

program. For a complete description of each, see Addendum I in the application kit.

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, [42 U.S.C. sections 241 and 247b, as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC Home Page on the Internet at <<http://www.cdc.gov>> (click on Funding). Please refer to Program Announcement Number 00127 when requesting information. To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Mattie B. Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, E-13, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: 770-488-2718, Email address: mij3@cdc.gov

For program technical assistance, contact: Marta Gwinn, MD, MPH, Senior Medical Epidemiologist, Office of Genetics and Disease Prevention, National Center for Environmental Health Centers for Disease Control and Prevention, K-28, 4770 Buford Highway, NE, Atlanta, GA 30341-3724, Telephone number: 770-488-3235, Email address: mlg1@cdc.gov

Dated: June 2, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 00141]

Notice of Availability of Funds; Surveillance of Intimate Partner Violence (IPV)

A. Purpose

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for Surveillance of Intimate Partner Violence (IPV). The purpose(s) of the program announcement are (1) to improve state injury surveillance capacity through the implementation of the Consensus Recommendations For Injury Surveillance In State Health Departments, September 1999 Report, for a copy of this report, visit the Internet site: (<http://www.injuryprevention.org/stipda/s-pubs>) and (2) to support the integration of population-based IPV surveillance systems into existing injury surveillance systems that will help determine the magnitude of IPV in population subgroups, and continued revision and testing of uniform definitions and recommended data elements. This program addresses "Healthy People 2010," a national activity to reduce morbidity and mortality and improve health. This announcement is related to the focus area of Injury and Violence Prevention. For the conference copy of "Healthy People 2010", visit the Internet site: <http://www.health.gov/healthypeople>.

B. Eligible Applicants

Assistance will be provided only to the official public health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. States previously funded under announcement number 94483 "State Injury Prevention Programs" are eligible to apply (Massachusetts, Michigan and Rhode Island). States previously funded under announcement number 99134 "State Injury Prevention Programs" are not eligible to apply (Kentucky and Oklahoma).

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant cooperative agreement contract, loan, or any other form.

C. Availability of Funds

Approximately \$1.2 million is available to fund up to four awards. It is expected that the average award will be \$300,000. It is expected that the awards will begin on or about September 30, 2000 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress, as evidenced by required reports, and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under (1) Recipient Activities, and CDC will be responsible for the activities listed under (2) CDC Activities.

1. Recipient Activities

a. Enhance existing injury surveillance activities to support Intimate Partner Violence (IPV) surveillance to identify victims and occurrences of IPV, including data describing the magnitude of the problem and the extent of injuries (i.e., who is affected, areas and persons at greatest risk, and the type and source of the information used).

b. Enhance an existing injury surveillance system, capable of linking with one or more health-related data sources to determine intimate partner violence incidence and prevalence in the targeted area (e.g., linkage of emergency department injury surveillance data or hospital discharge data with health-care based IPV surveillance data).

c. Enhance the capacity for general injury surveillance by incorporating the IPV surveillance system into other existing injury surveillance systems.

d. Using the Uniform Definitions for IPV Surveillance, assess the feasibility of enhancing existing injury surveillance and integrating a subset of the fifty recommended data elements: Uniform Definitions and Recommended Data Elements, 1999; <http://www.cdc.gov/ncipc/pub-res/intimate.html> into an existing health-care related injury surveillance system. Explain decisions made in selecting the subset of 50 data elements.

e. Establish and maintain cooperative partnerships with key personnel of potential data source agencies (*e.g.*, hospitals, emergency departments, etc.).

f. Monitor quality, representativeness and completeness of IPV surveillance data.

g. Collect and analyze surveillance data.

h. Produce and distribute periodic, progress reports to appropriate state and local agencies, and develop replication guidelines for future use by other states and localities.

i. Establish an advisory committee to exchange information and increase the likelihood of integrated injury surveillance systems.

In addition to the above, applicants should have well-developed surveillance capacity that includes the ability to: (See Consensus Recommendations for Injury Surveillance in State Health Departments—September 1999 Report.)

a. Access the 11 core data sets recommended for injury surveillance. The 11 data sets are vital records (VR), hospital discharge data (HDD), Fatality Analysis Reporting System (FARS), the Behavioral Risk Factor Surveillance System (BRFSS), the Youth Risk Behavioral Surveillance System (YRBSS), emergency department data (ED), medical examiner data and coroner data (ME), child death review data (CDR), the National Occupant Protection System (OPU), Uniform Crime Reporting System (UCR), and emergency medical services data (EMS).

b. Assess the completeness and validity of the 11 core data sets and evaluate the surveillance systems that generated these data using standard evaluation criteria.

c. Link data sets.

d. Ensure that each injury event is counted only once when using patient records.

e. Conduct special analyses.

f. Identify and measure interim program outcomes.

g. Evaluate state injury prevention program.

h. Use surveillance to support applied research.

i. Produce routine reports based on core data to support the five components of a model state injury prevention program: data collection and analysis; program design, implementation, and evaluation; coordination and collaboration; technical support and training; and public policy.

j. Develop and implement a surveillance system for additional major injury problems (*e.g.*, nonfatal interpersonal violence including

intimate partner violence, sexual assault, and child abuse).

k. Develop unique surveillance systems to meet the state's individual data needs.

2. CDC Activities

a. If needed, provide technical assistance in the design of all phases of the IPV surveillance programs, including consultation on data collection instruments and procedures.

b. Provide technical assistance in developing a standardized approach to surveillance and related evaluation activities.

c. Provide consultation and assistance in problem assessment and target population identification, the evaluation of coverage, cost, and impact of surveillance activities, and design of scientific protocols.

d. Collaborate in the analysis and dissemination of IPV surveillance data.

e. Provide up-to-date scientific information about intimate partner violence and coordinate with related activities at CDC's National Center for Injury Prevention and Control.

f. Assist in the transfer of information and methods developed in this program to other geographical areas.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The application will be evaluated on the Evaluation Criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 45 double-spaced pages, printed on one side, with one inch margins, no smaller than 12 point Courier Font. Number each page consecutively and provide a complete Table of Contents. The total number of pages should not exceed 60 pages including the appendix. No bound booklets, etc. should be attached.

In developing the application, the applicant must also include a two-page, double-spaced abstract. In following the format shown below, the applicant should also provide a detailed description of the first year activities and briefly describe future-year objectives and activities.

Format

1. Abstract.
2. Background and Need.
3. Goals.
4. Objectives.
5. Methodology.
6. Evaluation.
7. Coordination and Collaboration.
8. Project Management and Staffing.

9. Budget.

10. Human Subjects.

11. Other Requirements and Attachments.

F. Submission and Deadline

Application: Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before August 8, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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 independent 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.)

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

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Abstract (Not To Exceed Two Pages) (Not Scored)

The extent to which the applicant summarizes the existing injury surveillance system, the proposed IPV surveillance system, and the proposed integration of the IPV system into the injury surveillance system.

2. Background and Need (15 Points)

a. The extent to which the applicant documents the magnitude of the intimate partner violence problem in the applicant's targeted area, and provides a profile of the persons and groups at greatest risk.

b. The extent to which the applicant documents its current activities and previous experiences in injury surveillance, intimate partner violence surveillance, evaluation, and coordination with other agencies and potential partners.

c. The extent to which the applicant documents the current capacity and demonstrates the existence of a well-developed injury surveillance system to

collect and link health related data; what information is collected and what data sources are used, *e.g.* Hospital discharge data, emergency department data, and emergency services data, etc.

3. Goals (10 Points)

a. The extent to which the applicant states specific goals that indicate where the applicant anticipates the integration of intimate partner violence into the existing injury surveillance system will be at the end of the five-year project period.

b. The extent to which the applicant describes and provides evidence of its willingness and ability to undertake related projects to expand the capacity of the IPV surveillance system should additional funds become available.

4. Objectives (15 Points)

a. The extent to which the applicant states specific, time-phased, measurable and achievable objectives.

b. The extent to which the applicant relates the objectives directly to the project goals and the use of various health-related information sources, effort to achieve representativeness, surveillance system evaluation, collaboration, and demonstrates the utility of the surveillance system in replication efforts.

5. Methodology (20 Points)

a. The extent to which the applicant documents the capacity of the existing injury surveillance system; the proposed IPV surveillance system; and the proposed integration of the intimate partner violence surveillance system into the injury surveillance system.

b. The extent to which the applicant describes specific activities that are proposed to achieve each of the program objectives during the budget period.

c. The extent to which the applicant provides a time-line which indicates when each activity and preparations for activities will occur.

d. The extent to which the applicant provides evidence of an organizational chart that represents the actual structure of the integrated IPV injury surveillance system operating organization and its placement within the organizational units with existing jurisdiction and authority over other injury surveillance systems.

e. The extent to which the applicant provides evidence it has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research.

6. Evaluation (15 Points)

a. The extent to which the applicant describes the methods and design to be

used to evaluate the integrated subset of the IPV surveillance system into the injury surveillance system, including what will be evaluated, data to be used, who will perform the evaluation and the time it will take (timeline) to do the evaluation.

b. The extent to which the applicant provides evidence of staff availability, expertise, and capacity to evaluate surveillance activities.

7. Coordination and Collaboration (10 Points)

a. The extent to which the applicant describes the relationship between the program and other organizations, agencies, and health department units that will relate to the program or which conduct related activities.

b. The extent to which applicant provides evidence of collaboration with academic institutions, public safety officials, or with other agencies. In addition, the extent to which the applicant describes responsibilities and composition of the surveillance advisory committee.

8. Project Management and Staffing (15 Points)

a. The extent to which the applicant documents the experience in the management of intimate partner violence surveillance, and describes the roles and responsibilities of the project director, epidemiologist, and each staff member, including a description of staff with appreciable experience in other injury surveillance systems expected to work in the integrated surveillance system.

b. The extent to which the applicant describes the allocation of staff to the activities outlined in the Methodology section.

c. The extent to which the applicant includes letters in the appendix from each collaborating consultant or outside agency stating their willingness and ability to fulfill the proposed responsibilities.

9. Budget (Not Scored)

The extent to which the budget request is clearly explained, adequately justified, reasonable, sufficient, and consistent with the stated objectives and planned activities.

10. Human Subject (Not Scored)

a. The extent to which the applicant describes the degree to which human subjects may be at risk.

b. The extent to which the applicant describes assurances that all activities will conform to the requirements of 45 CFR part 46.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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

The following additional requirements are applicable to this program. For a complete description of each, see Addendum in the application package.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7 Executive Order 12372 Review
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2), and 391-394A [42 U.S.C. 241(a), 247b(k)(2), and 280b-280b-3] of the Public Health Service Act as amended.

J. Where To Obtain Additional Information

This and other CDC announcements are available through the CDC homepage on the Internet at: <http://www.cdc.gov>. To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the program announcement number (00141).

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from: Joanne Wojcik, Lead, Grants Management Specialist,

Announcement #00141, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number (770) 488-2717.

For program technical assistance, contact: John D. Hemphill, National Center for Injury Prevention and Control Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop K60, Atlanta, GA 30341, Telephone (770) 488-1285, Email address: jdh2@cdc.gov, FAX (770) 488-1011

Dated: June 2, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-14425 Filed 6-7-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 00066]

Using Private Provider Partnerships To Strengthen the Immunization Message; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2000 funds to fund a cooperative agreement program with national private provider organizations which was published in the **Federal Register** on May 1, 2000, [Vol. 65, No. 84, Pages 25334-25336]. The notice is amended as follows:

On page 25335, Third Column, under Section F. Submission and Deadline, the submission due date is revised to read on or before July 18, 2000.

Dated: June 2, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-14426 Filed 6-7-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 29, 2000, from 8:30 a.m. to 5:30 p.m. and on June 30, 2000, from 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Tracy K. Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at the FDA Website, www.FDA.GOV.

Agenda: On June 29, 2000, during the initial open session, the committee will discuss new drug application (NDA) 20-010, Lotrisone™ Lotion (clotrimazole/betamethasone dipropionate), Schering-Plough, Inc., for treatment of tinea pedis, tinea cruris, and tinea corporis; and NDA 20-996, Dermex II™ Ointment (zinc oxinate), Dermex Pharmaceuticals, Limited Liability Corp., for treatment of actinic keratosis, basal cell carcinoma, and squamous cell carcinoma. On June 30, 2000, the committee will discuss NDA 21-026, (miconazole nitrate, USP 0.25%) ointment, Johnson & Johnson Consumer Companies, Inc., for treatment of diaper dermatitis.

Procedure: On June 29, 2000, from 10 a.m. to 5:30 p.m. and on June 30, 2000, from 8:30 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 21, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. on June 29, 2000, and between approximately 8:30 a.m. and 9:30 a.m. on June 30, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 21, 2000, and submit a brief statement of the general

nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 29, 2000, from 8:30 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information regarding pending investigational new drug applications issues (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 31, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-14461 Filed 6-7-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 19, 2000, 10 a.m. to 5 p.m.

Location: Hilton, Salons D and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194, ext. 118, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12523. Please call the information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a device for the treatment of obesity.

Procedure: Interested persons may present data, information, or views,