipient provided."

(e) Prime recipients and sub-recipients of funds must file a renewed certification each Fiscal Year, in alignment with the award cycle. Prime recipients and sub-recipients that are already recipients as of the effective date of this regulation must file a certification upon any extension, amendment, or modification of the grant, cooperative agreement, contract, or other funding instrument that extends the term of such instrument, or adds additional funds to it.

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