

FY 1996 ALLOTMENT—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES—Continued

	Protection and advocacy	Percentage
Iowa .....	264,641	1.021334
Kansas .....	254,508	.982227
Kentucky .....	403,708	1.558037
Louisiana .....	465,263	1.795598
Maine .....	254,508	.982227
Maryland .....	334,983	1.292806
Massachusetts .....	441,992	1.705787
Michigan .....	836,270	3.227431
Minnesota .....	354,899	1.369668
Mississippi .....	315,378	1.217144
Missouri .....	458,338	1.768872
Montana .....	254,508	.982227
Nebraska .....	254,508	.982227
Nevada .....	254,508	.982227
New Hampshire .....	254,508	.982227
New Jersey .....	504,403	1.946651
New Mexico .....	254,508	.982227
New York .....	1,379,169	5.322651
North Carolina .....	630,628	2.433794
North Dakota .....	254,508	.982227
Ohio .....	998,081	3.851911
Oklahoma .....	304,757	1.176154
Oregon .....	261,963	1.010998
Pennsylvania .....	1,037,225	4.002980
Rhode Island .....	254,508	.982227
South Carolina .....	365,671	1.411240
South Dakota .....	254,508	.982227
Tennessee .....	491,491	1.896820
Texas .....	1,492,807	5.761216
Utah .....	254,508	.982227
Vermont .....	254,508	.982227
Virginia .....	498,317	1.923163
Washington .....	382,580	1.476498
West Virginia .....	276,040	1.065326
Wisconsin .....	447,725	1.727913
Wyoming .....	254,508	.982227
American Samoa .....	136,161	.525489
Guam .....	136,161	.525489
Northern Mariana Islands .....	136,161	.525489
Puerto Rico .....	809,142	3.122736
Palau .....	102,121	.394117
Virgin Islands .....	136,161	.525489

<sup>1</sup> This amount is \$806,682 less than the 1995 appropriation level. These funds are set aside for funding technical assistance and American Indian Consortiums. Public Law 103-230 authorizes spending up to two percent (2%) of the amount appropriated under Section 143 to fund technical assistance. American Indian Consortiums are eligible to receive the minimum amount under Section 142(c)(1)(A)(i). Unused funds will be reallocated in accordance with Section 142(c)(1) of the Act.

Dated: July 7, 1995.

**Bob Williams,**

*Commissioner, Administration on Developmental Disabilities.*

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BILLING CODE 4184-01-P

**Centers for Disease Control and Prevention**

[Announcement 547]

RIN 0905-ZA94

**Community Coalition Partnership Programs for the Prevention of Teen Pregnancy**

**Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for cooperative agreements to support the efforts of "hub" organizations to strengthen and evaluate the effectiveness of their community program to prevent initial and repeat teen pregnancies and related problems.

These cooperative agreements will support demonstration projects to plan for the implementation of appropriate and effective prevention intervention strategies for reaching the greatest proportion of teenagers in communities with high rates of teen pregnancy. "Hub" organizations are also encouraged, to the extent that it is feasible and desirable within their communities, to establish linkages with and participate in existing community-based efforts funded by the Federal government or others to prevent HIV/AIDS, sexually transmitted diseases, and first and repeat pregnancies among teenagers.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention

objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement directly addresses national objectives related to the priority areas of Family Planning and Educational and Community-Based Programs. Changes in the teen sexual behaviors will also have a positive impact on the achievement of HIV Infection and Sexually Transmitted Diseases national objectives. (For ordering a copy of "Healthy People 2000," see the section **Where To Obtain Additional Information.**)

#### Authority

This program is authorized under Section 317(k)(2) of the Public Health Service Act, as amended [42 U.S.C. 247b(k)(2)]. Applicable program regulations are found in 42 CFR Part 51b—Project Grants for Preventive Health Services.

#### Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, which prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care and early childhood development services are provided to children.

#### Eligible Applicants

Applications may be submitted by "Hub" organizations which are local public and nonprofit private social service, professional, or voluntary organizations that serve youth; and among others may include local affiliates of national organizations, hospitals, or local health, education, social service, mental health, or other local public service agencies, including local councils of Indian Tribes.

Eligible "Hub" organizations must have the following characteristics:

1. Serve communities (1) of at least 200,000 people and have (2) teen birth rates that are at least 50 percent above the national average of 62.1 births per 1,000 women 15-19 years of age—that is, communities that have birth rates of 93 births per 1000 among women who are 15-19 years of age, or higher. These data must be documented by a letter from the local health department that is attached with the Executive Summary section of the application.

2. The eligible "Hub" organization must be the lead organization for an existing teen pregnancy prevention community coalition of three or more private nonprofit and/or local public

organizations. The applicant must provide copies of formal agreements that document a history of collaboration to provide services, assistance, and opportunities to teens who live, study, and/or work in the community for the purpose of preventing initial and repeat pregnancies. (Copies of the formal agreements must be attached with the Executive Summary.)

3. A community is a specific area within which the "hub" organization and its partners will focus their efforts to help prevent teen pregnancies. This area must be defined by one or more contiguous neighborhoods, school districts, zip codes, or census tracts. The definition and/or description of the community must be provided with the Executive Summary section.

4. Eligibility characteristics must be clearly specified in the Executive Summary section of the application.

#### Availability of Funds

\$3.25 million to \$4.5 million is available in FY 1995 to fund approximately 12 demonstration projects for the development of Community Coalition Partnerships. It is expected that the average award will be \$270,000, ranging from \$150,000 to \$300,000. It is expected the awards will begin on or about September 30, 1995, and will be made for a 12-month budget period within a project period of up to 2 years. Funding estimates may vary and are subject to change.

Funds may be used to facilitate the strengthening and expansion of existing partnership coalitions; the planning and coordination of coalition program activities; and the documentation and evaluation of progress. This may include paying for staff time. Funds may not be used for facilities, direct services, or research.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds. CDC anticipates a new, competitive program announcement for the availability of funds during FY 1997 to support the implementation of community coalition partnership programs for the prevention of teen pregnancy.

#### Purpose

These cooperative agreement awards are to support the efforts of "hub" organizations to enhance their capacity to strengthen and evaluate the effectiveness of coalition partnership programs; and, to develop "Community Action Plans" for the implementation of comprehensive community programs for the prevention of initial and repeat teen pregnancies and related problems.

#### Program Requirements

"Hub" organizations should seek to involve all relevant organizations in the community to work in partnership to prevent teen pregnancies. The community coalition partnership program should seek to reach the greatest proportion of teens within the community, giving emphasis to those teens who are in high risk situations. "Hub" organizations are encouraged, to the extent that it is feasible and desirable within their communities, to establish linkages, and to work in concert with existing community-based efforts funded by the Federal government or others to prevent HIV/AIDS, sexually transmitted diseases, and first and repeat pregnancies among teenagers, as a means to strengthen the program to prevent teen pregnancy.

"Hub" organizations will work with current and/or new partner organizations to enhance the effectiveness of their teen pregnancy prevention efforts, and to increase the number of teens reached. Programs will involve teens in community service, job skills development, and other opportunities that build their self-esteem, self-sufficiency, and belief in themselves and their futures. In so doing, programs should strive to provide teens who are not yet sexually experienced with a strong incentive to remain abstinent, and teens who are sexually experienced with a strong incentive to delay pregnancies and childbearing until they are ready and able to assume the role and responsibilities of parents. For those teens who are sexually active, programs will promote the consistent and effective use of appropriate contraceptives, and will facilitate family planning counseling and services.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for the activities listed under B. (CDC Activities).

#### A. Recipient Activities

The "hub" organization will coordinate the efforts of coalition members and facilitate the development of partnerships among members in support of the community teen pregnancy prevention program. During the first year, each "hub" organization, will work with partner organizations and involve teens in a meaningful way, to:

1. Plan for the implementation of the general approach described above by:
  - a. Conducting a needs assessment to determine (1) the numbers and rates of

teen pregnancies and associated demographic and economic characteristics; (2) why some teens are getting pregnant and others are not;

(3) the perceived needs of teens; (4) the extent to which these needs are met in the community, or the extent to which program gaps exist; (5) the extent to which social norms support postponing teen pregnancy; and (6) the extent to which teen services, assistance, and opportunities are appealing, accessible, affordable, sufficiently intense, are in sufficient quantity and duration, provide for adequate continuity in "care providers", and are known to teens throughout the community.

b. Identifying effective intervention methods and adapting them for use with diverse groups of teens who live, study, and/or work in the program's community such that they build on the cultures of the teens; and preparing for the use of these interventions in a variety of community settings that might include, but are not limited to schools, after-school programs, youth clubs or organizations, clinical or social service settings, local media, communities of faith, work-sites that employ teens, and community volunteer service programs.

c. Specifying criteria that will be used to identify teens who are at greatest risk of becoming pregnant or getting someone pregnant, and a systematic approach to using these criteria as a means of linking teens to appropriate prevention services, assistance, and/or opportunities.

d. Field testing intervention components and modifying the components based on the results.

e. Prioritizing the gaps in services, assistance, opportunities, and social norms that need to be addressed, as well as the groups of teens most in need.

f. Developing a community action plan that establishes realistic objectives, partner roles, sources of sustainable funding, coordination mechanisms, approaches to targeting resources and services, schedules for accomplishing tasks and a delineation of responsibilities, and plans for evaluating progress and indicators of effectiveness.

2. Provide a full-time position with the responsibility, authority, professional training, and experience needed for leadership and coordination of program activities among coalition partners.

3. Serve as liaison between the coalition and its community partners, and CDC and its national partners.

4. Assess and document progress made, and plan for the evaluation of

indicators of program effectiveness in collaboration with CDC.

5. Share information about program design, implementation, and effectiveness with other recipients, other communities, and CDC and its national partners through site visits; demonstration, training, and dissemination workshops; and other means.

6. Participate in at least two workshops with other recipients, CDC, and CDC's national partners for the purposes of supporting the development of recipient community coalition partnership programs and developing strategies for nationwide replication of effective programs.

#### *B. CDC Activities*

1. Provide consultation and technical assistance to recipients with respect to program activities.

2. Facilitate the development of a national partnership between private and public sector organizations in support of community coalition partnership programs to prevent teen pregnancy and related problems.

3. Coordinate the planning and support of at least two planning, progress evaluation, demonstration, training, and/or dissemination workshops together with recipients and national partners.

4. Promote and collaborate in the transfer and dissemination of information, methods, and findings developed as part of this program.

#### **Evaluation Criteria (Total of 100 Points)**

Applications will be reviewed and evaluated according to the following criteria:

##### *A. Define Teen Pregnancy Problem and Current Prevention Efforts (25 points)*

The extent to which the applicant substantiates the community's teen pregnancy problem and identifies target populations of teens to be reached according to the level of risk of pregnancy that is associated with their living situation. The extent to which the applicant identifies gaps in current intervention components and demonstrates tangible, realistic potential that the existing interventions can be effectively strengthened or improved.

##### *B. Existing Coalition Program to Prevent Teen Pregnancy (10 points)*

The extent to which the existing coalition has a unified, well organized effort that is focused on clear goals, objectives, and activities related to the prevention of teen pregnancies; represents the combined efforts of three or more community organizations; provides appropriate support for current

activities; and demonstrates a long-term commitment to the existing program.

##### *C. Leadership Capability, Capacity, and Experience of the "Hub" Organization (10 points)*

The extent to which the applicant demonstrates sufficient leadership capability and capacity to efficiently and effectively use the resources requested.

##### *D. Proposed Goals, Objectives, Activities, and Evaluation (30 points)*

The extent to which the applicant has submitted specific, measurable, realistic, goals and objectives that utilize a systematic approach to reaching a large proportion of teenagers in the community. Activities appear likely to lead to the accomplishment of goals and objectives; proposed indicators of program progress and effectiveness appear implementable, incorporate the use of baseline information, and represent accepted approaches to program evaluation; the operational plan provides ample opportunity for the involvement of coalition partners, including teen councils and other teen groups, and proposes other appropriate means of obtaining input from teens into the design and development of the Community Action Plan and program; there is evidence that proposed intervention components are effective, and that they are well matched to the diverse groups of teens targeted in the proposal; and efforts are proposed to extend the use of effective small scale intervention approaches to a broader scale.

##### *E. Program Management and Staffing Plan (5 points)*

The extent to which the roles, responsibilities, lines of authority, and approach to managing the coalition partners are described; staffing, job descriptions, organizational chart, and resumes for proposed and current staff indicate an ability to carry out the proposed program.

##### *F. Evidence of Partner Support (15 points)*

The extent to which partners stipulate in written letters of support and agreement the delineation of responsibilities, commitment of resources, and a time frame for the support of the coalition partnership program. These letters of support and agreement should further describe the leadership role played by the "hub" organization in the past and present with respect to forging agreed upon goals, objectives, and operational plans; providing direction and oversight to the implementation of operational plans;

mobilizing community resources; and serving as the public relations representative for the coalition.

*G. Sharing of Experience and Information* (5 points)

Provide a written statement agreeing to share written program descriptions, intervention protocols, evaluation protocols, coalition management methods, training materials, and other useful tools and information through CDC-sponsored workshops and other approaches to dissemination, with other cooperative agreement recipients, CDC and its national partners, and other communities seeking to develop their own teen pregnancy prevention partnership programs.

*H. Budget and Accompanying Justification* (Not Weighted)

The extent to which the applicant provides a detailed, itemized budget, with accompanying justification, that is consistent with the stated objectives and planned program activities.

**Executive Order 12372 Review**

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. Indian tribes are strongly encouraged to request tribal government review of the proposed application. If SPOCs or tribal governments have any process recommendations on applications submitted to CDC, they should forward them to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Atlanta, GA 30305. The due date for state process recommendations is 30 days after the application deadline date for new awards [the appropriation for these awards was received late in the fiscal year and would not allow for an application receipt date which would accommodate the 60 day State recommendation process within FY 1995]. The Program Announcement

Number and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" for State or tribal process recommendations it receives after that date.

**Public Health Systems Reporting Requirements**

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

- a. A copy of the face page of the application (SF 424).
- b. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:
  - (1) A description of the population to be served;
  - (2) A summary of the services to be provided;
  - (3) A description of the coordination plans with the appropriate State and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

**Catalog of Federal Domestic Assistance Number**

The Catalog of Federal Domestic Assistance Number is 93.283.

**Other Requirements**

*Paperwork Reduction Act*

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

*HIV/AIDS Requirements*

Recipients must comply with the document entitled "Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions" (June 15, 1992), a copy of which is included in the application kit. In complying with the requirements for a program review panel, recipients are encouraged to use an existing program

review panel such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a government health department consistent with the content guidelines. The names of the review panel members must be listed on the Assurance of Compliance Form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved, this includes conference agendas. Before funds can be used to obtain HIV/AIDS-related materials, determine whether suitable materials are already available at the CDC National AIDS Clearinghouse.

**Application Submission and Deadline**

The original and two copies of the application PHS Form 5161-1 (Revised 7/92, OMB Control Number 0937-0189) must be submitted to Clara M. Jenkins, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E-18, Atlanta, GA 30305, on or before August 21, 1995.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

**Where to Obtain Additional Information**

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement Number 547. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all documents, business

management technical assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E-18, Atlanta, GA 30305, telephone (404) 842-6595.

Programmatic technical assistance may be obtained from Michael E. Dalmat, Dr. P.H., Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mail Stop K-20, Atlanta, GA 30341-3724, telephone (404) 488-5136.

Please refer to Announcement Number 547 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: July 10, 1995.

**Arthur C. Jackson,**

*Associate Director for Management and Operations, Centers for Disease Control And Prevention (CDC).*

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BILLING CODE 4163-18-P

## Food and Drug Administration

[Docket No. 91N-0450]

### Guideline for Quality Assurance in Blood Establishments; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guideline entitled "Guideline for Quality Assurance in Blood Establishments." This guideline is intended to assist manufacturers of blood and blood components, including blood banks, blood centers, transfusion services, and plasmapheresis centers, in developing quality assurance (QA) programs that are consistent with recognized principles of QA and current good manufacturing practice (CGMP). This guideline revises the draft "Guideline for Quality Assurance in Blood Establishments," dated June 17,

1993, and provides general information on procedures and practices that may be useful to blood establishments in developing and administering a QA program.

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the "Guideline for Quality Assurance in Blood Establishments" to the Congressional and Consumer Affairs Branch (HFM-12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852-1448, 301-594-1800. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the INTERNET may request the guideline be sent by return E-mail by sending a message to "GDE-QA@A1.CBER.FDA.GOV". The guideline may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) FTP using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, "CDV2.CBER.FDA.GOV". The "READ.ME" file in that subdirectory describes the available documents, which may be available as an ASCII text file (\*.TXT), or a WordPerfect 5.1 document (\*.w51), or both. A sample dialogue for obtaining the READ.ME file with a test based FTP program would be:

FTP CDV2.CBER.FDA.GOV

LOGIN ANONYMOUS

<ANY PASSWORD>

BINARY

CD CBER

GET READ.ME

EXIT

The guideline may also be obtained by calling the CBER FAX Information System (FAX-ON-DEMAND) at 301-594-1939 from a FAX machine with a touch tone phone attached or built-in. Submit written comments on this guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The "Guideline for Quality Assurance in Blood Establishments"

and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-594-3074.

**SUPPLEMENTARY INFORMATION:** On January 21 through 22, 1992, FDA sponsored a public workshop on QA in the manufacture of blood and blood products and provided a background information document on quality assurance to all registrants. That workshop was announced in the **Federal Register** on December 13, 1991 (56 FR 65094). FDA developed the "Draft Guideline for Quality Assurance in Blood Establishments," dated June 17, 1993, following the meeting, after considering the discussions at the workshop and comments received. FDA announced the availability of the draft guideline in the **Federal Register** on July 2, 1993 (58 FR 35959), and solicited comments. FDA has revised the draft guideline in response to public comment. The revisions are minor and intended to clarify the document. This guideline, dated July 14, 1995, provides general information on procedures and practices and may be useful to blood establishments in developing and administering a QA program.

To ensure the continued safety of the nation's blood supply, it is essential that blood establishments implement effective control over manufacturing processes and systems. FDA believes that this can be accomplished by each blood establishment developing a well planned, written, and managed QA program designed to recognize and prevent the causes of recurrent deficiencies in blood establishment performance. The emphasis of such a QA program is on preventing errors rather than detecting them retrospectively. The potential public health consequences require that all establishments, regardless of size, invest in QA.

The guideline includes discussions of the following: (1) The general concepts of a quality control/assurance program; (2) the function and reporting responsibilities of the QA unit; (3) the responsibilities of the QA unit in such areas as standard operating procedures, training and education, competency evaluation, proficiency testing, validation, equipment, error/accident reports, records management, lot release procedures and QA audits; and (4) the