<table>
<thead>
<tr>
<th>Flooding source(s)</th>
<th>Location of referenced elevation**</th>
<th>* Elevation in feet (NGVD)</th>
<th>+ Elevation in feet (NAVD)</th>
<th># Depth in feet above ground</th>
<th>Communities affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powers Brook</td>
<td>Approximately 100 feet downstream of Railroad</td>
<td>None</td>
<td>+1001</td>
<td>Village of Hudson, City of Stow.</td>
<td></td>
</tr>
<tr>
<td>Powers Brook Tributary 2</td>
<td>Approximately 100 feet upstream of Norton Road</td>
<td>None</td>
<td>+1074</td>
<td>City of Stow.</td>
<td></td>
</tr>
<tr>
<td>Yellow Creek</td>
<td>At confluence with Powers Brook</td>
<td>None</td>
<td>+1049</td>
<td>Unincorporated Areas of Summit County, City of Akron, City of Cuyahoga Falls.</td>
<td></td>
</tr>
<tr>
<td>Yellow Creek Overflow</td>
<td>Approximately 50 feet downstream of Riverview Road.</td>
<td>None</td>
<td>+1058</td>
<td>Unincorporated Areas of Summit County.</td>
<td></td>
</tr>
<tr>
<td>Yellow Creek Overflow</td>
<td>Approximately 70 feet above confluence with Yellow Creek.</td>
<td>None</td>
<td>+1066</td>
<td>Unincorporated Areas of Summit County.</td>
<td></td>
</tr>
<tr>
<td>Yellow Creek Overflow</td>
<td>Approximately 1,600 feet above confluence with Yellow Creek.</td>
<td>None</td>
<td>+1050</td>
<td>Unincorporated Areas of Summit County.</td>
<td></td>
</tr>
</tbody>
</table>

* 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.


**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 OGAH_Registration_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 Act, 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.


### List of Subjects in 45 CFR Part 88

- Federal aid programs
- Grants administration
- Programs and activities under the Leadership Act
- Sex trafficking
- Prostitution
- Organizational integrity of entities implementing Leadership Act programs and activities
- Certifications
- Paperwork reduction act
- Policies on families
- Unfunded Mandates Reform Act of 1995

### ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certifications</td>
<td>555</td>
<td>1</td>
<td>.5</td>
<td>277.5</td>
</tr>
</tbody>
</table>

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.


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

Approved: March 18, 2008.

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

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**Part 88—Organizational Integrity of Entities Implementing Leadership Act 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 activities inconsistent with a policy opposing prostitution and sex trafficking. Recipients include both prime recipients, who receive Leadership Act funds for HIV/AIDS programs directly 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 Leadership Act funds for HIV/AIDS programs indirectly from HHS through a contract, grant or other financial agreement with a recipient.
§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) An organization is ineligible to receive any Leadership Act funds unless it has provided the certifications required by §88.3.

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