actual or potential dealings by any physician with any payer or provider.

The fifth provision listed above (section II.A.5 of the proposed order) ensures that communications between any respondent and any payer within a ''messenger model'' arrangement be conveyed by a neutral third party (someone other than a physician with an active practice in the Austin area). In a messenger model arrangement, physicians individually convey and receive, through a third party, information, offers, and responses from and to payers or providers. See Statements of Antitrust Enforcement Policy in Health Care. Issued jointly by the Federal Trade Commission and the U.S. Department of Justice (August 28, 1996) at 43–52, 89–92, 125–27, 138–40, 4 Trade Reg. Rep. (CCH) ¶ 13,153. In addition, section V.A.2 of the order ensures that any respondent intending to use a messenger model arrangement provide prior notification to the Commission.

Section II.B prohibits respondents from exchanging, transferring, or facilitating the exchange or transfer of information among Austin area physicians concerning: (1) Negotiation with any payer or provider regarding reimbursement terms; or (2) actual or contemplated intentions or decisions with respect to any terms, dealings or refusals to deal with any payer or provider. Section II.C prohibits respondents from encouraging, advising, or pressuring any person, other than the government, to engage in any action that would be prohibited if the person were subject to the order.

Section II contains three provisos. The first permits each respondent medical practice group to participate in arrangements for the provision of physician services that are limited to physicians from the same medical practice group. The second proviso, as noted above, permits respondents to engage in conduct that is approved and supervised by the State of Texas, so long as that conduct is protected from liability under the federal antitrust laws pursuant to the state action doctrine. The state action doctrine protects from federal antitrust liability any private conduct that is both: (1) in accordance with a clearly articulated and affirmatively expressed state policy to supplant competition; and (2) actively supervised by the state itself. *See, e.g., FTC* v. *Ticor Title Insurance Co.*, 504 U.S. 621 (1992); *California Retail Liquor Dealers Ass'n* v. *Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

The third proviso allows respondents to engage in conduct (including collectively determining reimbursement and other terms of contracts with payers) that is reasonably necessary to operate any ''qualified risk-sharing joint arrangement'' or ''qualified clinically-integrated joint arrangement,'' provided respondents comply with the prior notification requirements set forth in section V of the order. The prior notification mechanism will allow the Commission to evaluate a specific proposed arrangement and assess its likely competitive impact. This requirement will help guard against any recurrence of acts and practices that have restrained competition and injured consumers.

As defined in the order, a ''qualified risk-sharing joint arrangement'' must satisfy three conditions. First, all physicians participating in the arrangement must share substantial financial risk from their participation in the arrangement. The definition illustrates ways in which physicians might share financial risk, tracking the types of financial risk-sharing set forth in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. Second, any agreement on prices or terms of reimbursement entered into by the arrangement must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Third, the arrangement must be non-exclusive—*i.e.,* it must not restrict the ability, or facilitate the refusal, of physicians participating in the arrangement to deal with payers individually or through any other arrangement.

A ''qualified clinically-integrated joint arrangement'' pertains to arrangements in which the physicians undertake cooperative activities to achieve efficiencies in the delivery of clinical services, without necessarily sharing substantial financial risk. As with risk-sharing arrangements, the definition of clinically integrated joint arrangements reflects the analysis contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care. According to the order's definition, the participating physicians must have a high degree of interdependence and cooperation through their use of programs to evaluate and modify their clinical practice patterns, in order to control costs and assure the quality of physician services provided through the arrangement. In addition, as with risk-sharing arrangements, the arrangement must be non-exclusive and any agreement on prices or terms of reimbursement entered into by the arrangement must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

Sections III.A and III.B require respondents to distribute the order and complaint to its members and other specified persons, including payers. Sections III.C and III.D require that each respondent, for the next five years: (2) Distribute copies of the order and complaint to new members and other specified persons; (2) publish annually to members and owners a copy of the order and complaint; and (3) brief members and owners annually on the meaning and requirements of the order and the antitrust laws.

Sections IV and VI consist of standard Commission reporting and compliance procedures. Section IV specifies that Texas Surgeons IPA must include in its annual reports information identifying each payer or provider that has communicated with Texas Surgeons IPA concerning a possible contract for physician services, the proposed terms of any such contract, and Texas Surgeons IPA's response to the payer or provider.

Finally, section VII of the proposed order contains a twenty year ''sunset'' provision under which the order terminates twenty years after the date the order was issued.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 00–10009 Filed 4–20–00; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00037]

Cancer Prevention and Control Activities; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a sole source cooperative agreement program for Cancer Prevention and Control Activities. This program addresses the ''Healthy People 2010'' priority area(s) related to Cancer.

The purpose of the program is to assist with the following:

1. Developing and disseminating current national, state, and community-based comprehensive information on cancer prevention and early detection.

2. Developing and disseminating professional education programs.

3. Promoting the analysis and development of surveillance and

research data, and its translation into public health messages, practice and programs.

4. Facilitating the exchange of expertise and coordination of programmatic efforts related to cancer prevention and control among a variety of public, private, and not-for-profit agencies at the national, state, tribal, and community level.

B. Eligible Applicants

Single Source

Assistance will be provided only to the American Cancer Society (ACS). No other applications are solicited. ACS is uniquely qualified to conduct information and education development and dissemination activities under this cooperative agreement because it has—

1. An extraordinary position as the nation's only voluntary, community-based cancer prevention and control organization dedicated to eliminating cancer as a major health problem through research, education, prevention, early detection and treatment of all cancers.

2. Access to cancer research, prevention, education and treatment programs and to the populations they serve through an extensive network that includes 2 million members, a National Society, 17 Divisions covering all states, 5 metropolitan areas, the District of Columbia and Puerto Rico, and more than 3,400 community-based unit offices.

3. Collaborative relationships with a broad range of national, state, and community-based public, private and not-for-profit organizations to disseminate information related to all aspects of cancer prevention and control; coordinate access to information and services for cancer patients, their families and others; and provide guidance and consultation at the national, state, and community level for a coordinated and comprehensive system of cancer activities. Therefore, the American Cancer Society is the only organization that can perform these activities.

C. Availability of Funds

Approximately $755,000 is available in FY 2000 to fund the projects listed below. It is expected that the awards will begin June 1, 2000, and will be made for a 12-month budget period within a project period of up to 3 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.

Project 1. Coordinated School Health Programs

Approximately $300,000 is available to support coordinated school health programs for cancer prevention and control for school-aged populations, parents, and relevant health and education personnel.

Project 2. Comprehensive Cancer Control Activities

Approximately $400,000 will be available to plan, implement, and evaluate cancer control activities for the public (including minority, older, and underserved populations), providers (including physicians, nurses, physician assistants, health educators, state health department personnel, and others), and decision makers (policy makers, state health department administrators, and others.)

Project 3. International Network of Women Against Tobacco (INWAT)

Approximately $35,000 is available to support activities which address the complex issues of tobacco use among women and girls internationally.

Project 4. Dissemination of Information on Oral Cancer

Approximately $20,000 is available to support the review and revision of currently available information and educational materials on oral cancer and incorporate oral cancer issues into educational outreach services and/or activities for dental and other health care providers.

Use of Funds

Cooperative agreement funds may not be expended to provide inpatient hospital or treatment services. Treatment is defined as any service recommended by a clinician, including medical and surgical intervention provided in the management of a diagnosed condition.

D. Program Requirements

Projects should emphasize activities in one or more of the following areas:

1. Development and dissemination of materials, conferences, workshops, and activities for public education on the prevention and early detection of cancer through behavior modification, including utilization of proven screening modalities for early detection (*e.g.,* fecal occult blood tests, sigmoidoscopy, mammography, Pap smears), avoidance of ultraviolet radiation exposure, prevention and cessation of tobacco use, improving nutrition and dietary practices, and increasing physical activity levels. Materials should be culturally competent, linguistically appropriate and developed for a broad audience of race/ethnic groups.

2. Coalition building, and coordination of resources and activities for adult and adolescent cancer education, promotion of prevention and early detection services, and referral to treatment and follow-up services.

3. Epidemiologic and behavioral research development and analysis of data on factors related to cancer outcomes and other diseases which may be influenced by tobacco, early detection (*e.g.,* fecal occult blood tests, sigmoidoscopy, mammography, Pap smears), avoidance of ultraviolet radiation exposure, nutrition and dietary practices, and increasing physical activity levels.

4. Development and dissemination of materials, conferences, workshops and activities for professional education in cancer prevention and early detection, and support of training opportunities in cancer epidemiology, prevention, early detection and program evaluation.

5. Development and evaluation of materials and activities to improve outreach to underserved populations for cancer prevention, early detection and follow-up services.

6. The grantee will participate in a six-month progress review meeting with appropriate representatives from CDC within 30 days of the sixth month of each budget period.

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

1. Recipient Activities

Project 1. Coordinated School Health Programs

A. Collaborate with state and local education agencies with data collection around youth risk behavior, and school policies and programs.

B. Support Coordinated School Health Programs as a priority among American Cancer Society's constituents and the public, with a special emphasis on four risk factors: Tobacco use, excessive consumption of fat and calories, inadequate physical activity, and obesity.

C. Support local, state, and national coalitions to improve Coordinated School Health Programs.

D. Collaborate with CDC funded and other national, non-governmental organizations in support of school health programs.

E. Participate with other appropriate agencies in planning the annual

National School Health Leadership Conference.

Project 2. Comprehensive Cancer Control Activities

A. Collaborate with state health departments on comprehensive cancer control training, planning, implementation, and evaluation activities. Develop leadership models for state health departments to utilize. Assess comprehensive cancer control collaboration models.

B. Coordinate and support activities related to colorectal and prostate cancer education and awareness. Collaborate with state health departments in the replication and evaluation of prostate and colorectal cancer training for providers and health care systems that promotes informed decisions; provides current, balanced information on the benefits and limitations of screening and treatment for these cancers; and provides information that will enable participants to overcome system barriers to implementing screening. Collaborate with appropriate agencies in reaching primary care providers with written information regarding screening for colorectal cancer and messages for their patients to raise awareness of the need for colorectal cancer screening.

C. Identify the critical components of effective breast and cervical cancer screening outreach/education partnerships between state health departments and other organizations, including ACS.

D. Develop evaluation measures to determine the impact of project activities and identify effective cancer prevention and control projects for future continuation, replication and/or dissemination.

E. Develop clear cancer education materials and/or other items that accurately and effectively convey appropriate health messages and behaviors to the targeted populations regarding lung, breast, cervical, colorectal, prostate, and skin cancers.

F. Identify opportunities for cancer issues management forums; coordinate and support cancer issues management forums among a variety of public, private, and not-for-profit agencies at the national, state, tribal, and community level.

G. Develop and implement studies that explore the effects and interactions between various lifestyle factors and health services on the risk of cancer and cancer mortality.

Project 3. International Network of Women Against Tobacco (INWAT)

A. Provide contacts primarily to women, individuals, and organizations working in tobacco control; collect and distribute information regarding global women and tobacco issues; and develop strategies to counter tobacco advertising and promotion. Strategies might include maintaining a website, a member directory and newsletter.

B. Provide assistance with the organization and planning of conferences on tobacco control such as the World Tobacco Conference.

C. Collaborate with state health departments to address tobacco use and prevention among women and girls.

D. Provide presentations on women and tobacco, with a strong emphasis on tobacco company marketing tactics at state and national meetings in the United States.

E. Promote female leadership in initiating the development of tobacco control organizations internationally.

Project 4. Dissemination of Information on Oral Cancer

A. Inventory and assess existing educational materials and other forms of information on oral cancer available to the public and health care providers.

B. Based on the assessment, revise educational materials and other forms of information on oral cancer to reflect up-to-date, science-based knowledge.

C. Conduct and evaluate outreach activities to increase knowledge and awareness among dental and other health care providers of information resources that address oral cancer issues.

D. Coordinate these activities with major organizations in dental health, such as the American Dental Association and its component state associations, the National Institute of Dental and Cranial Facial Research, and the Association of State and Territorial Dental Directors.

2. CDC Activities

A. Collaborate on and provide technical assistance for program activities.

B. Assist in the conduct of epidemiologic studies, research, and analysis using existing or newly created databases.

C. Participate in the development of plans for the sharing and dissemination of research, data analysis, evaluation efforts, demonstration projects and interventions, and other cancer information. Sponsor information exchanges through workshops, conferences, and other group mechanisms as appropriate .

D. Assist in defining the scope, development, and dissemination of plans and education materials, guidelines, and standards for cancer prevention and control activities.

E. Assist in developing and evaluating professional training opportunities for cancer prevention and control, particularly in the areas of prevention, early detection, surveillance, data analysis and cost-effectiveness.

F. Give guidance on cancer issues management topics to be considered and timing of consideration.

E. Application Content

Use the information in the ''Program Requirements,'' ''Other Requirements,'' and ''Evaluation Criteria'' sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 20 (twenty) double-spaced pages, printed on one side, with one-inch margins, and unreduced font.

A separate narrative is required for each Project which contains—

1. Statement of Need.—Identify opportunities for enhancement/improvement and existing gaps in the support of comprehensive cancer control and prevention activities. Describe the extent to which the proposed programs will fill existing gaps and provide a brief description of each programmatic plan or research activity.

2. Objectives. Establish and submit short- and long-term objectives for each project proposed in Section 1 (statement of need) above. Objectives must be specific, measurable, attainable, time phased, and realistic.

3. Operational Plan.—Submit an operational plan that addresses means for achieving each of the objectives established in Section 2 (objectives) above. Provide a concise description of each component or major activity and how it will be implemented. The plan must identify and establish a time line for the completion of each component or major activity.

4. Evaluation Plan.—Submit a quantitative plan for monitoring progress toward achieving each of the objectives stated in Section 2 (objectives) above.

5. Program Management.—Describe the need, functions, and qualification for each program or research personnel requested.

6. Budget.—Submit a detailed budget and narrative justification for each of the projects that is consistent with the purpose of the program and the proposed activities.

F. Submission and Deadline

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189).

By May 1, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

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

a. Received on or before the stated deadline date; or

b. Sent on or before the deadline date. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service.

Private metered postmarks shall not be acceptable 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 and will be returned to the applicant.

G. Evaluation Criteria

The application will be evaluated according to the following criteria by an independent review group appointed by CDC.

1. Need statement. The extent to which the applicant identifies specific opportunities and existing gaps related to the purpose of the program. (10 points)

2. Objectives. The degree to which short- and long-term objectives are specific, measurable, attainable, time phased, and realistic. (20 points)

3. Operational Plans. The adequacy of the applicant's plan to carry out the proposed activities, including the extent to which the applicant plans to work collaboratively with other organizations and individuals who may have an impact on cancer prevention and control objectives. (25 points)

4. Evaluation Plan. The extent to which the evaluation plan appears capable of monitoring progress toward meeting project objectives. (25 points)

5. Program Management. The extent to which proposed staff appear to be qualified and possess capacity to perform the project. (20 points)

6. Budget. The extent to which each line-item budget and narrative justification for Projects 1, 2, 3 and 4 are reasonable and consistent with the purpose and objectives of the program. (Not weighted)

7. Human Subjects. Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Not Weighted)

8. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

2. The proposed justification when representation is limited or absent.

3. A statement as to whether the design of the study is adequate to measure differences when warranted.

4. A statement as to whether the plans for recruitment and research for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of the following:

1. Annual written progress report must be submitted 30 days after the end of each budget period.

2. Financial status report (FSR) must be submitted 90 days after the end of each budget period.

3. Final financial and performance reports, must be submitted 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.

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

AR–1 Human Subjects Requirement
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–20 Conference Support

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance Number for this program is 93.283.

J. Where To Obtain Additional Information

To obtain additional information contact: Nealean K. Austin, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Announcement 00037 Centers for Disease Control and Prevention (CDC) Room 3000, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770)–488–2754, E-mail address nea1@cdc.gov

See also the CDC home page on the Internet: http://www.cdc.gov

For program technical assistance, contact: Corinne Graffunder, Chief, Section A, Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–57, Atlanta, GA 30341–3724, telephone (770) 488–4880, fax (770) 488–3230.

Dated: April 17, 2000.

John L. Williams,

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

[FR Doc. 00–9956 Filed 4–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93D–0139]

International Conference on Harmonisation; Draft Revised Guidance on Q1A(R) Stability Testing of New Drug Substances and Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft revised guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products.'' The draft revised guidance, which updates a guidance on the same topic published in the **Federal Register** of September 22, 1994 (the 1994 guidance), was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft revised guidance clarifies the 1994 guidance, adds information, and provides consistency with more recently published ICH guidances. The draft revised guidance is intended to reflect formal scientific principles for stability testing of drugs and should be useful to applicants submitting new drug applications for new molecular entities and associated drug products.