

Flooding source(s)	Location of referenced elevation**	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground		Communities affected
		Effective	Modified	
Powers Brook .....	Approximately 100 feet downstream of Railroad .....	None	+1001	Village of Hudson, City of Stow.
Powers Brook Tributary 2 .....	Approximately 100 feet upstream of Norton Road .....	None	+1074	City of Stow.
	At confluence with Powers Brook .....	+1049	+1051	
Yellow Creek .....	Approximately 1,120 feet upstream of Stow Road .....	None	+1058	Unincorporated Areas of Summit County, City of Akron, City of Cuyahoga Falls.
	Approximately 550 feet downstream of Riverview Road.	+734	+735	
Yellow Creek Overflow .....	Approximately 50 feet upstream of Medina Line Road	None	+1066	Unincorporated Areas of Summit County.
	Approximately 70 feet above confluence with Yellow Creek.	None	+1039	
	Approximately 1,600 feet above confluence with Yellow Creek.	None	+1050	

\* National Geodetic Vertical Datum.

+ North American Vertical Datum.

# Depth in feet above ground.

\*\* BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to William R. Blanton, Jr., Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

**ADDRESSES**

**City of Akron**

Maps are available for inspection at 166 South High Street, Suite 100, Akron, OH 44308.

**City of Cuyahoga Falls**

Maps are available for inspection at 2310 Second Street, Cuyahoga Falls, OH 44221.

**City of Macedonia**

Maps are available for inspection at 9691 Valley View Road, Macedonia, OH 44056.

**City of Stow**

Maps are available for inspection at 3760 Darrow Road, Stow, OH 44224.

**Unincorporated Areas of Summit County**

Maps are available for inspection at 1030 East Tallmadge Avenue, Akron, OH 44310.

**Village of Boston Heights**

Maps are available for inspection at 5595 Transportation Boulevard, Suite 100, Hudson, OH 44236.

**Village of Hudson**

Maps are available for inspection at 27 East Main Street, Hudson, OH 44236.

**Village of Silver Lake**

Maps are available for inspection at 2961 Kent Road, Silver Lake, OH 44224.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 7, 2008.

**David I. Maurstad,**

*Federal Insurance Administrator of the National Flood Insurance Program, Department of Homeland Security, Federal Emergency Management Agency.*

[FR Doc. E8-8323 Filed 4-16-08; 8:45 am]

**BILLING CODE 9110-12-P**

**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 Implementing Leadership Act Programs and Activities**

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Office of Global Health Affairs within the U.S. Department of Health and Human Services (HHS) is issuing this Notice of Proposed Rulemaking (NPRM) to obtain input from stakeholders and other interested parties regarding the separation that

must exist between a recipient 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 No. 108-25 (May 27, 2003), and an affiliate 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.

The proposed rule provides additional information on the policy requirement expressed in this law for entities that receive grants, contracts, or cooperative agreements from the U.S. Department of Health and Human Services ("HHS") to implement programs or projects under the authority

of the Leadership Act. Specifically, it describes the legal, financial, and organizational separation that must exist between these recipients of HHS HIV/AIDS funds and an affiliate organization that engages in activities that are not consistent with a policy opposing prostitution and sex trafficking.

**DATES:** To be assured consideration, written comments must be received on or before May 19, 2008.

**ADDRESSES:** You may submit written comments to the following address: U.S. Department of Health and Human Services, Office of Global Health Affairs, Room 639H, 200 Independence Avenue, SW., Washington, DC 20201. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., at Room 639H, 200 Independence Avenue, SW., Washington, DC 20201. Please call ahead to 1-202-690-6174, and ask for a representative in the Office of Global Health Affairs to schedule your visit.

You may also submit written comments electronically via the Internet at <http://www.regulations.gov>, or via e-mail to

[OGHA\\_Regulation\\_Comments@hhs.gov](mailto:OGHA_Regulation_Comments@hhs.gov). You can download an electronic version of the NPRM at <http://www.regulations.gov>. HHS/OGHA has also posted the NPRM and related materials to its Web site at the following Internet address: <http://www.globalhealth.gov/>.

**FOR FURTHER INFORMATION CONTACT:** William R. Steiger, PhD, Office of Global Health Affairs, Hubert H. Humphrey Building, Room 639H, 200 Independence Avenue, SW., Washington, DC 20201.

**SUPPLEMENTARY INFORMATION:**

**I. Statutory Authority**

This proposed rule implements a provision in the Leadership Act, section 301(f), 22 U.S.C. 7631(f), concerning restrictions on the use of funds covered by the Leadership Act. This provision prohibits the use of any funds made available to carry out the Leadership Act, or any amendment made by this Act, to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.

There is a related provision in the Leadership Act, Section 301(e), 22 U.S.C. 7631(e), that prohibits the use of funds made available to carry out the Act, or any amendment made by the Act, to promote or advocate the legalization or practice of prostitution or sex trafficking. This restriction, however, does not apply to the use of these funds for palliative care,

treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. Section 301(f) of the Leadership Act should be read together with Section 301(e).

**II. 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.

This proposed 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), which provides that organizations that are receiving Leadership Act funds must have a policy explicitly opposing prostitution and sex trafficking.

Any entity that receives Leadership Act funds for HIV/AIDS programs directly or indirectly ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking.

The U.S. Government is issuing this proposed rule on "Organizational Integrity" to clarify that the Government's organizational partners that have adopted a policy opposing prostitution and sex-trafficking may, consistent with this policy requirement, maintain an affiliation with separate 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 proposed rule. To maintain program integrity, adequate separation, as outlined in this proposed rule, is required between an

affiliate that expresses views on prostitution and sex trafficking contrary to the Government's message and any federally funded partner organization.

This proposed rule applies to funds used by the U.S. Department of Health and Human Services to implement HIV/AIDS programs and activities under the Leadership Act. The rule proposes certification language that organizations must provide to receive grants, cooperative agreements, contracts, and other funding instruments made available by HHS.

All prime recipients that receive U.S. Government funds ("prime recipients") must certify compliance with the proposed Rule on Organizational Integrity 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 the payment 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 proposed 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 proposed 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 in the usual course of its operations that relate to the organization's compliance with this proposed rule.

Nothing in the regulation is intended to lessen or relieve relevant prohibitions on Federal Government funding under other applicable Federal laws.

**III. Discussion of the Proposed Rule**

These sections discuss the proposed rule by defining the terms relevant to this proposed rule and discussing the restrictions on organizations that receive Leadership Act funds.

*Section 88.1 Definitions*

This Section defines the terms that are pertinent to this rule. Specifically, we propose 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 who receive

Leadership Act funds for HIV/AIDS programs directly from HHS.

“Prostitution” means procuring or providing any commercial sex act.

A “recipient” is a contractor, grantee, applicant or awardee who receives Leadership Act funds for HIV/AIDS programs directly or indirectly from HHS. Recipients are 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 the prime recipient, who receive Leadership Act funds for HIV/AIDS programs indirectly from HHS through a contract, grant or other financial agreement with a recipient.

### Section 88.2 Objective Integrity of Recipients

This section of the proposed rule describes the separation that must exist between a recipient 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 No. 108–25 (May 27, 2003), and an affiliate 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 an affiliate organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.

The criteria for affiliate independence in this proposed rule are 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 proposed rule clarifies that an independent 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 independent affiliate’s position on these issues will have no effect on the recipient organization’s eligibility for Leadership Act funds, so long as the affiliate satisfies the criteria for objective integrity and independence detailed in this proposed rule. By ensuring adequate separation between the recipient and affiliate organizations,

these criteria guard against a public perception that the affiliate’s views on prostitution and sex-trafficking may be attributed to the recipient organization, and thus to the Government, thereby avoiding the risk of confusing the Government’s message opposing prostitution and sex trafficking.

Under Paragraph (b) of this section, an organization is ineligible to receive any Federal funds for HIV/AIDS programs made available under the Leadership Act, unless it has provided the certifications required by § 88.3.

### Section 88.3 Certifications

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

The required certification implements the Organizational Integrity Section through 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 affiliated organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.

The certification contains Acknowledgement and Sub-Recipient 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 that such a certification becomes inaccurate; and that the prime recipient will ensure all its sub-recipients also provide the required certifications. As detailed in the Certifications Section, a sub-recipient must, at a minimum, 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 funding 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.

## IV. Impact Analysis

### 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 discretionary Leadership Act funding to include a section regarding “Prostitution and Related Activities.” The statute explicitly requires certifications.

### Executive Order 12866—Regulatory Planning and Review

The 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.

This benefits of this rule are to ensure that an appropriate separation exists between recipients of Leadership Act funds and affiliated entities that engage in activities inconsistent with a policy opposing prostitution and sex trafficking, which will prevent confusion of the Government’s message opposing prostitution and sex trafficking in Leadership Act programs and activities.

The cost of this rule is unlikely to be significant. Since 2004, HHS has required recipients of Emergency Plan funding to certify their compliance with Section 301(f) of the Leadership Act, and HHS/OGHA issued a “Guidance on Organizational Integrity,” similar to this proposed regulation, on July 23, 2007. Although HHS/OGHA directed HHS agencies to disseminate this Guidance to their contractors and grantees that receive funding under the Leadership Act, and provided means for the public to comment on that Guidance, including whether the document is economically significant under definitions provided by the Office of Management and Budget, no one has submitted comments.

### 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. The HHS has determined 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 proposed 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. These regulations will not have an impact on family well-being, as defined in this legislation.

*Paperwork Reduction Act*

To obtain or retain Leadership Act funding for HIV/AIDS programs and activities, 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 affiliated 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 affiliated organizations that engage in activities inconsistent with policies opposing prostitution and sex trafficking. HHS therefore estimates annual aggregate burden to collect the information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Certifications .....	555	1	.5	277.5

HHS has submitted this information collection to the Office of Management and Budget (OMB) for regular approval, and HHS will accept comments from the public, in accordance with the Paperwork Reduction Act of 1995. Comments received during the comment period should primarily focus on the following: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the Department’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) how to enhance the quality, utility, and clarity of the information to be collected; and (4) how to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., by permitting the electronic submission of responses).

All comments and suggestions, or questions regarding additional information, should go to HHS/OGHA.

**List of Subjects in 45 CFR Part 88**

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

Dated: February 26, 2008.

**William R. Steiger**,  
*Director, Office of Global Health Affairs.*

Approved: March 18, 2008.

**Michael O. Leavitt**,  
*Secretary of Health and Human Services.*

For the reasons stated in the preamble, the Office of Global Health Affairs amends 45 CFR 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.

**§ 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.

A “*recipient*” is a contractor, grantee, applicant or awardee who receives 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.

“*Sub-recipients*” are contractors, grantees, applicants or awardees, other than prime recipients, who receive Leadership Act funds for HIV/AIDS programs indirectly from HHS through a contract, grant or other financial agreement with a recipient.

**§ 88.2 Organizational integrity of recipients.**

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

- (1) The affiliated organization is a legally separate entity;
- (2) The affiliated 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 affiliated 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 affiliated organization to conduct activities inconsistent with a policy opposing prostitution and sex trafficking, and the extent of such activities by the affiliate;

(iv) The extent to which signs and other forms of identification that distinguish the recipient from the affiliated organization are present, and signs and materials that could be associated with the affiliated 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 affiliated 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.

#### § 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:

(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], as defined in 45 CFR part 88, from any affiliated 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 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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