

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Revision of Interim HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Educational Sessions in CDC Regional, State, Territorial, Local, and Community Assistance Programs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice for public comment.

SUMMARY: The purpose of this document is to seek public comment on proposed revision of the Interim HIV Content Guidelines, entitled "Content of AIDS-Related written materials, pictorials, audiovisuals, questionnaires, survey instruments, and educational sessions in CDC assistance programs" and to seek public comment on the proposed revisions. The HIV Content Guidelines were last revised in 1992. The purpose of these revisions are to (1) address advances in technology (mainly the advent of the Internet and the World Wide Web); (2) increase grantee accountability; (3) be consistent with new public law; and (4) improve clarity. Additionally, CDC has developed a separate guidance document for school-based assistance programs.

DATES: Submit comments on or before August 16, 2004.

ADDRESSES: Address all comments concerning this notice to HIV Content Guidelines Comments, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E56, Atlanta, Georgia 30333. Comments may be e-mailed to HIVComments@cdc.gov or faxed to (404) 639-3125.

FOR FURTHER INFORMATION CONTACT: David Hale, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E07, Atlanta, Georgia 30333. Telephone: (404) 639-8008.

SUPPLEMENTARY INFORMATION: The Centers for Disease Control and Prevention (CDC) has provided funds for HIV prevention programs since 1985. Since then, CDC, as part of the terms and conditions for receiving these funds, has required that all HIV educational and related materials must be reviewed by a Program Review Panel (PRP) designated by the recipient. The purpose of this requirement is to ensure a careful consideration of the content

and intended audience of the materials and programs because education about preventing HIV transmission involves effectively presenting information appropriate for the specific audience. On June 15, 1992, CDC published in the *Federal Register* (57 FR 26742) a guidance document for this review entitled "Content of AIDS-related written materials, pictorial, audiovisuals, questionnaires, survey instruments, and educational sessions in Centers for Disease Control assistance programs". These guidelines are currently in effect.

In this notice, CDC is proposing to revise the 1992 HIV Content Guidelines. The purpose of these revisions are to (1) Address advances in technology (mainly the advent of the Internet and the World Wide Web); (2) increase grantee accountability; (3) be consistent with new public law; and (4) improve clarity. CDC anticipates publishing a Final Guidance document within 120 days after the conclusion of the comment period. Additionally, CDC has developed a separate guidance document for school-based assistance programs.

Summary and Explanation of Revisions for Regional, State, Territorial, or Local, and Community Assistance Programs

The proposed HIV Content Guidelines now:

(1) *Require review and approval of HIV/AIDS educational materials placed on an organization's Web site.* When the requirements were developed for local review of HIV/AIDS education materials, the Internet and World Wide Web were not used by the general public as a major source of information as it is today. As a result, CDC is proposing revisions to the *Guidelines* to require that HIV/AIDS educational materials placed on a grantee's Web site be reviewed and approved by the organization's designated Program Review Panel (PRP). This requirement will not apply to materials developed by the U.S. Department of Health and Human Services.

(2) *Require that funded recipients ensure the PRP has determined that the materials comply with Section 317P of the Public Health Service Act.* Section 317P was added to the Public Health Service Act in 2000. This Section states, in part, that "education materials * * * that are specifically designed to address sexually transmitted diseases * * * shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the sexually transmitted

disease the materials are designed to address."

(3) *Clarify the requirement of the PRP by requiring identification of a PRP of no less than five persons who represent a reasonable cross-section of the jurisdiction in which the program is based to ensure better representation of the community to be served.* The current Guidelines require the identification of a PRP of no less than five persons who represent a reasonable cross-section of the *general population*. The proposed Guidelines require the identification of a PRP of no less than five persons who represent a reasonable cross-section of the *jurisdiction in which the program is based*. This clarification should ensure better representation of the community to be served.

(4) *Require each recipient to identify at least one PRP, established by a state, territory, or local health department or educational agency from the jurisdiction of the recipient.* This revision provides jurisdictions with the flexibility to establish the number of PRPs to meet demand.

(5) *Require PRPs to ensure that the title of materials developed and submitted for review reflects the content of the activity or program.* This revision will ensure that materials and their contents are clearly stated to the audience.

(6) *Require funded recipients to include a certification that accountable state, territorial or local health officials have independently reviewed educational materials for compliance with Sections 2500 and 317P of the Public Health Service Act.* This is a new requirement in the revised Guidelines and follows the same rationale of *Miller v. California*, 413 U.S. 15, 93 S.Ct. 2607 (1973) that defines "obscenity" by looking to the average person, applying contemporary community standards, as a way to ensure that material would be judged by its impact on an average person, rather than a particularly susceptible or sensitive person, or a totally insensitive one. The review responsibility, in the proposed Guidelines, is placed at the state and local level, specifically with state and local health officials.

(7) *Develop a separate guidance document for school-based assistance programs.* The current Guidelines apply to school-based assistance programs as well as regional, state, territorial, local, and community assistance programs. The proposed Guidelines separate the guidance into two documents for ease of use and clarity.

Summary and Explanation of Revision Applicable Only to Community-Based Programs

(8) *Require funded community-based organizations to identify a program review panel established by a state or local health department.* While the current Guidelines allow CDC-funded organizations to establish their own PRP, they are encouraged to use a PRP established by a health department or another CDC-funded organization. The proposed Guidelines will no longer permit organizations to establish their own PRP. Instead, recipients of HIV/AIDS funds are required to identify a PRP established by a state or local health department within their state's jurisdiction.

Dated: June 7, 2004.

James D. Seligman,

*Associate Director for Program Support,
Centers for Disease Control and Prevention.*

Interim HIV Content Guidelines for AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions for CDC Assistance Programs

I. Basic Principles

Controlling the spread of HIV infection and the occurrence of AIDS requires the promotion of individual behaviors that eliminate or reduce the risk of acquiring and spreading the virus. Messages must be provided to the public that emphasize the ways by which individuals can protect themselves from acquiring the virus. These methods include abstinence from illegal use of IV drugs as well as from sexual intercourse except in a mutually monogamous relationship with an uninfected partner.

For those individuals who do not or cannot cease risky behavior, methods of reducing their risk of acquiring or spreading the virus must also be communicated. Such messages are often controversial. The principles contained in this document are intended to provide guidance for the development and use of HIV/AIDS-related educational materials developed or acquired in whole or in part using CDC HIV prevention funds, and to require the establishment of at least one Program Review Panel by state and local health departments, to consider the appropriateness of messages designed to communicate with various groups. State and local health departments may, if they deem it appropriate, establish multiple Program Review Panels to consider the appropriateness of

messages designed to communicate with various groups.

A. Written materials (e.g., pamphlets, brochures, curricula, fliers), audiovisual materials (e.g., motion pictures and videotapes), pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings) and marketing, advertising, Web site-based HIV/AIDS educational materials, questionnaires or survey instruments should use terms, descriptors, or displays necessary for the intended audience to understand dangerous behaviors and explain practices that eliminate or reduce the risk of HIV transmission.

B. Written materials, audiovisual materials, pictorials, and marketing, advertising, Web site-based HIV/AIDS educational materials, questionnaires or survey instruments should be reviewed by a Program Review Panel established by a state or local health department, consistent with the provisions of section 2500(b), (c), and (d) of the Public Health Service Act, 42 U.S.C. Section 300ee(b), (c), and (d), as follows:

“SEC. 2500. USE OF FUNDS.

(b) Contents of Programs.—All programs of education and information receiving funds under this title shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(c) Limitation.—None of the funds appropriated to carry out this title may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.

(d) Construction.—Subsection (c) may not be construed to restrict the ability of an educational program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to, or to transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.”

C. Educational sessions should not include activities in which attendees participate in sexually suggestive physical contact or actual sexual practices.

D. Program Review Panels must ensure that the title of materials developed and submitted for review reflects the content of the activity or program.

E. When HIV materials include a discussion of condoms, the materials must comply with Section 317P of the Public Health Service Act, 42 U.S.C. Section 247b–17, which states in pertinent part:

“educational materials * * * that are specifically designed to address STDs * * *

shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address.”

II. Program Review Panel

Each recipient will be required to identify at least one Program Review Panel, established by a state or local health department from the jurisdiction of the recipient. These Program Review Panels will review and approve all written materials, pictorials, audiovisuals, marketing, advertising, and Web site materials, questionnaires or survey instruments (except questionnaires or survey instruments previously reviewed by an Institutional Review Board—these questionnaires or survey instruments are limited to use in the designated research project). The requirement applies regardless of whether the applicant plans to conduct the total program activities or plans to have part of them conducted through other organization(s) and whether program activities involve creating unique materials or using/distributing modified or intact materials already developed by others. Materials developed by the U.S. Department of Health and Human Services do not need to be reviewed by a panel. Members of a Program Review Panel should understand how HIV is and is not transmitted and understand the epidemiology and extent of the HIV/AIDS problem in the local population and the specific audiences for which materials are intended.

A. The Program Review Panel will be guided by the CDC Basic Principles (see Section I above) in conducting such reviews. The panel is authorized to review materials only and is not empowered either to evaluate the proposal as a whole or to replace any internal review panel or procedure of the recipient organization or local governmental jurisdiction.

B. Applicants for CDC assistance will be required to include in their applications the following:

1. Identification of at least one panel, established by a state or local health department, of no less than five persons who represent a reasonable cross-section of the jurisdiction in which the program is based. Since Program Review Panels review materials for many intended audiences, no single intended audience shall dominate the composition of the Program Review Panel, except as provided in subsection d below. In addition:

a. Panels that review materials intended for a specific audience should draw upon the expertise of individuals who can represent cultural sensitivities

and language of the intended audience, either through representation on the panel or as consultants to the panels.

b. Panels must ensure that the title of materials developed and submitted for review reflect the content of the activity or program.

c. The composition of Program Review Panels must include an employee of a state or local health department with appropriate expertise in the area under consideration, who is designated by the health department to represent the department on the panel.

d. Panels reviewing materials intended for racial and ethnic minority populations must comply with the terms of a–c above. However, membership of the Program Review Panel may be drawn predominantly from such racial and ethnic populations.

2. A letter or memorandum to the applicant from the state or local health department, which includes:

a. Concurrence with this guidance and assurance that its provisions will be observed.

b. The identity of members of the Program Review Panel, including their names, occupations, and any organizational affiliations that were considered in their selection for the panel.

C. When a cooperative agreement/grant is awarded and periodically thereafter, the recipient will:

1. Present for the assessment of the appropriately identified Program Review Panel(s) established by a state or local health department, copies of written materials, pictorials, audiovisuals, and marketing, advertising, Web site HIV/AIDS educational materials, questionnaires, and surveys proposed to be used. The Program Review Panel shall pay particular attention to ensure that none of the above materials violate the provisions of Sections 2500 and 317P of the Public Health Service Act.

2. Provide for assessment by the appropriately identified Program Review Panel(s) established by a state or local health department, the text, scripts, or detailed descriptions for written materials, pictorials, audiovisuals, and marketing, advertising, and Web site materials that are under development.

3. Prior to expenditure of funds related to the ultimate program use of these materials, assure that its project files contain a statement(s) signed by the chairperson of the appropriately identified Program Review Panel(s) established by a state or local health department, specifying the vote for approval or disapproval for each proposed item submitted to the panel.

4. Include a certification that accountable state or local health officials have independently reviewed written materials, pictorials, audiovisuals, and marketing, advertising, and Web site materials for compliance with Section 2500 and 317P of the Public Health Service Act and approved the use of such materials in their jurisdiction for directly and indirectly funded community-based organizations.

5. As required in the notice of grant award, provide to CDC in regular progress reports, signed statement(s) of the chairperson of the Program Review Panel(s) specifying the vote for approval or disapproval for each proposed item that is subject to this guidance.

D. CDC-funded organizations, which are national or regional (multi-state) in scope, or that plan to distribute materials as described above to other organizations on a national or regional basis, must identify a single Program Review Panel to fulfill this requirement. Those guidelines identified in Sections I.A. through I.D. and II.A. through II.C. outlined above also apply. In addition, such national/regional panels must include, as a member, an employee of a state or local health department.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interim HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Educational Sessions in CDC School-Based Assistance Programs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice for public comment.

SUMMARY: The purpose of this document is to seek public comment on proposed Interim HIV Content Guidelines, entitled “Content of AIDS-Related written materials, pictorials, audiovisuals, questionnaires, survey instruments, and educational sessions in CDC school-based assistance programs” and to seek public comment on the Interim Guidelines. The purpose of these Guidelines are to (1) Address advances in technology (mainly the advent of the Internet and the World Wide Web); (2) increase grantee

accountability; (3) be consistent with new public law; and (4) provide clarification for school-based assistance programs in the development of AIDS-related materials, pictorials, audiovisuals, questionnaires, survey instruments, marketing, advertising, and Web site materials, and educational sessions.

DATES: Submit comments on or before August 16, 2004.

ADDRESSES: Address all comments concerning this notice to Interim HIV Content Guidelines Comments (School-based Assistance Programs), Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E56, Atlanta, Georgia 30333. Comments may be e-mailed to HIVComments@cdc.gov or faxed to (404) 639–3125.

FOR FURTHER INFORMATION CONTACT: Tim Hack, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1600 Clifton Road, NE., Mailstop K29, Atlanta, Georgia 30333. Telephone: (770) 488–3249.

SUPPLEMENTARY INFORMATION: The Centers for Disease Control and Prevention (CDC) has provided funds for HIV prevention programs since 1985. Since then, CDC, as part of the terms and conditions for receiving these funds, has required that all HIV educational and related materials must be reviewed by a Program Review Panel (PRP) designated by the recipient. The purpose of this requirement is to ensure a careful consideration of the content and intended audience of the materials and programs because education about preventing HIV transmission involves effectively presenting information appropriate for the specific audience. On June 15, 1992, CDC published in the *Federal Register* (57 FR 26742) a guidance document for this review entitled “Content of AIDS-related written materials, pictorial, audiovisuals, questionnaires, survey instruments, and educational sessions in Centers for Disease Control assistance programs”. Currently, those Guidelines are in effect for school based assistance programs.

In this notice, CDC is proposing a separate guidance document for school-based assistance programs. The purpose of this document is to (1) address advances in technology (mainly the advent of the Internet and the World Wide Web); (2) increase grantee accountability; (3) be consistent with new public law; and (4) provide clarification for school-based assistance programs. CDC anticipates publishing a Final Guidance document for school-based assistance programs within 120