

United States Government Accountability Office Washington, DC 20548

B-308128

October 18, 2006

The Honorable Michael O. Leavitt Secretary of Health and Human Services

Subject: Abstinence Education: Applicability of Section 317P of the Public Health Service Act

Dear Mr. Secretary:

In responding to a congressional request on federal abstinence education grant programs, we identified a legal matter that requires the attention of the Department of Health and Human Services (HHS). In this regard, section 317P(c)(2) of the Public Health Service Act^1 requires certain educational materials to contain medically accurate information about condom effectiveness. HHS believes that this statute does not apply to materials prepared and used by recipients of federal abstinence education grants. As discussed below, we conclude that this requirement would apply to abstinence education materials prepared and used by federal grant recipients, depending upon the substantive content of those materials. We did not assess any particular abstinence education materials for compliance with section 317P(c)(2) and, therefore, reach no conclusions regarding statutory violations. However, in light of our conclusion, we recommend that HHS reexamine its position and adopt measures to ensure that, where applicable, abstinence education materials comply with this requirement.

BACKGROUND

As you know, HHS supports efforts to provide abstinence education primarily through grants to states, local communities, and private organizations under three programs. First, under section 510 of the Social Security Act,² HHS makes formula grants to states for the provision of abstinence education, targeting those most likely to have children out-of-wedlock. In addition, under section 1110 of the Social

¹ 42 U.S.C. § 247b-17(c)(2) (2000).

² 42 U.S.C. § 710 (2000 & Supp. III 2003).

Security Act,³ HHS awards community-based grants through a competitive process to public and private entities for the purpose of creating an environment that supports postponing sexual activity until marriage.⁴ Grants may be used to support before and after school programs, adult and peer mentoring, and parent education groups.⁵ Through the adolescent family life program established by Title XX of the Public Health Service Act,⁶ HHS also makes competitive grants to public and private nonprofit organizations, including community, school, and faith-based organizations, to facilitate abstinence education. The state formula and community-based grant programs are administered by the Administration for Children and Families (ACF) within HHS and the adolescent family life program is administered by the Office of Population Affairs, which is located in the Office of the Secretary.

Section 510(b)(2) of the Social Security Act defines "abstinence education" for purposes of the state formula grant program, effectively requiring grantees to meet eight criteria; annual appropriations acts and program announcements have extended these criteria to the community-based and adolescent family life program grants as well. Three of these criteria focus on the physical consequences of sexual activity, and one explicitly references sexually transmitted diseases. Specifically, abstinence education for which federal funds may be provided must (1) have as its exclusive purpose teaching the social, psychological, and health gains to be realized by abstaining from sexual activity; (2) teach that abstinence from sexual activity is the only certain way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, and other associated health problems; and (3) teach that sexual activity outside of the context of marriage is likely to have harmful psychological and

Page 2 B-308128

³ 42 U.S.C. § 1310 (2000 & Supp. IV 2004). This section authorizes the Secretary to make grants to states, local governments, and other entities for a wide range of demonstration projects.

⁴ Announcement, Department of Health and Human Services, Administration for Children and Families, *Community-Based Abstinence Education Program, Funding Opportunities FY 2006*, p. 3.

⁵ *Id*.

⁶ 42 U.S.C. §§ 300z *et seq.* (2000). Title XX authorizes the Secretary to make grants for demonstration projects to help communities provide appropriate care and prevention services in easily accessible locations. The term "prevention services" means necessary services to prevent adolescent sexual relations. 42 U.S.C. § 300z-1(a)(8).

⁷ 42 U.S.C. § 710(b)(2)(A)–(H).

⁸ See, e.g., Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-149, 119 Stat. 2833, 2855-56 (providing funds for community-based and adolescent family life program abstinence education grants consistent with the criteria at section 510(b)(2) and, with respect to community-based grants, further providing for grantees not to provide any other education regarding sexual conduct, except to the extent that health information or services are legally required to be provided and are provided in a setting different from abstinence education). See also Notice, Department of Health and Human Services, Office of the Secretary, Availability of Funds for Adolescent Family Life Demonstration Projects, 69 Fed. Reg. 17,888-89 (April 5, 2004); Announcement, Department of Health and Human Services, Administration for Children and Families, Community-Based Abstinence Education Program, Funding Opportunities FY 2006, p. 2.

physical effects. Annual announcements about the three grant programs also instruct grantees to incorporate material related to sexually transmitted diseases.⁹

During the course of our congressionally requested work on abstinence education, we identified a federal statute relevant to these grants. Section 317P of the Public Health Service Act addresses human papillomavirus specifically, as well as sexually transmitted diseases generally. Section 317P(c)(1) requires the Secretary to prepare and distribute educational materials to the public and health care providers that include information on human papillomavirus. Among other things, the materials are to address modes of transmission and the consequences of infection. Subsection (c)(2), which is pertinent to our review, states:

Educational material under paragraph (1), and all other relevant educational and prevention materials prepared and printed from this date forward for the public and health care providers by the Secretary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by contractors, grantees, or subgrantees thereof, that are specifically designed to address [sexually transmitted diseases] including [human papillomavirus] 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. Such requirement only applies to materials mass produced for the public and health care providers, and not to routine communications.

By letter of May 26, 2006, we solicited the views of HHS's General Counsel on the applicability of section 317P(c)(2) to the three abstinence education grant programs described above. In a response dated July 26, 2006, the Assistant Secretary for Children and Families advised that the statute does not apply, given the purpose of abstinence education programs and the populations targeted by program grantees.

DISCUSSION

By its own terms, section 317P(c)(2) is quite broad. It applies not only to the educational material on human papillomavirus described in the first paragraph of section 317P(c), but to "all other relevant educational and prevention materials" prepared by the Secretary of HHS. In addition, it extends to materials prepared by contractors, grantees, and subgrantees and to material pertaining to sexually transmitted diseases including, and thus not limited to, human papillomavirus. However, the provision contains a significant limitation: it extends only to materials

Page 3 B-308128

.

⁹ See, e.g., Announcement, Department of Health and Human Services, Administration for Children and Families, Community-Based Abstinence Education Program, Funding Opportunities FY 2006, pp. 2, 7-8; Announcement, Department of Health and Human Services, Administration for Children and Families, Section 510 Abstinence Education Program, FY 2006 Program Announcement, p. 9; Notice, Department of Health and Human Services, Office of the Secretary, Availability of Funds for Adolescent Family Life Demonstration Projects, 69 Fed. Reg. 17,888-89 (April 5, 2004).

that are "specifically designed to address" sexually transmitted diseases. The statute does not define this phrase and the legislative history provides no guidance as to its meaning.¹⁰

HHS has not issued a regulation or published guidance interpreting section 317P(c)(2). In addition, we found no references to that provision, which was enacted in December 2000, in grant application guidance or program announcements on abstinence education programs dating from 2001. Notably, HHS included a reference to section 317P(c)(2) in proposed content guidelines for AIDS-related materials issued in 2004. However, the proposed guidelines stated only that "When HIV materials include a discussion of condoms, the materials must comply with Section $317P\dots$ " This statement could be read to suggest that the statute only applies to materials designed to address sexually transmitted diseases if, and only if, the materials discuss condom use.

In our view, the interpretation of section 317P(c)(2) reflected in the proposed guidelines is not consistent with the statute. Neither the language nor the structure of section 317P(c)(2) supports an interpretation that the need to provide medically accurate information on condom effectiveness arises only where the materials include information on condoms. The provision does not state that educational materials prepared by the Secretary or by grantees *that are specifically designed to address condom use* shall contain medically accurate information regarding the

Page 4 B-308128

_

¹⁰ The sponsor of the provision was particularly concerned that women had been misled to believe that condoms were effective in preventing human papillomavirus and had suffered serious health consequences as a result. 146 Cong. Rec. H9844 (daily ed. Oct. 12, 2000) (statement of Representative Coburn). *See also* 146 Cong. Rec. H2692-93 (daily ed. May 9, 2000) (statement of Representative Coburn). This provision was initially included as an amendment to a bill that was subsequently enacted as the Breast and Cervical Cancer Prevention and Treatment Act of 2000. A similar provision had been contained in an earlier bill introduced by Representative Coburn. *See* H.R. 3248, 106th Cong. § 2 (1999). The provision was ultimately enacted as part of the Consolidated Appropriations Act, 2001. *See* Pub. L. No. 106-554, app. A, § 516, 114 Stat. 2763, 2763A-72 to 73 (Dec. 21, 2000).

¹¹ For the state and community-based programs, we reviewed the annual announcements for 2001 through 2006. For the adolescent family life program, we reviewed announcements for 2002 and 2004, the latest years for which they were published.

¹² See Notice, 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, 69 Fed. Reg. 33,824 (June 16, 2004); Notice, 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, 69 Fed. Reg. 33,826 (June 16, 2004).

¹³ 69 Fed. Reg. at 33,825 and 33,828.

¹⁴ See U.S. National Bank of Oregon v. Independent Ins. Agents of America, 508 U.S. 439, 455 (1993) ("Statutory construction 'is a holistic endeavor' . . . and, at a minimum, must account for a statute's full text, language as well as punctuation, structure, and subject matter.").

effectiveness of condoms in preventing sexually transmitted diseases. To the contrary, it provides that materials *that are specifically designed to address sexually transmitted diseases* shall contain medically accurate information on condom effectiveness. The syntax of the sentence and Congress's choice of the mandatory "shall" clearly indicate that materials specifically designed to address sexually transmitted diseases are to contain medically accurate information as to the effectiveness of condom use in preventing transmission of such diseases. Therefore, the Secretary, grantees, and others to whom the statute applies are required to include information on condom effectiveness, and that information must be medically accurate, in materials otherwise meeting the statutory criteria.

In response to our inquiries, the Assistant Secretary for Children and Families stated that materials prepared by its abstinence education grantees do not fall within the scope of section 317P(c)(2). He explained that the primary purpose of these programs is not to address sexually transmitted diseases and that, while grantees may address issues related to sexually transmitted diseases in communicating the importance of abstinence, they are to address these issues only within the broader context of abstinence education, as defined by law. Moreover, he pointed out that a variety of organizations receive abstinence education grants and materials are produced for different target populations.

The Assistant Secretary's response is not persuasive. Both the statutory definition of abstinence education and grant program materials distributed by HHS suggest that section 317P(c)(2) would apply to materials prepared and used by recipients of abstinence education grants, depending upon the substantive content of those materials. As discussed above, the governing statutory provision and program announcements incorporate multiple references to the physical consequences of sexual activity, specifically requiring information on sexually transmitted diseases to be an integral part of abstinence education programs. Notably, the 2006 program announcement for the community-based abstinence education program instructs grantees to develop curricula around themes and further instructs them to incorporate material around the subtheme of sexually transmitted diseases. In this regard, it offers several illustrations of appropriate program content and endorses the use of disease-specific information. It states that abstinence education programs may contain information on the limitations of contraception to consistently prevent sexually transmitted diseases, as well as information on the epidemiology of sexually transmitted diseases in the United States. 16 This information could include infection rates and modes of transmission for sexually transmitted diseases.¹⁷ Therefore, grantees could incorporate sufficiently specific information about these diseases to

Page 5 B-308128

¹⁵ See, e.g., United States v. Booker, 543 U.S. 220, 233-34 (2005); National Railroad Passenger Corp. v. Morgan, 536 U.S. 101, 109 (2002).

¹⁶ Announcement, Department of Health and Human Services, Administration for Children and Families, *Community-Based Abstinence Education Program, Funding Opportunities FY 2006*, p. 8.

¹⁷ *Id.*

lead to the conclusion that the materials were "specifically designed to address" sexually transmitted diseases, whether or not they were primarily designed to do so.¹⁸

The content of a student workbook commonly used by abstinence education grantees further suggests that section 317P(c)(2) may apply to federally funded abstinence education materials. The workbook contains eight chapters, each of which focuses on a dimension of abstinence. One chapter is dedicated to the topic of sexually transmitted diseases. Among other things, the chapter provides information on several sexually transmitted diseases, including human papillomavirus, in a series of brief paragraphs. For example, it explains that the human immunodeficiency virus or HIV affects the body's T-4 cells, which are central to the immune system and necessary for the body to fight diseases. It also points out that there is no cure for HIV. Although the chapter contains general statements about condom effectiveness, it does not contain information about the effectiveness or lack of effectiveness of condoms in preventing HIV or the other diseases it describes.

The Assistant Secretary's view that section 317P(c)(2) is inapplicable since ACF grants are made to a variety of grantees and materials are prepared for different target populations is also not persuasive. We do not believe that the applicability of section 317P(c)(2) turns on whether materials are prepared for all members of the public, as the Assistant Secretary suggests. As a general matter, abstinence education programs target broad segments of the population, namely, preadolescents and adolescents. While grantees may not prepare identical materials for all recipients of program services, they nonetheless may produce educational materials in large quantities for those members of the public for whom the materials are appropriate. We also note that the 2004 proposed content guidelines for AIDS-related materials did not reflect the Assistant Secretary's apparent view that section 317P(c)(2) only applies to materials distributed to all members of the public. Those proposed guidelines were designed to apply to materials used by school-based and other assistance programs rather than materials distributed to all members of the public.

CONCLUSION

The statutory requirement to include medically accurate information on condom effectiveness would apply to abstinence education materials prepared and used by federal grant recipients, depending upon the substantive content of those materials. While general references to sexually transmitted diseases would appear insufficient to trigger the application of section 317P(c)(2) of the Public Health Service Act, the inclusion of more detailed information as an essential element of the materials' design would require the incorporation of medically accurate information on condom

Page 6 B-308128

.

¹⁸ Language regarding abstinence education programs in annual appropriations acts does not make section 317P inapplicable to abstinence education materials. The language simply reiterates that funds made available are for abstinence-only education, rather than for educational efforts concerning other approaches to sexual conduct. The 2006 program announcement for the community-based program supports this reading, providing that abstinence education grantees may not promote, endorse, distribute, or demonstrate the use of contraception, although they may provide information on contraceptives as it supports a message of abstinence. *Id.* at 5-6.

¹⁹ Abstinence education curricula may include materials used directly by students.

effectiveness. As stated above, we did not assess any particular materials for compliance with section 317P(c)(2) and, therefore, reach no conclusions regarding statutory violations. However, in light of our conclusion, we recommend that HHS reexamine its position and adopt measures to ensure that, where applicable, abstinence education materials comply with this requirement.

Sincerely yours,

Gary L. Kepplinger General Counsel

Page 7 B-308128

cc: The Honorable Henry A. Waxman Ranking Minority Member Committee on Government Reform House of Representatives

> The Honorable Pete Stark Ranking Minority Member Subcommittee on Health Committee on Ways and Means House of Representatives

The Honorable Sherrod Brown Ranking Minority Member Subcommittee on Health Committee on Energy and Commerce House of Representatives

The Honorable Barbara Boxer
The Honorable Maria Cantwell
The Honorable Tom Coburn
The Honorable Richard J. Durbin
The Honorable Russell D. Feingold
The Honorable Dianne Feinstein
The Honorable Tom Harkin
The Honorable James M. Jeffords
The Honorable Edward M. Kennedy
The Honorable Frank R. Lautenberg
The Honorable Patrick Leahy
The Honorable Patty Murray
United States Senate

The Honorable Howard L. Berman The Honorable Lois Capps The Honorable Jay Inslee The Honorable Barbara Lee The Honorable Nita M. Lowey The Honorable Betty McCollum House of Representatives

Page 8 B-308128